Section 1: Overview

Introduction

This section provides an overview of an HIV Rapid Testing workshop. It contains information about:

- Workshop Goal
- Training Modules: Learning Objectives and Content Outline
- Learning Methods / Activities
- Recommended Certification Criteria
Workshop Goal

Participants will gain the knowledge and skills to perform HIV rapid tests accurately and reliably in a safe and professional manner in an era of expanding programs

Training Modules: Learning Objectives and Content Outline

<table>
<thead>
<tr>
<th>Module</th>
<th>Learning Objectives</th>
<th>Content Outline</th>
</tr>
</thead>
</table>
| 1 | Overview of HIV Infection | ▪ Describe the difference between HIV infection and AIDS  
▪ Discuss the HIV epidemics globally, regionally, and locally in terms of number of people affected  
▪ Define the terms antibody and antigen  
▪ Explain how "window period" may affect HIV testing results  
▪ Describe the progression of HIV infection | ▪ What is HIV?  
▪ What is AIDS?  
▪ The HIV pandemic  
▪ HIV transmission  
▪ Window period  
▪ Stages of HIV infection |
| Duration: 30 min | | |
| 2 | Integration of HIV Rapid Testing in HIV Prevention and Treatment Programs | ▪ Recognize the need for HIV testing and counseling (T&C) in HIV prevention programs  
▪ Describe the role of HIV rapid testing in supporting prevention and counseling programs  
▪ State the advantages of using HIV rapid tests in specific settings (e.g., VCT and PMTCT programs)  
▪ Describe the programs/ settings where HIV rapid tests are used in your country | ▪ Need for expanding access to HIV testing  
▪ Testing and counseling as an integral part of HIV prevention, care and support services  
▪ Client counseling and HIV rapid testing are a formidable combination in any HIV prevention strategy |

Duration: 30 min
<table>
<thead>
<tr>
<th>Module</th>
<th>Learning Objectives</th>
<th>Content Outline</th>
</tr>
</thead>
</table>
| 3 | Overview of HIV Testing Technologies | ▪ Discuss settings where HIV testing will be part of service delivery during an era of expanded services  
▪ Discuss the spectrum of testing technologies for HIV  
▪ Explain the advantages and disadvantages of HIV rapid tests  
▪ Accurately recognize individual test result as reactive, non-reactive, or invalid | ▪ Expansion of HIV rapid testing  
▪ Spectrum of HIV diagnostic tests  
▪ Challenges with HIV testing  
▪ Spectrum of HIV testing technologies  
▪ Advantages and disadvantages of HIV rapid testing  
▪ Three formats of rapid tests  
▪ Reading individual test results |
| 4 | HIV Testing Strategies and Algorithms | ▪ Discuss the process for developing a national testing algorithm  
▪ Explain how sensitivity, specificity, positive/negative predictive value relate to development of an HIV rapid testing algorithm  
▪ Explain the HIV rapid testing algorithm approved in your country  
▪ Determine HIV status following a particular algorithm | ▪ Testing strategies and algorithms  
▪ Developing national testing algorithm  
▪ Measuring performance of HIV rapid tests  
▪ Interpreting HIV status |
| 5 | Assuring the Quality of HIV Rapid Testing | ▪ Explain the systems approach to lab quality and its benefits  
▪ Identify the essential elements of a lab quality system and how they apply to HIV rapid testing  
▪ Recognize key factors that may compromise the quality of HIV rapid testing  
▪ Describe your responsibilities in preventing and detecting errors before, during, and after testing | ▪ The approach we take to achieve quality  
▪ Essential elements of a lab quality system  
▪ Quality assurance procedures at the HIV rapid testing site  
▪ How you can contribute to quality before, during, and after testing |
<table>
<thead>
<tr>
<th>Module</th>
<th>Learning Objectives</th>
<th>Content Outline</th>
</tr>
</thead>
</table>
| **6 Safety at the HIV Rapid Testing Site** | - Adhere to personal health and safety practices  
- Maintain a clean and organized workspace  
- Disinfect and dispose of infectious materials  
- Take appropriate actions following accidental exposure to potentially infectious specimen  
- Follow written safety procedures and keep proper safety records | - General safety practices  
- Work habits (personal, workspace, material)  
- Proper disposal of sharps and waste  
- Disinfection of work areas  
- Safety documentation |
| **Duration: 45 min** | | |
| **7 Preparation for Testing – Supplies and Kits** | - List and identify all the supplies required for HIV rapid testing  
- List and identify all the components of test kits for HIV rapid testing | - Supplies & materials  
- Test kits |
| **Duration: 50 min** | | |
| **8 Blood Collection: Finger prick** | - Explain the preparation tasks required for rapid tests  
- Put a client at ease while collecting blood  
- Collect blood from a finger prick accurately and confidently | - Preparation for testing  
- Educating your client  
- Performing finger prick |
| **Duration: 2-2.5 hrs** | | |
| **9 Performing HIV Rapid Tests: Demonstration and Practice** | - Perform 3 HIV rapid tests according to SOP  
- Perform multiple tests simultaneously  
- Accurately interpret individual test results  
- Accurately determine HIV status | - Overview of testing procedures  
- Workstation setup  
- Demonstration  
- Practice session with known specimens  
- Practice session with blinded specimens |
| **Duration: 5.5 hrs** | | |
| **10 Inventory: Managing Stocks at the HIV Rapid Testing Site** | - Maintain proper records  
- Maintain proper level of consumables  
- Use first-expiry-first-out concept when managing stocks  
- Inspect delivery of supplies before acceptance  
- Identify lot numbers and expiry dates  
- Keep kits and supplies in proper storage | - What is stock management?  
- Record keeping  
- Re-order levels  
- Receipt of consumables  
- Storage of consumables |
<p>| <strong>Duration: 1 hour</strong> | | |</p>
<table>
<thead>
<tr>
<th>Module</th>
<th>Learning Objectives</th>
<th>Content Outline</th>
</tr>
</thead>
</table>
| 11 Use and Care of Equipment at the HIV Rapid Testing Site | • Specify your responsibilities related to equipment  
• Routinely monitor the temperatures of refrigerators and freezers  
• Confirm that auto pipettes deliver specified volumes  
• Properly use and maintain centrifuges | • Rationale for using properly maintained equipment  
• Your responsibilities for equipment  
• Use and care of equipment at the HIV rapid testing site  
  o Refrigerator and freezer  
  o Pipette  
  o Centrifuge |
| 12 Quality Control | • Differentiate between internal and external controls  
• Use external quality controls at designated frequencies  
• Analyze common problems associated with invalid test results | • What is Quality Control (QC)?  
• Benefits of QC in rapid testing  
• Internal versus external quality control  
• Troubleshooting invalid results  
• Quality control records |
| 13 EQA: On-site Evaluation and Re-testing | • Assess operations at test site to determine if quality requirements are met  
• Take corrective actions following External Quality Assessment (EQA)  
• Keep appropriate records related to EQA  
• Avoid common problems associated with EQA specimen management | • What is EQA and why is it important?  
• EQA Responsibilities  
• EQA Methods  
  o Proficiency Testing  
  o On-Site Evaluation  
  o Re-testing  
• How to implement EQA |
| 14 Blood Collection and Handling: DBS | • Collect dried blood spots (DBS)  
• Package and store DBS in a way to maintain specimen integrity  
• Maintain DBS records  
• Distinguish between valid and invalid DBS | • Required supplies  
• How to collect and dry DBS  
• How to package and store DBS  
• Valid and invalid DBS  
• Hands-on practice |
<table>
<thead>
<tr>
<th>Module</th>
<th>Learning Objectives</th>
<th>Content Outline</th>
</tr>
</thead>
</table>
| 15 Documents and Records | ▪ Tell the difference between a document and a record  
▪ Explain the rationale for maintaining documents and records  
▪ Provide examples of documents and records kept at a test site  
▪ Follow the procedures as prescribed in SOPs  
▪ Describe how to properly keep and maintain test site documents and records  
▪ Describe the types of information typically not found in a manufacturer’s product insert | ▪ What are documents and records?  
**Documents**  
▪ Why are they important?  
▪ What documents should you keep?  
▪ Why is it important to follow SOPs?  
▪ What is the proper way to keep and maintain documents?  
**Records**  
▪ Why are they important?  
▪ What records should you keep?  
▪ What is the proper way to keep and maintain records? |
| 16 Professional Ethics | ▪ Describe ethical issues related to HIV rapid testing  
▪ Explain the importance of professional ethics  
▪ Apply ethical conduct to HIV rapid testing  
▪ Take appropriate actions to maintain client confidentiality | ▪ What is ethics?  
▪ Why is ethics important?  
▪ Who is responsible for ethics?  
▪ How is ethics applied to HIV rapid testing?  
▪ Maintaining confidentiality  
▪ Code of conduct |
Learning Methods / Activities:

The HIV Rapid Testing workshop includes the following types of activities to aid in accomplishing workshop goals and objectives:

- **Presentations** will allow participants gain knowledge through didactic exchange of information.

- **Group discussions** will allow participants to share experiences and ideas.

- **Role plays** will allow participants to learn through simulated situations.

- **Video presentations** will introduce participants to the procedural steps for collecting blood specimens, performing tests, and interpretation of results.

- **Demonstrations** will allow participants to observe a particular procedure or test prior to individual performance.

- **“Hands-on” practice exercises** will allow participants to experience collecting specimens, and performing, and interpreting a variety of HIV rapid tests.

- **Energizer / Games** will reinforce teaching points in fun and lively environment

For further details on these activities, and detailed suggestions for facilitating each of the modules of instruction, refer to Section 4 of this guide: *Presentation Slides and Trainer Notes.*
Competency Certification Criteria:

The following criteria are recommended for certification of individuals who perform HIV rapid testing. The criteria are based upon recommendations outlined in “Guidelines for Assuring Accuracy and Reliability of HIV Rapid Testing: Applying a Quality System Approach.” Please note: Certification criteria must reflect national policy.

A certificate of competency is awarded to participants upon meeting the requirements outlined below:

1) Successfully completing the HIV Rapid Testing training workshop by:
   ▪ Daily attendance
   ▪ Passing score of 80% on written post-workshop examination
   ▪ Passing score of 100 % on final practical examination

2) 100% accuracy of first 50 specimens tested under direct supervision
Section 2: Preparation

Introduction

Thorough preparation is essential to the success of your workshop. This section describes the activities that you must carry out in advance of the workshop to assure that the workshop achieves expected outcomes. Information on the basics of training (Section 3) should also be reviewed in advance so that you, as trainer, are adequately prepared to facilitate the workshop.

Participants (Target Audience)

This training packaged is designed to reach three levels of participants. The presentation slides include a legend that denotes the appropriate target audience.

- Laboratory workers
- Health workers (nurses)
- Counselors

The approach in which the content of this workshop is delivered may be different depending on whether the audience consists of laboratorians, lay counselors, nurses or other health professionals. It is important to have an understanding of your participant’s baseline knowledge and/or fears so that these can be adequately addressed during the workshop. It may be necessary to adjust the time allotted for a particular module of instruction or exercise based on identified need.

Suggested number of workshop participants and trainers

For optimum learning experience and management of the workshop, it is recommended that the number of participants should not exceed 20. This number is small enough for all participants to be fully engaged, yet large enough for a variety of experiences and viewpoints to be represented. It is equally important to have one trainer for every four to six participants to allow
participants ready access to trainers during demonstrations and practical exercise.

**Participant Notification Letter**

Notify participants well in advance of the date, location, and time of workshop. Be sure to include other pertinent information such as payment of per diems, etc.

**Breaks and Lunch**

Before the start of the workshop, arrange for morning and afternoon tea/coffee breaks, and plans for having lunch on or off-site.
Facilities and Equipment:

Training classrooms

For optimal learning experience and ease of managing logistics throughout the workshop, two rooms should be made available:

- Room A - for lectures, discussions, and viewing of the video/DVD
- Room B - for hands-on practical exercises.

The workshop can be held in any well-lit, distraction-free classroom with 1) tables and chairs, and 2) conveniently located outlets for computer and projection monitor. To facilitate discussion and interaction among participants, tables should be arranged in a semi-circle, or classroom style giving all participants an unobstructed view of the projection monitor. Avoid overcrowding. Bottled water and glasses should be made available on each table.

Classroom equipment – The classroom should have:

- 2 flip charts with easel
- a videotape player (VCR) with TV or DVD
- laptop computer
- projection monitor (LCD) compatible with computer
- extension cord
- wastebasket
- markers

Classroom supplies:
- Marking pens
- Masking tape for posting flip chart
- Note pads
- Pens and pencils
Demonstration and Practical Exercises: Materials, Supplies, and Kits

Make arrangements well in advance of the workshop to procure or secure the necessary materials, supplies and kits. Don't forget to arrange for transport of these items to workshop site. Any unused supplies should be held for future workshops.

**Materials and Supplies**

<table>
<thead>
<tr>
<th>Materials and Supplies</th>
<th># required</th>
</tr>
</thead>
<tbody>
<tr>
<td>70% Alcohol or methylated spirit swabs</td>
<td></td>
</tr>
<tr>
<td>Cotton gauze or wool</td>
<td></td>
</tr>
<tr>
<td>Sterile Lancets</td>
<td></td>
</tr>
<tr>
<td>Sharps bin or disinfectant jar for lancets</td>
<td></td>
</tr>
<tr>
<td>Sharps container</td>
<td></td>
</tr>
<tr>
<td>Timer (stopwatch, clock, or wrist watch)</td>
<td></td>
</tr>
<tr>
<td>Markers, Pens</td>
<td></td>
</tr>
<tr>
<td>Biohazard stickers/labels</td>
<td></td>
</tr>
<tr>
<td>Plastic bags for biohazard waste</td>
<td></td>
</tr>
<tr>
<td>Transfer or precision pipettes</td>
<td></td>
</tr>
<tr>
<td>Pipette tips</td>
<td></td>
</tr>
<tr>
<td>Band-Aids or plasters</td>
<td></td>
</tr>
<tr>
<td>Gloves</td>
<td></td>
</tr>
<tr>
<td>Aprons or laboratory coats</td>
<td></td>
</tr>
<tr>
<td>Paper towels</td>
<td></td>
</tr>
<tr>
<td>Soap or hand sanitizer for hand washing</td>
<td></td>
</tr>
<tr>
<td>Disinfectant e.g. Jik, Chlorox</td>
<td></td>
</tr>
<tr>
<td>Spray bottle for disinfectant</td>
<td></td>
</tr>
</tbody>
</table>
Test Kits

The following is a guide to use for assuring you have an adequate number of test devices on hand during the training workshop. The test kits should be those approved for use in the national testing algorithm. You will need to relate the required number of tests with the number of tests packaged in one kit. For example, if you need 100 tests, and a kit is packaged with 20 tests per kit, you will need to order 5 kits.

Number of Tests
Required for 20 Participants

<table>
<thead>
<tr>
<th>Hands-on Session I</th>
<th>Each participant conducts tests using one positive and one negative sample.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test</td>
<td>Practice</td>
</tr>
<tr>
<td>Test Kit 1 ( )</td>
<td>40</td>
</tr>
<tr>
<td>Test Kit 2 ( )</td>
<td>40</td>
</tr>
<tr>
<td>Test Kit 3 ( )</td>
<td>40</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Hands-on Session II</th>
<th>Each participant conducts tests using five blind samples.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test Kit 1 ( )</td>
<td>100 25 125</td>
</tr>
<tr>
<td>Test Kit 2 ( )</td>
<td>100 25 125</td>
</tr>
<tr>
<td>Test Kit 3 ( )</td>
<td>100 25 125</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Performance Exam</th>
<th>Each participant conducts tests using five blind samples.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test Kit 1 ( )</td>
<td>100 20 120</td>
</tr>
<tr>
<td>Test Kit 2 ( )</td>
<td>100 20 120</td>
</tr>
<tr>
<td>Test Kit 3 ( )</td>
<td>100 20 120</td>
</tr>
</tbody>
</table>

Summary – For 20 participants, you will need a total of 900 tests (300 tests of each kit).
Composition of Panels for Hands-on Sessions

The composition of the known positive and known negative samples and the blind samples used during the hands-on sessions is specified as serum,

Session I:

During hands-on session I, participants conduct tests using one positive and one negative sample. *Note:* All serum samples must be heat inactivated prior to use during the practical sessions.

Prepare a serum panel consisting of 2 samples (one HIV positive and one HIV negative) for each workshop participant. Care should be taken in labeling, handling, and storage of samples to maintain integrity.

Allow 2-3 days for preparation and testing of panels prior to the workshop.

**Sample Volume Required for Preparing Panels For 20 Participants**

<table>
<thead>
<tr>
<th>HIV Final Result</th>
<th>Sample Reactivity</th>
<th>Volume / Vial</th>
<th># of Participants</th>
<th>Volume (plus 10% for overage)</th>
<th>Total Volume Required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>Strong Positive</td>
<td>0.5 ml</td>
<td>20</td>
<td>10ml + 1ml</td>
<td>11 ml</td>
</tr>
<tr>
<td>Negative</td>
<td>Negative</td>
<td>0.5 ml</td>
<td>20</td>
<td>10ml + 1ml</td>
<td>11 ml</td>
</tr>
</tbody>
</table>
Session II and Final Practical Exam:

During the hands-on session II and final practical exam, participants are asked to conduct HIV rapid tests using 5 blinded samples. Therefore, a total of 10 blinded samples are required for each participant; 5 used for session II, and the remaining 5 used for the final practical exam. Note: All serum samples must be heat inactivated prior to use.

Prepare two sets of serum panels for each participant; one set for use during Session 2 and the other set for use during the Final Practical Examination. Each panel will be made up of 5 samples: 2 HIV strong positive, 1 HIV weak positive and 2 HIV negative. It is advisable to have extra panels on hand in case of problems or spillage. You will need to allow 3-4 days for preparation and testing of panels prior to the workshop.

Sample Volume
Required for Two 5-Sample Panels
For Each of 20 Participants

<table>
<thead>
<tr>
<th>HIV Status</th>
<th>Sample Reactivity</th>
<th># Samples</th>
<th>Volume / Vial</th>
<th># of Participants</th>
<th>Volume (plus 10% for overage)</th>
<th>Total Volume Required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>Strong Positive</td>
<td>4</td>
<td>0.5 ml</td>
<td>20</td>
<td>40ml + 4ml</td>
<td>44 ml</td>
</tr>
<tr>
<td>Positive</td>
<td>Weak* Positive</td>
<td>2</td>
<td>0.5 ml</td>
<td>20</td>
<td>20ml + 2ml</td>
<td>22 ml</td>
</tr>
<tr>
<td>Negative</td>
<td>Negative</td>
<td>4</td>
<td>0.5 ml</td>
<td>20</td>
<td>40ml + 4ml</td>
<td>44 ml</td>
</tr>
</tbody>
</table>

*Note: While it is desirable to include weak positive samples in the panel, it may be a challenge to obtain a sample that is uniformly weak positive with all test kits.

The table above indicates that to prepare 40 (+ 4 extra) panels each containing 2 HIV strong positive samples, one HIV weak positive sample and 2 HIV negative samples, you would need a minimum of 44 ml of serum from an HIV strong positive donor, 22 ml from an HIV weak positive donor, and 44 ml of serum from an HIV negative donor.
Labeling vials and panels:

For **Session II**, make 4 sets of 5 panels each containing 5 sample vials labeled as described in the table below:

<table>
<thead>
<tr>
<th>Panel Code</th>
<th>Number Of Sets</th>
<th>Strong Positive 1</th>
<th>Strong Positive 2</th>
<th>Weak Positive</th>
<th>Negative 1</th>
<th>Negative 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>4</td>
<td>A1</td>
<td>A2</td>
<td>A3</td>
<td>A4</td>
<td>A5</td>
</tr>
<tr>
<td>B</td>
<td>4</td>
<td>B1</td>
<td>B2</td>
<td>B3</td>
<td>B4</td>
<td>B5</td>
</tr>
<tr>
<td>C</td>
<td>4</td>
<td>C1</td>
<td>C2</td>
<td>C3</td>
<td>C4</td>
<td>C5</td>
</tr>
<tr>
<td>D</td>
<td>4</td>
<td>D1</td>
<td>D2</td>
<td>D3</td>
<td>D4</td>
<td>D5</td>
</tr>
<tr>
<td>E</td>
<td>4</td>
<td>E1</td>
<td>E2</td>
<td>E3</td>
<td>E4</td>
<td>E5</td>
</tr>
</tbody>
</table>

Each participant will receive one panel.

For the **Final Practical Exam**, make 4 sets of 5 panels containing 5 sample vials labeled as described in the table below:

<table>
<thead>
<tr>
<th>Panel Code</th>
<th>Number Of Sets</th>
<th>Strong Positive 1</th>
<th>Strong Positive 2</th>
<th>Weak Positive</th>
<th>Negative 1</th>
<th>Negative 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>4</td>
<td>A1</td>
<td>A2</td>
<td>A3</td>
<td>A4</td>
<td>A5</td>
</tr>
<tr>
<td>B</td>
<td>4</td>
<td>B1</td>
<td>B2</td>
<td>B3</td>
<td>B4</td>
<td>B5</td>
</tr>
<tr>
<td>C</td>
<td>4</td>
<td>C1</td>
<td>C2</td>
<td>C3</td>
<td>C4</td>
<td>C5</td>
</tr>
<tr>
<td>D</td>
<td>4</td>
<td>D1</td>
<td>D2</td>
<td>D3</td>
<td>D4</td>
<td>D5</td>
</tr>
<tr>
<td>E</td>
<td>4</td>
<td>E1</td>
<td>E2</td>
<td>E3</td>
<td>E4</td>
<td>E5</td>
</tr>
</tbody>
</table>

**Note**: If it is desirable, the panels for the Final Exam can have reversed Strong Positive and Negative sample labels so that the Exam panels will not repeat the same labeling scheme as the Session II panels. For example, in the Exam Panels, strong positive samples could be labeled A4 to E4 and A5 to E5, and the negative samples could be labeled A1 to E1 and A2 to E2.

**Validation of Panels:**
All panel samples used during the hands-on sessions MUST be validated prior to the workshop to assure that expected results are obtained on each HIV rapid test kit used.
Print Materials Needed During Training

As workshop facilitator/trainer, it is your responsibility to make sure the appropriate materials are available at the start of the workshop for each participant

- pre-course and post-course tests
- forms to record results of practical examinations
- daily evaluation questionnaire
- post workshop evaluation
- participant manual
- name tents
- name badges

Training Certificates – At the end of the workshop, each participant who has met the criteria for successful completion will receive a Certificate of Training. Prior to the workshop, you will need to:

- Identify appropriate individual(s) to who will sign the certificate
- Verify spelling of names
- Print certificates

Length of workshop:

A number of factors must be considered before deciding the length of a workshop:

1. What national policies must be addressed?
2. Who will be trained?
3. What is the background knowledge and skills of participants?
4. What modules or topics have participants received during previous training?
5. Is the amount of time sufficient for remediation and practice before final practical exam?
Training schedule

The theoretical and practical sessions of this workshop are designed to be delivered in 4 – 5 days.

A template is provided for finalizing your training schedule. Before conducting the workshop, finalize your schedule for the week by completing as follows:

- Write in planned times for breaks and lunch
- Add any additional presentations or activities not included in the template
- Write in planned times for tea/coffee breaks and lunch
- Fill in planned times for the activities in the Workshop Timing column. For example, if the workshop is scheduled to begin at 8:30 a.m., write 8:30 – 9:30 a.m. for the Welcoming remarks and introduction.
## Training Schedule Template

### MONDAY - DAY 1

<table>
<thead>
<tr>
<th>Start Time</th>
<th>End Time</th>
<th>Total Time</th>
<th>Description</th>
<th>Module #</th>
<th>Faculty</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>30</td>
<td>Registration</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 00</td>
<td>Welcome Remarks &amp; Introductions</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>15</td>
<td>Workshop Goals, Objectives</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>▪ Ground Rules, Parking Lot</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>30</td>
<td>Curriculum Overview</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>30</td>
<td>Pre-test</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>30</td>
<td>Overview of HIV Infection</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Integration of HIV Rapid Testing in HIV Prevention &amp; Treatment Programs</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>30</td>
<td>Overview of HIV Testing Technologies</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>30</td>
<td>HIV Testing Strategies and Algorithms</td>
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<tr>
<td></td>
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<td>Review, Q &amp; A, Evaluation</td>
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**Total Time**  
6 20
### TUESDAY - DAY 2

<table>
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<tr>
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<th>Description</th>
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<tbody>
<tr>
<td></td>
<td>Hours</td>
<td>Min.</td>
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</tr>
<tr>
<td>15</td>
<td>15</td>
<td>Assuring Quality of HIV Rapid Testing</td>
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<td>Professional Ethics</td>
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<td>50</td>
<td>50</td>
<td>Preparation for Testing: Supplies and Kits</td>
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<tr>
<td></td>
<td>2</td>
<td>Blood Collection: Fingerprick</td>
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</tr>
<tr>
<td></td>
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<td>Video</td>
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<td>Presentation/Demo</td>
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<td>Practice Session</td>
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<td>Review, Q&amp;A, Evaluation</td>
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<td>45</td>
<td>Performing HIV Rapid Tests</td>
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<td></td>
<td>Session 1</td>
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<td></td>
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<td>Session 2</td>
<td>9</td>
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</tr>
<tr>
<td></td>
<td>20</td>
<td>Review, Q&amp;A, Evaluation</td>
<td></td>
<td></td>
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<tr>
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<th>Module #</th>
<th>Faculty</th>
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<tr>
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<td>Inventory: Managing Stocks at the HIV Rapid Testing Site</td>
<td>10</td>
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</tr>
<tr>
<td></td>
<td>55</td>
<td>Use and Care of Equipment</td>
<td>11</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1 30</td>
<td>External Quality Assessment (EQA)</td>
<td>13</td>
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</tr>
<tr>
<td></td>
<td>1 30</td>
<td>Blood Collection and Handling: DBS</td>
<td>14</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2 00</td>
<td>Site Visits</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total Time</strong></td>
<td><strong>6 55</strong></td>
<td></td>
<td></td>
<td></td>
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### FRIDAY - DAY 5

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<th>Start Time - End Time</th>
<th>Total Time</th>
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<th>Module #</th>
<th>Faculty</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>30</td>
<td>Review of Site Visits</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>30</td>
<td>Q &amp; A</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>30</td>
<td>Written Post-Test</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>2 30</td>
<td>Final Practical Exam (Session 3)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>30</td>
<td>Summary/Reflections</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Closing Ceremony</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Awarding of Certificates</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total Time</strong></td>
<td><strong>5 15</strong></td>
<td></td>
<td></td>
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</tbody>
</table>
Are You Ready? Checklist

This checklist summarizes all the preparatory activities that must be completed before conducting an HIV Rapid Testing workshop. If you are not responsible for carrying out a workshop activity, make sure someone else has been assigned responsibility.

### ACTIVITY CHECKLIST:

**PREPARATION FOR HIV RAPID TEST WORKSHOP**

### BEFORE the WORKSHOP

<table>
<thead>
<tr>
<th>When complete</th>
<th>Activity: Six to Eight Weeks before Workshop</th>
</tr>
</thead>
<tbody>
<tr>
<td>✓✓ ✓✓</td>
<td>Adapt course content based on results of needs assessment.</td>
</tr>
<tr>
<td></td>
<td>Verify or develop training budget.</td>
</tr>
<tr>
<td></td>
<td>Identify target audience.</td>
</tr>
<tr>
<td></td>
<td>Agree on maximum number of participants.</td>
</tr>
<tr>
<td></td>
<td>Finalize names of trainers.</td>
</tr>
<tr>
<td></td>
<td>Finalize names of guest speakers for opening and closing ceremonies.</td>
</tr>
<tr>
<td></td>
<td>Send letter of invitation to co-trainers.</td>
</tr>
<tr>
<td></td>
<td>Send letter of invitation to speakers for opening and closing ceremonies.</td>
</tr>
<tr>
<td></td>
<td>Identify who will be responsible for each task: Develop a list of tasks necessary to present course, and negotiate with co-trainers to decide who will complete each task.</td>
</tr>
<tr>
<td></td>
<td>Meet with co-trainers to coordinate roles and responsibilities (announce date, site and agenda in advance of co-trainer meeting).</td>
</tr>
<tr>
<td></td>
<td>Develop and/or review the participant manual and other training material.</td>
</tr>
<tr>
<td></td>
<td>Determine training supplies and materials needed.</td>
</tr>
<tr>
<td></td>
<td>Develop a detailed agenda setting time-frame for course and speakers.</td>
</tr>
<tr>
<td></td>
<td>Set DATE and LOCATION for workshop. Verify that the date does not coincide with major events or religious holidays. Ensure that invited speakers agree on date and place.</td>
</tr>
</tbody>
</table>

<p>| ✓✓ ✓✓          | Activity: Four Weeks before Workshop |
|               | Develop workshop announcement and registration materials. |</p>
<table>
<thead>
<tr>
<th>Mail workshop announcement and registration materials to target audience. Announcement should include: “who should attend”, course title, course content/agenda, course objectives, date and location, instructions for registering, lodging/travel information (if necessary) and name of contact person.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Confirm arrangements for travel and lodging for co-trainers and guest speakers, if necessary.</td>
</tr>
<tr>
<td>Agree on arrangements such as per diem for co-trainers and guest speakers.</td>
</tr>
<tr>
<td>Identify site(s) and contacts for site visit(s), if included in agenda.</td>
</tr>
<tr>
<td>Send letter of confirmation to co-trainers.</td>
</tr>
<tr>
<td>Send letter of confirmation to guest speakers for opening and closing ceremony.</td>
</tr>
<tr>
<td>Send letter of confirmation to hosts of field visit site(s).</td>
</tr>
<tr>
<td>Develop course flyer and registration materials.</td>
</tr>
<tr>
<td>Set agenda for Opening Ceremony and Course Introduction.</td>
</tr>
<tr>
<td>Set agenda for Closing Session.</td>
</tr>
<tr>
<td>Order or assemble training supplies including pencils, pens, reagents, test kits and equipment.</td>
</tr>
<tr>
<td>Provide deadlines for co-trainers for submitting audiovisual materials, audiovisual equipment needs and handouts for printing.</td>
</tr>
</tbody>
</table>

**✓✓ ✓✓**

**When complete**

**Activity: Three Weeks before Workshop**

- Reserve audiovisual equipment (check working condition, extra light bulbs, and electrical outlet requirements).
- Obtain flip charts, pointers, felt tip markers and other training materials as needed.
- Confirm training venue location. Check venue for adequate light, space, seating arrangement, temperature control, handicap access, etc. If planning a wet workshop, check facility for appropriate space for laboratory supplies and equipment.
- Develop Pre- and Post-test forms.
- Develop Workshop Evaluation form.
<table>
<thead>
<tr>
<th>✓ When complete</th>
<th>Activity: Two Weeks before Workshop</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Print and assemble participant manual.</td>
</tr>
<tr>
<td></td>
<td>Print handouts, Pre-and Post-test forms, Evaluation forms, agenda, etc.</td>
</tr>
<tr>
<td></td>
<td>Check on progress of participant registration.</td>
</tr>
<tr>
<td></td>
<td>Assemble audiovisual materials (power point files, videos, overheads).</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>✓ When complete</th>
<th>Activity: One Weeks before Workshop</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Make name tags for participants, co-trainers and speakers.</td>
</tr>
<tr>
<td></td>
<td>Develop sign in sheet for participants.</td>
</tr>
<tr>
<td></td>
<td>Develop course completion form or course certificate.</td>
</tr>
<tr>
<td></td>
<td>Confirm audiovisual reservations.</td>
</tr>
<tr>
<td></td>
<td>Prepare supplies and training materials for transport to training site.</td>
</tr>
<tr>
<td></td>
<td>Review and rehearse training curriculum.</td>
</tr>
<tr>
<td></td>
<td>Prepare welcome and directional signs for the training site.</td>
</tr>
</tbody>
</table>

**DURING THE WORKSHOP**

<table>
<thead>
<tr>
<th></th>
<th>Day 1: One hour before start time:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Place welcome and directional signs at the facility</td>
</tr>
<tr>
<td></td>
<td>• Set up table to register/sign in participants and distribute training manual, name tags, training handouts and course agenda</td>
</tr>
<tr>
<td></td>
<td>• Check set up of room, check audiovisual equipment, adjust temperature, check supplies (markers, flip charts, etc.)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Day 1:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Day 1:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Conduct training according to agenda</td>
</tr>
<tr>
<td></td>
<td>• Conduct Pre-test.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Day 2 thru last day, one hour prior to schedule start time:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• check set up of room</td>
</tr>
<tr>
<td></td>
<td>• check audiovisual equipment</td>
</tr>
<tr>
<td></td>
<td>• adjust temperature</td>
</tr>
<tr>
<td></td>
<td>• Check that all necessary supplies are in place</td>
</tr>
</tbody>
</table>

| Last day: Conduct post-test and evaluation. |

**IMMEDIATELY AFTER THE WORKSHOP**

|                       | Debrief with co-trainers. |

|                       | Send thank you letters to speakers and other key officials. |
| **Assemble and evaluate pre-and post-test data.** |
| **Analyze workshop evaluation data.** |
| **Prepare report of training.** |

**1-3 MONTHS AFTER THE WORKSHOP**

- Follow up with participants to verify if they were able to apply knowledge and skills obtained during the workshop.
- Identify additional technical assistance or further training needed.
Section 3: Training Basics

What Does it Mean to Facilitate?
Facilitating means a lot of things. The table below provides an outline of the topics discussed in this section:

<table>
<thead>
<tr>
<th>Topics</th>
<th>What is Discussed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Know Your Audience</td>
<td>Demographics, knowledge, skills, attitudes, experience, job/position, education, and training needs</td>
</tr>
<tr>
<td>Apply Adult Learning Principles</td>
<td>• Understand adult learning principles&lt;br&gt;• Use repetition to encourage remembering&lt;br&gt;• Blend styles&lt;br&gt;• Provide a variety of learning methods and materials</td>
</tr>
<tr>
<td>Be Prepared to Train</td>
<td>• Know what you are training&lt;br&gt;• Use effective organization skills&lt;br&gt;• Practice&lt;br&gt;• Prepare the training room&lt;br&gt;• Have a backup plan</td>
</tr>
<tr>
<td>Manage the Training</td>
<td>• Manage training time&lt;br&gt;• Manage difficult participants&lt;br&gt;• Manage difficult locations and facilities&lt;br&gt;• Manage equipment and materials</td>
</tr>
<tr>
<td>Communicate Effectively</td>
<td>Facial expression, voice, eyes, ears, nose, hands, feet, mind, and heart</td>
</tr>
<tr>
<td>Engage the Participants</td>
<td>Using questions to engage participants and determine their level of understanding</td>
</tr>
<tr>
<td>Use Visual Aids Effectively</td>
<td>Tips on using visual aids</td>
</tr>
</tbody>
</table>
Know Your Audience

One of the most important aspects of training is to know who your audience is. Knowing who your target audience is will help you know how to design your training and also who to invite to the training course.

Following are some outcomes of identifying who the audience is:

- **Demographics (i.e., age, sex, where they work)**
  This will help with logistics of the training as well as for planning for the types of examples to use in the training.

- **Knowledge**
  Knowing the in-coming knowledge level of the topic will help determine what level of content is needed (low, medium, or high) and what type of exercises are needed.

- **Skills**
  It is important to know what the in-coming skill level is of the participants so you will know how to plan what skills to teach. It will help determine if the training is to provide new skills or simply a refresher to skills the participants already know.

- **Attitudes**
  Knowing what the attitudes are about the topic of the training can help address fears, concerns or biases during the training.

- **Experience**
  Knowing the experience level of the participants will help when designing the content and exercises. It will also help in knowing what technical level is required for training. In addition, it will help you can identify those people who have a lot of experience and can contribute to the discussions. Also for exercises you can pair-up participants who have a lot of experience with those who have less experience.

- **Job/position**
  Knowing the jobs or positions that the participants have will help you relate the training to their jobs.

- **Education**
  Knowing the education level and also the type of education of the participants can help you know what level of language to use, as well as what type of examples to use.

- **Training needs**
  Knowing what the training needs are of the participants will help you design your course to provide training skills that will actually be used. If participants don’t need certain things in a course it may help you know what information to delete or what to cover quickly.
Ways to Learn about the Audience

There are many ways to learn about the audience that include:

• Conduct a needs assessment
  • Have participants complete a pre-assessment form. It is best to have them complete the form and send it to you before the training but sometimes that does not work out. If so, have them complete it at the beginning of the training.
  • Before the training, talk with participants and others knowledgeable sources (i.e., supervisors)
  • During the training, include a “get-to-know-you” exercise
Apply Adult Learning Principles

Many people think that training adults is the same as teaching students in a traditional school system. But this is not true. Adults learn differently from children and require different training approaches. Knowing how adults learn is critical to the success of your training courses. The following chart describes some important adult learning principles and training techniques you can use to engage the adult learner.

<table>
<thead>
<tr>
<th>Principle</th>
<th>Training Technique</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adults bring a wealth of knowledge and experience and they want to share their knowledge and experience</td>
<td>Encourage participants to share their knowledge and experiences. Include activities that utilize their knowledge and experience</td>
</tr>
<tr>
<td>Adults are decision-makers and self-directed learners.</td>
<td>Include problem-solving activities</td>
</tr>
<tr>
<td>Adults have different learning styles that must be respected</td>
<td>Provide multiple ways for participants to learn the material</td>
</tr>
<tr>
<td>Adults want to participate rather than just listen to a lecture</td>
<td>Create a participatory learning environment with various types of activities</td>
</tr>
<tr>
<td>Adults are motivated by information or tasks that are meaningful and applicable to their jobs.</td>
<td>Relate the content and skills to the participants jobs</td>
</tr>
<tr>
<td>Adults prefer training that focuses on real life problems</td>
<td>Relate content to the types of problems they encounter in their jobs</td>
</tr>
<tr>
<td>Adults expect their time during training to be used carefully</td>
<td>Follow a realistic time schedule</td>
</tr>
<tr>
<td>Adults feel anxious if participating in a group that makes them look uninformed, either professionally or personally</td>
<td>Avoid criticism. Acknowledge all participants contributions.</td>
</tr>
<tr>
<td>Adults learn best in a positive environment where they feel respected and confident</td>
<td>Create a positive environment by provide positive feedback and showing respect to all participants.</td>
</tr>
<tr>
<td>Adults come from different cultures, lifestyles, religious preferences, genders, and ages.</td>
<td>Respect all differences and encourage participants to respect each other’s differences as well.</td>
</tr>
</tbody>
</table>
Three Basic Learning Styles
In addition to principles of adult learning there are three basic learning styles. These include

- **Visual**: Learn through watching, observing, and reading
- **Auditory**: Learn through hearing
- **Kinaesthetic**: Learn through moving, doing, practicing, and touching

Most people use all three styles, but usually have a dominant or preferable style. The style of learning that people use also depends on the skills and knowledge that are being taught.

For example:

**When learning how to counsel clients, participants use:**
- **Visual** – to learn protocols, observe good counselling behaviours
- **Auditory** – to learn ways to say certain things,
- **Kinaesthetic** – to learn how to counsel the patient, say the right words, show compassion, follow the right counselling methods

**When learning how to perform an HIV rapid test, participants use:**
- **Visual** – to see how to perform the tests
- **Auditory** – to learn ways to say certain things,
- **Kinaesthetic** – to practice performing the test

What Adults Remember
The following chart provides information on what adults remember. This is very important for knowing how to design your training. If a trainer only lectures then participants will probably only remember 20% of what is said. So creating a participatory training where participants are active and “saying and doing” will help them remember more from the training.

**What Adults Remember**
Use Repetition to Encourage Remembering
For people to actually learn something they sometimes have to hear it 7 times.

So Repeat, Repeat, Repeat
• In the Introduction: Tell them what you are going to tell them
• In the Presentation: Tell them
• In the Summary: Tell them what you just told them

So less content with more repetition may mean more learning will occur!

Blending Styles
Following is a well-known saying in training courses:
I hear and I forget.
I see and I remember.
I do and I understand.

But remember:
• Some people learn (and remember their learning) primarily by hearing others talk.
• Some people learn primarily when they only see someone do an activity or they can see visuals and printed materials
• Some people learn by moving and doing

Key Point to Learning Styles
So how do you plan your training given all of these different aspects about how people learn? The goal is not to focus on one style of learning but to use a blend of methods to reach the greatest number of adult learners. For example

Provide a variety of learning methods such as
• Lectures
• Discussions
• Role-plays
• Exercises (i.e., quizzes, brainstorm)

Provide a variety of training materials such as:
• Slides
• Manuals/handouts
• Videos
Be prepared to Train

Know what you are training – this is very critical to the success of the training. Even the best of training skills will not hide the fact that a trainer does not know the content.

- Know the goals and objectives of the training
- Know the content of the training
- Know the training activities (i.e., discussions, exercises, role-plays, demonstrations)

Use effective organizational skills

- Organize the training logically
- Follow a plan
- Use checklists
- Keep everyone informed

Practice

Practicing your training presentations helps to ensure that they will be successful.

- Out loud in front of a mirror (if you will be standing to present then practice that way)
- With the materials and equipment before the training
- Rehearse in the training room if possible
- Time your presentation

Prepare the Training Room

- Check room before the training
- Make sure all of your materials, supplies and equipment are available
- Arrange training room to allow for the best learning situation
- Test all equipment before the training
- Download files on the computers (if necessary)
- Prepare as much ahead of time as possible (i.e., flip chart pages, distribute manuals/handouts, arrange things for activities, exercises and demonstrations)

Have a Back-up Plan

Sometimes problems occur so it is best to have a back-up plan for those problems that can be anticipated.

- Have extra materials and supplies available
- Use multiple formats (handouts, slides, overhead transparencies, flip charts). Sometimes the electricity will go out and so the PowerPoint slides will not be able to be shown or maybe the bulb on the project will blow out. Having handouts available will enable the training to continue.
- Be flexible. Problems often occur so relax and adjust to the situation.
- Make positive situations out of negative ones. For example, when problems occur make them into a learning situation.
Manage the Training

As the facilitator you are the **manager of the training**. It is up to you to create a successful training that meets the goals and objectives. Following are some suggestions for how to manage the training.

**Do Your Best to KEEP ON TIME – it shows respect for:**
- Your commitment to the time allotted
- The participants so they know what to expect
- Those that follow your presentation so they don’t have to rush through or cut short their presentations

**Ways to Keep on Time**
- **Practice before the training.** Practice the presentation out loud. Review your material so you will know what can be covered quickly and if necessary deleted. Practice your presentation using the equipment. This will help you determine how long it takes for presentations and activities.
- **Use a clock that the facilitator can see.**
- **Use an agenda that shows the amount of time** for presentations as well as the times of day. For example:
  
  8:30 – 9:00   30 minutes.
  
  This reinforces the amount of time that each presentation takes so that people don’t have to add it up in their heads.
- **Review the agenda with all facilitators ahead of time.** Emphasize the importance of staying on time and how it shows respect.
- **Set up a time keeping structure and review with facilitators**
  - Designate a time-keeper to provide visual reminders with signs that show
  - 5 minutes
  - 1 minute
  - Stop
  - If necessary, use a bell to signal the end of the time
  - If the bell doesn’t work you may have to interrupt
- **Keep the training focused on the objectives**
- **Let participants know what to expect.** Review the agenda at the beginning of each day.
- **Use the “parking lot”** for discussions that take too much time or are related to but not critical to the training – but they are critical to the participants
  - The “parking lot” is a sheet of flip chart paper posted on the wall of the training room. The purpose is to provide a place to put interesting topics that are taking up too much time or are related to but not critical to the training. These topics are usually critical to the participants. The topics are written on paper and sit in the “parking lot” until time is available to discuss them at the end of the course or during breaks, lunch or at the end of the day.
- **Refer to handouts** in the manual for more details
- **Know the “need to know” content**
- **Know what content or activities can be shortened or deleted**
• **Adjust the schedule when things take longer**
  – Shorten breaks, lunch
  – Lengthen the day
  – Delete some presentations or activities

**Manage Difficult Participants**

Managing participants in a training situation is an important skill to have as a trainer. Using “ground rules” (see handout on Ground Rules) at the beginning of the training can provide a means of establishing how people should act during the training.

When there are participants who are difficult, it is up to the trainer to manage the situation so that participants do not disrupt the training. Following are examples of difficult participants and how their behavior can be managed

- **“Dominates the conversation”**
  There is usually at least one person in each group that tries to dominate the conversation. They frequently have a lot of experience and knowledge and are very eager to share that with everyone.
  Ways to manage this behavior include:
  o Refer to the ground rules (Be sure to include in the ground rules that no one person should dominate the conversation and that all participants should have the opportunity to contribute)
  o Thank them for their valuable contribution and say that we need to also hear from other participants
  o Mention that they have already provided a lot to the discussion and you want to hear what other people have to say
  o Use body language such as not looking at them when asking for responses and standing in front of them and looking at the other participants for responses
  o When asking for responses it may become necessary to ignore them
  o It may become necessary to interrupt them and summarize their comments before hearing from other participants
  o Give them a task to do that supports the course objectives
  o If necessary, speak to them outside the training room

- **“Interrupts others”**
  Some participants have a habit of interrupting others so as the trainer it is important to manage this type of behavior. Ways to manage this behavior include:
  o Refer to the ground rules (make sure that one-person should talk at a time is included as a ground rule at the beginning of the training).
  o If they continue interrupt mention that the other person was not finished.
  o If necessary, speak to them outside the training room

- **“Know-it-all”**
  Some participants will try to challenge the trainer or try to make the trainer look bad. They think they know everything and will make remarks to undermine the knowledge or authority of the trainer. Ways to manage this behavior include:
- Acknowledge their valuable experience and ask if there are other opinions
- When they ask you a question ask them what they think the answer is or open up the question to others
- Give them a task to do to help with the training
- If necessary, speak to them outside the room

**“Does not participate”**
Some participants will not respond. They may be shy, or not interested, or have been forced to attend the training, or may not be an appropriate person to be attending the training. Whatever, the reason it is important to encourage all participants to contribute. Ways to manage this behavior include
- Use your body language to encourage them to participate.
- Look directly at them when asking to hear from some of the people who have not contributed
- Stand by them and look at them when asking questions
- Talk to them outside the training room to establish a connection
- Find out about their experience and knowledge so that can be incorporated into questions.
- Ask them to help you in some way (i.e., write on the flip chart, pass out papers, summarize key concepts)
- If necessary, ask them outside the training room why they are not involved in the training.

**“Does not want to be at the training”**
Some participants are forced to come to the training by their supervisors. So they can resent the training and see it as a punishment rather than an opportunity to learn. Ways to manage this behavior include:
- During the introduction to the training you can mention that everyone is coming to the training for different reasons that you would like to set a tone of open-mindedness because everyone can learn something from any situation.
- Emphasize the value of each individual and how they will contribute to the success of the training.
- Specify the follow-up process to the training. Emphasize that they may need to demonstrate the skills as part of their job requirements.

Also, some people like to attend trainings because it simply gets them away from the office or they can earn extra money through the per diem. As a result, they may not think that their active participation or learning the content is necessary. Ways to manage this behavior include:
- Emphasize the value of each individual and how they will contribute to the success of the training.
- Ask them to help you in some way.
- If necessary ask them outside the training room why they are not involved in the training.
- Specify the follow-up process to the training. Emphasize that they may need to demonstrate the skills as part of their job requirements.
This situation can be avoided by ensuring that the right participants attend the training. Communicate with supervisors about the criteria for who should participate in the training.

Manage Difficult Training Locations
Location of training course
Adult learners have responsibilities for their families and their jobs and so it is difficult for them to attend trainings away from work or their families.

- **Too close to work**
  - Some locations are too close to work and they get distracted. Choose a location that ensures that participants will provide their undivided attention – this might mean a hotel in another city.
  - If it is important for participants to do course work at night, it is important that the training be held out of town where they stay in a hotel. Adult learners have responsibilities for their families so it is difficult for them to do work at night.
  - Participants are more likely to arrive on time and be focused on the training if they stay in a hotel.

- **Difficult to get to**
  If locations are difficult to get to it can discourage participants from attending. This is an important consideration if the training is held in the same city where the participants live. If it is difficult to travel to the location it can be more expensive and require extra time to get to.
  - Choose a location that is easy to get to.

Training room
- **Temperature** - The temperature of the training room can cause participants to be too hot or too cold. And the “best temperature” will vary from person to person. Try to choose a medium temperature that is comfortable for “most” participants.
- **Electricity** - There needs to be adequate electrical outlets for the training and the outlets need to be in appropriate locations. If extension cords have to be used make sure they are secured so people do not trip over them.
- **Lighting** - In appropriate lighting can be very distracting to the training especially when showing slides. So try to choose a training room that enables you to lower the lights enough for people to see the slides, computer screens, videos but bright enough to read their handouts.
- **Layout** - When the training room is too big, too small, or too narrow it can cause problems. It is important to check out the room before the training to ensure that it is the right size and can be set up in a way that maximizes learning and provides a comfortable environment.
- **Noise** – noise level can be distracting. So choose a training location that does not have outside noise level.

Manage Difficult Things
- **Equipment problems**
• Sometimes equipment (especially computers) does not work
• Sometimes equipment does not arrive
• Sometimes the wrong equipment is sent.

Plan ahead and have back-up plans. Be sure to checkout the equipment before the training to prevent unexpected problems during the training. If equipment is provided by someone else (or a company) be sure to put your request in writing and double check before the training that the correct equipment will be provided.

• Materials
  • Sometimes these do not arrive on time
  • Sometimes the manual was not assembled correctly.
  • Not enough materials
These problems can be avoided if you plan ahead and have materials delivered in plenty of time to correct any mistakes.
Communicate Effectively

Being a good facilitator requires having good communication skills. You have many ways of communicating that can help you in your training.

<table>
<thead>
<tr>
<th>Ways to Communicate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Facial expression</td>
</tr>
<tr>
<td>Voice</td>
</tr>
<tr>
<td>Eyes</td>
</tr>
</tbody>
</table>

Use your Facial Expression

- **Set the tone of the training** (friendly and supportive) if your expression is friendly and approachable it will encourage participants to engage in the training
- **Convey a friendly expression** – Smiles are contagious. If you smile, participants tend to smile back. This is one way to create a friendly and supportive training environment.
- **Provide positive reinforcement** – By smiling when people respond, they are more likely to respond again
- **Show enthusiasm** – If you show enthusiasm for your training it encourages the participants to be enthusiastic also

Use your Voice

Your voice is the **main way and most important way to communicate** with participants.

**Your voice**

- Sets the tone of the training (friendly and supportive)
- Conveys most of the training content
- Shows enthusiasm
- Encourages participation
- Provides positive reinforcement
- Can be used to help manage the training

Use trainer’s voice

- Project your voice so everyone can hear you – what you have to say is important and it is critical that everyone hears you.
- Vary your pitch – so you sound interesting and provide emphasis to those things that are important
- Use a comfortable and varied pace – to provide interest and emphasis. If you speak too fast, participants might miss some of your most important information. If you speak too slowly, it can put them to sleep. It is also
It is important to use the appropriate pacing for the types of training you are doing. For demonstrations or complex information, you will need to speak a little slower. If your accent or language is different from the participants then speak slowly enough that they can easily understand you.

- Speak at the right technical level
- Use a friendly tone
- Use a microphone, if necessary. Practice using a microphone and check with the participants about what is the best level for your voice. Don’t hold the microphone too close or too far away. Also, ask participants to speak into the microphone when they are asking questions or commenting.

**Use your Eyes**

**Way to communicate with participants**

- Show enthusiasm
- Encourage participation
- Provide positive reinforcement
- Manage the training

**Way to observe**

It is important for you to observe what is happening with the participants to determine things such as:

- Are participants engaged?
- Do participants understand?
- What is the energy level?
- Are there group dynamics?
- Who is not participating?

**Use your Ears**

**Important way to communicate with participants**

- Listen to participants. This is a very important skill for a facilitator especially when creating a participatory learning environment
  - Listen and wait for participants to finish what they are saying
  - Use pauses to allow participants respond
  - Use silence to manage the training

**Way to hear**

- Do participants understand?
- Are there concerns?
- What are the needs of the participants?
Use your Nose

- To “sniff” out problems
- If there is trouble in the air check it out
  For example problems with equipment – sometimes equipment becomes too hot. Or other types of problems that might occur might include personal problems between participants or people not understanding the content.

Use your Hands

- **Show expression.** Be natural about using your hands. They are a great way to show expression and emphasis.
- **Encourage participation.** An open hand is a non-verbal signal to encourage people to comment.
- **Provide positive reinforcement.** Sometimes a pat on the shoulder can be comforting.
- **Demonstrate procedures.** Hands are used to demonstrate procedures and processes.
- **Use media.** Of course you use your hands when using media.

Use your Feet

Moving around the training room is beneficial to both the participants and facilitators.

- **To encourage participation.** Moving towards a participant when they comment can encourage them to contribute. It makes you more accessible to the participants. Hiding behind a podium creates a barrier between you and the participants – which creates a formal non-participatory training.
- **To ease nervousness.** Walking around can help ease nervousness and make you feel more relaxed in front of the participants.
- **To provide variety.** If you walk around, participants are looking in various places – not always at one spot.
- **To manage the training.** Standing in front of a difficult person with your back to them can convey the message that you want to hear from other people. Standing by people who don’t respond can encourage them to contribute.

Moving around is good, but do not move around so much that it is distracting.

Use your Mind

- **Be adaptable and resourceful.** If problems arise, adapt to the situation and use your resourcefulness to handle the situation.
- **Be creative.** Training can be fun or boring. It is up to you to bring it to life. Think of new and participatory ways to teach the content of the course.
- **Anticipate problems.** Think ahead to what problems might occur and determine possible solutions. This is part of having a back-up plan.
- **Make positive situations out of negative ones.** When problems occur make them learning situations.
Use your Heart

- **Show respect.** Participants come from many backgrounds and it is important as a facilitator that you show respect for all individuals. Even if you do not agree with them, you need to respect their point of view. If you set the tone of showing respect to all participants it will help them show respect for each other.

- **Recognize that everyone has their own style.** Not everyone will do things the same way or at the same pace. As a facilitator, it is important to show acceptance for different ways of doing things.

- **Show support when people make mistakes.** As adults we all get embarrassed when we make mistakes. By showing support for them in these situations you create a positive and safe learning environment.

- **Show compassion.** We all have problems and difficult situations. So it is important to show compassion for participant.

A Great Communicator

In conclusion, a great communicator needs to have:

- **Smile of a pig** – pigs have a constant smile on their face.
- **Eyes of a tiger** – tigers are extremely alert and can even see things in the dark
- **Ears and nose of an elephant** – elephants have enormous ears and a giant nose that can sense things from miles away
- **Hands of a monkey** – monkeys are very dexterous
- **Feet of a gecko** – geckos have little suction cups on their feet to allow them to walk anywhere – including up walls and on ceilings
- **Mind of a fox** – foxes are very smart and very quick to adapt to situations
- **Heart of a whale** – being the largest animal on earth whales also have the biggest heart
- **Voice of a mockingbird** – Mocking birds have beautiful voices and sing many songs so there is variety in their voice.
Engage the Participants

Engaging participants in the training can be both challenging and rewarding. There are many training techniques that help participants stay engaged. For example:

- Create participatory learning situations
- Use a variety of:
  - Presentation styles
  - Media
  - Learning activities and exercises where they can apply the information
- Change the pace and activity (about every 20 minutes)
- Use examples that participants can relate to their jobs/situations
- Use humor (where appropriate)
- Use questions during your presentations

Use Questions to Engage the Participants

- Encourages all participants to contribute
- Allows for differences of opinions
- Encourages participants to share knowledge and experiences
- Keeps participants alert

Use Questions to Determine Participants Knowledge and Understanding

- Ask participants to explain complex issues
- Ask participants how they would apply information to their jobs
- Ask participants to repeat key content during reviews

There are three types of Questions

- Closed-ended
  A closed-ended question solicits a short, closed-ended answer such as “yes” or “no” or just a few words, and does not generate discussion by limiting what the participant says.
  Examples
  - Is it X or Y...
  - Do you need ...
  - Have you ever...
  Beneﬁts of using close-ended questions are that they can be used for a ﬁnal answer, a conclusion, or for conﬁrmation.
  Limitations of using close ended questions are that they do not encourage very much participation

- Open-ended Questions
  This type of question solicits descriptive answers and generates discussion.
  Examples:
  - What are some ways...


• How can you do...
• Why would you want to...
• Tell me about...

**Benefits of using open-ended questions** are that they encourage the audience to participate, to share their ideas and experiences.

• **Probing Questions**

These are questions that probe for more information and ask participants to share their opinions or ideas about a subject.

**Examples:**
• Tell me more about...
• Could you explain...
• Would you elaborate..
• What would be an example...
• Anything else...

**A benefit of using probing questions** is that it encourages participants to share more details and go into greater depth.

**Quiz: Name the type of question**

1. How can trainers manage the training course?
2. What are some communication techniques you can use in training?
3. Tell me more about the techniques?
4. Have you ever dealt with a difficult participant before?


**Use Questions Effectively**

• Ask questions that focus on the “need to know” information
• Be sure not to embarrass participants by “putting them on the spot” with difficult questions they cannot answer
• Repeat questions and comments from participants to make sure that everyone in the room has heard them
• Give positive feedback when participants contribute
• If you do not know the answer ask participants to answer or state you don’t know but you will find out

**What Should you do When Participants Do Not Respond to a Question?**

• Maintain a deliberate silence
• Repeat or rephrase the question or rephrase the question
• Use body language or eye contact to encourage participants to contribute
• Encourage answers with positive statements (Take your time. I know some of you have had experience with this and I would like to hear about your experience.)
• Give an example
• As a last resort, answer the question yourself if none of the participants answers.
How do you Elicit More from Participants after an Initial Response?

- Make a reflective statement giving a sense of what the participant said (“What I heard you say was….”)
- Invite elaboration (“This is very interesting. Can you tell us more?”)
- Encourage other participants to comment (“Can anyone else comment or add to that?”)
Use Visual Aids Effectively

(Adapted from Witt Communications Inc.)

Visual aids are an aid to communication, not a substitute for it. To retain your relationship with the learners, don’t let your visual aids upstage or overpower you. It is especially important and difficult to maintain the speaker-audience interaction while using slides or Power-Point presentations in a dimly lit room.

1. Plan your presentation before you create visual aids

Start by asking what you want the audience to do as a result of hearing your presentation. Then figure out what they need to know to do what you want them to do. Then create a simple outline that logically and clearly develops your main points. Finally, create visuals aids to support your message.

2. Use visual aids sparingly

They are aids to your presentation—not its sum and substance. Use them to highlight and support your key points.

3. Make visual aids visible to the entire audience

Projecting an image people can’t see is as senseless as speaking so softly people can’t hear.

4. Talk to the audience, not the visual aid

The 80/20 rule applies here. Look at the audience at least 80% of the time.

5. Avoid over-using laser pointers

Your aid should be so clear and easy for your audience to follow. Use laser pointers sparingly.

6. Explain the content of the visual aid when you first show it

As soon as you show people an object, they look at it—even if you’re talking about something else. Don’t make them divide their attention.

7. When you finish with the visual aid, remove it, cover it or turn it off.

Same as # 6

8. Limit the amount of material on any one visual aid

Use each slide to convey a single point. Bullet points—no more than fore to five per slide—should explain, illustrate, or substantiate that one point.

9. Avoid clip art from well-known sources.
It’s almost always boring and amateurish.

10. **Be prepared to give your presentation without your visual aids**

   Murphy’s Law applies in spades to everything involving technology and an audience. Have a backup plan in case something goes wrong. Take a hard copy of your slides or an overhead projector and transparencies or prepared newsprint.
HIV Rapid Testing Workshop Introduction

**Purpose**
To provide an overview of the HIV Rapid Testing workshop.

**Pre-requisite Modules**
None

**Module Time**
30 minutes

### Module Overview

<table>
<thead>
<tr>
<th>Step</th>
<th>Time</th>
<th>Activity/Method</th>
<th>Content</th>
<th>Resources Needed</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>10 min</td>
<td>Presentation</td>
<td>Workshop overview</td>
<td>Slides 1-7</td>
</tr>
<tr>
<td>2</td>
<td>20 min</td>
<td>Activity</td>
<td>Participant introduction</td>
<td>Slide 8</td>
</tr>
</tbody>
</table>

### Material/Equipment Checklists
- Workshop agenda handout
<table>
<thead>
<tr>
<th>Slide Number</th>
<th>Teaching Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td><strong>Workshop Introduction</strong></td>
</tr>
<tr>
<td></td>
<td>DISPLAY this slide before you begin the workshop.</td>
</tr>
<tr>
<td>2</td>
<td><strong>Workshop Goal</strong></td>
</tr>
<tr>
<td></td>
<td>STATE the goal on the slide.</td>
</tr>
<tr>
<td>3-4</td>
<td><strong>This Workshop Has 16 Modules</strong></td>
</tr>
<tr>
<td></td>
<td>EXPLAIN the modules that will be covered in the workshop.</td>
</tr>
<tr>
<td>5</td>
<td><strong>How Will You Learn?</strong></td>
</tr>
<tr>
<td></td>
<td>EXPLAIN The participants will learn from a variety of ways, which include lecture, discussion, paper-based exercises, instructional video on how to perform HIV rapid tests, hands-on practices, games, and role plays.</td>
</tr>
<tr>
<td>6</td>
<td><strong>Certification Criteria</strong></td>
</tr>
<tr>
<td></td>
<td>EXPLAIN the requirements for obtaining certification for performing HIV rapid tests.</td>
</tr>
<tr>
<td>7</td>
<td><img src="Image" alt="Customization Notes" /></td>
</tr>
<tr>
<td>8</td>
<td><strong>Activity</strong></td>
</tr>
<tr>
<td></td>
<td><strong>Let’s Introduce Ourselves</strong></td>
</tr>
<tr>
<td></td>
<td>ASK each participant to introduce him or herself by providing the following information:</td>
</tr>
<tr>
<td></td>
<td>▪ Name</td>
</tr>
<tr>
<td></td>
<td>▪ Job position</td>
</tr>
<tr>
<td></td>
<td>▪ Organization</td>
</tr>
<tr>
<td></td>
<td>▪ Expectation for the workshop</td>
</tr>
</tbody>
</table>
Module 1: Overview of HIV Infection

Purpose
To provide the participants with the basic terms and concepts related to HIV infection.

Pre-requisite Modules
None

Module Time
30 minutes

Learning Objectives
At the end of this module, participants will be able to:
• Describe the difference between HIV infection and AIDS
• Discuss the HIV epidemics globally, regionally, and locally in terms of number of people affected
• Define the terms: antibody and antigen
• Explain how “window period” may affect HIV testing results
• Describe the progression of HIV infection

Module Overview

<table>
<thead>
<tr>
<th>Step</th>
<th>Time</th>
<th>Activity/ Method</th>
<th>Content</th>
<th>Resources Needed</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2 min</td>
<td>Presentation</td>
<td>Module introduction</td>
<td>Slides 1-3</td>
</tr>
<tr>
<td>2</td>
<td>25 min</td>
<td>Presentation</td>
<td>HIV/AIDS overview</td>
<td>Slide 4-19</td>
</tr>
<tr>
<td>3</td>
<td>3 min</td>
<td>Q&amp;A</td>
<td>Summary</td>
<td>Slide 20</td>
</tr>
</tbody>
</table>

Material/Equipment Checklists
- PowerPoint slides or transparencies
- Overhead projector or computer w/LCD projector
- Prepared Flipchart – content outline
- Handout – WHO Staging System for HIV Infection and Disease in Adults and Adolescents
<table>
<thead>
<tr>
<th>Slide Number</th>
<th>Teaching Points</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>TIPS</strong></td>
<td>For participants without medical or laboratory background, keep the presentation simple and avoid using technical jargons without explaining them first. For participants with medical or technical background, you may need to provide more in-depth information.</td>
</tr>
<tr>
<td>1</td>
<td><strong>Module 1: Overview of HIV Infection</strong>&lt;br&gt;DISPLAY this slide before you begin the module.</td>
</tr>
<tr>
<td>2</td>
<td><strong>Learning Objectives</strong>&lt;br&gt;STATE the objectives on the slide.</td>
</tr>
<tr>
<td>3</td>
<td><strong>Content Overview</strong>&lt;br&gt;EXPLAIN the topics that will be covered in this module.</td>
</tr>
<tr>
<td><strong>Flipchart</strong></td>
<td>WRITE the content outline on a flipchart prior to training. REFER to it frequently to orient participants to where they are in the module.</td>
</tr>
<tr>
<td>4</td>
<td><strong>What is HIV?</strong>&lt;br&gt;STATE Many people see HIV and AIDS as being the same thing, and therefore make the assumption that someone who is HIV-positive could die tomorrow. This is not true. It is important to distinguish between HIV and AIDS.&lt;br&gt;STATE the points on the slide.&lt;br&gt;• HIV stands for Human Immunodeficiency Virus.&lt;br&gt;• It is the virus that causes AIDS.</td>
</tr>
<tr>
<td>5</td>
<td><strong>Types of HIV Virus</strong>&lt;br&gt;EXPLAIN the two types of HIV virus.&lt;br&gt;ADD the following points:&lt;br&gt;• Both produce the same patterns of illness. HIV 2 causes a slower progression of disease than HIV 1.&lt;br&gt;• It is important for tests to detect the HIV subtypes that are present in the region. Otherwise, testing may lead to false negative results.</td>
</tr>
<tr>
<td>Slide Number</td>
<td>Teaching Points</td>
</tr>
<tr>
<td>--------------</td>
<td>-----------------</td>
</tr>
</tbody>
</table>
| 6            | **Structure of HIV**  
|              | EXPLAIN the structure of the HIV virus.  
|              | • Like all viruses, it is made up of 2 main elements: the external envelope, and the internal core.  
|              | • HIV is a retrovirus.  
|              | HIGHLIGHT specific test methods are used to detect and measure certain parts of the virus. For example, a test to detect the core of the virus called p24 is used to detect early or pediatric infections. |
| 7            | **What is AIDS?**  
|              | STATE points on the slide.  
|              | ADD the following points:  
|              | • HIV infection leads to a weakened immune system. This makes a person with HIV vulnerable to infections.  
|              | • AIDS results when HIV infection progresses to an advanced stage, damaging the immune system to a point at which the body can no longer fight illness.  
|              | • Drugs are available which can treat HIV and AIDS.  
|              | • These drugs are called antiretrovirals (ARVs). They prevent the virus from replicating and slow the progress of the disease.  
|              | • Currently, there is still no cure for AIDS or a vaccine that will prevent HIV infection.  
|              | SUMMARIZE by stating AIDS is the final stage of the disease caused by infection with a type of virus called HIV. |
| 8            | **HIV vs. AIDS**  
<p>|              | DESCRIBE the difference between HIV and AIDS with the points on the slide. |</p>
<table>
<thead>
<tr>
<th>Slide Number</th>
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</tr>
</thead>
<tbody>
<tr>
<td><strong>TIPS</strong></td>
<td>Lay counselors may need more information about the immune system. Consider providing additional content to lay counselors.</td>
</tr>
<tr>
<td></td>
<td><strong>How HIV weakens the immune system</strong></td>
</tr>
<tr>
<td></td>
<td>Our blood contains white and red blood cells. Normally the white cells fight off and kill any germs which enter our bodies. They do this by eating up the germs and by producing chemicals called antibodies which kill them. In this way our bodies fight off many different germs and we stay healthy.</td>
</tr>
<tr>
<td></td>
<td>Sometimes we have symptoms of illness when our white cells are fighting the germs, but usually the white cells win and we get better.</td>
</tr>
<tr>
<td></td>
<td>HIV weakens the immune system by entering and destroying our white cells. As more and more white cells are killed, the body becomes less and less able to fight off the many different germs which live around and in our bodies all the time. After many years the white cells are so damaged that these germs, which normally do not cause problems, can cause deadly diseases.</td>
</tr>
<tr>
<td>9</td>
<td><strong>How is HIV Transmitted?</strong></td>
</tr>
<tr>
<td></td>
<td>EXPLAIN the points on the slide.</td>
</tr>
<tr>
<td>10</td>
<td><strong>HIV: A Global Pandemic</strong></td>
</tr>
<tr>
<td></td>
<td>STATE the following:</td>
</tr>
<tr>
<td></td>
<td>• This slide provides estimates for the numbers of persons living with HIV in different continents in 2003. Between 34 and 46 million persons live with HIV; most of these in Africa.</td>
</tr>
<tr>
<td></td>
<td>• HIV infection is a worldwide epidemic – a pandemic – affecting people everywhere.</td>
</tr>
<tr>
<td></td>
<td>Customize these two slides with regional and local data about HIV epidemic and impact.</td>
</tr>
<tr>
<td>11</td>
<td><strong>HIV Epidemic in Sub-Saharan Africa</strong></td>
</tr>
<tr>
<td></td>
<td>POINT OUT the following on the slide:</td>
</tr>
<tr>
<td></td>
<td>• The growing number of people living with HIV and AIDS</td>
</tr>
<tr>
<td></td>
<td>• The growing trend of HIV prevalence</td>
</tr>
<tr>
<td>12</td>
<td><strong>HIV Epidemic: Local Facts &amp; Impact</strong></td>
</tr>
<tr>
<td></td>
<td>EXPLAIN the local HIV infection rate and its impact on local community.</td>
</tr>
<tr>
<td>Slide Number</td>
<td>Teaching Points</td>
</tr>
<tr>
<td>--------------</td>
<td>-----------------</td>
</tr>
<tr>
<td>13</td>
<td><strong>Basic Terms</strong></td>
</tr>
<tr>
<td></td>
<td>STATE the definition of antigen and antibody on the slide.</td>
</tr>
<tr>
<td>14</td>
<td><strong>Testing for Viral Infection and Immune Response</strong></td>
</tr>
<tr>
<td></td>
<td>EXPLAIN HIV infection can be measured in terms of:</td>
</tr>
<tr>
<td></td>
<td>- The amount of virus circulating in the body –called the viral load</td>
</tr>
<tr>
<td></td>
<td>- The amount of antigen – p24 antigen – circulating in the body</td>
</tr>
<tr>
<td></td>
<td>- Proteins or cells that protect the body against infection – IgG and IgM antibodies, and CD4 cells</td>
</tr>
<tr>
<td></td>
<td><strong>TIPS</strong></td>
</tr>
<tr>
<td></td>
<td>Consider providing additional information about measuring human response to HIV infection by discussing B and T cells when teaching people with a laboratory or medical background.</td>
</tr>
<tr>
<td></td>
<td>T and B cells are types of white blood cells called lymphocytes that provide protection against infection. B cells are responsible for producing antibodies. There are three types of T cells.</td>
</tr>
<tr>
<td></td>
<td>- <strong>Helper T-Cells</strong> (also called CD4+ cells) help other cells destroy infective organisms.</td>
</tr>
<tr>
<td></td>
<td>- <strong>Suppressor T-Cells</strong> (also called CD8+ cells) suppress the activity of other lymphocytes so they don't destroy normal tissue.</td>
</tr>
<tr>
<td></td>
<td>- <strong>Killer T-Cells</strong> (also called cytotoxic T lymphocytes, or CTLs, and are another kind of or CD8+ cell) recognize and destroy abnormal or infected cells.</td>
</tr>
<tr>
<td></td>
<td>Over a period of time, HIV infects and kills white blood cells called CD4 lymphocytes or (T cells), leaving the body unable to fight off certain kinds of infections.</td>
</tr>
<tr>
<td>15</td>
<td><strong>Evolution of Antibodies</strong></td>
</tr>
<tr>
<td></td>
<td>DESCRIBE the timeframe by which antibodies are produced.</td>
</tr>
<tr>
<td></td>
<td>STATE Specific antibodies are detected at certain times over the course of infection</td>
</tr>
<tr>
<td></td>
<td>POINT to the area of the slide labeled Window Period.</td>
</tr>
<tr>
<td></td>
<td>TRANSITION to providing additional explanation on the meaning of “window period”</td>
</tr>
<tr>
<td>Slide Number</td>
<td>Teaching Points</td>
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<td>--------------</td>
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</tr>
</tbody>
</table>
| 16           | **Window Period**  
EXPLAIN window period as the phase when you have been infected with HIV, but antibody levels are not detectable.
ADD THE FOLLOWING POINTS:  
• Seroconversion occurs during the window period.  
• “Seroconversion” is a term used to describe the change from non-detectable to detectable antibody levels. Specimen may test initially non-reactive, but change to testing reactive after a certain time period.  
• Seroconversion occurs generally 3-8 weeks after the initial infection. |
| 17           | **Disease Progression**  
STATE the points on the slide.  
DEFINE viral load as the amount of HIV virus circulating in the bloodstream. |
| 18           | **WHO HIV/AIDS Classification System**  
STATE WHO (World Health Organization) marks the progression of HIV infection with four stages.  
RELATE the clinical course of HIV infection with WHO’s classification system.  
REFER participants to the handout in their manual for details of WHO’s classification system.  
POINT OUT that testing at any stage allows for triage towards treatment. |
| 19           | **Can Disease Progression Be Delayed?**  
STATE the points on the slide. |
| 20           | **Summary**  
ASK participants to answer the questions on the slide.  
ANSWER any questions participants may have. |
Module 2: Integration of HIV Rapid Testing in HIV Prevention and Treatment Programs

Purpose
To provide the participants with the basic concepts of HIV prevention using HIV rapid tests combined with counselling.

Pre-requisite Modules
None

Module Time
30 minutes

Learning Objectives
At the end of this module, participants will be able to:

• Recognize the need for HIV testing and counseling (T&C) in HIV prevention programs
• Describe the role of HIV rapid testing in supporting prevention and counseling programs
• State the advantages of using HIV rapid tests in specific settings (e.g., VCT and PMTCT programs)
• Describe the programs/settings where HIV rapid tests are used in your country

Module Overview

<table>
<thead>
<tr>
<th>Step</th>
<th>Time</th>
<th>Activity/Method</th>
<th>Content</th>
<th>Resources Needed</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>5 min</td>
<td>Presentation</td>
<td>Introduction</td>
<td>Slides 1-6</td>
</tr>
<tr>
<td>2</td>
<td>8 min</td>
<td>Presentation</td>
<td>Application of Voluntary Counseling and Testing (VCT)</td>
<td>Slide 7-11</td>
</tr>
<tr>
<td>3</td>
<td>12 min</td>
<td>Presentation</td>
<td>VCT in PMTCT</td>
<td>Slide 12-18</td>
</tr>
<tr>
<td>4</td>
<td>5 min</td>
<td>Q&amp;A</td>
<td>Summary</td>
<td>Slide 19</td>
</tr>
</tbody>
</table>

Material/Equipment Checklists

- PowerPoint slides or transparencies
- Overhead projector or computer w/LCD projector
- Prepared Flipchart – content outline
### Teaching Guide

<table>
<thead>
<tr>
<th>Slide Number</th>
<th>Teaching Points</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>TIPS</strong></td>
<td>For participants <strong>without</strong> counseling background, define acronyms such as: CT, PMTCT, ANC, L&amp;D.</td>
</tr>
</tbody>
</table>
| 1            | **Integration of HIV Rapid Testing in HIV Prevention and Treatment Programs**  
**DISPLAY** this slide before you begin the module. |
| 2            | **Learning Objectives**  
**STATE** the objectives on the slide. |
| 3            | **Content Overview**  
**EXPLAIN** the topics that will be covered in this module. |
| **Flipchart**| WRITE the content outline on a flipchart prior to training.  
**REFER** to it frequently to orient participants to where they are in the module. |
| 4            | **HIV/AIDS Program Strategy**  
**STATE** the points on the slide.  
**PROVIDE** the following background notes:  
- WHO and the US government have set targets for the number of people who are to be on ART by a given time period. For this to happen, host governments and multilateral partners will need to implement integrated prevention, treatment and care strategies. |
| **Customization Notes** | Customize the slide by providing additional information on country-specific statistics. |
| 5            | **Current Status of HIV Testing**  
**STATE** the points on the slide.  
**ADD** the following point:  
- Countries of sub-Saharan Africa and the Caribbean are home to nearly 30 million people with HIV/AIDS, nearly 70 percent of the world’s total. |
<table>
<thead>
<tr>
<th>Slide Number</th>
<th>Teaching Points</th>
</tr>
</thead>
</table>
| 6            | **HIV Testing Occurs in a Variety of Settings**  
POINT OUT the settings where testing will likely to occur during an era of expansion of services include: Testing & Counselling Centers (T & C), Antenatal Clinics (ANC), Blood Banks, Surveillance programs, TB clinics, hospitals, and Sexually Transmitted Infections (STI) Clinics  
HIGHLIGHT that while all settings where testing occurs can triage persons to treatment and care, tuberculosis (TB) clinics and hospitals will be the primary venues for providing antiretroviral treatment to HIV infected persons, and for providing care to HIV affected persons.  
HIGHLIGHT T&C, ANC, Blood Banks, and surveillance are the primary venues for providing prevention programs. |
| 7            | **HIV T&C As An Entry Point to HIV Prevention, Care and Support Services**  
Discuss the role of HIV TC in all the services and programs indicated. |
| 8            | **Testing and Counseling**  
STATE points on the slide.  
- HIV prevalence among VCT clients usually slightly higher than national prevalence  
- Most clients, if infected, are asymptomatic so VCT is not a primary venue for accessing ARV eligible persons |
|              | **Customization Notes**  
Customize these slides with country, regional or local data demonstrating the impact of routine HIV counseling and testing as an integral part of health services. |
<table>
<thead>
<tr>
<th>Slide Number</th>
<th>Teaching Points</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>9</strong></td>
<td><strong>Clinic-Based HIV Testing and Counseling</strong></td>
</tr>
<tr>
<td></td>
<td>STATE points on the slide.</td>
</tr>
<tr>
<td></td>
<td>• Data from antenatal clinics suggest increase in acceptance of HIV testing when offered as part of routine care</td>
</tr>
<tr>
<td></td>
<td>• In Kenya, supported clinic sites offering VCT increased acceptance of HIV testing from 57% to over 80%; and in Botswana increase from 70% to 90% was noted.</td>
</tr>
<tr>
<td></td>
<td>• Malawi Hospital study, 2003: 70% of medical, 36% of surgical patients were HIV infected</td>
</tr>
<tr>
<td></td>
<td>• Malawi STI clinic, 2003: 38% of persons tested had HIV infection</td>
</tr>
<tr>
<td></td>
<td>• Kenya hospital study, 2003: over 90% of TB patients were HIV infected</td>
</tr>
<tr>
<td><strong>10</strong></td>
<td><strong>Community-Based Testing and Counseling</strong></td>
</tr>
<tr>
<td></td>
<td>STATE Points on the slide</td>
</tr>
<tr>
<td></td>
<td>• Dramatic increase in providing HIV services in Kenya by funding community and faith based CT sites. In 2000, only 3 sites; in 2003, 220 sites that served over 200,000 clients</td>
</tr>
<tr>
<td><strong>11</strong></td>
<td><strong>Couples Testing and Counseling</strong></td>
</tr>
<tr>
<td></td>
<td>STATE Points on the slide</td>
</tr>
<tr>
<td></td>
<td>EXPLAIN discordant couples means one person test positive and the other person test negative</td>
</tr>
<tr>
<td></td>
<td>ADD the following points:</td>
</tr>
<tr>
<td></td>
<td>• Sero-discordance in African countries may account for 33% of HIV transmissions.</td>
</tr>
<tr>
<td></td>
<td>• HIV TC has been shown to decrease HIV transmission by up to 90%</td>
</tr>
<tr>
<td><strong>12</strong></td>
<td><strong>HIV T&amp;C As An Entry Point to HIV Prevention, Care and Support Services</strong></td>
</tr>
<tr>
<td></td>
<td>STATE the following and TRANSITION to the next slide.</td>
</tr>
<tr>
<td></td>
<td>• Offering routine HIV counseling and testing to women at health clinics, labor and delivery clinics and antenatal clinics has a major impact on prevention of transmission of HIV virus from mother to child</td>
</tr>
<tr>
<td>Slide Number</td>
<td>Teaching Points</td>
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<tr>
<td>--------------</td>
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<tr>
<td></td>
<td>Customize the slide by providing country-specific statistics.</td>
</tr>
<tr>
<td>Slides 13</td>
<td></td>
</tr>
<tr>
<td>13</td>
<td><strong>Mother-to-Child HIV Infections</strong>&lt;br&gt;STATE the points on the slide.</td>
</tr>
<tr>
<td>14</td>
<td><strong>Preventing Mother to Child Transmission (PMTCT)</strong>&lt;br&gt;STATE the points on the slide.</td>
</tr>
<tr>
<td>15</td>
<td><strong>Core Interventions for PMTCT</strong>&lt;br&gt;STATE the points on the slide.</td>
</tr>
<tr>
<td>16</td>
<td><strong>Core PMTCT Interventions Depend on a Woman Knowing Her HIV Status</strong>&lt;br&gt;STATE the points on the slide.</td>
</tr>
<tr>
<td>17</td>
<td><strong>Rational for Promoting HIV Rapid Tests for PMTCT</strong>&lt;br&gt;EXPLAIN HIV rapid tests are very useful in resource-poor settings where women may make only one antenatal clinic visit.&lt;br&gt;STATE the rationale on the slide.</td>
</tr>
<tr>
<td>18</td>
<td><strong>Current International Recommendations for Testing and Counseling in PMTCT</strong>&lt;br&gt;STATE the points on the slide.</td>
</tr>
<tr>
<td>19</td>
<td><strong>Summary</strong>&lt;br&gt;Ask the participants the questions on the slide.&lt;br&gt;ANSWER any questions the participants may have.</td>
</tr>
</tbody>
</table>
Module 3: Overview of HIV Testing Technologies

Purpose
To provide the participants with a basic knowledge of HIV testing and how HIV rapid test results are interpreted.

Pre-requisite Modules
Module 1: Overview of HIV Infection

Module Time
1 hour 5 minutes

Learning Objectives
At the end of this module, participants will be able to:
• Discuss settings where HIV testing will be part of service delivery during an era of expanded services
• Discuss the spectrum of testing technologies for HIV
• Explain the advantages and disadvantages of HIV rapid tests
• Accurately recognize individual test result as reactive, non-reactive, or invalid

Module Overview

<table>
<thead>
<tr>
<th>Step</th>
<th>Time</th>
<th>Activity/Method</th>
<th>Content</th>
<th>Resources Needed</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2 min</td>
<td>Presentation</td>
<td>Module introduction</td>
<td>Slides 2-3; Prepared flipchart – content outline</td>
</tr>
<tr>
<td>2</td>
<td>5 min</td>
<td>Presentation; Discussion</td>
<td>Expansion of HIV Testing</td>
<td>Slides 4-6</td>
</tr>
<tr>
<td>3</td>
<td>15 min</td>
<td>Exercise</td>
<td>Spectrum of HIV Tests</td>
<td>Slides 7-16;</td>
</tr>
<tr>
<td>4</td>
<td>30 min</td>
<td>Presentation; Discussion</td>
<td>HIV Rapid Testing Technologies</td>
<td>Slides 17-32</td>
</tr>
<tr>
<td>5</td>
<td>5 min</td>
<td>Exercise</td>
<td>Interpreting Individual HIV Rapid Test Results</td>
<td>Slide 33; Exercise Sheets: Interpreting Individual HIV Rapid Test Results</td>
</tr>
<tr>
<td>6</td>
<td>8 min</td>
<td>Q&amp;A</td>
<td>Key messages Summary</td>
<td>Slides 34-35</td>
</tr>
</tbody>
</table>
Material/Equipment Checklists:

- PowerPoint slides or transparencies
- Overhead projector or computer w/LCD projector
- Flipchart
- Multiple sets of samples showing reactive, non-reactive, and invalid test results from each test approved for use in-country
- Exercise sheets: Interpreting Individual HIV Rapid Tests
### Teaching Guide

<table>
<thead>
<tr>
<th>Slide Number</th>
<th>Teaching Points</th>
</tr>
</thead>
</table>
| 1 | **Module 3: Overview of HIV Testing Technologies**  
DISPLAY this slide before you begin the module. Make sure participants are aware of the transition into a new module. |
| 2 | **Learning Objectives**  
STATE the objectives on the slide. |
| 3 | **Content Overview**  
EXPLAIN the topics that will be covered in this module. |
| Flipchart | WRITE the content outline on a flipchart prior to training.  
REFER to it frequently to orient participants to where they are in the module. |
| 4 | **HIV Testing Occurs in a Variety of Settings**  
DESCRIBE the graphic on the slide by making the following points:  
- HIV testing will occur in a variety of settings outside of the laboratory  
- The settings where testing will likely to occur during an era of expansion of services include: Testing & Counselling Centers (T & C), Antenatal Clinics (ANC), Blood Banks, Surveillance programs, TB clinics, hospitals, and Sexually Transmitted Infections (STI) Clinics  
HIGHLIGHT the following points:  
- While all settings where testing occurs can triage persons to treatment and care, tuberculosis (TB) clinics and hospitals will be the primary venues for providing anti-retroviral treatment to HIV infected persons, and for providing care to HIV affected persons.  
- T&C, ANC, Blood Banks, and surveillance are the primary venues for providing prevention programs. |
<table>
<thead>
<tr>
<th>Slide Number</th>
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</thead>
</table>
| 5            | **Expansion of Testing Services**<br>EXPLAIN the following points:  
|              | ▪ Testing will need to be integrated at all levels of testing services, and that testing must be linked to referral services, e.g., ANC and VCT.  
|              | ▪ To facilitate the expected high volume of testing, non-traditional test sites will need to be incorporated into the national testing strategy. These non-traditional sites must however be linked back to the lab referral network and a quality management system.  |
| 6            | **Use of HIV Testing Technologies in the Continuum of Care**<br>A variety of tests are performed at different stages. HIV rapid tests play an important role in initially identifying those who are infected with the HIV virus.  
|              | Other tests, e.g., CD4 and viral load, play an important role in determining whether therapy can be initiated, and once initiated, if the drugs are working or not.  |
| 7            | **Spectrum of HIV Tests**<br>POINT OUT this list reflects commonly performed test associated with HIV. Some tests are for diagnostic purposes, e.g., EIAs, rapid tests, Western Blot, and p24  
|              | Other tests are supplemental in monitoring disease progression, such as CD4 and viral load.  |
| 8            | **Challenges of HIV Testing**<br>EMPHASIZE the following points:  
|              | ▪ The ability of some test to detect early infections is sub-optimal  
|              | ▪ Specialized testing is required to diagnose HIV infection in infants younger than 18 months.  
|              | ▪ The variability of HIV viruses impacts upon the sensitivity the specificity of HIV tests. Early generation of HIV test kits could not detect antibodies produced against strains of group O.  
|              | ▪ Cross reactivity with other health conditions or infections decreases performance of the assay, e.g., cytomegalovirus and Epstein-Barr virus.  
|              | ▪ Some technologies require specific equipment that must be properly maintained.  
<p>|              | ▪ The skill required to accurately perform and interpret tests varies; from minimal to high level of skill |</p>
<table>
<thead>
<tr>
<th>Slide Number</th>
<th>Teaching Points</th>
</tr>
</thead>
</table>
| 9            | **Enzyme Immunoassays (EIAs)**  
STATE the points on the slide |
| 10           | **Enzyme Immunoassays (EIAs) - Cont’d**  
DESCRIBE how Enzyme Immunoassay works.  
- Sample is added to micro-well plate that has been coated with HIV antigen(s).  
- After a series of reagent additions, incubations and washings, the plate is placed in reading device.  
- The reading device measures the optical density of color that develops if HIV antibody is present in the client’s sample.  
EMPHASIZE multiple factors can affect testing. As previously described a certain level of technical skill AND functioning equipment is a must. |
| 11           | **HIV Rapid Tests**  
STATE the points on the slide.  
HIGHLIGHT an added advantage for using rapid tests is the ability to use whole blood.  
EMPHASIZE that while HIV rapid tests, in general, is considered to be low in complexity, all test must be appropriately evaluated prior to use. It is equally important that the test be validated for use in the environment where testing will occur.  
EMPHASIZE the need for appropriate training on use of test. |
<table>
<thead>
<tr>
<th>Slide Number</th>
<th>Teaching Points</th>
</tr>
</thead>
</table>
| 12           | **Western Blot / Line Immunoassays**  
STATE The Western Blot is a supplemental test for confirming HIV infection.  
EXPLAIN the cellulose strip on the right.  
DESCRIBE key issues involved:  
• It lacks standardization in performance and interpretation.  
• Although considered a confirmation test, this assay has a high range of indeterminate results.  
• It is a complex test.  
• It is very expensive. |
| 13           | **HIV p24 Antigen**  
STATE the points on the slide. |
| 14           | **CD4 T-Lymphocyte**  
STATE the points on the slide.  
EMPHASIZE the need for instruments to be properly maintained, such as the BD FASCount, and BD FASCAliber seen on this slide. |
| 15           | **Viral Load**  
STATE the points on the slide. The higher the viral load (number of copies of HIV in the blood), the greater the progression of the disease.  
EMPHASIZE a number of Issues exist with this test:  
• Kits and reagents are expensive  
• Demanding molecular techniques  
• Concerns over contamination  
• Experienced technicians required  
• Difficult/complex assays  
• Need separate dedicated supplies, equipment (including biosafety cabinets), and air conditioned rooms  
• Need constant source of electrical power  
• PCR-based technologies susceptible to genetic variation and low copy number |
<table>
<thead>
<tr>
<th>Slide Number</th>
<th>Teaching Points</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Define terms such PCR, and explain low copy number when teaching participants without lab background.</td>
</tr>
<tr>
<td><strong>TIPS</strong></td>
<td>Complexity of HIV Tests Varies*</td>
</tr>
<tr>
<td>16</td>
<td>4 levels of complexity for HIV tests have been described in a number of WHO reports. The complexity of tests varies, from minima – level 1, to complex - level 4, in terms of equipment, and technical skill.</td>
</tr>
<tr>
<td>17</td>
<td><strong>HIV Rapid Tests provides excellent tool for expansion of services</strong></td>
</tr>
<tr>
<td></td>
<td>TRANSITION into HIV rapid tests.</td>
</tr>
<tr>
<td></td>
<td>STATE HIV rapid testing provides excellent tool for expansion of services. The remaining module will focus on HIV rapid tests.</td>
</tr>
<tr>
<td>18</td>
<td><strong>HIV Rapid Tests: Advantages</strong></td>
</tr>
<tr>
<td></td>
<td>DISCUSS the advantages on the slide.</td>
</tr>
<tr>
<td></td>
<td>EMPHASIZE if clients do not obtain their HIV results, this is a missed opportunity for therapy or preventative measures.</td>
</tr>
<tr>
<td></td>
<td>ASK participants to share any stories that illustrate the adverse effects of having to wait a long time for test results.</td>
</tr>
<tr>
<td></td>
<td>For participants without any lab or medical background:</td>
</tr>
<tr>
<td></td>
<td>• EXPLAIN the term reagent. A reagent is a substance used in a chemical reaction to detect or produce other substances.</td>
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<tr>
<td></td>
<td>• EXPLAIN why some lab materials need refrigeration, and others don’t, emphasizing the consequences of not refrigerating materials that require refrigeration (kits e.g. Capillus, and serum quality controls).</td>
</tr>
<tr>
<td>19</td>
<td><strong>HIV Rapid Tests: Disadvantages</strong></td>
</tr>
<tr>
<td></td>
<td>STATE the points on the slide</td>
</tr>
<tr>
<td></td>
<td>DISCUSS past and present problems in slow turn-around of results from the laboratory, and the poor come-back rate of clients to obtain their results (due to fear, cost issues, transport issues, etc.).</td>
</tr>
<tr>
<td>Slide Number</td>
<td>Teaching Points</td>
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<tr>
<td></td>
<td><strong>TIPS</strong></td>
</tr>
<tr>
<td></td>
<td>For participants without any lab or medical background:</td>
</tr>
<tr>
<td></td>
<td>• EXPLAIN that although the tests are not difficult, they will require a lot of practice and supervision to become proficient.</td>
</tr>
<tr>
<td></td>
<td>• EMPHASIZE they must not feel afraid or embarrassed to stop at any time and ask questions.</td>
</tr>
<tr>
<td>20</td>
<td><strong>Body Fluids Used for HIV Rapid Testing</strong></td>
</tr>
<tr>
<td></td>
<td>EXPLAIN that HIV tests could be performed on a wide range of body fluids. Serum, plasma, whole blood and oral fluids are used the most.</td>
</tr>
<tr>
<td></td>
<td>ASK participants what each fluid is and the typical method for obtaining each.</td>
</tr>
<tr>
<td></td>
<td><strong>TIPS</strong></td>
</tr>
<tr>
<td></td>
<td>For participants without any lab or medical background:</td>
</tr>
<tr>
<td></td>
<td>• Briefly DESCRIBE these different fluids.</td>
</tr>
<tr>
<td></td>
<td>• INFORM them that the samples they will use for HIV rapid testing will most likely be whole blood drawn from their clients’ fingertips.</td>
</tr>
<tr>
<td></td>
<td><strong>TIPS</strong></td>
</tr>
<tr>
<td></td>
<td>Slides 21, 22, 23, 25, 26, 29, and 30 are highly technical. We recommend that you do not present these slides to lay counsellors.</td>
</tr>
<tr>
<td></td>
<td>If you do present these slides,</td>
</tr>
<tr>
<td></td>
<td>• EXPLAIN every technical term on the slides</td>
</tr>
<tr>
<td></td>
<td>• USE analogies and examples to help participants understand.</td>
</tr>
<tr>
<td>21</td>
<td><strong>Three Formats of HIV Rapid Tests</strong></td>
</tr>
<tr>
<td></td>
<td>STATE that there are three main formats or types for rapid HIV tests, and you will explain each format in the following slides.</td>
</tr>
<tr>
<td>22</td>
<td><strong>How Immunoconcentration Works</strong></td>
</tr>
<tr>
<td></td>
<td>EXPLAIN the graphic on the slide.</td>
</tr>
<tr>
<td></td>
<td>DESCRIBE how Immunoconcentration works.</td>
</tr>
<tr>
<td></td>
<td>• Flow-through (or immunoconcentration) devices are usually cartridges, with HIV antigen attached to a membrane.</td>
</tr>
<tr>
<td></td>
<td>• The specimen and individual reagents are each added to the cartridge in a series of steps.</td>
</tr>
<tr>
<td></td>
<td>• Presence of HIV antibody is indicated by the development of a colored spot or line.</td>
</tr>
<tr>
<td>Slide Number</td>
<td>Teaching Points</td>
</tr>
<tr>
<td>--------------</td>
<td>----------------</td>
</tr>
<tr>
<td>23</td>
<td>Tests Based on Immunoconcentration</td>
</tr>
<tr>
<td></td>
<td>STATE the devices mentioned in the slide (DESCRIBE more fully ones used in-country).</td>
</tr>
<tr>
<td></td>
<td>DESCRIBE the graphics on slide.</td>
</tr>
<tr>
<td>24, 27, 28, 31</td>
<td>Modify these slides if necessary:</td>
</tr>
<tr>
<td></td>
<td>• Delete tests not used in your country’s algorithm</td>
</tr>
<tr>
<td></td>
<td>• Replace photos with in-country examples</td>
</tr>
<tr>
<td>24</td>
<td>Reading Results: Genie II</td>
</tr>
<tr>
<td></td>
<td>EXPLAIN how to read results from Genie II.</td>
</tr>
<tr>
<td></td>
<td>• If non-reactive, you will only see one visible dot in the control region</td>
</tr>
<tr>
<td></td>
<td>• If reactive, you will see either one or two visible dots. One dot for HIV 1, and the other for HIV 2</td>
</tr>
<tr>
<td></td>
<td>• At the control dot, Human IgG links to membrane-bound anti-human IgG</td>
</tr>
<tr>
<td></td>
<td>Note: It will be helpful to physically point to the control dot.</td>
</tr>
<tr>
<td>25</td>
<td>How Immunochromatography Works</td>
</tr>
<tr>
<td></td>
<td>EXPLAIN the graphic on the slide by describing how Immunochromatography works.</td>
</tr>
<tr>
<td></td>
<td>• Specimen is applied to a pad (filter) where it mixes with gold or selenium colloid-antigen conjugate. This mix migrates through the nitrocellulose strip to immobilized recombinant antigens and synthetic peptides at the patient window.</td>
</tr>
<tr>
<td></td>
<td>• If HIV antibodies are present then a red line will form in the test area of the strip.</td>
</tr>
<tr>
<td>25</td>
<td>TIPS</td>
</tr>
</tbody>
</table>
|              | SIMPLIFY the explanation when teaching participants without lab background:
<table>
<thead>
<tr>
<th>Slide Number</th>
<th>Teaching Points</th>
</tr>
</thead>
</table>
| 26           | **Tests Based on Immunochromatography**  
EXPLAIN how lateral flow devices work.  
- Capillary flow (lateral flow) devices resemble dipsticks.  
  All of the necessary reagents are usually incorporated  
  into the test strip embedded in the device.  
- Specimen (and sometimes buffer or a reagent) added to  
  the strip flows across the reagents, and a colored line  
  develops in the presence of antibody.  
- Most lateral flow devices also have an internal control  
  that detects human IgG. This internal control indicates  
  that specimen was added to the test strip. If no human  
  IgG is detected, an internal control line does not develop  
  indicating an invalid test.  
STATE the devices mentioned in the slide (DESCRIBE more  
fully ones used in-country). |
| TIPS         | SIMPLIFY the explanation when teaching participants without  
lab background: |
| 27           | **Reading Results: Determine**  
EXPLAIN how to read test results from Determine test kit.  
- The reactive reaction shows two lines  
  - One for the control band.  
  - The other for the test. A band in the test area  
    means a reactive result.  
- A non-reactive reaction will show a control band only.  
- The control band (line) must always be present for the  
  test results to be valid. |
| 28           | **Reading Results: OraQuick**  
ASK participants to explain OraQuick test results on the slide. |
<table>
<thead>
<tr>
<th>Slide Number</th>
<th>Teaching Points</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>29</strong></td>
<td><strong>How Particle Agglutination Works</strong></td>
</tr>
<tr>
<td></td>
<td>DESCRIBE how particle agglutination works by describing the graphic on the slide.</td>
</tr>
<tr>
<td></td>
<td>• The round circles represent antigen-coated latex particles that bind to antibodies to HIV (represented by the “Y”). Note: POINT TO each figure as you describe the graphic.</td>
</tr>
<tr>
<td></td>
<td>• Agglutination or clumping occurs when the antibodies bind to the antigen-coated particles</td>
</tr>
<tr>
<td></td>
<td>• Agglutination assays were among the first of the rapid tests developed.</td>
</tr>
<tr>
<td></td>
<td>• Inexperienced persons or those who do not conduct the tests frequently may have problem with differentiating the coarseness or clumping of individual particles from true agglutination. They sometimes “over-interpret” agglutination, which result in a larger number of false-positives.</td>
</tr>
<tr>
<td></td>
<td><strong>TIPS</strong></td>
</tr>
<tr>
<td></td>
<td>SIMPLIFY the explanation when teaching participants without lab background:</td>
</tr>
<tr>
<td><strong>30</strong></td>
<td><strong>Tests Based on Agglutination</strong></td>
</tr>
<tr>
<td></td>
<td>STATE the devices mentioned in the slide (DESCRIBE more fully ones used in-country).</td>
</tr>
<tr>
<td></td>
<td>DESCRIBE the 3 images on the slide, using Capillus as the main example (as it is the most commonly used agglutination test):</td>
</tr>
<tr>
<td></td>
<td>• Left – The blood is placed in the oval area, also called the mixing well.</td>
</tr>
<tr>
<td></td>
<td>• Center – The specimen travels along the thin tubes in the slide.</td>
</tr>
<tr>
<td></td>
<td>• Right – If the blood contains antibodies to the HIV virus, visible clumping or agglutination can be seen.</td>
</tr>
<tr>
<td>Slide Number</td>
<td>Teaching Points</td>
</tr>
<tr>
<td>--------------</td>
<td>-----------------</td>
</tr>
<tr>
<td><strong>31</strong></td>
<td><strong>Reading Results: Capillus</strong>&lt;br&gt;DISCUSS the three different results on the slide.&lt;br&gt;• ASK participants to describe what they see in the slide.&lt;br&gt;• POINT OUT the clumping or agglutination in the reactive sample, and the smooth liquid without clumps in the non-reactive test.&lt;br&gt;• MENTION that unlike other test previously discussed, there is no control line to let the tester know that the test has worked correctly. However, the test kit includes a positive and negative control, which can be used to verify on a regular basis that the test is working properly.</td>
</tr>
<tr>
<td><strong>Transition</strong></td>
<td>STATE that there is a third possible result – the control line is not present.&lt;br&gt;REMIND that when the control line fails to show, it indicates that the test has failed. The result is therefore called “invalid.”&lt;br&gt;TRANSITION into next slide.</td>
</tr>
<tr>
<td><strong>32</strong></td>
<td><strong>There Are Only Three Possible Outcomes for Single HIV Antibody Tests</strong>&lt;br&gt;REVIEW the terms on the slide.&lt;br&gt;EMPHASIZE these are the terms when interpreting the outcome of a single test.&lt;br&gt;EMPHASIZE if a test yields an invalid result; meaning no control band or line is present, the test has failed. The test MUST be repeated using a new test device.</td>
</tr>
<tr>
<td><strong>Customization Notes</strong></td>
<td>If the tests used in the exercise are not in your country’s algorithm, consider replacing them with tests that are.</td>
</tr>
<tr>
<td><strong>33</strong></td>
<td><strong>EXERCISE – Interpreting Individual HIV Rapid Test Results</strong>&lt;br&gt;REFER participants to the exercise in their manual.&lt;br&gt;ASK participants to spend 3 minutes, working alone, to identify the results.&lt;br&gt;DISCUSS the answers as a group.</td>
</tr>
<tr>
<td><strong>TIPS</strong></td>
<td>Consider having multiple sets of real samples available to pass around, with each set containing three different test results (reactive, non-reactive, and invalid) for each test approved in-country. The more participants, the more sets you will need.</td>
</tr>
<tr>
<td>Slide Number</td>
<td>Teaching Points</td>
</tr>
<tr>
<td>--------------</td>
<td>-----------------</td>
</tr>
</tbody>
</table>
| 34 | **Key Messages**  
STATE the points on the slide. |
| 35 | **Summary**  
ASK participants to answer the questions on the slide.  
ANSWER any questions the participants may have. |
Module 4: HIV Testing Strategies and Algorithms

Purpose
To provide the participants with a basic understanding of how HIV rapid tests are selected for the country’s algorithm and how HIV status is determined following the algorithm.

Pre-requisite Modules
- Module 1: Overview of HIV Infection
- Module 3: Overview of HIV Testing Technologies

Module Time
1 hour

Learning Objectives
At the end of this module, participants will be able to:
- Discuss the process for developing a national testing algorithm
- Explain how sensitivity, specificity, positive/negative predictive value relate to development of an HIV rapid testing algorithm
- Explain the HIV rapid testing algorithm approved in your country
- Determine HIV status following a particular algorithm

Module Overview

<table>
<thead>
<tr>
<th>Step</th>
<th>Time</th>
<th>Activity/Method</th>
<th>Content</th>
<th>Resources Needed</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2 min</td>
<td>Presentation</td>
<td>Module introduction</td>
<td>Slides 1-3; Prepared flipchart – content outline</td>
</tr>
<tr>
<td>2</td>
<td>15 min</td>
<td>Presentation; Discussion</td>
<td>Strategies and Algorithms</td>
<td>Slides 4-10</td>
</tr>
<tr>
<td>3</td>
<td>20 min</td>
<td>Presentation; Discussion</td>
<td>Evaluating Test Performance</td>
<td>Slides 11-16</td>
</tr>
<tr>
<td>4</td>
<td>10 min</td>
<td>Presentation; Discussion</td>
<td>Testing Algorithms</td>
<td>Slides 17-19</td>
</tr>
<tr>
<td>5</td>
<td>5 min</td>
<td>Exercise</td>
<td>Interpreting HIV status using testing algorithm</td>
<td>Slide 20; Exercise Sheets: Interpreting HIV Status Using Testing Algorithm</td>
</tr>
<tr>
<td>6</td>
<td>3 min</td>
<td>Presentation; Discussion</td>
<td>Possible Outcomes of HIV Testing</td>
<td>Slides 21</td>
</tr>
<tr>
<td>7</td>
<td>5 min</td>
<td>Q&amp;A</td>
<td>Summary</td>
<td>Slide 22</td>
</tr>
</tbody>
</table>
Material/Equipment Checklists:

- PowerPoint slides or transparencies
- Overhead projector or computer w/LCD projector
- Flipchart
- Handouts:
  - Exercise #1: Interpreting HIV Status Using Testing Algorithm
  - Exercise #2: Interpreting HIV Status Using Testing Algorithm
<table>
<thead>
<tr>
<th>Slide Number</th>
<th>Teaching Points</th>
</tr>
</thead>
</table>
| 1            | **Module 4: HIV Testing Strategies and Algorithms**  
DISPLAY this slide before you begin the module. Make sure participants are aware of the transition into a new module. |
| 2            | **Learning Objectives**  
STATE the objectives on the slide. |
| 3            | **Content Overview**  
EXPLAIN the topics that will be covered in this module. |
| **Flipchart**| WRITE the content outline on a flipchart prior to training.  
REFER to it frequently to orient participants to where they are in the module. |
| 4            | **Strategies and Algorithms**  
DEFINE Strategies and Algorithms by STATING the points on the slide. |
| 5            | **Strategies and Algorithms (Cont’d)**  
HIGHLIGHT the points on the slide |
| 6            | **HIV Testing Strategies**  
EXPLAIN parallel and serial testing can be part of any testing strategy.  
DEFINE parallel and serial testing by STATING points on the slide |
<table>
<thead>
<tr>
<th>Slide Number</th>
<th>Teaching Points</th>
</tr>
</thead>
</table>
| 7            | **Testing Algorithms Should be Developed at National Level**  
Before any test is adopted in country for use, a series of key steps must be taken.  
STATE the key steps.  
EMPHASIZE:  
- Because multiple tests are marketed and available in-country, each country must identify the appropriate tests for use within given environment  
- A standardized approach to developing an algorithm must be taken. This involved building consensus and developing policy before a test is brought to national scale. |
| 8            | **Timeline for Developing National Testing Algorithm**  
HIGHLIGHT a number of activities must be accomplished before a test is fully implemented  
EMPHASIZE the following points:  
- tests undergo a series of evaluations before they are adopted for use country-wide  
- timeline for accomplishing each phase of the evaluation process is indicated on the slide |
For lab staff and health workers, consider providing the following information on test evaluation process:

- **Phase I**: samples with known HIV results are tested at the laboratory using a number of different kits. The results of the rapid tests are compared with the original laboratory results. Ones that worked the best are then evaluated in phase II.

- **Phase II**: clients are tested at a rapid testing site by the tests under evaluation, and the same sample is tested at the laboratory using laboratory tests. The results are compared, and the rapid tests that worked the best will be used in phase III.

- **Phase III**: is the final phase whereby certain rapid tests have been approved by the MoH and are used at rapid testing sites.

For participants without lab or health background, consider providing the following information:

- Samples are tested at the laboratory and at points of service by numerous kits.

- The ones that work best to detect HIV infections are approved by the MoH for nation-wide use.

### Advantages of National Testing Strategies and Algorithms

**HIGHLIGHT** nationally adopted testing strategies and algorithms facilitates:

- Standardizing the tests used in country. Supporting a limited number of tests is more feasible and practical than many different tests.

- Bulk procurement facilitates cost control

### Key Factors in Determining a Country’s Algorithm

A number of factors contribute to the selection of specific tests in a country’s algorithm.

STATE the factors listed on the slide
### Slide Number 11

**Evaluating Test Performance: Basic Terms**

One of the factors considered when determining a country’s algorithm is the performance of the tests. This performance is based on how close a test under consideration agrees 100% with the result of another test, i.e., reference method or “gold standard”, also referred to as the true result or actual HIV status.

STATE the definitions on the slide

EXPLAIN the basic difference between Se, Sp and PPV, NPV
- Se & Sp relate to the performance of the test capacity
- PPV & NPV relate to the probably of the individual being infected or not when the test yields a positive or negative result

### Slide Number 12

**Calculating Sensitivity, Specificity, PPV & NPV**

This table provides the formulas for calculating Se, Sp, PPV, & NPV.

**A** = true positives; that is the test under evaluation yields a positive result AND the “gold standard” yielded a positive result

**C** = false negatives; that is the test under evaluation yielded a negative result, while the “gold standard” or true value was positive

**A+C** = all people who are truly infected with HIV

**B** = false positives; that is the test under evaluation yields a positive result, while the “gold standard” or true value was negative

**D** = true negatives; that is the test under evaluation yields a negative result AND the “gold standard” or true value yielded a negative result

**B+D** = all people who are truly NOT infected with HIV
13 **Calculating Sensitivity, Specificity, PPV & NPV (Cont’d)**

This table illustrates the calculation of Se, Sp, PPV & NPV.

Evaluation of a rapid test on a panel of specimens that have been tested by the gold standard to determine actual HIV status is shown to contain HIV antibodies to 374 samples and no HIV antibodies to 626 samples.

Of the 374 serum samples that were antibody positive, the rapid test classified 370 of the samples as positive.

Of the 626 samples that were HIV antibody negative by the gold standard, 624 were classified by the rapid tests as not containing HIV antibodies.

**STATE** the final results of Se, Sp, PPV, & NPV.

**ASK** participants what does this really mean?

- Test performance of the HIV rapid test under evaluation is nearly as good as the results of the “gold standard” or true value.
- The HIV test will yield highly accurate results

**BUT**, while these results indicated very good performance, you must also keep in mind that the performance is influenced by the makeup of the population.

14 **HIV Rapid Test Performance**

**STATE** – as illustrated in the example in the previous slide, no test is 100% sensitive or 100 % specific when compared to the “gold standard”

15 **How Prevalence Affects PPV & NPV**

If we know the sensitivity and specificity of the kit and the prevalence of HIV in the population, we can theoretically calculate the predictive value of the performed test.

16 **How Prevalence Affects PPV & NPV (Cont’d)**

**EMPHASIZE** in general, the higher the prevalence, the higher the PPV. Conversely, the lower the prevalence, the lower the PPV.
<table>
<thead>
<tr>
<th>Slide Number</th>
<th>Teaching Points</th>
</tr>
</thead>
</table>
| 17           | Testing Algorithm Describes the Sequence of Tests to be Performed  
DESCRIBE what a testing algorithm is. (Defined in slide title)  
EXPLAIN the rationale for using multiple tests and the implications when a client obtains an inaccurate test result:  
• False positive (that is, inaccurately reported as positive)  
• False negative (that is, inaccurately reported as negative)  
DEFINE the term “Discordant.” |
| 18           | Ideal Algorithm  
STATE the points on the slide |
| TIPS Slides 19 | For participants without any lab background:  
• Explain the algorithm slowly. Participants may have never seen an algorithm before.  
• Go over it step by step. Use Slide Build feature when presenting the algorithm. |
<p>| Customization Notes 19 | Show country-specific testing algorithm with appropriate test names inserted. |</p>
<table>
<thead>
<tr>
<th>Slide Number</th>
<th>Teaching Points</th>
</tr>
</thead>
</table>
| **19**       | **Testing Algorithm**  
|              | DESCRIBE in-country test algorithm.  
|              | EMPHASIZE testing sites must never use any kits, other than the ones described in the countries algorithm, and have been evaluated and approved for use by the Ministry of Health.  
|              | STATE that in a parallel testing algorithm involves two tests running at the same time.  
|              | HIGHLIGHT the following key points:  
|              | • When both tests are reactive, the final HIV result is positive.  
|              | • When both tests are non-reactive, then the final HIV result is negative.  
|              | • If one test is reactive and the other is non-reactive, then a third test known as a tiebreaker is performed.  
|              | • The tie-breaker determines the final result – if the tiebreaker is reactive, then the final HIV result is positive; if the tiebreaker is non-reactive, then the final HIV result is negative.  
|              | EMPHASIZE that test 1, 2 and 3 are different rapid tests. |
| **Customization Notes** | Modify the exercises and table of possible HIV test outcomes based on your country’s testing algorithms. |
| **20**       | **Exercise: Interpreting HIV Status Using Testing Algorithm**  
| **Exercise** | REFER participants to the exercise in their manual.  
| **5 Minutes**| ASK participants to spend 3 minutes, working alone, on the exercise.  
|              | DISCUSS the answers as a group. |
| **21**       | **Possible HIV Test Outcomes: Parallel Testing Algorithm**  
|              | DISCUSS the various combinations of possible HIV test results and how to interpret HIV status in each scenario.  
|              | EMPHASIZE that all invalid test results must be repeated. |
| **22**       | **Summary**  
|              | ASK participants to answer the questions on the slide.  
|              | ANSWER any remaining questions the participant may have. |
Module 5: Assuring the Quality of HIV Rapid Testing –
A Systems Approach to Quality

Purpose
To provide an overview of the lab quality system so that participants will adopt a broad systems view toward quality. Furthermore, they will understand where errors may occur in the rapid testing process and their responsibilities in preventing and detecting them.

Pre-requisite Modules
None

Module Time
1 hour and 15 minutes

Learning Objectives
At the end of this module, you will be able to:
• Explain the systems approach to lab quality and its benefits
• Identify the essential elements of a lab quality system and how they apply to HIV rapid testing
• Recognize key factors that may compromise the quality of HIV rapid testing
• Describe your responsibilities in preventing and detecting errors before, during, and after testing

Module Overview

<table>
<thead>
<tr>
<th>Step</th>
<th>Time</th>
<th>Activity/Method</th>
<th>Content</th>
<th>Resources Needed</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>5 min</td>
<td>Presentation</td>
<td>Module introduction</td>
<td>Slides 1-4; Prepared flipchart – content outline</td>
</tr>
<tr>
<td>2</td>
<td>5 min</td>
<td>Discussion</td>
<td>Dining Out: A quality exercise</td>
<td>Slide 5</td>
</tr>
<tr>
<td>3</td>
<td>20 min</td>
<td>Presentation; Discussion</td>
<td>Systems approach to lab quality</td>
<td>Slides 6-23</td>
</tr>
<tr>
<td>4</td>
<td>20 min</td>
<td>Energizer</td>
<td>Are you “Positive” or “Negative?”</td>
<td>Slide 24; Cabbage ball 1</td>
</tr>
<tr>
<td>5</td>
<td>5 min</td>
<td>Presentation</td>
<td>Quality assurance vs. quality control</td>
<td>Slides 25-27</td>
</tr>
<tr>
<td>5</td>
<td>15 min</td>
<td>Discussion; Presentation</td>
<td>Preventing and detecting errors before, during and after testing</td>
<td>Flipchart; Slide 28-35</td>
</tr>
<tr>
<td>6</td>
<td>5 min</td>
<td>Q&amp;A</td>
<td>Summary</td>
<td>Slide 36</td>
</tr>
</tbody>
</table>

1- Instructions for constructing the cabbage ball are provided at the end of this document.
Material/Equipment Checklists:

- PowerPoint slides or transparencies
- Overhead projector or computer w/LCD projector
- Cabbage ball (constructed prior to workshop)
- Flipchart
<table>
<thead>
<tr>
<th>Slide Number</th>
<th>Teaching Points</th>
</tr>
</thead>
</table>
| 1 | **Module 5: Assuring the Quality of HIV Rapid Testing**  
DISPLAY this slide before you begin the module. Make sure participants are aware of the transition into a new module. |
| 2 | **Learning Objectives**  
STATE the objectives on the slide |
| 3 | **Content Overview**  
EXPLAIN that these are the topics that will be covered in this module  
EMPHASIZE that this module provides an overview of the quality system and details on specific elements of the quality system. |
| Flipchart | WRITE the content outline on a flipchart prior to training.  
REFER to it frequently to orient participants to where they are in the module. |
| 4 | **What is “Quality”?**  
STATE the definition on the slide  
EMPHASIZE that a service would include providing and interpreting an HIV Rapid Test. |
<table>
<thead>
<tr>
<th>Slide Number</th>
<th>Teaching Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td><strong>Group Discussion</strong>&lt;br&gt;5 minutes &lt;br&gt;Flipchart</td>
</tr>
<tr>
<td></td>
<td>“Dining Out”: A Quality Experience&lt;br&gt;STATE Quality can be evaluated in anything we experience.&lt;br&gt;EXPLAIN that you can better understand the concept of quality and quality systems, by thinking about what you might experience at a restaurant:&lt;br&gt;ASK What you might expect for a quality experience at a restaurant.&lt;br&gt;NOTE participants’ responses on a flipchart.&lt;br&gt;STATE If your expectations as a customer are met by the restaurant, the restaurant has provided you with “quality” service.&lt;br&gt;Simply put: Quality Management is having systems in place to continually evaluate:&lt;br&gt;• What is being done&lt;br&gt;• How it is being done&lt;br&gt;• What are opportunities for improvement&lt;br&gt;• How to make changes for improvement&lt;br&gt;• What is the impact of the change/improvement&lt;br&gt;ASK participants to keep the restaurant scenario in mind as they view and discuss the following slides.</td>
</tr>
<tr>
<td>6</td>
<td><strong>Why Quality?</strong>&lt;br&gt;EXPLAIN why quality is important:&lt;br&gt;• Quality at a testing site will result in accurate and correct performance of the HIV Rapid Test&lt;br&gt;• Quality at a testing site will result in accurate and reliable test results which are essential to all aspects of patient health, including prevention, care and treatment</td>
</tr>
<tr>
<td>Slide Number</td>
<td>Teaching Points</td>
</tr>
<tr>
<td>--------------</td>
<td>-----------------</td>
</tr>
<tr>
<td>7</td>
<td><strong>A Systems Approach to Quality</strong></td>
</tr>
<tr>
<td></td>
<td>STATE the approach we take to ensure lab quality is a systems approach.</td>
</tr>
<tr>
<td></td>
<td>• A systems approach examines all components in the system, not just focusing on any one component.</td>
</tr>
<tr>
<td></td>
<td>• A systems approach places as much emphasis on identifying and describing the connections between system components as on identifying and describing the components themselves.</td>
</tr>
<tr>
<td></td>
<td>EXPLAIN the concept further by using the human body as an example.</td>
</tr>
<tr>
<td></td>
<td>• A headache may be caused by disorder in other parts of the human body system. You need to look at other parts to find out what’s wrong with the head.</td>
</tr>
<tr>
<td></td>
<td>• Similarly, to achieve total quality in the lab or testing site, you need to look at all the activities, direct or indirect, that may contribute to quality.</td>
</tr>
<tr>
<td>8</td>
<td><strong>Definition of A Lab Quality System</strong></td>
</tr>
<tr>
<td></td>
<td>READ the definition on the slide.</td>
</tr>
<tr>
<td></td>
<td>STATE by adopting the systems approach to lab quality, a lab quality system would encompass all activities that contribute to quality directly or indirectly.</td>
</tr>
<tr>
<td>9</td>
<td><strong>Benefits of a Quality System</strong></td>
</tr>
<tr>
<td></td>
<td>EXPLAIN the benefits of a quality system to the HIV rapid testing sites.</td>
</tr>
<tr>
<td>10</td>
<td><strong>The Lab Quality System</strong></td>
</tr>
<tr>
<td></td>
<td>STATE a lab quality system has 12 components, each of which will be explained in further detail.</td>
</tr>
<tr>
<td></td>
<td>POINT OUT the 12 components.</td>
</tr>
</tbody>
</table>
### Flipchart

REFER to the flipchart from the discussion earlier. Relate each statement to a specific quality system essential. For example:

- You notice a government certificate of passed inspection posted near the entrance (*Assessment: external evaluation*)
- The reservation you made has been recorded and honored (*Information Management; Documents & Records*)
- You are treated courteously by a knowledgeable staff (*Personnel: training, supervision; Organization: standards, accountability*)
- Your order was taken promptly and meal was served in a reasonable amount of time (*Process control*)
- You ordered a menu item, and the restaurant had all the necessary ingredients to prepare the dish (*Inventory Management*)
- The food was well presented, fresh and flavorful (*Inventory management, storage, procurement*)
- Your overcooked steak was promptly replaced with a properly cooked steak (*Occurrence Management: correcting error; Equipment: maintenance, troubleshooting; Customer service*)
- Before paying the bill, you were asked if your experience met your expectations and what would you have liked improved (*Process improvement; Organization: commitment to quality, standards*)

### TIPS

For these 12 slides (lab quality system components), your teaching should focus on not just what each component is, but also the cause-and-effect relationships among them. The key message is: **they are all inter-connected; each and every component must be present to achieve total quality in the lab.**

This module is highly conceptual and abstract. Try to provide as many concrete examples and analogies as possible.

### Customization

If a lab quality system has been established, provide specific in-country information for each component of the quality system.
<table>
<thead>
<tr>
<th>Slide Number</th>
<th>Teaching Points</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>11</strong></td>
<td><strong>Organization</strong></td>
</tr>
<tr>
<td></td>
<td>EXPLAIN organization is the leadership or party responsible for establishing and managing the overall quality program. The quality system must start with the organization.</td>
</tr>
<tr>
<td></td>
<td>To ensure total lab quality, organization needs to:</td>
</tr>
<tr>
<td></td>
<td>• Create quality policy and standards</td>
</tr>
<tr>
<td></td>
<td>• Secure sufficient resources to maintain quality requirements</td>
</tr>
<tr>
<td></td>
<td>• Clearly define roles and accountability</td>
</tr>
<tr>
<td></td>
<td>• Cultivate a culture committed to quality</td>
</tr>
<tr>
<td></td>
<td>INDICATE this component is closely linked to other components such as personnel, equipment, process improvement, and customer service.</td>
</tr>
<tr>
<td>Slide Number</td>
<td>Teaching Points</td>
</tr>
<tr>
<td>--------------</td>
<td>-----------------</td>
</tr>
<tr>
<td><strong>12</strong></td>
<td><strong>Personnel</strong></td>
</tr>
</tbody>
</table>

EXPLAIN personnel are the most important component in the lab quality system because it is linked to all other components. To achieve total lab quality, we need to have the right people on the right jobs all motivated and competent to perform. Consider:

- **Human resource planning** – What skills do you need? How many people do you need? When do you need them?
- **Hiring** – What is the hiring practice that will help you attract the right people? It should start with a clear job description that defines duties, responsibilities, and required skills.
- **Retention** – What is your plan to retain your people once they are hired? How are you going to address the issue of high turnover?
- **Supervision** – Supervisors are critical in that they communicate performance expectations, model proper behaviors, provide feedback, and motivate the employees. They make sure employees have the support required for performance, which includes information, tools, and consultation for problem solving.
- **Training** – Upon assignment to a testing site, staff must be oriented to site polices and operations. Due to method changes and frequent staff turnover, training must be provided to update employee skills. Initial and on-going competency assessment is required for all staff performing testing.
- **Performance management** – This entails all the activities that ensure an employee’s on-the-job performance. It involves goal setting, performance coaching, feedback, monitoring, appraisal, and performance improvement measures.
<table>
<thead>
<tr>
<th>Slide Number</th>
<th>Teaching Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>13</td>
<td><strong>Equipment</strong></td>
</tr>
</tbody>
</table>

EXPLAIN equipment used at the HIV rapid testing site may include refrigerator, freezer, and precision pipettes. Laboratories that serve as referral labs for HIV rapid testing site must ensure that equipment used is appropriate for the task and kept in optimal working order. This is achieved by:

- Selecting the right equipment. The purchasing contract should include installation and initial calibration; regular service; and training to operate the equipment.
- Setting up mechanism for regular preventative maintenance and routine calibration to ensure uninterrupted service and prolonged life span of the equipment.
- Ensuring readily available technical expertise for timely repair in case of equipment breakdown.
- Stocking up on parts that break frequently
- Establishing troubleshooting procedures
- Creating a maintenance log and regularly reviewing all documentation
- Retiring equipment properly. This involves putting up signage, removing from premise, and salvaging reusable parts.

INDICATE this component is closely linked to other components such as personnel, purchasing and inventory, documents and records, and facilities and safety.
## Slide Number 14

### Purchasing and Inventory

EXPLAIN purchasing is primarily handled by a central procurement and inventory process. Laboratory staff should be involved during the process of defining criteria for the materials and supplies needed.

Purchasing and inventory involves:

- Defining criteria for products and services to be purchased
- Establishing a system to receive, inspect, accept, store incoming materials
- Maintaining proper inventory
- Developing a system to connect materials to appropriate patients, activities, or records
  - This is important in the event of notices from manufacturers of potential problems with specific kit lot #.
  - You will know what lot # was used only if this information is recorded.

INDICATE this component is closely linked to other components such as organization, process control, documents and records, and facilities and safety.
<table>
<thead>
<tr>
<th>Slide Number</th>
<th>Teaching Points</th>
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</thead>
<tbody>
<tr>
<td><strong>15</strong></td>
<td><strong>Process Control</strong></td>
</tr>
<tr>
<td></td>
<td>EXPLAIN process control.</td>
</tr>
<tr>
<td></td>
<td>• Process control refers to the activities and techniques performed to ensure:</td>
</tr>
<tr>
<td></td>
<td>o Testing procedures are correctly performed</td>
</tr>
<tr>
<td></td>
<td>o The environment is suitable for reliable testing</td>
</tr>
<tr>
<td></td>
<td>o The test kit works as expected to produce accurate and reliable results</td>
</tr>
<tr>
<td></td>
<td>• Process control concerns all aspects of the laboratory, not just the testing procedures. Examples include ensuring that:</td>
</tr>
<tr>
<td></td>
<td>o Test methods are appropriately evaluated.</td>
</tr>
<tr>
<td></td>
<td>o Testing sites have on hand up-to-date standard operating procedures.</td>
</tr>
<tr>
<td></td>
<td>o All staff follow SOPs (Standard Operating Procedures) exactly as written.</td>
</tr>
<tr>
<td></td>
<td>o Specimens are appropriately collected, handled/processed, stored, transported, and discarded.</td>
</tr>
<tr>
<td></td>
<td>o QC (quality control) is performed and monitored.</td>
</tr>
<tr>
<td></td>
<td>INDICATE this component is closely linked to other components such as personnel, purchasing and inventory, assessment, and facilities and safety.</td>
</tr>
<tr>
<td><strong>16</strong></td>
<td><strong>Documents and Records</strong></td>
</tr>
<tr>
<td></td>
<td>EXPLAIN document and records may be paper-based or computer-based. Regardless of the format, a system must be established in order to:</td>
</tr>
<tr>
<td></td>
<td>• Create standards for forms</td>
</tr>
<tr>
<td></td>
<td>• Manage document revision, approval, and distribution</td>
</tr>
<tr>
<td></td>
<td>• Manage patient test records</td>
</tr>
<tr>
<td></td>
<td>• Maintain document storage, retrieval, and destruction</td>
</tr>
<tr>
<td></td>
<td>INDICATE this component is closely linked to other components such as purchasing and inventory, information management, assessment, and occurrence management.</td>
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<tr>
<td>Slide Number</td>
<td>Teaching Points</td>
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<td>--------------</td>
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</tbody>
</table>
| 17           | **Information Management**  
EXPLAIN information management refers to these activities:  
- Manage incoming and outgoing information  
- Establish standards for gathering information  
- Ensure the privacy and confidentiality of patient information  
EXPLAIN that these activities can often be facilitated by computers. If computers are used, personnel must be trained in relevant computer skills such as word processing, spreadsheet, and database.  
INDICATE this component is closely linked to other components such as personnel, documents and records, and customer service. |
| 18           | **Occurrence Management**  
EXPLAIN occurrence management.  
- It deals with lab problems and errors as they occur.  
- Examples of occurrences include accidental spills or needle injuries.  
- There must be a pre-defined approach and system for dealing with errors.  
  - Keep a record of all circumstances related to the error or problem.  
  - Keep a record of corrective action taken and any communications with affected persons.  
  - This information is useful for those monitoring the testing, for any internal audits, and for use if further inquiries from patients or physicians occur.  
INDICATE this component is closely linked to other components such as process control, documents and records, and customer service. |
<table>
<thead>
<tr>
<th>Slide Number</th>
<th>Teaching Points</th>
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</thead>
<tbody>
<tr>
<td>19</td>
<td><strong>Assessment</strong></td>
</tr>
<tr>
<td></td>
<td>EXPLAIN assessment is the periodic examining and monitoring of laboratory operations to established requirements. It involves external and internal evaluation.</td>
</tr>
<tr>
<td></td>
<td>• It is good practice for testing sites to periodically conduct self-evaluation of their operations against quality requirements. Any gaps identified can be addressed immediately.</td>
</tr>
<tr>
<td></td>
<td>• There are two types of external evaluation or assessment.</td>
</tr>
<tr>
<td></td>
<td>o Testing sites may be routinely monitored in the form of supervisory visits.</td>
</tr>
<tr>
<td></td>
<td>o External assessments may be conducted by external agencies for accreditation purposes. This is usually done by an independent body to objectively assess compliance with established quality requirements of published standards.</td>
</tr>
<tr>
<td></td>
<td>INDICATE this component is closely linked to other components such as organization, personnel, and process control</td>
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<td>Slide Number</td>
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<tr>
<td><strong>20</strong></td>
<td><strong>Process Improvement</strong></td>
</tr>
<tr>
<td></td>
<td>EXPLAIN process improvement refers to activities designed to:</td>
</tr>
<tr>
<td></td>
<td>• Identify and eliminate causes of poor quality</td>
</tr>
<tr>
<td></td>
<td>• Reduce waste and improve efficiency by eliminating non-value added activities</td>
</tr>
<tr>
<td></td>
<td>o Sometimes formal studies are conducted and results are statistically analyzed. An example might be efficiency of a testing site in reporting client results. Does it take 2 hours to report a result that can be reported within 30 minutes?</td>
</tr>
<tr>
<td></td>
<td>o But it doesn't always have to be formal. Opportunities for process improvement are everywhere if you pay attention.</td>
</tr>
<tr>
<td></td>
<td>DISCUSS the following examples to help participants understand the concept.</td>
</tr>
<tr>
<td></td>
<td>• You are required to dispose of sharps after each test. But the sharps container is located in a separate room from the testing area. This situation discourages testers from following the recommended safety practice and increases potential hazard if used sharps are transported to the container next door. What should you do?</td>
</tr>
<tr>
<td></td>
<td>• You are required to retrieve a test record or report from a given day, but it takes you a long time to sort through the piles of paper. After locating the record, there is missing information</td>
</tr>
<tr>
<td></td>
<td>INDICATE component is closely linked to other components such as organization, personnel, documents and records, process control, and customer service</td>
</tr>
<tr>
<td>Slide Number</td>
<td>Teaching Points</td>
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</tr>
</tbody>
</table>
| **21**       | **Customer Service**  
ASK participants, “who are your customers?”  
- The patient/client is the ultimate customer.  
- However, we must not forget the clinician, program staff, and epidemiologists. These people are our internal customers.  
EMPHASIZE everyone at the HIV rapid testing site has responsibility for providing good customer service, from the receptionist, counselor, and lab staff.  
- Each test site should actively seek information on both internal and external satisfaction through customer surveys and interviews.  
- Use data collected for process improvement  
- Value and reward staff providing good service  
INDICATE this component is closely linked to other components such as personnel, documents and records, process control, and process improvement |
| **22**       | **Facilities and Safety**  
EXPLAIN it is important to:  
- Ensure that facilities, testing and storage areas are adequate in order to produce reliable test results, e.g., monitoring testing and storage area temperatures  
- Provide an adequate and safe work environment  
INDICATE this component is closely linked to other components such as organization, personnel, purchasing and inventory, occurrence management, process control, and customer service. |
| **23**       | **The Lab Quality System**  
POINT OUT some components (highlighted in yellow) will be further explored in later modules.  
ASK if participants have any questions. |
<table>
<thead>
<tr>
<th>Slide Number</th>
<th>Teaching Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>TIPS</td>
<td>The next activity is an energizer. Energizers are short, fun activities that “break up” periods of concentrated learning. They often involve physical movement and a lot of fun. They serve as “mental breaks” so participants are refreshed and ready for more learning that follows. Some energizers incorporate learning content. The following is an example. It summarizes the 12 components of Quality Lab Systems and furthers participants’ understanding of the concept by providing concrete examples.</td>
</tr>
<tr>
<td>24 Activity</td>
<td><strong>Activity: Are You “Positive” or “Negative?”</strong></td>
</tr>
<tr>
<td>20 minutes</td>
<td>CONSTRUCT the cabbage ball prior to the module. (NOTE: Instructions are located at the end of this module.) FOLLOW the procedure below when conducting the activity.</td>
</tr>
<tr>
<td></td>
<td>INFORM participants of the activity.</td>
</tr>
<tr>
<td></td>
<td>POINT OUT the instructions on the slide.</td>
</tr>
<tr>
<td></td>
<td>DESIGNATE one corner of the room as “Positive” (statement that describes a factor contributing to quality), and another as “Negative” (statement that describes a factor contributing to lack of quality).</td>
</tr>
<tr>
<td></td>
<td>START the activity by tossing the cabbage ball to any participant.</td>
</tr>
<tr>
<td></td>
<td>ENSURE the activity proceeds in an orderly fashion following the sequence below. (Consider playing the first two rounds as demonstration to familiarize the participants with the procedure.) A participant:</td>
</tr>
<tr>
<td></td>
<td>o Catches the ball</td>
</tr>
<tr>
<td></td>
<td>o Peels one statement off the ball</td>
</tr>
<tr>
<td></td>
<td>o Reads the statement to the entire group and decides whether it is positive or negative</td>
</tr>
<tr>
<td></td>
<td>o Tosses the ball to the next person</td>
</tr>
<tr>
<td></td>
<td>o Walks to the appropriate corner based on the statement (The process repeats)</td>
</tr>
<tr>
<td></td>
<td>CONCLUDE the activity by answering any questions participants may have.</td>
</tr>
<tr>
<td></td>
<td>If time allows, repeat this activity using new cabbage balls.</td>
</tr>
<tr>
<td>25</td>
<td><strong>Who Is Responsible for Quality?</strong></td>
</tr>
<tr>
<td></td>
<td>STATE quality is everyone’s responsibility.</td>
</tr>
<tr>
<td>Slide Number</td>
<td>Teaching Points</td>
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<tr>
<td>--------------</td>
<td>-----------------</td>
</tr>
<tr>
<td>Transition</td>
<td>STATE:</td>
</tr>
<tr>
<td></td>
<td>• We just had an overview of what the lab quality system encompasses.</td>
</tr>
<tr>
<td></td>
<td>• Next we will talk about what you can do to contribute to lab quality.</td>
</tr>
<tr>
<td></td>
<td>• But first, let’s define some terms – QA and QC.</td>
</tr>
<tr>
<td></td>
<td>• You play an important role in both.</td>
</tr>
<tr>
<td>26</td>
<td><strong>Quality Assurance vs. Quality Control</strong></td>
</tr>
<tr>
<td></td>
<td>EXPLAIN the difference between quality assurance (QA) and quality control (QC).</td>
</tr>
<tr>
<td></td>
<td>STATE QC is part of QA.</td>
</tr>
<tr>
<td>27</td>
<td><strong>The Quality Assurance Cycle</strong></td>
</tr>
<tr>
<td></td>
<td>STATE quality assurance is applied throughout the testing process at all testing sites. It is not a one time event. The slide illustrates that this is a continual process.</td>
</tr>
<tr>
<td></td>
<td>EXPLAIN the 3 phases and the activities associated with each phase.</td>
</tr>
<tr>
<td>28</td>
<td><strong>Why Do Errors Occur?</strong></td>
</tr>
<tr>
<td></td>
<td>STATE each bullet on the slide.</td>
</tr>
<tr>
<td></td>
<td>RELATE each error to the appropriate lab quality system components. For example, if the error of “kits not stored properly” occurs, ask participants which part of the quality system breaks down that caused such an error.</td>
</tr>
<tr>
<td></td>
<td>ASK participants, “What are some errors that may occur during pre-testing, testing, and post-testing phase in the QA cycle?”</td>
</tr>
<tr>
<td></td>
<td>NOTE participant responses on a flip chart.</td>
</tr>
<tr>
<td>29</td>
<td><strong>Pre-testing Errors</strong></td>
</tr>
<tr>
<td></td>
<td>PRESENT the slide.</td>
</tr>
<tr>
<td></td>
<td>ACKNOWLEDGE points that have been mentioned by the participants in the discussion.</td>
</tr>
<tr>
<td>30</td>
<td><strong>Preventing and Detecting Errors – Before Testing</strong></td>
</tr>
<tr>
<td></td>
<td>PRESENT the slide.</td>
</tr>
<tr>
<td></td>
<td>EMPHASIZE every tester is responsible for preventing and detecting errors.</td>
</tr>
<tr>
<td>Slide Number</td>
<td>Teaching Points</td>
</tr>
<tr>
<td>--------------</td>
<td>----------------</td>
</tr>
</tbody>
</table>
| 31           | **Testing Errors**  
PRESENT the slide.  
ACKNOWLEDGE points that have been mentioned by the participants in the discussion.  
EXPLAIN “incorrect reagents used” (last bullet) refers to using buffers from a different kit. |
| 32           | **Preventing and Detecting Errors – During Testing**  
PRESENT the slide.  
EMPHASIZE every tester is responsible for preventing and detecting errors. |
| 33           | **Post-testing Errors**  
PRESENT the slide.  
ACKNOWLEDGE points that have been mentioned by the participants in the discussion. |
| 34           | **Preventing and Detecting Errors – After testing**  
PRESENT the slide.  
EMPHASIZE every tester is responsible for preventing and detecting errors. |
| 35           | **Why is Quality System Important to Rapid Testing?**  
REVIEW the points on the slide. |
| 36           | **Summary**  
ASK participants to answer the questions on the slide.  
ANSWER any questions participants may have. |
Instructions for Making A Cabbage Ball

1. Determine the number of participants in the workshop.
2. Print out as many statements (listed below) as the participants. PRINT EACH STATEMENT ON A SEPARATE PIECE OF PAPER.
3. Sort these statements into a random order so that not all positive statements are together.
4. Start by crumpling the first statement into a tight small ball.
5. Add the next layer with another statement.
6. Repeat the process until all statements have been added to the ball.

Positive Statements

The Ministry of Health announced that a system for monitoring Quality Assurance would be implemented throughout all levels of rapid HIV testing.

The reference laboratory provided proficiency samples to test sites to help them evaluate their testing performance.

The Ministry of Health established a team to periodically monitor testing sites.

A test site is keeping records of the number of tests used each month in order to assure that an adequate supply of kits and reagents will be maintained.

A test site used standard forms and log sheets to make recording and review of data easier.

The competency of each staff performing HIV rapid tests was assessed twice a year to assure they have maintained the appropriate knowledge and skills to perform their job.

The testing site established a protocol for taking corrective actions to address adverse events.

Temperature logs were maintained for recording, twice a day, the temperature of the reagent/test kit storage area.

At the beginning of each day of testing, a responsible staff person evaluated the HIV rapid test kits by analyzing a known positive and known negative HIV control sample.

The testing site established a “chain of command” and assigned specific quality management tasks to responsible individuals.

New employees demonstrated competency before they were allowed to perform HIV rapid tests.

The testing site implemented a plan for maintaining and servicing equipment used at the HIV rapid testing.

Test site staff helped define criteria for the materials and services needed to carry out quality HIV rapid testing.

The testing site assigned a person to receive and inspect incoming supplies and reagents.
**Negative Statements**

A new staff member failed to record the test results for 3 clients tested early in the day. Based on her memory, she entered the results later in the day.

New test kits were received and placed on the storage shelf in front of test kits that were already there.

A new staff member received no orientation to site policies and procedures before beginning to perform HIV rapid tests.

For three days a testing site manager did not return a call from a physician who had requested a copy of test results for her patient.

You noticed the standard operating procedure was missing from the test site. You decided to follow the SOP you borrowed from a neighboring country.

Due to staff shortages, the testing site cancelled the first scheduled internal assessment for the year.

Due to frequent problems with transport, the reference laboratory suspended shipping quality control materials to the sites in its province.

During lunch, the testing site manager overhead that a “sharps” incident had occurred earlier in the week but had not been reported.

Following an on-site assessment, several deficiencies were noted. The testing site manager decided that the deficiencies were minor and did not require any remedial action.

You noticed that the sharps container was missing from the testing area. You decided to use a plastic bag to collect the lancets until the end of the day when you had time to look for the sharps container.

The refrigerator that stored test reagents and controls stopped functioning overnight, but the temperature only went up 3 degrees above the acceptable range. You felt this was not a significant change and proceeded to test the clients.
Module 6: Safety at the HIV Rapid Testing Site

**Purpose**
To provide the participants with necessary attitudes, knowledge, and skills about lab safety so they will take precautions to prevent infections at the HIV rapid testing site.

**Pre-requisite Modules**
Module 5: Assuring the Quality of HIV Rapid Testing

**Module Time**
45 minutes

**Learning Objectives**
At the end of this module, participants will be able to:
- Adhere to personal health and safety practices
- Maintain a clean and organized workspace
- Disinfect and dispose of infectious materials
- Take appropriate actions following accidental exposure to potentially infectious specimen
- Follow written safety procedures and keep proper safety records

**Module Overview**

<table>
<thead>
<tr>
<th>Step</th>
<th>Time</th>
<th>Activity/Method</th>
<th>Content</th>
<th>Resources Needed</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>10 min</td>
<td>Presentation</td>
<td>Module introduction</td>
<td>Slides 1-6; prepared flipchart – content outline</td>
</tr>
<tr>
<td>2</td>
<td>20 min</td>
<td>Presentation; Discussion</td>
<td>Safety practices</td>
<td>Slides 7-26; eye wash units; Bio-hazard poster; sharp containers; Materials required for demonstrating how to handle a spill</td>
</tr>
<tr>
<td>3</td>
<td>5 min</td>
<td>Q&amp;A</td>
<td>Summary</td>
<td>Slide 27</td>
</tr>
<tr>
<td>4</td>
<td>10 min</td>
<td>Discussion</td>
<td>Safety practices and you</td>
<td>Flipchart</td>
</tr>
</tbody>
</table>
Material/Equipment Checklists

- PowerPoint slides or transparencies
- Overhead projector or computer w/LCD projector
- Prepared flipchart – content outline, discussion questions
- Eye wash units
- Bio-Hazard poster or sticker
- Sharp containers
- Materials required for demonstrating how to handle a spill
- Handouts:
  - Guidelines for Post Exposure Prophylaxis (PEP)
  - Example: Emergency Contact List
  - Log of Work Related Injuries and Illnesses
# Teaching Guide

<table>
<thead>
<tr>
<th>Slide Number</th>
<th>Teaching Points</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1</strong></td>
<td><strong>Module 6: Safety at the HIV Rapid Testing Site</strong></td>
</tr>
<tr>
<td></td>
<td>DISPLAY this slide before you begin the module. Make sure participants are aware of the transition into a new module.</td>
</tr>
<tr>
<td><strong>2</strong></td>
<td><strong>The Lab Quality System</strong></td>
</tr>
<tr>
<td></td>
<td>REMIND participants that site safety is one component of the lab quality system.</td>
</tr>
<tr>
<td><strong>3</strong></td>
<td><strong>Why Is Safety Important?</strong></td>
</tr>
<tr>
<td></td>
<td>DISCUSS why performing HIV tests poses a potential health hazard to the tester. ENCOURAGE participants to share their thoughts.</td>
</tr>
<tr>
<td></td>
<td>ASK, “What is it about performing rapid testing on a client that could put the tester at risk?” (Answer – The tester may come into contact with blood from the client, and all specimens should be treated as though potentially hazardous).</td>
</tr>
<tr>
<td></td>
<td>ASK, “What might be present in the client’s blood that would be dangerous to others?” (Answer – Agents that can cause infection. Such agents may also be called pathogens, and since these pathogens live in blood, they are called blood-borne pathogens).</td>
</tr>
<tr>
<td></td>
<td>ASK participants to give some examples (e.g. HIV, Hepatitis).</td>
</tr>
<tr>
<td></td>
<td>TELL true stories or relay your personal experiences about what happened when someone did not take safety precautions.</td>
</tr>
</tbody>
</table>

**TIPS**

Stories or scenarios that evoke emotions (fear, shock, sympathy, sorrow, etc.) are excellent ways in getting participants to pay attention and adopting the right attitudes about lab safety. This is especially important when teaching participants without medical or lab experience.
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<thead>
<tr>
<th>Slide Number</th>
<th>Teaching Points</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>4</strong></td>
<td><strong>What Else Needs Protection?</strong></td>
</tr>
<tr>
<td></td>
<td>EXPLAIN that besides tester and client, we also need to:</td>
</tr>
<tr>
<td></td>
<td>• Protect other people from infection</td>
</tr>
<tr>
<td></td>
<td>o Never leave blood spills that could infect others.</td>
</tr>
<tr>
<td></td>
<td>o Never leave used lancets lying around for anyone else to pick up – they could prick themselves with HIV contaminated lancets.</td>
</tr>
<tr>
<td></td>
<td>o Always seal contaminated waste – you don’t want to risk infecting the person who removes contaminated waste from the rapid testing site.</td>
</tr>
<tr>
<td></td>
<td>• Protect integrity of test products</td>
</tr>
<tr>
<td></td>
<td>o It is important not to contaminate unused tests.</td>
</tr>
<tr>
<td></td>
<td>o If a new unused test is contaminated by a drop of blood from a previous client, the test may not yield accurate result when used on the next client.</td>
</tr>
<tr>
<td></td>
<td>• Protect the environment from hazardous material</td>
</tr>
<tr>
<td></td>
<td>o Care should be taken to avoid transferring contaminated materials into areas outside of the testing area.</td>
</tr>
<tr>
<td><strong>5</strong></td>
<td><strong>Learning Objectives</strong></td>
</tr>
<tr>
<td></td>
<td>STATE the objectives on the slide.</td>
</tr>
<tr>
<td><strong>6</strong></td>
<td><strong>Content Overview</strong></td>
</tr>
<tr>
<td></td>
<td>EXPLAIN the topics that will be covered in this module.</td>
</tr>
<tr>
<td><strong>Flipchart</strong></td>
<td>REFER to the previously prepared flipchart to orient participants to where they are in the module.</td>
</tr>
<tr>
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</tbody>
</table>
| 7 | **Universal or Standard Precautions**  
DISCUSS the implications of the text on the slide. ENCOURAGE participants to share their thoughts.  
ASK, “Why should every blood sample be treated as though it is infectious?” (Answer: Harmful agents/organisms may be present in a client’s blood. If a person comes into direct contact with the blood, that person could be infected.)  
CONCLUDE that as a result, we must follow safety practices in every step of the testing process. |
| 8 | **Apply Safety Practices Throughout the Testing Process**  
HIGHLIGHT the safety practices within each phase of testing.  
- Before testing - specimens shall be transported in a manner to prevent contamination of workers, patients, environment  
  - Use appropriate packing containers  
  - Follow national and international postal and transport regulations  
- During testing – Apply safety rules when performing finger-prick and actual testing of the client’s blood.  
- After testing  
  - Clean up working area  
  - Properly dispose of contaminated waste |
<table>
<thead>
<tr>
<th>Slide Number</th>
<th>Teaching Points</th>
</tr>
</thead>
</table>
| 9            | **Develop Personal Safe Work Habits**  
**DISCUSS** each personal safe work habit. **ENCOURAGE** participants to share their thoughts.  
ASK, “Why do testers need to wash their hands between testing each client?” (Answer: To wash away any germs that might be present on the tester’s hands – this will ensure that no infections are passed from the tester or previous client onto the next new client.)  
ASK, “Why do we need to wear fresh gloves for each new client?” (Answer: To protect the client and tester from cross-infection – the transfer of infection from one person to another.)  
ASK, “Why wear lab coat or apron?” (Answer: This is to protect the tester from reagent spills, client’s blood.  
ASK, “Why do we need to get rid (or not re-use) of used sharp objects such as needles or lancets?” (Answer: Sharp objects can cut human skin. Any germs or pathogens present on the lancet can be passed from the lancet into that person’s blood through the cut.)  
**10** | **Develop Personal Safe Work Habits (Cont’d)**  
**CONTINUE** the discussion of personal safe work habit. **ENCOURAGE** participants to share their thoughts.  
ASK, “Why is pipetting by mouth strictly forbidden?” (Answer: You run the risk of accidentally swallowing or coming into direct contact with harmful materials.)  
ASK, “Why is eating, drinking, or smoking not allowed in the test site?” (Answer: Harmful germs or pathogens can be an entry point to the from touching contaminated objects followed by contact with your mouth.)  
ASK, “Why is it important to keep food away from the testing area or a refrigerator that contains blood samples?” (Answer: Infectious agents/pathogens can be carried in food and transmitted to people.)  
**STRESS** the importance of “Never let your mouth touch anything from work, such as pens, pencils, etc.”  
**TIPS**  
Again, sharing personal stories or experiences will increase participants’ motivation to adopt these personal safety routines. |
<table>
<thead>
<tr>
<th>Slide Number</th>
<th>Teaching Points</th>
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</thead>
<tbody>
<tr>
<td>11</td>
<td><strong>Maintain Clean &amp; Orderly Work Space</strong></td>
</tr>
<tr>
<td></td>
<td>DISCUSS each safe work habit. ENCOURAGE participants to share their thoughts.</td>
</tr>
<tr>
<td></td>
<td>ASK, “Why keep work areas uncluttered?” (Answer: So there is less chance for accidents.)</td>
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<td></td>
<td>ASK, what does disinfect mean? (Answer: To kill any harmful germs/pathogens).</td>
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<td></td>
<td>ASK, “Why disinfect daily?” (Answer: Just because a work area was disinfected yesterday, it does not mean it is still free of germs today.)</td>
</tr>
<tr>
<td></td>
<td>ASK, “Why limit access to the lab?” (Answer: It is important to prevent other people from risk of infection, as well as to protect the client’s confidentiality. Limiting access also prevents distractions).</td>
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<tr>
<td></td>
<td>ASK, “Why keep supplies locked?” (Answer: To prevent unauthorized persons having access to potentially dangerous objects such as lancets)</td>
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<td></td>
<td>EXPLAIN the eye wash unit: its purpose and how to use.</td>
</tr>
<tr>
<td></td>
<td>STATE that the eye wash unit is used to clean one’s eyes when they are accidentally splashed with any type of specimen; for example from patients, controls, reagents, etc.</td>
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<tr>
<td></td>
<td>EXHIBIT an eye wash bottle and pass it around for everyone to see.</td>
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<tr>
<td></td>
<td>SHOW how to use the unit.</td>
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<td></td>
<td><strong>Note:</strong> If an eye wash unit is not available, please consult your local infection control personnel for alternate procedures to follow in the event of an accidental splash.</td>
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<tr>
<td></td>
<td>EXPLAIN the term “bio-hazard.”</td>
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<tr>
<td></td>
<td>• Examples of bio-hazard materials include: client’s blood, used test kits, anything that comes into contact with client’s blood, etc.</td>
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<tr>
<td></td>
<td>• It is a good practice to put a Bio-Hazard sign on any containers holding the waste from your tests.</td>
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<tr>
<td></td>
<td>SHOW a “Bio-hazard” poster or sticker from your country.</td>
</tr>
<tr>
<td></td>
<td>SHARE a personal story or experience to illustrate the importance of these practices.</td>
</tr>
<tr>
<td>Slide Number</td>
<td>Teaching Points</td>
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<td>--------------</td>
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</tbody>
</table>
| **Transition** | SUMMARIZE safe work habits – personal, work space, and material.  
ASK participants if they have any questions before moving on to the next topic. |
| **12** | **Take Precautions to Avoid Needle Stick Injury**  
STATE that needle-stick injury can be dangerous because infected blood containing pathogens can be transferred to the person and cause infection.  
DISCUSS ways to avoid needle stick injury due to:  
• Lack of concentration – One should focus on where the needle is, one’s hand, and client’s hand. Don’t let yourself be distracted.  
• Inexperience – Only people who have received appropriate training should perform the finger-stick procedure.  
• Lack of concern for others  
  o Always get rid of used needles or lancets according to proper procedures. Place used lancets in the sharps disposal container.  
  o Do not leave used needles or lancets lying around.  
  o Clean up after each client.  
STATE that special measures are required for disposing of needles and sharps. Transition to next slide. |
<table>
<thead>
<tr>
<th>Slide Number</th>
<th>Teaching Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>13</td>
<td><strong>Drop Used Sharps in Special Containers</strong></td>
</tr>
<tr>
<td></td>
<td>STATE that there are many makes, shapes and sizes of sharp bins. However, all sharp containers should have:</td>
</tr>
<tr>
<td></td>
<td>• A lid</td>
</tr>
<tr>
<td></td>
<td>• Puncture-proof or thick walls</td>
</tr>
<tr>
<td></td>
<td>• A large enough hole for lancets and needles</td>
</tr>
<tr>
<td></td>
<td>• Leakproof sides and bottom</td>
</tr>
<tr>
<td></td>
<td>• A label or color code indicating bio-hazard material</td>
</tr>
<tr>
<td></td>
<td>• Sufficient quantity available at each testing site</td>
</tr>
<tr>
<td></td>
<td>HIGHLIGHT not all sharps containers need be purchased commercially. An empty bleach container will suffice such as seen on the right. This type container meets all previously mentioned specification. Additionally, the opening is small so that you cannot insert your hand.</td>
</tr>
<tr>
<td>14</td>
<td><strong>Do’s and Don’ts: Sharps and Waste Containers</strong></td>
</tr>
<tr>
<td></td>
<td>EXPLAIN the bullet points on the slide:</td>
</tr>
<tr>
<td></td>
<td>• You could injure yourself if you try to bend needles or lancets.</td>
</tr>
<tr>
<td></td>
<td>• Never shake sharps containers to create space because this leads to formation of aerosols. Aerosols are tiny invisible droplets in the air that can also carry infectious agents/pathogens.</td>
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<tr>
<td></td>
<td>EXPLAIN the two different types of containers on the slide:</td>
</tr>
<tr>
<td></td>
<td>• The left one is a plastic bag for contaminated waste. It should not be used for sharp objects as they can pierce the bag and injure someone.</td>
</tr>
<tr>
<td></td>
<td>• The red plastic container on the right is suitable for sharp objects as the plastic is thick enough so that sharp objects cannot puncture the container. It also has a lid.</td>
</tr>
<tr>
<td>Slide Number</td>
<td>Teaching Points</td>
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</tbody>
</table>
| 15 | **Do’s and Don’ts: Sharps and Waste Containers**  
FACILITATE a discussion of the picture on the left. What’s wrong about it? ENSURE the following points are brought up.  
- Open container containing a mixture of blood, sharps, and other contaminated waste  
- No lid  
- No label to warn people of bio-hazard waste  
- Placed on the floor and prone to spill  
NOTE: Consider replacing the left picture with a real example from your country. |
| 16 | FACILITATE a discussion of the picture on the right. What’s right about it? ENSURE the following points are brought up.  
- Container made of thick plastic. This is appropriate for disposing of sharps.  
- Bottle has a lid and sealed  
Plastic bag will be securely tied once filled. This is appropriate for disposing of contaminated waste such as used gauze. This type of container is NOT appropriate for disposal of sharps. |
| 17 | **Never Place Needles or Sharps in Office Waste Containers**  
DISCUSS why one should never place needles or sharps in office waste containers and what the consequences might be.  
EMPHASIZE that contaminated waste should be kept separate for office waste. It is the tester’s responsibility not to put any other persons at risk of infection.  
POINT OUT the image of the right illustrates improper disposal of objects. Sharps are mixed with non-sharp items and opening exposed posng a potential hazard.  
SHARE a story or personal experience of improper handling of sharps and consequences |
| 18 | **Policy for Handling Sharps**  
STATE the points on the slide. |

SUMMARIZE key points about handling/disposing of sharps with this slide.
<table>
<thead>
<tr>
<th>Slide Number</th>
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</tr>
</thead>
<tbody>
<tr>
<td><strong>Customization</strong></td>
<td><strong>Notes</strong></td>
</tr>
</tbody>
</table>
| 19 | Customize the slide with the following information:  
- National policy on handling bio-hazard waste, if available  
- Local procedures for disposing of contaminated waste |
| 19 | **Incineration of Waste**  
DEFINE Incineration. Incineration is the burning of contaminated waste to destroy and kill micro-organisms  
STATE points on the slide  
Also POINT OUT that contaminated waste should be burned to completion. By completion we mean burned beyond re-use.  
EXPLAIN local procedures for disposing of contaminated waste if incineration is not available at the test site.  
EMPHASIZE care should be taken in transporting waste from one site to another for incineration.  
ASK “Does your procedure include burying waste in a pit?”  
DISCUSS pits vs. incineration. |
| Transition | ASK participants if they have any questions before moving on to the next topic. |
| 20 | **Disinfect Work Areas with Bleach**  
REMIND participants that daily disinfection of work surface is part of the general safe practice that participants need to follow to keep a clean and orderly work area. |
| 21 | **Different Cleaning Jobs Require Different Bleach Solutions**  
EXPLAIN that for spills, you should a 10% bleach solution. The larger the spill, the longer the contact with the 10% bleach solution.  
EXPLAIN that for general disinfection purposes use a 1% solution. For example, wiping down all surfaces at the end of the day. |
<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td><strong>Customization</strong></td>
<td>If local bleach list the concentration sodium hypochlorite in parts per million (ppm), explain how to make a 10% or 1% solution.</td>
</tr>
<tr>
<td><strong>Notes</strong></td>
<td><strong>22</strong></td>
</tr>
<tr>
<td>22</td>
<td><strong>Making a 10% Bleach Solution</strong></td>
</tr>
<tr>
<td></td>
<td>EXPLAIN the key points on the slide.</td>
</tr>
<tr>
<td></td>
<td>DEMONSTRATE how to prepare a 10% bleach. Take a 1 litre empty bottle that has been marked with 100 mls = 1 part. Explain the bleach should reach this level, then fill up to the next mark with water, this 900 mls = 9 parts.</td>
</tr>
<tr>
<td></td>
<td>EMPHASIZE bleach solutions should be made at the beginning of each week.</td>
</tr>
<tr>
<td></td>
<td>Work surfaces should be disinfected, at a minimum, at the end of each day.</td>
</tr>
<tr>
<td>23</td>
<td><strong>In Case of A Spill or Splash</strong></td>
</tr>
<tr>
<td></td>
<td>STATE the points on the slide.</td>
</tr>
<tr>
<td></td>
<td>EMPHASIZE that one should never leave any spills unattended.</td>
</tr>
<tr>
<td>24</td>
<td><strong>In Case of an Accident</strong></td>
</tr>
<tr>
<td></td>
<td>STATE the points on the slide.</td>
</tr>
<tr>
<td></td>
<td>REFER participant to handout “Guidelines for Post Exposure Prophylaxis”</td>
</tr>
<tr>
<td>Transition</td>
<td>SUMMARIZE general safety practice (work habits, handling sharps, and disinfecting work areas).</td>
</tr>
<tr>
<td></td>
<td>ASK if participants have any questions before moving on to the next topic.</td>
</tr>
<tr>
<td></td>
<td>EXPLAIN the points on the slide.</td>
</tr>
<tr>
<td></td>
<td>REMIND participants that everyone has responsibility for implementing safety practices.</td>
</tr>
<tr>
<td>Slide Number</td>
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<td>--------------</td>
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</tbody>
</table>
| 26           | **Consult In-Country Safety Manuals for Policy and Guidelines**  
SHOW and pass around the country’s safety manuals. If one is not available, indicate there are several reference manuals that can serve as a resource. SHOW the CDC, WHO, or ISO copies.  
EXPLAIN what SOP (Standard Operating Procedures) is and why it is important to follow SOP.  
REFER to the procedures related to safety that are found in a test site. Walk participants through so they get an idea what is covered in it.  
- Housekeeping  
- Personal protection  
- Personnel responsibilities  
- Decontamination & Waste Disposal  
- Emergency procedures  
  - In-lab first aid  
  - Accidental injury  
  - Post exposure prophylaxis  
  - Contacts |
| 27           | **Summary**  
ASK participants to answer the questions on the slide.  
ANSWER any questions participants may have. |
| Flipchart    | **Discussion**  
REFER to the previously prepared flipchart  
ASK participants to reflect on these questions:  
- Which of the lab safety practices do you think will NOT be easy for you to do and why not?  
- What are some possible challenges that will prevent you from adhering to the safety guidelines?  
- Can you think of ways to overcome that challenge?  
FACILITATE a group discussion for participants to share their thoughts on these questions. |
### Teaching Points

<table>
<thead>
<tr>
<th>Slide Number</th>
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</thead>
<tbody>
<tr>
<td>TIPS</td>
<td>The purpose for this discussion is to discover any hidden issues related to adopting the right attitudes toward lab safety. The trainer should also help participants work out plans to work around those challenges.</td>
</tr>
</tbody>
</table>
Module 7: Preparation for Testing - Supplies and Kits

Purpose
To allow participants to become familiar and comfortable with the different supplies and materials required for HIV rapid testing.

Pre-requisite Modules
None

Module Time
50 minutes

Learning Objectives
At the end of this module, participants will be able to:
• List and identify all the supplies required for HIV rapid testing
• List and identify all the components of test kits for HIV rapid testing

Module Overview

<table>
<thead>
<tr>
<th>Step</th>
<th>Time</th>
<th>Activity/Method</th>
<th>Content</th>
<th>Resources Needed</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2 min</td>
<td>Presentation</td>
<td>Module introduction</td>
<td>Slides 1-2</td>
</tr>
<tr>
<td>2</td>
<td>15 min</td>
<td>Memory game</td>
<td>Supplies and materials</td>
<td>Slide 3; materials &amp; supplies</td>
</tr>
<tr>
<td>3</td>
<td>10 min</td>
<td>Presentation</td>
<td>Identifying supplies &amp; materials</td>
<td>Slides 4-18; materials &amp; supplies</td>
</tr>
<tr>
<td>4</td>
<td>8 min</td>
<td>Presentation; Hands-on activity</td>
<td>Examining test kits</td>
<td>Slide 19; test kits</td>
</tr>
<tr>
<td>5</td>
<td>10 min</td>
<td>Activity</td>
<td>Organizing work area</td>
<td>Slide 20; materials, supplies, &amp; test kits</td>
</tr>
<tr>
<td>5</td>
<td>5 min</td>
<td>Q&amp;A</td>
<td>Summary</td>
<td>Slide 21</td>
</tr>
</tbody>
</table>

Material/Equipment Checklists
- PowerPoint slides or transparencies
- Overhead projector or computer w/LCD projector
- Rapid testing materials, supplies, and kits laid out on a table – have enough sets for display and passing around
- Handout: Checklist of Supplies and Materials
**Teaching Guide**

<table>
<thead>
<tr>
<th>Slide Number</th>
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</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td><strong>Module 7: Preparation for Testing – Supplies and Kits</strong>&lt;br&gt;DISPLAY this slide before you begin the module. Make sure participants are aware of the transition into a new module.</td>
</tr>
<tr>
<td>2</td>
<td><strong>Learning Objectives</strong>&lt;br&gt;STATE the objectives on the slide.</td>
</tr>
<tr>
<td>3</td>
<td><strong>Game</strong>&lt;br&gt;<strong>15 Minutes</strong>&lt;br&gt;<strong>Memory Game: Supplies and Materials</strong>&lt;br&gt;DISPLAY all the materials and supplies in an exhibit area (e.g., at the back of the classroom).&lt;br&gt;INTRODUCE each item to the participants (about 5 min):&lt;br&gt;  • What it is&lt;br&gt;  • What it is used for&lt;br&gt;CONDUCT the game according to instructions on the slide.&lt;br&gt;DEBRIEF the game.&lt;br&gt;  ASK, “What materials and supplies are required for rapid testing?”&lt;br&gt;  WRITE participants’ responses on a flipchart.</td>
</tr>
<tr>
<td>4-6</td>
<td><strong>Supplies and Materials Checklist</strong>&lt;br&gt;USE the checklist to see if all items are covered by the participants.</td>
</tr>
<tr>
<td>7-18</td>
<td><strong>TIPS</strong>&lt;br&gt;When teaching participants <em>without a laboratory or medical background</em>, allow more time for the game. But keep in mind that keeping the time compressed makes the game more challenging and fun.</td>
</tr>
<tr>
<td></td>
<td><strong>TIPS</strong>&lt;br&gt;DISPLAY each item.&lt;br&gt;  • ASK, “What is this item used for?”&lt;br&gt;  • DISCUSS the answer.&lt;br&gt;ALLOW participants to touch each item so they become familiar with the different supplies&lt;br&gt;EMPHASIZE that these are examples of the types of supplies that may be used in testing sites. That is, brand names may differ from site to site.</td>
</tr>
<tr>
<td></td>
<td><strong>NOTE:</strong> Key points are listed below.</td>
</tr>
<tr>
<td>Slide Number</td>
<td>Teaching Points</td>
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</tr>
<tr>
<td>7</td>
<td><strong>Gloves</strong></td>
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<tr>
<td></td>
<td>• Gloves are used for safety reasons, to protect both you and the patient or client.</td>
</tr>
<tr>
<td></td>
<td>• It is important that the proper size gloves are used. Wearing gloves that are too large may pose a safety hazard, and becomes cumbersome to work with. Also, long nails may puncture the glove making them ineffective.</td>
</tr>
<tr>
<td></td>
<td>• Gloves must be changed between patients, and disposed of in a container labeled as bio-hazardous waste.</td>
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<tr>
<td></td>
<td>• Never use gloves that have been previously used or are torn.</td>
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<td></td>
<td>SPECIAL NOTE:</td>
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<tr>
<td></td>
<td>• Consider latex allergies when selecting the type of glove to use</td>
</tr>
<tr>
<td>8</td>
<td><strong>Alcohol Swabs</strong></td>
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<tr>
<td></td>
<td>• Alcohol is used to cleanse the finger before pricking the client's finger.</td>
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<tr>
<td></td>
<td>• Alternatively, use a bottle of rubbing alcohol and cotton wool</td>
</tr>
<tr>
<td></td>
<td>SHOW rubbing alcohol and cotton wool if they are to be used in place of alcohol swabs.</td>
</tr>
<tr>
<td>9</td>
<td><strong>Cotton Gauze or Cotton Balls</strong></td>
</tr>
<tr>
<td></td>
<td>• Cotton balls are used to wipe away the first drop of blood, and to stop bleeding after specimen is collected.</td>
</tr>
<tr>
<td></td>
<td>• They are single use</td>
</tr>
<tr>
<td></td>
<td>• Contaminated and should be disposed of with other hazardous waste.</td>
</tr>
<tr>
<td>10</td>
<td><strong>Sterile Lancets</strong></td>
</tr>
<tr>
<td></td>
<td>• There are a variety of lancets available for use. Some are easier to use than others.</td>
</tr>
<tr>
<td></td>
<td>• One difference in the types of lancets is the depth of the puncture made by the retractable blade.</td>
</tr>
<tr>
<td></td>
<td>PASS AROUND the lancet that will be used in-country.</td>
</tr>
<tr>
<td>Slide Number</td>
<td>Teaching Points</td>
</tr>
<tr>
<td>--------------</td>
<td>----------------</td>
</tr>
<tr>
<td></td>
<td><strong>Pipette</strong></td>
</tr>
<tr>
<td>11</td>
<td>• Pipettes are used to collect a specified volume of blood specimen from the fingertip.</td>
</tr>
<tr>
<td></td>
<td>• There are 2 types of pipettes commonly used.</td>
</tr>
<tr>
<td></td>
<td>o The transfer pipette is a disposable plastic item that is used only once. Be sure to dispose of this along with other contaminated waste.</td>
</tr>
<tr>
<td></td>
<td>o The automatic pipette is used to collect a specified volume of blood and is most often used in laboratories. A disposable tip is attached to the end of the pipette for collecting the blood. After use, the tip is ejected or removed and is disposed of along with other contaminated waste.</td>
</tr>
<tr>
<td></td>
<td>o The loop is another tool used to collect a specified volume of blood. This is used with some kits.</td>
</tr>
<tr>
<td></td>
<td>PASS AROUND whichever pipette will be used in-country</td>
</tr>
<tr>
<td>12</td>
<td><strong>Timer</strong></td>
</tr>
<tr>
<td></td>
<td>• Shown here are two types of timer that can be used for waiting the specified time to elapse before test results are read.</td>
</tr>
<tr>
<td></td>
<td>• You may also use a watch, or clock.</td>
</tr>
<tr>
<td>13</td>
<td><strong>Standard Operating Procedures and Forms</strong></td>
</tr>
<tr>
<td></td>
<td>• Each site will also need to follow standard operating procedures, and use standard forms for recording test results.</td>
</tr>
<tr>
<td>14</td>
<td><strong>Labeling Pens and Writing Pens</strong></td>
</tr>
<tr>
<td></td>
<td>• A permanent marker as seen on the left is best used for labeling test devices.</td>
</tr>
<tr>
<td></td>
<td>• Ball point pens are used to fill in forms.</td>
</tr>
<tr>
<td></td>
<td>• Never use pencils, especially for recording client results – results can be erased and changed....</td>
</tr>
<tr>
<td>Slide Number</td>
<td>Teaching Points</td>
</tr>
<tr>
<td>--------------</td>
<td>----------------</td>
</tr>
</tbody>
</table>
| 15           | **Sharps Disposal Bins / Disinfectant Jar**  
POINT OUT that there are many different types of disposal bins.  
SHOW an example of a jar with disfectant and lid, which can be used in the absence of a formal disposal bin.  
REMIND participants that all sharps containers must be labeled as bio-hazard waste. Stickers with a symbol indicating biohazard waste may be available in your area.  
EMPHASIZE that regardless of the brand or type of container, it should be one in which your hand cannot reach inside.  
ASK participants to recall what bio-hazard mean. |
| 16           | **Proper Disposal of Contaminated Waste**  
• Image on the left – Non-Sharps contaminated waste can be disposed of in a container that does not have a closable lid.  
• Image on the right – All sharps must be stored in a container with a closable lid. |
| 17           | **Waste Disposal**  
• All containers for contaminated waste will likely not be red as seen in the previous images. Note the image on the left contains contaminated waste that has a closable lid. This floor model offers the option of stepping on the opener so that you hands will not have to touch the container. |
| 18           | **Household Bleach and Container**  
POINT OUT:  
• The cup for measuring 1 part bleach and 9 parts water  
• The pen used for labeling the spray bottle  
• The tape used for attaching to the bottle for labeling with the expiration date. Bleach solutions lose its disinfecting power after 7 days. |
| 19           | **Examine Test Kits**  
DISPLAY the kits that are used in-country, all the components of each test kit laid out on a table.  
SHOW the components of each kit.  
ALLOW participants to touch the kits so they become familiar with them. |
<table>
<thead>
<tr>
<th>Slide Number</th>
<th>Teaching Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>20</td>
<td><strong>Organize Your Work Area</strong></td>
</tr>
<tr>
<td></td>
<td>STATE that having an organized workspace is key to producing quality results. It is important to:</td>
</tr>
<tr>
<td></td>
<td>• Have necessary supplies placed within reach at the testing area before testing.</td>
</tr>
<tr>
<td></td>
<td>• Keep working area neat, clean and organized.</td>
</tr>
<tr>
<td></td>
<td>EMPHASIZE that once the tester sits with the client; it will make the client even more nervous if the tester has to keep getting up to collect more supplies.</td>
</tr>
<tr>
<td>Activity</td>
<td><strong>10 Minutes</strong></td>
</tr>
<tr>
<td></td>
<td>ASK a participant volunteer to:</td>
</tr>
<tr>
<td></td>
<td>• Organize a testing area with the supplies, materials, and test kits as the rest of the group observe.</td>
</tr>
<tr>
<td></td>
<td>Explain why the testing area is organized as such.</td>
</tr>
<tr>
<td></td>
<td>All test materials on protective pad</td>
</tr>
<tr>
<td></td>
<td>Easy access to test materials (left-handed?)</td>
</tr>
<tr>
<td></td>
<td>No reaching across client (touching client with biohazard material) or across biohazard container (avoid toppling over container)</td>
</tr>
<tr>
<td></td>
<td>Box lids open for easy access to materials</td>
</tr>
<tr>
<td></td>
<td>INVITE other participants to make comments or suggestions.</td>
</tr>
<tr>
<td></td>
<td>DEBRIEF by discussing what makes a good testing area.</td>
</tr>
<tr>
<td>21</td>
<td><strong>Summary</strong></td>
</tr>
<tr>
<td></td>
<td>ASK participants to answer the questions on the slide.</td>
</tr>
<tr>
<td></td>
<td>ANSWER any questions participants may have.</td>
</tr>
</tbody>
</table>
## Module 8: Blood Collection – Finger Prick

**Purpose**
To provide the participants with necessary knowledge and skills to perform finger prick.

**Pre-requisite Modules**
- Module 6: Safety at the HIV Rapid Testing Site
- Module 7: Preparation for Testing – Supplies & Kits

**Module Time**
2-2 ½ hours

**Learning Objectives**
At the end of this module, participants will be able to:
- Explain the preparation tasks required for rapid tests
- Put a client at ease while collecting blood
- Collect blood from a finger prick accurately and confidently

### Module Overview

<table>
<thead>
<tr>
<th>Step</th>
<th>Time</th>
<th>Activity/Method</th>
<th>Content</th>
<th>Resources Needed</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>5 min</td>
<td>Presentation</td>
<td>Module introduction</td>
<td>Slides 1-3</td>
</tr>
<tr>
<td>2</td>
<td>20 min</td>
<td>Presentation; Discussion</td>
<td>Overview of initial steps &amp; finger prick procedures</td>
<td>Slides 4-10; video sections Initial Steps and Finger Prick</td>
</tr>
<tr>
<td>3</td>
<td>10 min</td>
<td>Demonstration</td>
<td>Finger prick procedures</td>
<td>Slide 11</td>
</tr>
<tr>
<td>4</td>
<td>15 min</td>
<td>Role play</td>
<td>Rehearsing finger-pricking a client</td>
<td>Slide 12</td>
</tr>
<tr>
<td>5</td>
<td>10 min</td>
<td>Practice</td>
<td>Transfer pipette</td>
<td>Slide 13</td>
</tr>
<tr>
<td>6</td>
<td>60-85 min</td>
<td>Practice</td>
<td>Finger prick</td>
<td>Slide 14</td>
</tr>
<tr>
<td>7</td>
<td>5 min</td>
<td>Q&amp;A</td>
<td>Summary</td>
<td>Slide 15</td>
</tr>
</tbody>
</table>
Material/Equipment Checklists

- PowerPoint slides or transparencies
- Overhead projector or computer w/LCD projector
- Prepared Flipchart – content outline
- Video and equipment to play the video
- One-page job aid for finger prick
- Assemble several packets of the materials and supplies required for finger prick. These packets will be used during for demonstration, role play, and hands-on practices.
- Small containers of water to practice use of transfer pipette
### Teaching Guide

<table>
<thead>
<tr>
<th>Slide Number</th>
<th>Teaching Points</th>
</tr>
</thead>
</table>
| 1            | **Module 8: Blood Collection - Finger Prick**  
DISPLAY this slide before you begin the module. Make sure participants are aware of the transition into a new module. |
| 2            | **Learning Objectives**  
STATE the objectives on the slide. |
| 3            | **Content Overview**  
EXPLAIN the topics that will be covered in this module. |
| **Flipchart** | WRITE the content outline on a flipchart prior to training.  
REFER to it frequently to orient participants to where they are in the module. |
| **TIPS**     | If the participants are lab and health workers, they may already be familiar with finger prick. In that case, acknowledge their skills, but emphasize that it is important for them to learn and follow the accurate procedures for HIV rapid testing. Adapt the module according to their skill level while making sure to teach the right procedure. Ask them to comment on the new things they have learned at the end of the module. |
| **TIPS**     | CUE the videotape to the right place using the counter readings below. |

<table>
<thead>
<tr>
<th>Videotape Section</th>
<th>Counter Reading</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial Steps</td>
<td>05:50</td>
</tr>
<tr>
<td>Finger Prick</td>
<td>11:35</td>
</tr>
</tbody>
</table>

If using the DVD format, select the desired section from the menu.  
DISPLAY relevant slide both **before** and **after** the video. It serves the following purposes.  
- Before the video, it directs participants’ attention to the key messages in the video.  
- After the video, you can use the questions on the slide to review key learning points.
<table>
<thead>
<tr>
<th>Slide Number</th>
<th>Teaching Points</th>
</tr>
</thead>
</table>
| 4            | **Video: Initial Steps (Duration 5:45)**  
FOLLOW the procedure below:  
- INFORM participants that they are going to watch a video about initial steps prior to performing any HIV rapid tests.  
- READ the questions on the slide, which you expect them to answer at the end of the video segment.  
- ENCOURAGE participants to take notes while watching the video.  
- PLAY the video.  
- ANSWER any questions participants have.  
- DEBRIEF by asking participants to answer the questions on the slide. |
| 5            | **Video: Finger Prick (Duration 3:00)**  
FOLLOW the procedure below:  
- INFORM participants that they are going to watch a video about the finger prick procedure.  
- READ the questions on the slide, which you expect them to answer at the end of the video segment.  
- ENCOURAGE participants to take notes while watching the video.  
- PLAY the video.  
- ANSWER any questions participants have.  
- DEBRIEF by asking participants to answer the questions on the slide. |
| 6            | **Pre-collection Safety Precautions**  
REMIND the participants to always follow universal safety precautions to protect the client and the tester, even though this step is not mentioned in the video or the one-page job aid.  
- Wash hands before and after testing each client  
- Put on gloves before collecting blood  
- If blood is spilled, mop it up and disinfect the area immediately. |

**Transition**  
REFER participants to the one-page finger prick job aid in their manual.  
INFORM participants that you are going to review the finger prick procedure step by step before demonstration.
<table>
<thead>
<tr>
<th>Slide Number</th>
<th>Teaching Points</th>
</tr>
</thead>
</table>
| 7            | **Finger Prick – Getting Started**  
ARRANGE all supplies for finger prick on a front table.  
SHOW each item one by one.  
ASK participants to:  
• Identify each item  
• Explain what it is used for |
| 8            | **Finger Prick – Finger Preparation**  
PROVIDE additional tips: before finger prick, the tester should…  
• Explain to the client what you are going to do. Tell them it will hurt slightly, just like a pin-prick.  
• Ask the client to rub his/her hands together to improve blood circulation.  
• Ask client to rest the hand on the table.  
• The pricker should hold the clients finger firmly to prevent client from pulling away during the prick  
EXPLAIN the steps on the slide as you build the slide one step at a time. |
| 9            | **Finger Prick – Collecting Blood**  
EXPLAIN the steps on the slide as you build the slide one step at a time.  
EMPHASIZE the importance of getting the first finger prick right.  
• It is important to perform this procedure correctly to get sufficient blood; otherwise a failed prick will result in additional finger pricks.  
  o Applying pressure to the finger before the prick will result in better blood flow.  
  o The tester must not be afraid of hurting the client.  
• The more you have to repeat the finger prick, the more disturbing it is for the client.  
• PRICK WITH CONFIDENCE!! |
| 10           | **Finger Prick - Proper Disposal**  
REMIND participants of the importance of using proper containers to dispose of used lancets and materials. |
| 11 Demonstration |  
10 Minutes | **Instructor-led Demonstration**  
DEMONSTRATE the finger prick procedure step by step. |
<table>
<thead>
<tr>
<th>Slide Number</th>
<th>Teaching Points</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>TIPS</strong></td>
<td>Depending on the number of participants you have and the number of instructors available, you may want to break the participants into smaller groups for the demonstration. When demonstrating,</td>
</tr>
<tr>
<td><strong>TIPS</strong></td>
<td>• Show each step slowly and methodically.</td>
</tr>
<tr>
<td><strong>TIPS</strong></td>
<td>• Talk out loud as you perform, but keep your statements brief.</td>
</tr>
<tr>
<td><strong>TIPS</strong></td>
<td>• Repeat the procedure a few times, making sure each time you do exactly the same thing so you don’t confuse participants.</td>
</tr>
<tr>
<td><strong>TIPS</strong></td>
<td>• Share tips from your experience.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Role Play</th>
<th>Role Play: Rehearsing Finger-Pricking a Client</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Role Play 15 Minutes</strong></td>
<td>FOLLOW the procedure below when conducting the role play:</td>
</tr>
<tr>
<td><strong>Role Play 15 Minutes</strong></td>
<td>INFORM participants that they are going to have a role play to practice performing a finger prick on a client.</td>
</tr>
<tr>
<td><strong>Role Play 15 Minutes</strong></td>
<td>POINT OUT the instructions on the slide.</td>
</tr>
<tr>
<td><strong>Role Play 15 Minutes</strong></td>
<td>PASS OUT the supplies (except the lancets).</td>
</tr>
<tr>
<td><strong>Role Play 15 Minutes</strong></td>
<td>EMPHASIZE that no actual finger prick is to happen.</td>
</tr>
<tr>
<td><strong>Role Play 15 Minutes</strong></td>
<td>SIGNAL when it is time to switch roles.</td>
</tr>
<tr>
<td><strong>Role Play 15 Minutes</strong></td>
<td>DEBRIEF the role play by asking:</td>
</tr>
<tr>
<td><strong>Role Play 15 Minutes</strong></td>
<td>• What went well? What did not?</td>
</tr>
<tr>
<td><strong>Role Play 15 Minutes</strong></td>
<td>• What was difficult for you? What was easy?</td>
</tr>
<tr>
<td><strong>Role Play 15 Minutes</strong></td>
<td>• What did you learn form this experience?</td>
</tr>
</tbody>
</table>

<p>| <strong>WARNING</strong> | No actual finger pricking is done at this role play. It only involves “acting out” the procedure without using the lancets. If you choose to pass out the lancets, make sure participants understand that they are not to stick their partner’s fingers. |</p>
<table>
<thead>
<tr>
<th>Slide Number</th>
<th>Teaching Points</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>13</strong></td>
<td><strong>Hands-on Practice: Transfer Pipette</strong></td>
</tr>
<tr>
<td><strong>Practice</strong></td>
<td><strong>10 Minutes</strong></td>
</tr>
<tr>
<td><strong>DEMONSTRATE</strong> the right way to use the pipette.</td>
<td></td>
</tr>
<tr>
<td><strong>•</strong> Grasp the transfer pipette by the bulb and depress the bulb completely.</td>
<td></td>
</tr>
<tr>
<td><strong>•</strong> Insert the tip of the pipette into the blood or liquid requiring pipetting with the tip close to the bottom of the vial or close to the finger and release the bulb pressure.</td>
<td></td>
</tr>
<tr>
<td><strong>•</strong> The liquid in the vial will be aspirated into the long part of the pipette.</td>
<td></td>
</tr>
<tr>
<td><strong>•</strong> Gently squeeze the bulb to dispense the required number of drops.</td>
<td></td>
</tr>
<tr>
<td><strong>CONDUCT</strong> the practice session:</td>
<td></td>
</tr>
<tr>
<td><strong>DISTRIBUTE</strong> materials to each participant.</td>
<td></td>
</tr>
<tr>
<td><strong>POINT OUT</strong> the instructions on the slide.</td>
<td></td>
</tr>
<tr>
<td><strong>REMIND</strong> participants of the time limits.</td>
<td></td>
</tr>
<tr>
<td><strong>DEBRIEF</strong> by:</td>
<td></td>
</tr>
<tr>
<td><strong>•</strong> Pointing out the commonly-made mistakes you have observed during the practice session.</td>
<td></td>
</tr>
<tr>
<td><strong>•</strong> Asking participants to share their experience and key learning from the practice.</td>
<td></td>
</tr>
<tr>
<td><strong>14</strong></td>
<td><strong>Hands-On Practice: Finger Prick</strong></td>
</tr>
<tr>
<td><strong>Practice</strong></td>
<td><strong>60 Minutes</strong></td>
</tr>
<tr>
<td><strong>CONDUCT</strong> the practice session.</td>
<td></td>
</tr>
<tr>
<td><strong>INFORM</strong> participants what they are going to do.</td>
<td></td>
</tr>
<tr>
<td><strong>DISTRIBUTE</strong> to all participants the supplies required to perform a finger prick.</td>
<td></td>
</tr>
<tr>
<td><strong>POINT OUT</strong> the instructions on the slide.</td>
<td></td>
</tr>
<tr>
<td><strong>REFER</strong> participants to the one-pager job aid in their manual.</td>
<td></td>
</tr>
<tr>
<td><strong>SIGNAL</strong> when it is time to switch roles (every 15 minutes).</td>
<td></td>
</tr>
<tr>
<td><strong>DEBRIEF</strong> by:</td>
<td></td>
</tr>
<tr>
<td><strong>•</strong> Pointing out the commonly-made mistakes you have observed during the practice session.</td>
<td></td>
</tr>
<tr>
<td><strong>•</strong> Asking participants to share their experience and key learning from the practice.</td>
<td></td>
</tr>
<tr>
<td><strong>•</strong> Reassuring participants that they will improve as they gain more experience.</td>
<td></td>
</tr>
<tr>
<td>Slide Number</td>
<td>Teaching Points</td>
</tr>
<tr>
<td>--------------</td>
<td>-----------------</td>
</tr>
<tr>
<td>TIPS</td>
<td>Be prepared to provide plenty of personal attention and one-on-one assistance to participants during hands-on practice. This is particularly important when teaching people without health or lab background. Set up the groups in such a way that you are able to monitor 3 or 4 groups at a time.</td>
</tr>
<tr>
<td>15</td>
<td><strong>Summary</strong></td>
</tr>
<tr>
<td></td>
<td>ASK participants to answer the questions on the slide. ANSWER any questions participants may have.</td>
</tr>
</tbody>
</table>
Module 9: Performing HIV Rapid Tests (Demo and Practice)

Purpose
To provide the participants with necessary knowledge and skills to accurately perform 3 HIV rapid tests and to determine HIV status.

Pre-requisite Modules
- Module 3: Overview of HIV Testing Technologies
- Module 4: HIV Testing Strategies & Algorithms
- Module 6: Safety at the HIV Rapid Testing Site
- Module 7: Preparation for Testing – Supplies & Kits
- Module 8: Blood Collection – Fingerprick

Module Time
5 ½ hours

Learning Objectives
At the end of this module, participants will be able to:
- Perform 3 HIV rapid tests according to Standard Operating Procedure (SOP)
- Perform multiple tests simultaneously
- Accurately interpret individual test results
- Accurately determine HIV status

Module Overview

<table>
<thead>
<tr>
<th>Step</th>
<th>Time</th>
<th>Activity/Method</th>
<th>Content</th>
<th>Resources Needed</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>5 min</td>
<td>Presentation</td>
<td>Module introduction</td>
<td>Slides 1-3</td>
</tr>
<tr>
<td>2</td>
<td>15 min</td>
<td>Presentation; Discussion</td>
<td>Slide overview of testing procedures</td>
<td>Slides 4-36; dry room; One-pager job aids</td>
</tr>
<tr>
<td>3</td>
<td>10 min</td>
<td>Activity</td>
<td>Workspace setup</td>
<td>Slide 37; practical room; supplies &amp; test kits</td>
</tr>
</tbody>
</table>

Steps 4 & 5 are concurrent sessions. Participants are divided into 2 groups and take turns participating in step 4 and Step 5.

<table>
<thead>
<tr>
<th>Step</th>
<th>Time</th>
<th>Activity/Method</th>
<th>Content</th>
<th>Resources Needed</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>1 hr 15 min</td>
<td>Demo &amp; practice</td>
<td>HIV rapid tests</td>
<td>Slide 38; practical room; supplies &amp; test kits; known samples</td>
</tr>
<tr>
<td>5</td>
<td>1 hr 15 min</td>
<td>Presentation; Discussion</td>
<td>Video review of testing procedures</td>
<td>Slides 39-44; videotape; dry room</td>
</tr>
</tbody>
</table>

End of concurrent sessions

<table>
<thead>
<tr>
<th>Step</th>
<th>Time</th>
<th>Activity/Method</th>
<th>Content</th>
<th>Resources Needed</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td>10 min</td>
<td>Presentation; Discussion</td>
<td>Video overview of multi-test algorithm</td>
<td>Slides 45-47; videotape; dry room</td>
</tr>
<tr>
<td>7</td>
<td>2 hrs 15 min</td>
<td>Practice</td>
<td>Conducting multiple HIV rapid tests</td>
<td>Slides 48-49; supplies &amp; test kits; panels of samples; practical room</td>
</tr>
<tr>
<td>8</td>
<td>5 min</td>
<td>Q&amp;A</td>
<td>Summary</td>
<td>Slide 50</td>
</tr>
</tbody>
</table>
Material/Equipment Checklists

- PowerPoint slides or transparencies
- Overhead projector or computer w/LCD projector
- Prepared Flipchart – content outline
- Video and equipment to play the video
- Materials, supplies, and test kits required for rapid testing. Refer to Section 2: Preparation for quantities needed.
- Panels of blood samples for testing. Refer to Section 2: Preparation for quantities needed and preparation guidance.
- One-pager job aids for HIV rapid tests
- Handouts:
  - Job Aids for the tests in your country’s testing algorithm
  - Video script for HIV rapid tests
  - Practical exercise recording worksheet

Advanced Preparation

- Setup trainer Workspace with necessary supplies and kits.
- To better manage the space and facilitate learning, you will need 2 rooms:
  - Room A – a dry or clean room for presentation
  - Room B – a practical room for demo and practice.
## Module 9: Performing HIV Rapid Tests (Demonstration and Practice)

### 1. Module 9: Performing HIV Rapid Tests (Demonstration and Practice)

DISPLAY this slide before you begin the module. Make sure participants are aware of the transition into a new module.

### 2. Learning Objectives

STATE the objectives on the slide.

STATE that the three HIV rapid test kits that we’re going to demonstrate today are the ones included in the country algorithm: the screening test (*name of test*), confirmation test (*name of test*) and tiebreaker test (*name of test*).

### 3. Content Overview

EXPLAIN the process and logistics of this module.

- Two rooms have been set up: a dry room for presentation and a practical room for demonstration and hands-on practice.
- All participants will watch a presentation together to learn the procedures for three HIV rapid tests. This will take place in the room they are currently in, the dry room (A).
- They will then all move to the practical room (B) to setup their work stations.
- Then the participants will split into two groups.
  - Group I will stay in Room B for demo and hands-on practice. This group will learn the individual tests with known samples.
  - Group II will go back to Room A to watch video and review the testing procedures.
- Then these two groups will switch.
- After a break, briefly convene the participants in the dry room for the Multiple HIV Tests video and slide presentation to prepare for the next practice session.
- Then all participants will go to the practical room (B) to practice multi-test algorithm using blind samples.

ANNOUNCE that there will be a one-hour optional hands-on session for participants who wish for additional help or more practice. It will be offered at (insert time, could be at a lunch break or at the end of a day)
<table>
<thead>
<tr>
<th>Slide Number</th>
<th>Teaching Points</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Flipchart</strong></td>
<td>WRITE the content outline on a flipchart prior to training. REFER to it frequently to orient participants to where they are in the module.</td>
</tr>
<tr>
<td><strong>Slide overview of the test procedures (Room A)</strong></td>
<td>Instructions for five tests are provided here for reference purpose only. Refer to only those slides that are part of the country algorithm and will be taught in the workshop.</td>
</tr>
<tr>
<td><strong>Customization Notes</strong></td>
<td>• Capillus (slides # 4-10)</td>
</tr>
<tr>
<td>4-36</td>
<td>• Determine (slides # 11-16)</td>
</tr>
<tr>
<td></td>
<td>• Hema-Strip (slides # 17-23)</td>
</tr>
<tr>
<td></td>
<td>• OraQuick (slides # 24-30)</td>
</tr>
<tr>
<td></td>
<td>• Uni-Gold (slides # 31-36)</td>
</tr>
<tr>
<td><strong>Customization Notes</strong></td>
<td>If your country uses tests not included in this material, you may still model after the teaching methodology here to teach those tests. Pay attention to:</td>
</tr>
<tr>
<td></td>
<td>• The sequence of instructional events</td>
</tr>
<tr>
<td></td>
<td>• How test demonstration is conducted</td>
</tr>
<tr>
<td></td>
<td>• How hands-on practice is conducted (including specimens provided for the practice)</td>
</tr>
<tr>
<td></td>
<td>• How video is presented</td>
</tr>
<tr>
<td>4</td>
<td><strong>Capillus</strong></td>
</tr>
<tr>
<td></td>
<td>INFORM the participants that the next few slides address the test procedure for Capillus.</td>
</tr>
<tr>
<td>5</td>
<td><strong>Capillus: Getting Ready</strong></td>
</tr>
<tr>
<td></td>
<td>EXPLAIN the steps on the slide as you build the slide one step at a time.</td>
</tr>
<tr>
<td></td>
<td>• Use a permanent marker to label test with client’s ID</td>
</tr>
<tr>
<td>6</td>
<td><strong>Capillus: Reagent Preparation</strong></td>
</tr>
<tr>
<td></td>
<td>EXPLAIN the steps on the slide as you build the slide one step at a time.</td>
</tr>
<tr>
<td></td>
<td>Add the following information for Step 4:</td>
</tr>
<tr>
<td></td>
<td>• It is important to gently mix reagent.</td>
</tr>
<tr>
<td></td>
<td>• Vigorously shaking will result in air bubbles, which make it difficult to dispense the correct amount in the next step.</td>
</tr>
<tr>
<td>Slide Number</td>
<td>Teaching Points</td>
</tr>
<tr>
<td>--------------</td>
<td>----------------</td>
</tr>
</tbody>
</table>
| 7            | **Capillus: Collecting Specimen**  
EXPLAIN the steps on the slide as you build the slide one step at a time.  
ADD the following points:  
• The pre-calibrated pipette is included with the kit.  
• The pipette is set to collect 10µl. |
| 8            | **Capillus: Applying Specimen to Test Slide**  
EXPLAIN the steps on the slide as you build the slide one step at a time. |
| 9            | **Capillus: Getting Results**  
EXPLAIN the steps on the slide as you build the slide one step at a time.  
ADD the following information for Step 11:  
• If a timer is not available, use your watch or clock on the wall to monitor the time.  
• It is a good practice to write down the starting time or projected end time to help you keep track of time.  
ADD the following information for Step 12:  
• In addition to test results, the tester should also record on appropriate forms the following information:  
  o The test date  
  o Client identification  
  o Name of the person performing the test  
  o The name of the test  
  o The expiration date  
  o Test lot number  
  o Control lot number |
| 10           | **Capillus: Test Interpretation**  
REMIND the participants how to read the Capillus results.  
• There are two possible test results, reactive or non-reactive.  
• Capillus does not have an internal control line. |
| 11           | **Determine**  
INFORM the participants that the next few slides address the test procedure for Determine. |
<table>
<thead>
<tr>
<th>Slide Number</th>
<th>Teaching Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>12</td>
<td><strong>Determine: Reagent Preparation</strong></td>
</tr>
<tr>
<td></td>
<td>EXPLAIN the steps on the slide as you build the slide one step at a time.</td>
</tr>
<tr>
<td></td>
<td>• Remember to have on hand the chase buffer because it is not included in the kit.</td>
</tr>
<tr>
<td></td>
<td>• When tearing off one test strip it is easier if you bend the unopened strip back and forth, then tear the strip away from the others.</td>
</tr>
<tr>
<td></td>
<td>• Once the test strip is opened, do not touch the testing area.</td>
</tr>
<tr>
<td>13</td>
<td><strong>Determine: Collecting Specimen</strong></td>
</tr>
<tr>
<td></td>
<td>EXPLAIN the steps on the slide as you build the slide one step at a time.</td>
</tr>
<tr>
<td>14</td>
<td><strong>Determine: Applying Specimen and Buffer to Test Strip</strong></td>
</tr>
<tr>
<td></td>
<td>EXPLAIN the steps on the slide as you build the slide one step at a time.</td>
</tr>
<tr>
<td></td>
<td>ADD the following information for Step 7:</td>
</tr>
<tr>
<td></td>
<td>• Check to see that the sample is moving along the test strip – this will take a moment.</td>
</tr>
<tr>
<td></td>
<td>• If not, add one more drop of buffer to the strip.</td>
</tr>
<tr>
<td></td>
<td>• But, do not waste buffer.</td>
</tr>
<tr>
<td>15</td>
<td><strong>Determine: Getting Results</strong></td>
</tr>
<tr>
<td></td>
<td>EXPLAIN the steps on the slide as you build the slide one step at a time.</td>
</tr>
<tr>
<td></td>
<td>ADD the following information for Step 8:</td>
</tr>
<tr>
<td></td>
<td>• If a timer is not available, use your watch or clock on the wall to monitor the time.</td>
</tr>
<tr>
<td></td>
<td>• It is a good practice to write down the starting time or projected end time to help you keep track of time.</td>
</tr>
<tr>
<td></td>
<td>ADD the following information for Step 9:</td>
</tr>
<tr>
<td></td>
<td>• In addition to test results, the tester should also record on appropriate forms the following information:</td>
</tr>
<tr>
<td></td>
<td>o The test date</td>
</tr>
<tr>
<td></td>
<td>o Client identification</td>
</tr>
<tr>
<td></td>
<td>o Name of the person performing the test</td>
</tr>
<tr>
<td></td>
<td>o The name of test</td>
</tr>
<tr>
<td></td>
<td>o The expiration date</td>
</tr>
<tr>
<td></td>
<td>o Test lot number</td>
</tr>
<tr>
<td></td>
<td>o Control lot number</td>
</tr>
<tr>
<td>Slide Number</td>
<td>Teaching Points</td>
</tr>
<tr>
<td>--------------</td>
<td>-----------------</td>
</tr>
</tbody>
</table>
| 16 | **Determine: Test Interpretation**  
REMIND the participants how to read the Determine results.  
- There are three possible test results: reactive, non-reactive, and invalid.  
- Any visible line in the patient/client window should be read as reactive, when the control line is also visible.  
- Note: A shadow may be seen, but this is not to be understood as reactive specimen. You must see a visible colored line for the specimen to be interpreted as reactive. |
| 17 | **Hema-Strip**  
INFORM the participants that the next few slides address the test procedure for Hema-Strip. |
| 18 | **Hema-Strip: Getting Ready**  
EXPLAIN the steps on the slide as you build the slide one step at a time. |
| 19 | **Hema-Strip: Collecting Specimen**  
EXPLAIN the steps on the slide as you build the slide one step at a time.  
ENSURE participants understand that either blood from a finger prick or serum from a vial is used, but not both. |
| 20 | **Hema-Strip: Buffer Preparation**  
EXPLAIN the steps on the slide as you build the slide one step at a time.  
ADD the following information to Step 5:  
- The buffer vial should be placed in such a way that the foil side is facing up. |
| 21 | **Hema-Strip: Applying Specimen and Buffer to Test Strip**  
EXPLAIN the steps on the slide as you build the slide one step at a time. |
<table>
<thead>
<tr>
<th>Slide Number</th>
<th>Teaching Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>22</td>
<td><strong>Hema-Strip: Getting Results</strong>&lt;br&gt;EXPLAIN the steps on the slide as you build the slide one step at a time.&lt;br&gt;ADD the following information for Step 8:&lt;br&gt;• If a timer is not available, use your watch or clock on the wall to monitor the time.&lt;br&gt;• It is a good practice to write down the starting time or projected end time to help you keep track of time.&lt;br&gt;ADD the following information for Step 9:&lt;br&gt;• In addition to test results, the tester should also record on appropriate forms the following information:&lt;br&gt;  o The test date&lt;br&gt;  o Client identification&lt;br&gt;  o Name of the person performing the test&lt;br&gt;  o The name of test&lt;br&gt;  o The expiration date&lt;br&gt;  o Test lot number&lt;br&gt;  o Control lot number</td>
</tr>
<tr>
<td>23</td>
<td><strong>Hema-Strip: Test Interpretation</strong>&lt;br&gt;REMIND the participants how to read the Hema-Strip results.&lt;br&gt;• There are three possible test results: reactive, non-reactive, and invalid.&lt;br&gt;• Any visible line in the patient/client window should be read as reactive, when the control line is also visible.</td>
</tr>
<tr>
<td>24</td>
<td><strong>OraQuick</strong>&lt;br&gt;INFORM the participants that the next few slides address the test procedure for OraQuick.</td>
</tr>
<tr>
<td>25</td>
<td><strong>OraQuick: Getting Ready</strong>&lt;br&gt;EXPLAIN the steps on the slide as you build the slide one step at a time.&lt;br&gt;REMIND participants to have on hand the blue stand that is included in the kit.&lt;br&gt;• To prevent contamination, leave the testing device in its pouch, until needed&lt;br&gt;• Do not touch the flat pad&lt;br&gt;• Carefully place the vial in the stand. Do not snap the vial in the stand as splashing may occur.</td>
</tr>
<tr>
<td>Slide Number</td>
<td>Teaching Points</td>
</tr>
<tr>
<td>--------------</td>
<td>-----------------</td>
</tr>
<tr>
<td>26</td>
<td><strong>OraQuick: Collecting Specimen (Blood or Oral Fluids)</strong>&lt;br&gt;EXPLAIN the steps on the slide as you build the slide one step at a time.&lt;br&gt;REMIND participants to discard the loop in a bio-hazard container.</td>
</tr>
<tr>
<td>27</td>
<td><strong>OraQuick: Transferring Specimen (Blood Only)</strong>&lt;br&gt;EXPLAIN the steps on the slide as you build the slide one step at a time.&lt;br&gt;EMPHASIZE this step is for blood specimens only. Oral fluids do not need this step.</td>
</tr>
<tr>
<td>28</td>
<td><strong>OraQuick: Inserting Test Device Into Buffer Vial</strong>&lt;br&gt;EXPLAIN the steps on the slide as you build the slide one step at a time.&lt;br&gt;• Do not remove the device from the vial until you are done reading the results</td>
</tr>
<tr>
<td>29</td>
<td><strong>OraQuick: Getting Results</strong>&lt;br&gt;EXPLAIN the steps on the slide as you build the slide one step at a time.&lt;br&gt;ADD the following information for Step 8:&lt;br&gt;• If a timer is not available, use your watch or clock on the wall to monitor the time.&lt;br&gt;• It is a good practice to write down the starting time or projected end time to help you keep track of time.&lt;br&gt;ADD the following information for Step 9:&lt;br&gt;• In addition to test results, the tester should also record on appropriate forms the following information:&lt;br&gt;  o The test date&lt;br&gt;  o Client identification&lt;br&gt;  o Name of the person performing the test&lt;br&gt;  o The name of test&lt;br&gt;  o The expiration date&lt;br&gt;  o Test lot number&lt;br&gt;  o Control lot number</td>
</tr>
<tr>
<td>Slide Number</td>
<td>Teaching Points</td>
</tr>
<tr>
<td>--------------</td>
<td>-----------------</td>
</tr>
</tbody>
</table>
| 30           | **OraQuick: Test Interpretation**  
REMIND the participants how to read the OraQuick results.  
  - There are three possible test results: reactive, non-reactive, and invalid.  
  - Any visible line within the triangle of the Test(client) area should be read as reactive, when the control line is also visible within the C triangle. |
| 31           | **Uni-Gold**  
INFORM the participants that the next few slides address the test procedure for Uni-Gold. |
| 32           | **Uni-Gold: Getting Ready**  
EXPLAIN the steps on the slide as you build the slide one step at a time.  
ADD the following information to Step 1:  
  - The plastic pipette is included in the kit. |
| 33           | **Uni-Gold: Collecting Specimen**  
EXPLAIN the steps on the slide as you build the slide one step at a time.  
ENSURE participants understand that either blood from a finger prick or serum from a vial is used, but not both. |
| 34           | **Uni-Gold: Adding Specimen and Reagent to Test Device**  
EXPLAIN the steps on the slide as you build the slide one step at a time.  
  - Check to ensure the sample immediately moves along the test device.  
  - If not, add one more drop of buffer. |
<table>
<thead>
<tr>
<th>Slide Number</th>
<th>Teaching Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>35</td>
<td>Uni-Gold: Getting Results</td>
</tr>
<tr>
<td></td>
<td>EXPLAIN the steps on the slide as you build the slide one step at a time.</td>
</tr>
<tr>
<td></td>
<td>ADD the following information for Step 6:</td>
</tr>
<tr>
<td></td>
<td>• If a timer is not available, use your watch or clock on the wall to monitor the time.</td>
</tr>
<tr>
<td></td>
<td>• It is a good practice to write down the starting time or projected end time to help you keep track of time.</td>
</tr>
<tr>
<td></td>
<td>ADD the following information for Step 7:</td>
</tr>
<tr>
<td></td>
<td>• In addition to test results, the tester should also record on appropriate forms the following information:</td>
</tr>
<tr>
<td></td>
<td>o The test date</td>
</tr>
<tr>
<td></td>
<td>o Client identification</td>
</tr>
<tr>
<td></td>
<td>o Name of the person performing the test</td>
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<tr>
<td></td>
<td>o The name of test</td>
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<tr>
<td></td>
<td>o The expiration date</td>
</tr>
<tr>
<td></td>
<td>o Test lot number</td>
</tr>
<tr>
<td></td>
<td>o Control lot number</td>
</tr>
<tr>
<td>36</td>
<td>Uni-Gold: Test Interpretation</td>
</tr>
<tr>
<td></td>
<td>REMIND the participants how to read the Uni-Gold results.</td>
</tr>
<tr>
<td></td>
<td>• There are three possible test results: reactive, non-reactive, and invalid.</td>
</tr>
<tr>
<td></td>
<td>• Any visible line in the patient/client window should be read as reactive, when the control line is also visible.</td>
</tr>
<tr>
<td>Logistics Notes</td>
<td>Show the following 2 slides before moving participants out of the dry room.</td>
</tr>
<tr>
<td>37</td>
<td>Activity: Workspace Setup</td>
</tr>
<tr>
<td></td>
<td>INFORM all participants that they are going to setup their own Workspaces in the practical room where the lab session will be conducted.</td>
</tr>
<tr>
<td></td>
<td>READ the instructions on the slide.</td>
</tr>
<tr>
<td>38</td>
<td>Hands-On Practice: Individual Tests</td>
</tr>
<tr>
<td></td>
<td>EXPLAIN the instructions for hands-on practice session.</td>
</tr>
<tr>
<td></td>
<td>EMPHASIZE that participants should not discard their test devices until the instructor has checked them.</td>
</tr>
<tr>
<td>Slide Number</td>
<td>Teaching Points</td>
</tr>
<tr>
<td>--------------</td>
<td>-----------------</td>
</tr>
<tr>
<td><strong>Workspace setup (Room B)</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Activity</strong></td>
<td>ASK participants to move to Room B (the practical room). After Workspaces have been set up:</td>
</tr>
</tbody>
</table>
| 10 minutes   | • DIVIDE the participants into two groups: Group I and Group II.  
• ASK Group I to stay in the practical room for demo and practice while Group II goes back to the dry room for video presentation. |
| **Logistics Notes** | Group I (demo and practice) and Group II (video) activities happen concurrently. After 1 hour 15 minutes, switch the groups so that Group I will move to the dry room to watch the video while Group II will move to the practical room for demo and practice. |
| **Concurrent Session: Demo and Practice (Room B)** | |
| **TIPS** | To facilitate retention, follow the sequence below for the demo and practice session: |
| | • Instructor demonstration (Test 1)  
• Participant practice (Test 1)  
• Instructor demonstration (Test 2)  
• Participant practice (Test 2)  
• Instructor demonstration (Test 3)  
• Participant practice (Test 3) |
| | To save time, after instructor’s demonstration of one test, participants can start their hands-on practice during the incubation time of the instructor’s test. Therefore, each set of demo and practice should take 20-25 minutes. The total time for the demo-and-practice session will be no more than 75 minutes. |
| **Demonstration** | DEMONSTRATE the procedure for ________ (test 1) using specimens labelled as positive and negative.  
ASK participants to gather around you while you demonstrate. |
<p>| 15 minutes/test | |</p>
<table>
<thead>
<tr>
<th>Slide Number</th>
<th>Teaching Points</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>TIPS</strong></td>
<td>When demonstrating,</td>
</tr>
<tr>
<td></td>
<td>• Commit to memory each step in the testing procedure and relevant notes</td>
</tr>
<tr>
<td></td>
<td>• Have one-pager handy for easy reference</td>
</tr>
<tr>
<td></td>
<td>• Show each step slowly and methodically</td>
</tr>
<tr>
<td></td>
<td>• Talk out loud as you perform, but keep your explanation brief and clear</td>
</tr>
<tr>
<td></td>
<td>• If you repeat the procedure, make sure each time you do exactly the same thing so you don’t confuse the participants</td>
</tr>
<tr>
<td></td>
<td>• Point out commonly made mistakes during incubation time</td>
</tr>
<tr>
<td></td>
<td>• Allow time for Q &amp;A</td>
</tr>
<tr>
<td>Practice</td>
<td>ASK participants to pull out of their manual the one-page job aids for easy reference during the practice session. (Note: There will not be enough room on tabletop for supplies and binder.)</td>
</tr>
<tr>
<td>15 minutes/test</td>
<td>REMIND participants of the instructions for the hands-on practice.</td>
</tr>
<tr>
<td><strong>TIPS</strong></td>
<td>INFORM participants that:</td>
</tr>
<tr>
<td></td>
<td>• If timers are not available, the clock on the wall is for their use during testing practice.</td>
</tr>
<tr>
<td></td>
<td>• They should feel free to raise their hands if they need anything or have a question.</td>
</tr>
<tr>
<td></td>
<td>• They should record results using worksheet provided.</td>
</tr>
<tr>
<td></td>
<td>MONITOR participant performance during the practice.</td>
</tr>
<tr>
<td></td>
<td>• Provide as much personal attention and assistance as possible.</td>
</tr>
<tr>
<td></td>
<td>• Make sure participants are following the right procedures.</td>
</tr>
<tr>
<td>Logistics Notes</td>
<td>After one round of demonstration and practice (for one test), repeat the same process for test 2 and test 3.</td>
</tr>
</tbody>
</table>
This video includes segments for 6 tests. Show the video segments and slides for relevant tests only. Use the video counter below to help you cue up the right segment.

<table>
<thead>
<tr>
<th>Videotape Section</th>
<th>Counter Reading</th>
</tr>
</thead>
<tbody>
<tr>
<td>Capillus</td>
<td>14:35</td>
</tr>
<tr>
<td>Determine</td>
<td>20:25</td>
</tr>
<tr>
<td>Hema-Strip</td>
<td>25:33</td>
</tr>
<tr>
<td>OraQuick</td>
<td>30:35</td>
</tr>
<tr>
<td>Uni-Gold</td>
<td>36:55</td>
</tr>
<tr>
<td>Virocheck</td>
<td>41:07</td>
</tr>
</tbody>
</table>

Show the video one segment at a time. Never show the video segments all at once without discussing in between.

Use the relevant slide both before and after each segment. The slide serves the following purposes:

- Before the video, it directs participants’ attention to the key messages in the video.
- After the video, you can use the questions on the slide to review key learning points.

**Video: Capillus**

FOLLOW the procedure for showing the video segment.

INFORM participants that they are going to watch a video about (Test Name).

POINT OUT the questions on the slide, which you expect them to answer at the end of the video segment.

ENCOURAGE participants to take notes while watching the video.

PLAY the video.

ANSWER any questions participants have.

DEBRIEF by asking participants to answer the questions on the slide.
<table>
<thead>
<tr>
<th>Slide Number</th>
<th>Teaching Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>41</td>
<td><strong>Video: Determine</strong>&lt;br&gt;FOLLOW the standard procedure (see above) for showing the video segment.</td>
</tr>
<tr>
<td>42</td>
<td><strong>Video: Hema-Strip</strong>&lt;br&gt;FOLLOW the standard procedure (see above) for showing the video segment.</td>
</tr>
<tr>
<td>43</td>
<td><strong>Video: OraQuick</strong>&lt;br&gt;FOLLOW the standard procedure (see above) for showing the video segment.</td>
</tr>
<tr>
<td>44</td>
<td><strong>Video: Uni-Gold</strong>&lt;br&gt;FOLLOW the standard procedure (see above) for showing the video segment.</td>
</tr>
</tbody>
</table>

**End of Concurrent Session**
<table>
<thead>
<tr>
<th>Slide Number</th>
<th>Teaching Points</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Multiple HIV tests video and slide presentation (Room A)</strong></td>
<td>Depending on the in-country testing algorithm and tests used, the video segment “Multiple HIV Tests” may not apply. However, it provides a good model for you to modify the content with in-country examples. If you choose not to show this video segment, make sure you cover your discussion with all the key points from the video.</td>
</tr>
<tr>
<td><strong>Video: Multiple HIV Tests</strong></td>
<td>FOLLOW the standard procedure for showing video. DISPLAY the slide before and after the video.</td>
</tr>
<tr>
<td><strong>Videotape Section</strong></td>
<td><strong>Counter Reading</strong></td>
</tr>
<tr>
<td>Multiple HIV Tests</td>
<td>45:30</td>
</tr>
<tr>
<td><strong>REFRESH participants’ memory of the in-country testing algorithm.</strong></td>
<td><strong>FACILITATE a discussion of the procedures for performing the specific in-country multi-test algorithm.</strong> Discussion questions may include:</td>
</tr>
<tr>
<td></td>
<td>• What preparation work is required?</td>
</tr>
<tr>
<td></td>
<td>• How should you set up the testing area?</td>
</tr>
<tr>
<td></td>
<td>• Which test should you do first? Why?</td>
</tr>
<tr>
<td></td>
<td>• How should you set the timer for individual tests? For multiple tests?</td>
</tr>
<tr>
<td><strong>Customize slides #46-48 by:</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Displaying your country’s approved algorithm in slide #46.</td>
</tr>
<tr>
<td></td>
<td>• Deleting slide #48 if your country uses a parallel algorithm.</td>
</tr>
<tr>
<td></td>
<td>• Deleting slide #47 if your country uses a serial algorithm.</td>
</tr>
<tr>
<td><strong>Country Algorithm</strong></td>
<td>REVIEW the country’s algorithm.</td>
</tr>
<tr>
<td><strong>Possible Outcomes in a Parallel Algorithm</strong></td>
<td>REFER participants to the Possible Outcomes handout in their manual. ASK them to take it out of the manual for easy reference during the next practice. REVIEW the slide with the participants.</td>
</tr>
<tr>
<td>Slide Number</td>
<td>Teaching Points</td>
</tr>
<tr>
<td>--------------</td>
<td>-----------------</td>
</tr>
<tr>
<td>48</td>
<td><strong>Hands-On Practice: Multi-Test Algorithm</strong>&lt;br&gt;INFORM participants of the next activity.&lt;br&gt;EXPLAIN the hands-on practice:&lt;br&gt;• Participants will conduct tests simultaneously following the testing algorithm.&lt;br&gt;• Participants will do this 5 times, each time using the designated blind specimen.&lt;br&gt;• Participants will record individual test results and determine the HIV status of each specimen.</td>
</tr>
<tr>
<td>49</td>
<td><strong>Hands-On Practice: Multi-Test Algorithm (Cont’d)</strong>&lt;br&gt;READ the instructions on the slide.&lt;br&gt;INFORM participants that they will now move to the practical room for the demo and practice of multi-test algorithm.</td>
</tr>
<tr>
<td>Logistics Notes</td>
<td>After showing the <em>Multiple HIV Tests</em> video and slides 45-48, move the participants to the practical room for the demo and hands-on practice session.</td>
</tr>
<tr>
<td>Multiple HIV test hands-on practice session (Room B)</td>
<td>Practice 2 hours&lt;br&gt;INFORM participants that:&lt;br&gt;• If timers are not available, the clock on the wall is for their use during testing practice.&lt;br&gt;• They should feel free to raise their hands if they need anything or have a question.&lt;br&gt;MONITOR participant performance during the practice.&lt;br&gt;• Provide as much personal attention and assistance as possible.&lt;br&gt;• Make sure participants are following the right procedures.</td>
</tr>
<tr>
<td>15 minutes</td>
<td>DEBRIEF the practice by:&lt;br&gt;• Discussing the results&lt;br&gt;• Pointing out the commonly-made mistakes you have observed during the practice session&lt;br&gt;• Asking participants to share their experience and key learning from the practice&lt;br&gt;• Answering any questions participants might have</td>
</tr>
<tr>
<td>Slide Number</td>
<td>Teaching Points</td>
</tr>
<tr>
<td>--------------</td>
<td>----------------</td>
</tr>
<tr>
<td>50</td>
<td><strong>Summary</strong></td>
</tr>
<tr>
<td></td>
<td>ASK participants to answer the questions on the slide.</td>
</tr>
<tr>
<td></td>
<td>ANSWER any questions participants may have.</td>
</tr>
<tr>
<td></td>
<td>IDENTIFY participants who will be in the optional hands-on session.</td>
</tr>
</tbody>
</table>
Module 10: Inventory – Managing Stocks at the HIV Rapid Testing Site

Purpose  To equip the participants with necessary knowledge so they can properly manage the stocks at the rapid testing sites.

Pre-requisite Modules  • Module 5: Assuring the Quality of HIV Rapid Testing

Module Time  1 hour

Learning Objectives  At the end of this module, participants will be able to:

• Maintain proper records
• Maintain proper level of consumables
• Use first-expiry-first-out concept when managing stocks
• Inspect delivery of supplies before acceptance
• Identify lot numbers and expiry dates
• Keep kits and supplies in proper storage

Module Overview

<table>
<thead>
<tr>
<th>Step</th>
<th>Time</th>
<th>Activity/Method</th>
<th>Content</th>
<th>Resources Needed</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>5 min</td>
<td>Presentation</td>
<td>Module introduction</td>
<td>Slides 1-4&lt;br&gt;Prepared flipchart – content outline</td>
</tr>
<tr>
<td>2</td>
<td>10 min</td>
<td>Presentation Discussion</td>
<td>Overview of stock management</td>
<td>Slides 5-10&lt;br&gt;Flipchart</td>
</tr>
<tr>
<td>3</td>
<td>10 min</td>
<td>Presentation</td>
<td>Inventory records</td>
<td>Slides 11-15&lt;br&gt;Sample stock card &amp; stock book (in participant manual)</td>
</tr>
<tr>
<td>4</td>
<td>20 min</td>
<td>Presentation Exercises</td>
<td>Re-ordering</td>
<td>Slides 16-22</td>
</tr>
<tr>
<td>5</td>
<td>8 min</td>
<td>Presentation Activity</td>
<td>Receiving and storage</td>
<td>Slides 23-25&lt;br&gt;Sets of test kits</td>
</tr>
<tr>
<td>6</td>
<td>7 min</td>
<td>Q&amp;A</td>
<td>Summary &amp; key messages</td>
<td>Slides 26-27</td>
</tr>
</tbody>
</table>
Material/Equipment Checklists:

- PowerPoint slides or transparencies
- Overhead projector or computer w/LCD projector
- Flipchart for content outline
- Multiple sets of the three in-country test kits (used in exercise for participants to examine lot numbers and expiry dates)
- Handouts:
  - Sample stock card
  - Sample stock book
<table>
<thead>
<tr>
<th>Slide Number</th>
<th>Teaching Points</th>
</tr>
</thead>
</table>
| 1            | **Module 10: Inventory Management**  
DISPLAY this slide before you begin the module. Make sure participants are aware of the transition into a new module. |
| 2            | **The Lab Quality System**  
REMIND participants that inventory is a component of the Lab Quality System. |
| 3            | **Learning Objectives**  
STATE the objectives on the slide. |
| 4            | **Content Overview**  
EXPLAIN the topics that will be covered in this module. |
| **Flipchart** | WRITE the content outline on a flipchart prior to training.  
REFER to it frequently to orient participants to where they are in the module. |
| 5            | **Stock Management Means...**  
STATE the definition on the slide. |
| **Customization Notes** | Insert photo of local stockroom |
| 6            | **Stock at a Rapid Test Site Includes...**  
EXPLAIN the two types of inventory kept at a HIV rapid test site.  
ASK participants to name all kits and supplies. |
<table>
<thead>
<tr>
<th>Slide Number</th>
<th>Teaching Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>7</td>
<td><strong>Stock Management Leads to High Quality Testing</strong></td>
</tr>
<tr>
<td></td>
<td>EXPLAIN the importance of stock management at a rapid testing site.</td>
</tr>
<tr>
<td></td>
<td>• The provision of a smooth and continuous rapid HIV testing service to clients at PMTCT and VCT sites largely depends on the availability of the kits and other consumables at all times.</td>
</tr>
<tr>
<td></td>
<td>• Sufficient kits and supplies must be ordered and present at the site well in advance before a new site starts testing.</td>
</tr>
<tr>
<td></td>
<td>• It is important not to over-stock or under-stock supplies at a rapid testing site.</td>
</tr>
<tr>
<td></td>
<td>EMPHASIZE the potential loss of service to client if no kits are available at site</td>
</tr>
</tbody>
</table>

|              | EXPLAIN the negative effects associated with under-stocking. |
|              | • When testing clients, all supplies need to be on hand immediately. Poor planning in the ordering system will result in insufficient supplies mid-flow of testing clients. This in turn will result in a stopping of testing. |
|              | • The entire testing system at the site could be seriously compromised until further supplies are present at the site. Sites that are severely lacking in supplies could result in closure of that site until supplies arrive. |

|              | EXPLAIN the negative effects associated with over-stocking. |
|              | • Properly managing your stocks will allow for only having an adequate number of supplies on hand. |
|              | • Overstocking can lead to waste and potential for kits expiring before use, leading to compromised test results. |
|              | • A reminder: NEVER USE EXPIRED KITS! |

<p>|              | SHARE personal examples or stories: |
|              | • Consequences of running out of supplies (e.g. if there are no lancets at the site, then the patients finger cannot be pricked, and so no testing can take place.) |
|              | • Consequences of over-stocking supplies (waste, expired kits used by mistake, etc.) |</p>
<table>
<thead>
<tr>
<th>Slide Number</th>
<th>Teaching Points</th>
</tr>
</thead>
</table>
| 8            | **How Do You Manage Stock?**  
PRESENT the scenario to participants.  
FACILITATE a discussion by asking, “As a store owner, what must you do to maintain adequate stocks?”  
NOTE participants’ responses on a flipchart.  
HIGHLIGHT the point that shop owners must always know the following:  
• What and how much stock they have  
• When they need to replenish their stocks  
• The amount of merchandise to order  
• When, what, and how much stock has been ordered  
• Where everything is stored  
• When and how much fresh stock has been received, and by whom |
| 9            | **Stock Management Involves Knowing...**  
DEFINE stock management in the context of HIV rapid testing, drawing analogy from the sundry shop scenario.  
EXPLAIN that proper stock management means that a site supervisor will always know:  
• What stocks and how much is present at the site at any given time  
• When to order fresh supplies – and know approximately how long it takes to deliver  
• How much has been ordered and when was it ordered.  
• When fresh supplies were received at the site – who received the supplies, what date and how much.  
• Where all individual supplies are stored  
STATE To know everything mentioned above, one must have a stock management plan. |
<table>
<thead>
<tr>
<th>Slide Number</th>
<th>Teaching Points</th>
</tr>
</thead>
</table>
| 10           | **Stock Management Involves...**  
  * Performing regular stock counts  
  * Maintaining proper inventory records  
  * Determining when to re-order  
  * Re-ordering proper amount of supplies  
  * Placing orders promptly  
  * Inspecting and logging in new stock when received  
  * Ensuring proper storage of inventory  
  INFORM participants that each of the above will be explained in the rest of the module. |
| 11           | **Perform a “Stock Count”**  
  STATE in order to know exactly what and how much stock you have, the best way is to perform a stock count.  
  EXPLAIN the key points on the slide.  
  FACILITATE a discussion by asking the following questions:  
  * Why it is important to account for each and every item in the inventory?  
  * What do you need to do in order to account for every item in the inventory?  
  DISCUSS the risk of theft – its impact on the site and individual. |
<table>
<thead>
<tr>
<th>Slide Number</th>
<th>Teaching Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>12</td>
<td><strong>Maintain Proper Inventory Records</strong></td>
</tr>
</tbody>
</table>

EXPLAIN that an efficient stock management depends upon accurate record keeping. Keeping records will:

- Save you time – you should know the quantity in stock without counting. Allows easy handover of the “store” to your colleague if you are not at work. Allows you to observe the pattern of consumption.
- Protects you – You are protected against accusations of theft. You can also keep track of deliveries when they arrive, in case of disputes.
- Prevents over-stocking and under-stocking.
- Allows for estimation of supplies for a year for budgeting purposes.

EXPLAIN all of the above points are accomplished by keeping two types of records for inventory control.

- Stock card
  - Each item in stock must be recorded on a card.
  - This card can simply be a heavyweight index card.
  - For ease of use and access, the cards should be stored in alphabetical order according to the item name.
- Stock book
  - The stock book contains a listing of all items in the “store”.
  - It must be routinely updated when orders are placed and received.
  - It also serves as a source of reference to track orders that have been placed and not received.
  - The information recorded in the stock book may help a site adjust the lead times based on history of deliveries. Using an accurate lead time will better ensure that a site has on hand the materials needed to conduct HIV rapid testing.
<table>
<thead>
<tr>
<th>Slide Number</th>
<th>Teaching Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>13</td>
<td><strong>Stock Card: An Example</strong>&lt;br&gt;REITERATE that each item used in the laboratory should be recorded on a stock card.&lt;br&gt;EXPLAIN how to complete a sample stock card using Determine as an example.&lt;br&gt;• Item Name – “Determine”&lt;br&gt;• Unit – The number per box or container, e.g., 100 tests per kit&lt;br&gt;• Minimum Stock is calculated based on the usage rates (to be explained later)&lt;br&gt;• Received from and issued to – <em>This is country specific</em>&lt;br&gt;• Balance – must be recorded each time a stock item is received of issued.&lt;br&gt;EMPHASIZE that a physical stock count should be performed monthly, with this total indicated on the form. Any discrepancies should be noted and investigated&lt;br&gt;REFER participants to their manual for examples of completed stock cards. Answer any questions they may have about the stock card examples.</td>
</tr>
<tr>
<td>14</td>
<td><strong>Stock Book: An Example</strong>&lt;br&gt;EXPLAIN how to complete a sample stock book.&lt;br&gt;REFER participants to their manual for examples of a completed form in a stock book. Answer any questions they may have about the examples.</td>
</tr>
<tr>
<td>15</td>
<td><strong>Reconciling Stock with Records</strong>&lt;br&gt;EMPHASIZE the importance of establishing an accounting system that tracks items that come in, items that are used, and items that are remaining in the stock.&lt;br&gt;• Ideally, the number of a certain item remaining in the stock should equal the number of the item that came in minus the number used.&lt;br&gt;• But in reality, there is usually a discrepancy due to loss.&lt;br&gt;DISCUSS possible causes for the loss and ways to minimize loss.</td>
</tr>
<tr>
<td>16</td>
<td><strong>Determine When to Re-order</strong>&lt;br&gt;REVIEW the definition of the terms on the slide.</td>
</tr>
<tr>
<td>Slide Number</td>
<td>Teaching Points</td>
</tr>
<tr>
<td>--------------</td>
<td>-----------------</td>
</tr>
<tr>
<td><strong>TIPS</strong></td>
<td>Refer participants back to their earlier discussion of the sundry shop owner (slide #8). It is likely that they have discussed these concepts without using the exact terminology. It helps them understand these terms if they have real examples to relate to.</td>
</tr>
<tr>
<td><strong>Customization Notes</strong> 17-18</td>
<td>If an in-country maximum lead time has been established, replace the number on the slides (12 weeks) with the in-country time.</td>
</tr>
</tbody>
</table>
| 17          | **Calculating Minimum Stock Level**  
EXPLAIN the formula and example on the slide. |
| 18          | **Exercise: Calculating Minimum Stock Level**  
ASK participants to work out the answer (1 minute).  
ASK a volunteer to provide the answer.  
WRITE the solutions on the flipchart to ensure understanding from all participants.  
(Answer: 60) |
| 19          | **Determine How Much to Re-order**  
EXPLAIN the points on the slide.  
INFORM participants that the next two slides provide an example and practice. |
| 20          | **Determine Full Stock Level**  
EXPLAIN the concept of “full stock level.”  
PROVIDE analogies or examples that participants can relate to (such as the sundry shop, amount of maize meal at home).  
DISCUSS the consequences of a stock level that is too high (too much in stock) and too low (too little in the stock).  
EXPLAIN the example on the slide. |
<table>
<thead>
<tr>
<th>Slide Number</th>
<th>Teaching Points</th>
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</thead>
<tbody>
<tr>
<td>21</td>
<td><strong>Exercise: Determine Full Stock Level</strong></td>
</tr>
<tr>
<td></td>
<td>ASK participants to work out the answers (3 minutes).</td>
</tr>
<tr>
<td></td>
<td>ASK volunteers to provide the answers.</td>
</tr>
<tr>
<td></td>
<td>WRITE the solutions on the flipchart to ensure understanding from all participants.</td>
</tr>
<tr>
<td></td>
<td>(ANSWER:</td>
</tr>
<tr>
<td></td>
<td><em>Maximum Usage = 320 tests/month</em></td>
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<tr>
<td></td>
<td>320/15 = 21.3 kits (\rightarrow) rounded up to 22 kits/month</td>
</tr>
<tr>
<td></td>
<td><em>Minimum stock level = 22X3 = 66 kits</em></td>
</tr>
<tr>
<td></td>
<td><em>Full stock level = 66 + 22 = 88 kits</em></td>
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</tr>
<tr>
<td>22</td>
<td><strong>Place Orders Properly</strong></td>
</tr>
<tr>
<td></td>
<td>REMIND participants of the importance of not to either over-stock or under-stock.</td>
</tr>
<tr>
<td><strong>Customization Notes</strong></td>
<td>22</td>
</tr>
<tr>
<td></td>
<td>If the in-country requisition (re-order) process has been established, provide that information here.</td>
</tr>
<tr>
<td></td>
<td>If sites are responsible for direct purchasing, specifications should be clearly outlined.</td>
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<tr>
<td>Slide Number</td>
<td>Teaching Points</td>
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<tr>
<td>--------------</td>
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</tbody>
</table>
| 23           | **Inspect Delivery of New Orders**  
EXPLAIN the points on the slides.  
- Check to ensure what has been ordered was delivered. For example, if 100 Uni-Gold kits have been ordered, check to make sure 100 kits have been delivered.  
- Inspect condition of supplies. Check that supplies received are in good order. Never accept kits that are either short-dated or that have already expired. Short-dated means items that will expire before they can be used.  
- Not only do you date each item when received, but date each item, particularly the buffers, when opened or put to use.  
DISCUSS:  
- What to do if your order doesn’t arrive  
- What to do if you receive a partial order  
- What to do if a box has been opened or is damaged  
- What paperwork must be completed to report discrepancies in what you ordered and what you received  
- What to do if central stores is out of stock |
| 24           | **Examine Lot Number & Expiry Date**  
STATE that it is important to note the expiry dates of the kits received.  
- Properly managing your stocks will prevent storage of kits that will be outdated before they can be used.  
- DO NOT mix lot numbers. Keep devices and corresponding buffers together.  
DISCUSS:  
- What to do with if you receive and accept short-dated stock.  
- The mechanism for transfer of stock from site-to-site |
<table>
<thead>
<tr>
<th>Slide Number</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Activity 5 minutes</td>
<td><strong>DISTRIBUTE</strong> the test kits for participants to examine their lot numbers and expiry dates. <strong>ANSWER</strong> any questions participants may have.</td>
</tr>
</tbody>
</table>
| 25 | **Ensure Proper Storage of Inventory**  
EXPLAIN the points on the slide:  
• Kits and supplies should be kept in locked storeroom or cupboard. Theft of kits is common, and following strict inventory procedures will immediately identify problem areas.  
• Store according to manufacturer’s instructions. Adhere to the storage temps required by the manufacturer. Some kits can be stored at room temperature, while others require refrigerated temps of 2-8 degrees centigrade.  
• Place in well ventilated clean and tidy room  
• Store away from direct sunlight  
• Place items on shelves – Where possible, items should be stored in an orderly fashion on shelves, keeping like items together.  
• Always place new shipments of supplies and kits behind existing ones. This will re-enforce the principle of first expiry, first out. General supplies without expiration date should be stored according to first in, first out principle.  
DISCUSS the “First-Expiry-First-out” rule.  
ASK participants for examples of how that rule applies to daily life. Examples may include: eat day-old food before food purchased today. |
| 26 | **Summary**  
ASK participants to answer the questions on the slide. |
| 27 | **Key Messages**  
STATE the key messages on the slide.  
ANSWER any questions participants may have. |
Module 11: Use and Care of Equipment at the HIV Rapid Testing Site

**Purpose**
To help participants understand exactly what is expected of them concerning the care and use of equipment at the HIV rapid test site and to equip them with the necessary skills.

**Pre-requisite Modules**
- Module 5: Assuring the Quality of HIV Rapid Testing

**Module Time**
55 minutes

**Learning Objectives**
At the end of this module, participants will be able to:
- Specify their responsibilities related to equipment at the HIV rapid test site
- Routinely monitor the temperatures of refrigerators or freezers
- Confirm auto pipettes deliver specified volumes
- Properly use and maintain centrifuges

**Module Overview**

<table>
<thead>
<tr>
<th>Step</th>
<th>Time</th>
<th>Activity/Method</th>
<th>Content</th>
<th>Resources Needed</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>5 min</td>
<td>Presentation</td>
<td>Module introduction</td>
<td>Slides 1-6 Prepared flipchart – content outline</td>
</tr>
<tr>
<td>2</td>
<td>5 min</td>
<td>Presentation Discussion</td>
<td>Responsibilities concerning equipment</td>
<td>Slides 7-8</td>
</tr>
<tr>
<td>3</td>
<td>25 min</td>
<td>Presentation Activity</td>
<td>Refrigerator &amp; freezer Pipettes Centrifuge</td>
<td>Slides 9-23 Pipettes Centrifuge</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Demonstration</td>
<td></td>
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</tr>
<tr>
<td>4</td>
<td>15 min</td>
<td>Activity</td>
<td>Create a Maintenance Activity List</td>
<td>Slide 24 Flipcharts</td>
</tr>
<tr>
<td>5</td>
<td>5 min</td>
<td>Q&amp;A</td>
<td>Summary</td>
<td>Slide 25</td>
</tr>
</tbody>
</table>

**Material/Equipment Checklists:**
- PowerPoint slides or transparencies
- Overhead projector or computer w/LCD projector
- Flipchart for content outline and small-group activity
- Handouts: Daily Temperature Check Chart, Generic Maintenance Form
- Precision and disposable pipettes – have several sets to pass around
- Centrifuge
<table>
<thead>
<tr>
<th>Slide Number</th>
<th>Teaching Points</th>
</tr>
</thead>
</table>
| **Customization** | Modify this module based on the equipment your participants will be using at the test sites. For example, consider:  
- What type of pipettes will they be using  
- Whether a centrifuge will be available on site |
| **Customization** | Also modify this module based on participants’ jobs and responsibilities.  
- For lab management or supervisors, put emphasis on the oversight responsibilities.  
- For lab technicians or testers, put emphasis on execution and following procedures. |
| 1 | **Module 11: Use and Care of Equipment**  
DISPLAY this slide before you begin the module. Make sure participants are aware of the transition into a new module. |
| 2 | **The Lab Quality System**  
REMIND participants that equipment is a component of the Lab Quality System. This component addresses:  
- Equipment selection  
- Equipment acquisition  
- Equipment installation and initial calibration/validation  
- Maintenance service and repair  
- Troubleshooting  
- Retiring equipment and disposition |
| 3 | **Learning Objectives**  
STATE the objectives on the slide. |
| 4 | **Content Overview**  
EXPLAIN the topics that will be covered in this module. |
| **Flipchart** | WRITE the content outline on a flipchart prior to training.  
REFER to it frequently to orient participants to where they are in the module. |
<table>
<thead>
<tr>
<th>Slide Number</th>
<th>Teaching Points</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>5</strong></td>
<td><strong>Functioning Equipment is Vital to Quality Service</strong></td>
</tr>
<tr>
<td></td>
<td>EXPLAIN the rationale for properly maintaining equipment.</td>
</tr>
<tr>
<td></td>
<td>• Reliable results aid clinical diagnosis. Unreliable results may result in incorrect diagnosis and treatment of the patient.</td>
</tr>
<tr>
<td></td>
<td>• If equipment is properly maintained, it is less likely to breakdown before its next service and is less likely to perform inadequately due to lack of maintenance.</td>
</tr>
<tr>
<td><strong>6</strong></td>
<td><strong>Equipment at HIV Rapid Testing Site</strong></td>
</tr>
<tr>
<td></td>
<td>STATE HIV Rapid Testing can be performed with minimal equipment. At a minimum, there are 4 pieces of equipment that may be used at the rapid testing site.</td>
</tr>
<tr>
<td></td>
<td>EXPLAIN the use of each type of equipment.</td>
</tr>
<tr>
<td></td>
<td>• Refrigerators store reagents, kits, and quality control materials requiring refrigerator storage (such as Capillus).</td>
</tr>
<tr>
<td></td>
<td>• Freezers store specimens collected for EQA purposes prior to transport to a reference laboratory. Quality control specimens may also be stored in a freezer.</td>
</tr>
<tr>
<td></td>
<td>• Pipettes collect or transfer specimen to test device.</td>
</tr>
<tr>
<td></td>
<td>• Centrifuges separate cells from serum/plasma</td>
</tr>
<tr>
<td></td>
<td>EMPHASIZE all equipment used at the testing site must be properly maintained. Using equipment that has not been properly maintained may compromise the quality of test results.</td>
</tr>
<tr>
<td><strong>7</strong></td>
<td><strong>Management Responsibilities: Ensure Test Site Readiness</strong></td>
</tr>
<tr>
<td></td>
<td>EXPLAIN lab management is responsible for making sure the test site is ready to receive and install a new piece of equipment. This includes:</td>
</tr>
<tr>
<td></td>
<td>• Assigning responsibilities – this includes oversight of all lab equipment and individual responsibilities.</td>
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<tr>
<td></td>
<td>• Establishing inventory record – Each piece of equipment must have an inventory record. This record contains pertinent information such as make and model, maintenance and service record, and manufacturer contact information.</td>
</tr>
<tr>
<td></td>
<td>• Training the operators – Everyone using any piece of laboratory equipment must be properly trained. Training must include troubleshooting.</td>
</tr>
<tr>
<td>Slide Number</td>
<td>Teaching Points</td>
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</tbody>
</table>
| 8            | **Your Responsibilities: Execute at Test Site**  
EXPLAIN the responsibilities of the test site staff.  
DISCUSS the reason against using malfunctioning equipment. |
| 9            | **Function Checks Verify that Equipment is Working Properly**  
EXPLAIN function checks – they are activities performed periodically to ensure that:  
- Equipment is working properly before use  
- Equipment is properly maintained for peak performance  
PROVIDE examples of function checks at the HIV rapid test site. |
| 10           | **Refrigerator and Freezer: Use and Care**  
EXPLAIN the points on the slide. |
| 11           | **Refrigerator & Freezer: Temperature Checks**  
EXPLAIN this photo illustrates routine monitoring of temperatures of this refrigerator.  
- It is good practice to attach the form for recording temps directly on the front of the refrigerator for easy access.  
- Inserting it into a protector page will guard against tearing of paper. |
| 12           | **Refrigerator & Freezer: Temperature Log**  
EXPLAIN this form is an example of what should be used to record and monitor refrigerator/freezer temps.  
REFER participants to a sample temperature log in the participant manual. |
| 13           | **Types of Pipettes**  
EXPLAIN the difference between the two types of pipettes.  
EMPHASIZE never re-use disposable items. Doing so will cause cross contamination. |
<p>| Activity     | PASS around a few sets of precision and disposable pipettes for everyone to see and touch. |</p>
<table>
<thead>
<tr>
<th>Slide Number</th>
<th>Teaching Points</th>
</tr>
</thead>
</table>
| 14           | **Pipette: Use and Care**  
EXPLAIN the points on the slide.  
EXPAND the first bullet: Select a pipette with delivery range close to the volume required. For example, if 50 micro liters (ul) of specimen is required, use a 100 ul pipette.  
EMPHASIZE never lay the pipette on its side when liquid is in the tip – doing so will cause the specimen to flow into to the pipette shaft and damage the pipette. |
| 15           | **Pipette: Use and Care (Cont’d)**  
EXPLAIN the points on the slide.  
EXPAND the third bullet: Air bubbles in the tip can greatly reduce pipetting accuracy. If an air bubble is trapped within the tip during intake, do the following:  
- Dispense the sample into the original vessel  
- Check the tip immersion depth  
- Pipette more slowly  
- If an air bubble appears a second time, discard the tip and use a new one.  
EMPHASIZE the following safety practices. (REMIND participants of the safety module)  
- Care should be taken to discard pipette tips in the appropriate container. Used pipette tips should not be found on the floor, as this poses a safety hazard.  
- Never re-use a pipette tip, which causes cross contamination and will compromise patient results. A fresh tip should be used for each sample. |
| **Customization Notes** | If precision pipettes are used at test sites, provide hands-on practice. |
| 16-17        | **Precision Pipettes Require Performance Checks**  
The analytical balance should have a scale of 0.1 to 0.0001 mg |
| 16           | **Pipette: Steps for Checking Reproducibility**  
EMPHASIZE performance checks include reproducibility and calibration.  
EXPLAIN the procedures for checking reproducibility. |
<table>
<thead>
<tr>
<th>Slide Number</th>
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</tr>
</thead>
<tbody>
<tr>
<td>18</td>
<td><strong>Pipette: Troubleshooting</strong>&lt;br&gt;EXPLAIN the points on the slide.</td>
</tr>
<tr>
<td>19</td>
<td><strong>Customization Notes</strong>&lt;br&gt;For participants without a lab background, or who have never seen a centrifuge, add the following steps before showing the next few slides:&lt;br&gt;SHOW a centrifuge.&lt;br&gt;DEMONSTRATE how it works.&lt;br&gt;NAME all parts that will be mentioned in the following slides.</td>
</tr>
<tr>
<td>19</td>
<td><strong>Centrifuge: Use and Care</strong>&lt;br&gt;EXPLAIN the bullets on the slide.&lt;br&gt;□ Always operate with the lids closed – Operating a centrifuge without the lid closed poses an unnecessary safety hazard.&lt;br&gt;□ Balance contents before turning on. – For example, if there is only one sample to be centrifuged, a tube identical in size and volume must be placed in the rotor opposite the tube. Note: The rotor is the part of the centrifuge that holds the tubes and rotates during operation.&lt;br&gt;□ Check for vibration – There may be several reasons why a centrifuge vibrates. When vibration occurs, you'll need to:&lt;br&gt;➢ Stop operation of the centrifuge.&lt;br&gt;➢ Determine the cause of the noise or vibration.&lt;br&gt;➢ Correct immediately to prevent severe damage to the centrifuge or injury to the worker. Refer to the owner’s manual for possible causes aside from improper balancing.&lt;br&gt;□ Do not open until the lid until the rotor has come to a complete stop.&lt;br&gt;□ Keep lids on tubes when spinning – Do not take the tops off the tubes before spinning. Doing so will cause splashing and creating of aerosols from potentially infectious material.</td>
</tr>
<tr>
<td>20</td>
<td><strong>Centrifuges: Function Checks</strong>&lt;br&gt;EXPLAIN separation activity is a function of both centrifugal force and timing. Proper balance, lubrication and rotor function are essential for proper centrifugation to occur.</td>
</tr>
<tr>
<td>Slide Number</td>
<td>Teaching Points</td>
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<td>--------------</td>
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</tr>
<tr>
<td>21</td>
<td><strong>Centrifuge: Routine Maintenance</strong></td>
</tr>
<tr>
<td></td>
<td>EXPLAIN how to clean the centrifuge:</td>
</tr>
<tr>
<td></td>
<td>▪ Clean interior daily with soap and water, wipe with a disinfectant</td>
</tr>
<tr>
<td></td>
<td>▪ Wipe spills using 10% bleach solution</td>
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<tr>
<td></td>
<td>▪ After cleaning, run the centrifuge at varying RPMs to check the braking mechanism and ensure a smooth gradual stop</td>
</tr>
<tr>
<td></td>
<td>EXPLAIN what to do when noticing unusual noises:</td>
</tr>
<tr>
<td></td>
<td>▪ Stop operation of the centrifuge</td>
</tr>
<tr>
<td></td>
<td>▪ Follow manufacturer’s recommendation on activation and release of brakes</td>
</tr>
<tr>
<td></td>
<td>▪ Correct immediately to prevent severe damage to the centrifuge or injury to the worker</td>
</tr>
<tr>
<td></td>
<td>MENTION brushes need to be inspected every 3-6 months and replaced according to manufacturer specifications.</td>
</tr>
<tr>
<td>22</td>
<td><strong>Centrifuge Safety</strong></td>
</tr>
<tr>
<td></td>
<td>STATE the bullets on the slide.</td>
</tr>
<tr>
<td></td>
<td>STATE simply turning the power off does not remove power to the centrifuge.</td>
</tr>
<tr>
<td>23</td>
<td><strong>Keep a Log for All Maintenance Activities</strong></td>
</tr>
<tr>
<td></td>
<td>MENTION the need for documenting problems, corrective action, preventive maintenance, cleaning, and inspections.</td>
</tr>
<tr>
<td></td>
<td>REFER participants to a sample, generic maintenance log in the participant manual.</td>
</tr>
<tr>
<td>24</td>
<td><strong>Exercise: Create a Maintenance Activity Log</strong></td>
</tr>
<tr>
<td>Activity</td>
<td>FOLLOW the procedure below when conducting the activity:</td>
</tr>
<tr>
<td>15 minutes</td>
<td>INFORM participants of the activity.</td>
</tr>
<tr>
<td></td>
<td>READ the instructions on the slide.</td>
</tr>
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<td></td>
<td>PROVIDE a flipchart for each work group.</td>
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<tr>
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<td>ALLOW 10 minutes for the small group to work.</td>
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<td></td>
<td>DEBRIEF by asking volunteers to present their lists and solicit comments from other participants.</td>
</tr>
<tr>
<td>Slide Number</td>
<td>Teaching Points</td>
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</tbody>
</table>
| **24**       | Alternative way to conduct this activity:  
|              | If all the participants come from the same test site, or if you have time constraint, you may modify this activity by facilitating a large group discussion (instead of having small work groups) to create the activity list. |
| **25**       | **Summary**     |
|              | ASK participants to answer the questions on the slide.  
|              | ANSWER any questions participants may have. |
Module 12: Quality Control

Purpose
To help participants understand the importance of quality control for HIV rapid testing, and acquire the knowledge and skills required for conducting quality control at a rapid testing site.

Pre-requisite Modules
- Module 3: Overview of HIV Testing Technologies
- Module 4: HIV Testing Strategies & Algorithms
- Module 5: Assuring the Quality of HIV Rapid Testing

Module Time
45 minutes

Learning Objectives
At the end of this module, participants will be able to:
- Differentiate between internal and external controls
- Use external quality controls at designated frequencies
- Analyze common problems associated with invalid test results

Module Overview

<table>
<thead>
<tr>
<th>Step</th>
<th>Time</th>
<th>Activity/Method</th>
<th>Content</th>
<th>Resources Needed</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>3 min</td>
<td>Presentation</td>
<td>Module introduction</td>
<td>Slides 1-4; prepared flipchart – content outline</td>
</tr>
<tr>
<td>2</td>
<td>7 min</td>
<td>Presentation; Discussion</td>
<td>Internal Vs. external quality control</td>
<td>Slides 5-11</td>
</tr>
<tr>
<td>3</td>
<td>10 min</td>
<td>Presentation; Discussion</td>
<td>Troubleshooting invalid results</td>
<td>Slides 12-15</td>
</tr>
<tr>
<td>4</td>
<td>15 min</td>
<td>Activities</td>
<td>Exercise #1: Interpreting Rapid Test Results</td>
<td>Slides 16-18; Exercises #1 &amp; #2 sheets</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Exercise #2: Resolving Un-reportable Test Results</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>5 min</td>
<td>Presentation; Discussion</td>
<td>Quality control records</td>
<td>Slides 19-21; Quality Control recording worksheet</td>
</tr>
<tr>
<td>6</td>
<td>5 min</td>
<td>Q&amp;A</td>
<td>Summary</td>
<td>Slide 22-23</td>
</tr>
</tbody>
</table>
Material/Equipment Checklists

- PowerPoint slides or transparencies
- Overhead projector or computer w/LCD projector
- Prepared flipchart – content outline
- Handouts:
  - Exercise #1: Interpreting Rapid Test Results
  - Exercise #2: Resolving Un-reportable Test Results
  - Daily Record of Quality Control Results
## Teaching Guide

<table>
<thead>
<tr>
<th>Slide Number</th>
<th>Teaching Points</th>
</tr>
</thead>
</table>
| 1 | **Module 12: Quality Control**  
DISPLAY this slide before you begin the module. Make sure participants are aware of the transition into a new module. |
| 2 | **The Lab Quality System**  
REMIND participants that quality control is one component of the laboratory quality system. |
| 3 | **Learning Objectives**  
STATE the objectives on the slide. |
| 4 | **Content Overview**  
EXPLAIN the topics that will be covered in this module. |
| **Flipchart** | REFER to it frequently to orient participants to where they are in the module. |
| 5 | **What is Quality Control (QC)?**  
STATE that the primary benefit of quality control is that:  
- It shows the tester that the test is working correctly.  
- Accurate test results can be reported with confidence.  
HIGHLIGHT there are 2 levels of QC for HIV rapid testing:  
- Testing of samples with known results to verify if the procedure is working properly  
- Interpreting the presence or absence of control bands/lines within the device itself  
EMPHASIZE that if problems or errors occur, we must immediately take corrective actions before we give results to patients. |
| **TIPS** | SHARE stories from personal or others’ experiences about the consequences of negligence or lack of quality control.  
Stories or scenarios that evoke emotions (fear, shock, sympathy, sorrow, etc.) are excellent ways in getting participants to pay attention and adopting the right attitudes about quality control. This is especially important when teaching participants without medical or lab experience. |
<table>
<thead>
<tr>
<th>Slide Number</th>
<th>Teaching Points</th>
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</thead>
<tbody>
<tr>
<td><strong>6</strong></td>
<td><strong>Sources of Controls</strong></td>
</tr>
<tr>
<td></td>
<td>STATE that there are two types of quality control for HIV rapid testing: internal and external to the test kit.</td>
</tr>
<tr>
<td></td>
<td>EXPLAIN <strong>Internal</strong> quality control.</td>
</tr>
<tr>
<td></td>
<td>- Control samples with known reactivity may be included with the test kit that you would test as you would patient/client specimens.</td>
</tr>
<tr>
<td></td>
<td>- Another type of internal control is an area or region within the individual testing device. This area or region is also termed the procedural or in-built control. This type of control verifies the flow of either specimen and/or buffer through the test device resulting in an appearance of a line or dot in the control region. In other words, in some test devices, a line in the control area may appear even if a specimen is not added, unlike other test devices with an anti-IgG control. In this instance, a control line will not appear if IgG is not detected.</td>
</tr>
<tr>
<td></td>
<td>- Since it is not always known if the test devices include a true IgG control, it is important to test an external control sample.</td>
</tr>
<tr>
<td></td>
<td>EXPLAIN <strong>External</strong> quality control.</td>
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<tr>
<td></td>
<td>- Control samples that do not come with the test kit. They are provided by an external source such as your regional reference laboratory or a commercial supplier.</td>
</tr>
<tr>
<td></td>
<td>- This type of control should also be tested in the same manner as you would test a patient or client specimen.</td>
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<tr>
<td></td>
<td>EXPLAIN that for both internal and external control samples, you already know whether the control is positive or negative. Once tested, you should receive the expected results. If not, this is one sign that there is a problem with your testing operation.</td>
</tr>
<tr>
<td><strong>7</strong></td>
<td><strong>Internal and External Quality Control</strong></td>
</tr>
<tr>
<td></td>
<td>HIGHLIGHT the types of quality control previously discussed.</td>
</tr>
<tr>
<td></td>
<td>POINT OUT the control band on the test device.</td>
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<tr>
<td></td>
<td>DISCUSS the photo on the left – control samples are often received in tubes called cryovials. This photo illustrates control samples neatly stored in a Styrofoam container.</td>
</tr>
<tr>
<td>Slide Number</td>
<td>Teaching Points</td>
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<tr>
<td><strong>8</strong></td>
<td><strong>Examples of Tests that Include Internal Control</strong></td>
</tr>
<tr>
<td></td>
<td>STATE that all the rapid tests listed on the slide have internal control as part of their kits.</td>
</tr>
<tr>
<td></td>
<td>ASK, “One of these tests differ from the rest in that it does not have internal control incorporated into its test device. Which one is it?”</td>
</tr>
<tr>
<td></td>
<td>SOLICIT responses from the participants. (PROVIDE a hint if participants have difficulty coming up with the correct answer: this test is based on agglutination format.)</td>
</tr>
<tr>
<td><strong>9</strong></td>
<td><strong>Capillus Kit Comes with Internal Control Samples</strong></td>
</tr>
</tbody>
</table>
|              | PROVIDE and EXPLAIN the correct answer: Capillus.  
|              | • Its test format is based on agglutination, and therefore does not have a built-in control on the strip within the device.  
|              | • The kit includes controls from the manufacturer – also considered control internal to the test kit.  
|              | • These control samples internal to the kit should be test in the same way as client samples. |
| TRANSITION   | STATE Even though the kit supplies internal controls, other non-kit controls from external sources must also be tested to validate the kit itself. This applies to all types of kits. |
| **Customization Notes** | Customize these two slides with in-country information such as where the external control materials come from, and the designated frequencies for testing control samples. |
| **10**       | **Sources of External Quality Control Samples** |
|              | STATE that external controls may either be obtained from commercial manufacturers, or from another laboratory that has prepared validated quality control samples in-house. |
|              | STATE It is important to store controls appropriately. For controls obtained commercially, it is important to store according to the manufacturer instructions. For in-house prepared controls, these should be refrigerated upon receipt. |
|              | EMPHASIZE the following points for both types of controls.  
|              | • Label vial with date when first used  
|              | • Test before expiry date  
<p>|              | • Take care as to not contaminate the control materials. |</p>
<table>
<thead>
<tr>
<th>Slide Number</th>
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</tr>
</thead>
</table>
| TIPS         | When teaching laboratory technicians, consider adding the following content. **STATE:**  
• Regardless of where external control materials come from, it is important to have procedures and logistics in place for a regular and ongoing supply of controls to all testing sites. **EXPLAIN:**  
• The process for requesting supply of control materials  
• How the batches of control materials are transported to the testing sites  
• How often controls are transported  
• Who should be contacted if a problem arises with the controls |
| 11           | **Frequency of Use: When Should You Test External Control Samples?**  
EXPLAIN the key points on the slide. At a minimum, controls should be tested:  
• Once a week  
• When a new shipment of control materials or test kits are received at the testing site  
• Beginning of a new lot number  
• Most kits do not require refrigeration, but some (such as Capillus) do. If these kits have been stored under non-refrigeration temperatures, then the lot must be tested using external controls to verify the integrity of the test kit. |
| 12           | **Invalid Results – What Do You Do?**  
EXPLAIN the key points on the slide.  
MAKE SURE everyone is aware of an alternate testing algorithm in the event of repeated invalid on any one test kit |
<p>| 13-14        | For these two slides, add any other problems, causes and actions that have been observed in your country, if necessary. |</p>
<table>
<thead>
<tr>
<th>Slide Number</th>
<th>Teaching Points</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>13</strong></td>
<td><strong>Troubleshooting Invalid Results</strong></td>
</tr>
<tr>
<td></td>
<td>STATE the problems on the slide.</td>
</tr>
<tr>
<td></td>
<td>ASK participants what may cause each problem.</td>
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<tr>
<td></td>
<td>EXPLAIN what may cause the lack of reddish, pink, or purple line or dot in the control window</td>
</tr>
<tr>
<td></td>
<td>STATE the importance of always following the Standard Operating Procedure (SOP) for each type of test being used, as the following may differ from kit to kit:</td>
</tr>
<tr>
<td></td>
<td>- Sample volume – This may differ from kit to kit, and might differ depending on the sample type (e.g. whole blood vs. serum).</td>
</tr>
<tr>
<td></td>
<td>- Buffer volume – Some kits require different volumes of buffer.</td>
</tr>
<tr>
<td></td>
<td>- Incubation time – This time may also differ from kit to kit. Always follow the time required by the manufacturer.</td>
</tr>
</tbody>
</table>

| **14**       | **Troubleshooting Invalid Results – Cont’d** |
|              | STATE the problems on the slide. |
|              | ASK participants what may cause each problem. |
|              | EXPLAIN what may cause positive band using negative control (i.e. false positive). |
|              | ASK participants what may cause the next problem. |
|              | EXPLAIN what may cause an extremely faint control line |
|              | NOTE other potential problems, potential causes, and actions to take on a flipchart. |

<p>| <strong>15</strong>       | <strong>Possible HIV Test Outcomes: Parallel Algorithm</strong> |
|              | REMIND participants that there are a variety of combinations of outcomes when following a multi-test algorithm. |</p>
<table>
<thead>
<tr>
<th>Slide Number</th>
<th>Teaching Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>16 Activity</td>
<td><strong>Exercise #1: Interpreting Rapid Test Results</strong></td>
</tr>
<tr>
<td>5 minutes</td>
<td>READ the instructions on the slide.</td>
</tr>
<tr>
<td></td>
<td>ALLOW 3 minutes for the exercise.</td>
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<tr>
<td></td>
<td>DEBRIEF the exercise by discussing the correct answers.</td>
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<tr>
<td></td>
<td>Consider replacing the three tests here with tests in your country’s algorithm.</td>
</tr>
<tr>
<td>17 Activity</td>
<td><strong>Exercise #2: Resolving Un-reportable Test Results</strong></td>
</tr>
<tr>
<td></td>
<td>REFER to the exercise sheet in the participant manual.</td>
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<tr>
<td></td>
<td>EXPLAIN the scenario for this exercise.</td>
</tr>
<tr>
<td></td>
<td>• Tester received discordant test results from test 1 (Determine) and test 2 (Uni-gold).</td>
</tr>
<tr>
<td></td>
<td>• The algorithm called for a third test (or tie breaker) to determine HIV status of patient.</td>
</tr>
<tr>
<td>18 Flipchart</td>
<td><strong>Exercise #2: Resolving Un-reportable Test Results (Cont’d)</strong></td>
</tr>
<tr>
<td></td>
<td>ASK participants to answer the questions in the exercise.</td>
</tr>
<tr>
<td></td>
<td>ALLOW 3 minutes for the exercise.</td>
</tr>
<tr>
<td></td>
<td>DEBRIEF the exercise by discussing the correct answers.</td>
</tr>
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<td></td>
<td>NOTE their responses on a flipchart.</td>
</tr>
<tr>
<td></td>
<td>ASK participants to think of the role of quality control in providing confidence with reporting results and determining actions to take.</td>
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<tr>
<td></td>
<td>DEBRIEF the discussion by summarizing key learning points.</td>
</tr>
<tr>
<td>19</td>
<td><strong>Maintaining Quality Control Records</strong></td>
</tr>
<tr>
<td></td>
<td>EXPLAIN the key points on the slide.</td>
</tr>
<tr>
<td>20 Customization Notes</td>
<td>If your country uses a different form from the example provided on the slide for recording and monitoring quality control results, insert it here.</td>
</tr>
<tr>
<td>Slide Number</td>
<td>Teaching Points</td>
</tr>
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</tbody>
</table>
| 20           | **Quality Control Record: An Example**  
|              | EXPLAIN the following points:  
|              | • This is one example of the type of record that can be kept on site.  
|              | • During a review of QC results, it is easier to have one log of all QC results rather than going from page to page in a logbook.  
|              | • A format such as this also provides an easy glance at consistent frequency in testing QC samples, and readily identification of problems. |
| 21           | **Periodic Review of Records**  
|              | STATE that QC results must be reviewed periodically. WHY? For early detection of problems  
|              | • As indicated, daily review before accepting results, and weekly or monthly review by site supervisor.  
|              | • QC results will also be reviewed by any external assessment or audit visits.  
|              | • Keep in mind that if problems are detected, corrective actions must be immediately taken. |
| 22-23        | **Summary**  
|              | ASK participants to answer the questions on the slide.  
|              | ANSWER any questions participants may have. |
Module 13: External Quality Assessment – On-site Evaluation and Re-testing

**Purpose**
To provide participants an overview of External Quality Assessment with focus on on-site evaluation and re-testing.

**Pre-requisite Modules**
- Module 5: Assuring the Quality of HIV Rapid Testing

**Module Time**
1 hour 30 minutes

**Learning Objectives**
At the end of this module, participants will be able to:
- Assess operations at test site to determine if quality requirements are met
- Take corrective actions following External Quality Assessment (EQA)
- Keep appropriate records related to EQA
- Avoid common problems associated with EQA specimen management

**Module Overview**

<table>
<thead>
<tr>
<th>Step</th>
<th>Time</th>
<th>Activity/Method</th>
<th>Content</th>
<th>Resources Needed</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>3 min</td>
<td>Presentation</td>
<td>Module introduction</td>
<td>Slides 1-4</td>
</tr>
<tr>
<td>2</td>
<td>7 min</td>
<td>Presentation/Discussion</td>
<td>EQA: what, why, responsibilities</td>
<td>Slide 5-9</td>
</tr>
<tr>
<td>3</td>
<td>15 min</td>
<td>Presentation/Discussion</td>
<td>EQA methods</td>
<td>Slides 10-18</td>
</tr>
<tr>
<td>4</td>
<td>20 min</td>
<td>Presentation/Discussion</td>
<td>Implementing on-site evaluation</td>
<td>Slides 19-30</td>
</tr>
<tr>
<td>5</td>
<td>30 min</td>
<td>Role play</td>
<td>On-site evaluation visit</td>
<td>Slides 31</td>
</tr>
<tr>
<td>6</td>
<td>10 min</td>
<td>Presentation/Discussion</td>
<td>Implementing re-testing</td>
<td>Slides 32-40</td>
</tr>
<tr>
<td>7</td>
<td>5 min</td>
<td>Q&amp;A</td>
<td>Summary</td>
<td>Slide 41</td>
</tr>
</tbody>
</table>
Material/Equipment Checklists

- PowerPoint slides or transparencies
- Overhead projector or computer w/LCD projector
- Prepared Flipchart – content outline
- Handouts:
  - Corrective Action Form
  - On-site Evaluation Checklist
  - Example Specimen Transfer Log for Re-Testing
### Slide Number | Teaching Points
--- | ---
1 | **Customization**
   - Customize the module according to the participants’ job positions and responsibilities (management versus testing personnel). The icons at the bottom of each slide indicate suggested audiences.
   - Other modifications are also required throughout the module to provide specific information on in-country EQA program

2 | **Module 13: EQA (On-site Evaluation and Re-Testing)**
   - DISPLAY this slide before you begin the module. Make sure participants are aware of the transition into a new module.

3 | **The Quality System**
   - REMIND participants that EQA is a component of the Laboratory Quality System.
     - This is a graphic illustrating the essential elements of a laboratory quality system.
     - EQA methods comprise both Process Control and Assessment.

4 | **Learning Objectives**
   - STATE the objectives on the slide.

5 | **Content Overview**
   - EXPLAIN the topics that will be covered in this module.

   - **Flipchart**
     - WRITE the content outline on a flipchart prior to training.
     - REFER to it frequently to orient participants to where they are in the module.

6 | **External Quality Assessment (EQA): Definition**
   - STATE the definition of EQA on the slide.
<table>
<thead>
<tr>
<th>Slide Number</th>
<th>Teaching Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td><strong>Why EQA?</strong></td>
</tr>
<tr>
<td></td>
<td>EXPLAIN the points on the slide.</td>
</tr>
<tr>
<td></td>
<td>▪ Results may be compared between laboratories offering not only an opportunity for performances checks, but an opportunity to systematically identify problems with kits or operations.</td>
</tr>
<tr>
<td></td>
<td>▪ Training needs may be identified and evaluated.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>7</th>
<th><strong>EQA: Conducted at Three Levels</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>PROVIDE the following points:</td>
</tr>
<tr>
<td></td>
<td>▪ For EQA program to be effective, the Ministry of Health must establish an organizational structure and assign responsibility to assure that on-site monitoring occurs in all locations.</td>
</tr>
<tr>
<td></td>
<td>▪ In most countries, the National Reference Laboratory (NRL) has overall oversight responsibility. However, to have better reach in meeting the needs of rural test sites or points of service, this may be best accomplished with oversight by provincial labs.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>7-9</th>
<th><strong>Customization Notes</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Modify the next three slides according to in–country EQA process, structure, roles and responsibilities.</td>
</tr>
<tr>
<td>Slide Number</td>
<td>Teaching Points</td>
</tr>
<tr>
<td>--------------</td>
<td>-----------------</td>
</tr>
<tr>
<td>8</td>
<td><strong>Management Responsibilities: An Overview</strong></td>
</tr>
<tr>
<td></td>
<td>PROVIDE the following explanations:</td>
</tr>
<tr>
<td></td>
<td>- Someone of authority must take responsibility for EQA. If job titles are not the same as those on the slide, then tasks should be accomplished by designated individuals.</td>
</tr>
<tr>
<td></td>
<td>- Management must designate a staff member with the responsibility to establish and implement the EQA program.</td>
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<tr>
<td></td>
<td>- Management will determine how and when they are advised of the outcomes of the EQA program. The best way to ensure EQA reports are reviewed by management is by including them as an agenda item in management review meetings.</td>
</tr>
<tr>
<td></td>
<td>- Ideally the person conducting the on-site visit should have an understanding of the Quality Management System, knowledge of testing technologies, ability to analyze situations and good communication skills.</td>
</tr>
<tr>
<td>9</td>
<td><strong>Testing Personnel’s Responsibilities</strong></td>
</tr>
<tr>
<td></td>
<td>EXPLAIN the points on the slide.</td>
</tr>
<tr>
<td>10</td>
<td><strong>EQA Methods</strong></td>
</tr>
<tr>
<td></td>
<td>STATE there are three main EQA methods:</td>
</tr>
<tr>
<td></td>
<td>- Proficiency testing (PT)</td>
</tr>
<tr>
<td></td>
<td>- On-site evaluation, which is sometimes referred to as on-site monitoring visits or audits</td>
</tr>
<tr>
<td></td>
<td>- Rechecking or retesting of specimens</td>
</tr>
<tr>
<td></td>
<td>CLARIFY that:</td>
</tr>
<tr>
<td></td>
<td>- This module will focus primarily on on-site evaluation and re-testing.</td>
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<tr>
<td></td>
<td>- Proficiency panel may be used during on-site visits.</td>
</tr>
<tr>
<td>11</td>
<td><strong>What is Proficiency Testing?</strong></td>
</tr>
<tr>
<td></td>
<td>EXPLAIN proficiency testing by STATING the points on the slide.</td>
</tr>
<tr>
<td>Slide Number</td>
<td>Teaching Points</td>
</tr>
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<td>--------------</td>
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</tr>
</tbody>
</table>
| **12**       | **What is On-site Evaluation?**  
EXPLAIN on-site evaluation:  
- On-site evaluation provides a realistic picture of laboratory practices.  
- It also provides a means for assisting with problem areas.  
EMPHASIZE the point that these visits should be instructional rather than punitive. |
| **13**       | **What is On-site Evaluation? – Cont’d**  
EXPLAIN further that the main purpose of on-site visits is to observe the testing site under routine conditions in order to check that it is meeting quality requirements. |
| **14**       | **What is Re-testing?**  
EXPLAIN re-testing. |
| **15**       | **EQA Should Lead to Corrective Actions**  
DEFINE corrective action as an action taken to correct a problem or non-conformance within the QMS.  
PROVIDE examples of a non-conformance:  
- Production of an incorrect result  
- Any step within a process which contributed to an incorrect result  
- When the documented quality system is not followed exactly as intended  
- When the quality system does not meet the requirements of quality standards or requirements |
<table>
<thead>
<tr>
<th>Slide Number</th>
<th>Teaching Points</th>
</tr>
</thead>
</table>
| 16 | **Problems May Occur Throughout the Testing Process**  
EXPLAIN the following points:  
- The problems may lie anywhere in the testing process.  
- The integrity of the specimen may have been compromised during preparation, shipping or after receipt by improper storage or handling  
EMPHASIZE the following points:  
- Most problems occur in the pre and post analytic phase of testing.  
- Due to the numbers of specimens collected and transported by various test sites, care must be taken to ensure proper transcription of data throughout the testing process |
| 17 | **Take Corrective Actions**  
EXPLAIN the points on the slide. |
| 18 | **Sample Corrective Action Form**  
REFER participants to the form in the participant manual. |
| 19 | **How To Implement EQA**  
STATE:  
- This module focuses on on-site evaluation and re-testing processes.  
- We will discuss implementation of on-site evaluation next. |
| 20 | **On-Site Evaluation Process**  
PROVIDE an overview of the on-site evaluation process.  
NOTE: For testers – EMPHASIZE they should understand the process for how the visits will be conducted. This will assist them in preparing for a productive visit. |
<p>| 21 | The form on the slide is an example of a checklist that can be used to assess the site’s quality system. Countries may need to adapt this checklist to include specific country requirements reflecting national policy. |</p>
<table>
<thead>
<tr>
<th>Slide Number</th>
<th>Teaching Points</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>21</strong></td>
<td><strong>On-Site Evaluation Checklist</strong></td>
</tr>
<tr>
<td></td>
<td>REFER participants to the form in the participant manual.</td>
</tr>
<tr>
<td></td>
<td>DISCUSS each section of the form.</td>
</tr>
<tr>
<td></td>
<td>Customization Notes</td>
</tr>
<tr>
<td><strong>22</strong></td>
<td><strong>Tester Responsibilities: Ensuring a Productive Site Visit</strong></td>
</tr>
<tr>
<td></td>
<td>EMPHASIZE testers play an important role in ensuring a productive site visit.</td>
</tr>
<tr>
<td></td>
<td>HIGHLIGHT the tasks the testers should perform before, during and after the visit.</td>
</tr>
<tr>
<td></td>
<td>EMPHASIZE the need to take corrective actions, immediately, if any are identified. This will help ensure the continued quality of testing.</td>
</tr>
<tr>
<td><strong>23</strong></td>
<td><strong>On-site Evaluation: Pre-Evaluation Preparation</strong></td>
</tr>
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<td></td>
<td>EXPLAIN the points on the slide:</td>
</tr>
<tr>
<td></td>
<td>▪ Someone should take responsibility for preparing for onsite visits</td>
</tr>
<tr>
<td></td>
<td>▪ A team consisting of both program and laboratory staff should collectively plan for and conduct the on-site visit. Doing so will provide a comprehensive view of the testing site, and will prevent vertical assessments.</td>
</tr>
<tr>
<td></td>
<td>▪ Appropriate training should be provided for those who will serve as assessors.</td>
</tr>
</tbody>
</table>
### Slide Number 24: On-site Evaluation: Pre-Evaluation Preparation

**STATE** the recommended frequency for site visits are referenced in the Guidelines for Applying Quality Systems to HIV Rapid Testing developed through a consensus process in Johannesburg, May 2004.

**EXPLAIN** frequency of the visit may be determined by a number of factors:

- Previous results where problems or deficiencies have been noted, due to complaint or follow-up
- Number of trained assessors
- Minimum frequency 2x year for established sites
- Quarterly for new sites

**EXPLAIN** advantages and disadvantages for unannounced visits.

- Announcing the date of the visit will ensure that relevant staff will be present during the visit.
- Unannounced visits will most likely give you a true picture of routine practice. These unscheduled visits aim to fix the problem and improve the system to prevent recurrence.

**STATE** evaluation visits may be conducted in response to a problem within the system. Schedule evaluation visits during a time that will minimize disruption of services.

### Slide Number 25: On-site Evaluation: Entrance Interview

**EXPLAIN** the points on the slide.
<table>
<thead>
<tr>
<th>Slide Number</th>
<th>Teaching Points</th>
</tr>
</thead>
</table>
| 26           | **On-site Evaluation: Information Gathering**  
|              | PROVIDE the following points:  
|              |   - It is important to gather information in an organized, consistent manner to make decisions about the site’s quality system.  
|              |   - Try to minimize disruption to the workflow of testing site for your information gathering effort.  
|              |   - Observation of test performance. This may be accomplished by observing staff performing actual patient/client testing, or by use of proficiency panel comprised of 5-10 specimens. Site assessors should plan in advance to arrive at site with proficiency panel. Provision of proficiency panel is the responsibility of reference labs.  
|              |   - At all times, respect patient privacy and confidentiality. |
| 27           | **On-site Evaluation: Outcome Assessment**  
|              | EXPLAIN the decision algorithm in the slide.  
|              | Further EXPLAIN if problems are detected, the assessor should determine the impact of the problem in relation to patient test outcome.  
|              |   - Does the problem result in inaccurate test results?  
|              |   - Does the problem result in a high probability of inaccurate test results?  
|              |   - Is immediate corrective action necessary? |
| 28           | **On-Site Evaluation: Exit Conference**  
|              | EXPLAIN the procedure in conducting an exit conference. |
| 29           | **On-site Evaluation: Reporting**  
|              | EXPLAIN the points on the slide.  
<p>|              | ADD each country should determine who should receive the report. It is recommended that the report be submitted to Quality Manager, Site Manager, Program Manager, or MoH. |
|              | Provide a real assessment report from a visit actually performed in your country. |</p>
<table>
<thead>
<tr>
<th>Slide Number</th>
<th>Teaching Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>30</td>
<td><strong>Sample Assessment Report</strong>&lt;br&gt;REFER participants to the Sample Assessment Report in the participant manual.&lt;br&gt;DISCUSS each section of the report, including subsequent actions required by the tester.</td>
</tr>
<tr>
<td>31 Role Play</td>
<td><strong>Role Play: On-site Evaluation Visit</strong>&lt;br&gt;FOLLOW the procedure below when conducting the role play:&lt;br&gt;- INFORM participants that they are going to have a role play.&lt;br&gt;- POINT OUT the instructions on the slide.&lt;br&gt;- ASSIGN roles to four volunteers (or pre-selected prior to the role play).&lt;br&gt;DEBRIEF the role play by asking:&lt;br&gt;  - What did you observe?&lt;br&gt;  - What did you learn?</td>
</tr>
<tr>
<td>31 Customization Notes</td>
<td>Role Play Scenarios&lt;br&gt;These are examples of the kinds of situations that may be observed. Edit this list to reflect actual situations that have been encountered within country.&lt;br&gt;- Improper workstation setup&lt;br&gt;- Possible things to observe leading to problem areas:&lt;br&gt;  - Cell phone ringing while conducting testing&lt;br&gt;  - Used lancet on floor – missed placing in discard bin&lt;br&gt;  - Time for test cut short…in hurry to go home&lt;br&gt;  - Missing or incomplete test records&lt;br&gt;  - Missing temperature logs&lt;br&gt;  - Improper performance of test&lt;br&gt;  - Breaching confidentiality</td>
</tr>
<tr>
<td>32</td>
<td><strong>How To Implement EQA</strong>&lt;br&gt;TRANSITION to discussion of re-testing.</td>
</tr>
<tr>
<td>33</td>
<td><strong>Issues to Consider Prior to Implementing a Re-testing Program</strong>&lt;br&gt;STATE the points on the slide.</td>
</tr>
<tr>
<td>Slide Number</td>
<td>Teaching Points</td>
</tr>
<tr>
<td>--------------</td>
<td>-----------------</td>
</tr>
</tbody>
</table>
| 34           | **Statistical Basis for Re-testing: Error Detection**  
               PROVIDE the following points:  
               - This chart is an excerpt from the CDC/WHO Guidelines for applying quality systems to HIV rapid testing. The purpose here is to illustrate the number of specimens that will need to be re-tested to statistically detect 1 or 5% error at the 95% confidence level.  
               - If re-testing is to be one of the EQA methods, it must be based upon statistical considerations.  
               - Countries must realize the numbers of specimens for re-testing will quickly overwhelm the reference laboratory.  
               - Outcome of re-testing must be analyzed for effective and timely feedback. |
| 35           | **Re-testing: Example Sampling Plan**  
               STATE the following:  
               This slide provides an example of how to determine your sampling plan, given a specified time period.  
               1. Determine number of specimens required to detect specific error detection rate over a one month time period  
               2. For 1% error detection rate, 225 specimens will need to be re-tested.  
               3. How many specimens must then be collected per week and per day? Approximately 50 specimens per week, or approximately 11 specimens per day  
               EMPHASIZE specimens MUST be collected randomly. Every effort should be made to avoid systematic sampling bias. |
| 36           | **Re-testing Process**  
               STATE the re-testing process on the slide. |
| 37           | **Tester Responsibilities: Re-Testing**  
               EMPHASIZE the points on the slide. |
<table>
<thead>
<tr>
<th>Slide Number</th>
<th>Teaching Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>38</td>
<td><strong>Specimen Requirements</strong></td>
</tr>
<tr>
<td></td>
<td>STATE the points on the slide.</td>
</tr>
<tr>
<td></td>
<td>EMPHAZIE all specimens should be properly labeled. At a minimum, include specimen identification number and date of collection.</td>
</tr>
<tr>
<td>39</td>
<td><strong>EQA Specimen Transfer Log</strong></td>
</tr>
<tr>
<td></td>
<td>This form is an example of information that needs to be captured for transferring EQA specimens to a reference laboratory. Replace this form, if necessary, to reflect standard operating procedures.</td>
</tr>
<tr>
<td></td>
<td><strong>Customization Notes</strong></td>
</tr>
<tr>
<td>39</td>
<td><strong>EQA Specimen Transfer Log</strong></td>
</tr>
<tr>
<td></td>
<td>REFER participants to EQA Specimen Transfer Log in the participant manual.</td>
</tr>
<tr>
<td></td>
<td>INSTRUCT participants on how to complete the form.</td>
</tr>
<tr>
<td>40</td>
<td><strong>Specimen Management : Common Problems</strong></td>
</tr>
<tr>
<td></td>
<td>EXPLAIN the points on the slide.</td>
</tr>
<tr>
<td></td>
<td>ADD:</td>
</tr>
<tr>
<td></td>
<td>- Given the volume of specimens that may be required for re-testing, care must be taken to avoid errors that may occur in the pre-analytic and post-analytic phase of testing.</td>
</tr>
<tr>
<td></td>
<td>- Remember – a test result is only as good as the specimen received for testing.</td>
</tr>
<tr>
<td></td>
<td>MENTION the next module will cover the skills of collecting and handling Dry Blood Spots (DBS) as part of the re-testing process.</td>
</tr>
<tr>
<td>41</td>
<td><strong>Summary</strong></td>
</tr>
<tr>
<td></td>
<td>ASK participants to answer the questions on the slide.</td>
</tr>
<tr>
<td></td>
<td>ANSWER any questions participants may have.</td>
</tr>
</tbody>
</table>
Module 14: Blood Collection and Handling – DBS

Purpose
To provide the participants with skills to collect and handle dried blood spots (DBS) for EQA purposes

Pre-requisite Modules
- Module 6: Safety at HIV Rapid Testing Site
- Module 8: Blood Collection – Fingerprick
- Module 13: EQA

Module Time
1 ½ hours

Learning Objectives
At the end of this module, participants will be able to:
- Collect dried blood spots (DBS)
- Package and store DBS in a way to maintain specimen integrity
- Maintain DBS records
- Distinguish between valid and invalid DBS

Module Overview

<table>
<thead>
<tr>
<th>Step</th>
<th>Time</th>
<th>Activity/Method</th>
<th>Content</th>
<th>Resources Needed</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>5 min</td>
<td>Presentation</td>
<td>Module introduction</td>
<td>Slides 1-7</td>
</tr>
<tr>
<td>2</td>
<td>20 min</td>
<td>Presentation; Activity; Demonstration</td>
<td>Procedures for collecting, drying, packaging, and storing DBS</td>
<td>Slide 8-20; DBS supplies (for display and demonstration)</td>
</tr>
<tr>
<td>3</td>
<td>10 min</td>
<td>Presentation; Discussion</td>
<td>Valid vs. invalid DBS</td>
<td>Slides 21-29</td>
</tr>
<tr>
<td>4</td>
<td>50 min</td>
<td>Demonstration; Practice Exercise</td>
<td>Collecting DBS</td>
<td>Slide 30-32; DBS supplies (for practice)</td>
</tr>
<tr>
<td>5</td>
<td>5 min</td>
<td>Q&amp;A</td>
<td>Summary</td>
<td>Slide 33</td>
</tr>
</tbody>
</table>

Material/Equipment Checklists
- PowerPoint slides or transparencies
- Overhead projector or computer w/LCD projector
- Prepared Flipchart – content outline
- One-pager job aid for finger prick
- Handout: Example Specimen Transfer Log for Re-Testing
- Materials and supplies required for collecting and handling DBS. Have enough sets for participant inspection, demonstration and hands-on practices.
<table>
<thead>
<tr>
<th>Slide Number</th>
<th>Teaching Points</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Customization Notes</strong></td>
<td>SIMPLIFY this module if participants already know how to collect and handle DBS. But make sure they all follow the standard procedures outlined in this module.</td>
</tr>
</tbody>
</table>
| 1 | **Module 14: Blood Collecting and Handling (DBS)**  
DISPLAY this slide before you begin the module. Make sure participants are aware of the transition into a new module. |
| 2 | **What Is a Dried Blood Spot (DBS)?**  
STATE the bullets on the slide.  
EXPLAIN why DBS samples are useful for re-testing. They are:  
- Easy to collect  
- Easy to store  
- Easy to transport |
| 3 | **EQA Re-testing**  
REMIND participants that two types of specimens may be collected at the site for referral to a reference lab for re-testing: serum/plasma or dried blood spots (DBS).  
This module focuses on DBS.  
REVIEW EQA re-testing. |
| 4 | **Learning Objectives**  
STATE the objectives on the slide. |
| 5 | **Content Overview**  
EXPLAIN the topics that will be covered in this module. |
| **Flipchart** | WRITE the content outline on a flipchart prior to training.  
REFER to it frequently to orient participants to where they are in the module. |
| 6 | **What Are Your Responsibilities?**  
STATE the tester’s (or lab technician’s) job responsibilities related to collecting and handling EQA specimens.  
EMPHASIZE the importance of the specimen quality – a test result is only as good as the specimen collected. |
<table>
<thead>
<tr>
<th>Slide Number</th>
<th>Teaching Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>7 EQA Specimen Transfer Log</td>
<td>REFER participants to form in their manual. EMPHASIZE the importance of accurate data entry. PROVIDE examples of typical transcription errors.</td>
</tr>
<tr>
<td>8 Required Supplies for DBS</td>
<td>DESCRIBE the supply items on the slide and what each is used for. EMPHASIZE that while the collection card may include 5 circles, only one patient/client’s blood may be collected on one card. MENTION other supplies required:</td>
</tr>
<tr>
<td>Activity 3 minutes</td>
<td>PASS around the supply items for all participants to examine.</td>
</tr>
<tr>
<td>9 How to Collect DBS</td>
<td>REVIEW Universal Safety Precautions.</td>
</tr>
<tr>
<td></td>
<td>ASK “What are some key safety practices you need to keep in mind when collecting blood?” WRITE their answers on a flipchart. ENSURE the following items are covered:</td>
</tr>
<tr>
<td></td>
<td>▪ Treat all blood samples as though they are infectious</td>
</tr>
<tr>
<td></td>
<td>▪ Wash hands</td>
</tr>
<tr>
<td></td>
<td>▪ Wear gloves and apron/lab coat</td>
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<td></td>
<td>▪ Take precaution to avoid needle injury</td>
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<td>▪ Dispose of contaminated sharps and waste appropriately</td>
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<td>Slide Number</td>
<td>Teaching Points</td>
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<td></td>
<td>EMPHASIZE the importance of labeling all blood collection cards. It is unacceptable to submit a blood card for testing that has not been properly labeled. EMPHASIZE AGAIN that while the collection card may include 5 circles, only one patient/client’s blood may be collected on one card.</td>
</tr>
<tr>
<td></td>
<td>STATE DBS collection is usually done through finger prick. REVIEW finger prick procedures ASK participants to recall the steps in the procedures. REFERENCE the job aid for finger prick.</td>
</tr>
<tr>
<td></td>
<td>DESCRIBE the procedure for collecting DBS. • Apply gentle pressure to the finger and allow a large drop of free flowing blood to collect at the puncture site. • Working quickly, hold the filter paper by the edges and touch the filter paper gently against the large drop of blood and in one step allow a sufficient quantity of blood to soak through and completely fill or saturate a circle. A completed saturated spot will contain 100 µl of blood. • Repeat, until you have collected enough blood to fill at least 3 circles on the blood collection card. • Completing filling the circle is important because the laboratory will need to use a hole puncher to punch a section of the circle of blood for testing • If collecting spots using a pipette, collect 100 µl of blood and gently apply to filter paper. ADD the following tips: • DO NOT press the filter paper against the puncture site. • Apply blood to only one side of the filter paper. • Do not layer successive drops of blood or apply blood more than once in the same collection circle. • Do not “milk” the finger as excessive milking or squeezing the puncture site might cause hemolysis of the specimen or result in collection of tissue fluids with the specimen, which might adversely affect the test result. (NOTE: “hemo-” means red cells, “-lysis” means destruction, “hemolysis” means destruction of red cells.)</td>
</tr>
<tr>
<td></td>
<td>INFORM participants they are going to practice at the end of the module.</td>
</tr>
<tr>
<td>Slide Number</td>
<td>Teaching Points</td>
</tr>
<tr>
<td>--------------</td>
<td>-----------------</td>
</tr>
<tr>
<td>10</td>
<td><strong>How to Dry DBS</strong>&lt;br&gt;EXPLAIN the DBS should be dried at room temp horizontally. In addition to keeping away from direct sunlight, the spots should be protected from dust and in some cases flying insects. Care should be taken to avoid exposing DBS to environmental conditions that may compromise the integrity of the specimen. An example might be drying the spots near an open window. Why? Sunlight and dust may come in contact with the DBS during the drying procedure.</td>
</tr>
<tr>
<td>11</td>
<td><strong>Dry Completely Before Packaging</strong>&lt;br&gt;PROVIDE the following points:&lt;br&gt;• There are several ways in which you can effectively dry DBS&lt;br&gt;• The image on the left is one that was taken in India. DBS are dried horizontally between bamboo.&lt;br&gt;• The image on the right can be obtained from Schleicher &amp; Schuell Bioscience, Inc. (Manufacturer of DBS collection cards)&lt;br&gt;• DBS change from bright red to dark red as they dry.</td>
</tr>
<tr>
<td>12</td>
<td><strong>How to Package DBS for storage</strong>&lt;br&gt;PROVIDE an overview of the steps.</td>
</tr>
<tr>
<td>13-17, 19</td>
<td><strong>Demonstration</strong>&lt;br&gt;DEMONSTRATE each step with actual items as you show each slide.</td>
</tr>
<tr>
<td>13</td>
<td><strong>1. Stacking DBS</strong>&lt;br&gt;EXPLAIN placing weighing or glycine paper between DBS cards before transport prevents cross-contamination.</td>
</tr>
<tr>
<td>14</td>
<td><strong>2. Insert Into Sealable Plastic Bag</strong>&lt;br&gt;STATE you can typically place up to 15 DBS cards in each plastic bag. The bag should be just the right size to hold the cards. Avoid using bags that are too big as the cards will shuffle inside the bag.&lt;br&gt;EMPHASIZE that sandwich bags will not work as many of these are of the type where you fold the top. The bag should be a sealable heavy duty plastic bag, one that will prevent moisture from entering.</td>
</tr>
<tr>
<td>Slide Number</td>
<td>Teaching Points</td>
</tr>
<tr>
<td>--------------</td>
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</tr>
</tbody>
</table>
| 15           | **3. Add Desiccant Packets**  
Desiccant packets serve as a drying agent.  
STATE at least 5 desiccant packs should be placed in each bag. Some sites may need more or fewer packets in each bag depending on environmental and storage conditions.  
POINT OUT that desiccant packets vary in size. The ones seen here are the smaller ones. |
| 16           | **4. Add Humidity Cards and Seal Bag**  
STATE - Often humidity cards must be recharged before use.  
EXPLAIN what to do if the humidity card is pink at the 30% level.  
- Recharge card and desiccant pack by heating at 50-60 °C for 3-4 hours in a drying oven.  
- Cool 10 minutes.  
- IMMEDIATELY RETURN card and desiccant pack to sealable plastic bag.  
- Note: If a drying oven is not available, place cards and excessive number of desiccant packets in a sealable bag or envelope |
| 17           | **5. Label Outside of Plastic Bag with Contents**  
STATE permanent marker should be used to clearly label the contents on the bag. |
| 18           | **How to Store DBS**  
STATE the points on the slide.  
It is also acceptable to store DBS in a Styrofoam box.  
Avoid placing spots in an malfunctioning refrigerator where water may drip on or soak the spots |
| 19           | **How to Package DBS for Shipping**  
DESCRIBE the steps on the slide.  
POINT OUT the sealable plastic bag has a label on the outside indicating bio-hazardous contents. |
| 20           | **EQA Specimen Transfer Log**  
STATE the transfer log is sent out with the specimens. |
<table>
<thead>
<tr>
<th>Slide Number</th>
<th>Teaching Points</th>
</tr>
</thead>
</table>
| **TIPS 21-30** | Use interactive teaching technique for these slides. Facilitate group discussions about what makes a specimen valid or invalid. For example, when showing an invalid DBS specimen, ask:  
  - “Why do you think this specimen is not acceptable?”  
  - “What do you think may have caused it to become invalid?” |
| **21 Valid DBS Specimen** | EXPLAIN the specimen is valid because:  
  - 100 µl of blood has been collected in each circle completely saturating or filling the circle  
  - The filter paper card has been labeled with appropriate identification.  
  - If you look at the other side of the card, you will see blood soaked through to the other side. |
| **22 Valid DBS Specimen** | DISCUSS why this specimen is valid:  
  - On the card with MB/KP/120, the blood is spreading from one circle to another due to the anemia (anemic blood is more fluid)  
  - This is still considered a valid specimen. Blood has completely filled the circle.  
POINT OUT to the participants that the third and fifth circles have been punched (hence the white area in the middle). |
| **23 Invalid DBS Specimen** | DISCUSS why this specimen is invalid – insufficient quantity for testing.  
DISCUSS what may have caused it:  
  - Removing filter paper before blood has completely filled circle or before blood has soaked through to the other side  
  - Applying blood to filter paper with a capillary tube  
  - Filter paper coming in contact with gloved or ungloved hands or substances such as hand lotion or powder, either before or after blood specimen collection |
<table>
<thead>
<tr>
<th>Slide Number</th>
<th>Teaching Points</th>
</tr>
</thead>
</table>
| 24           | **Invalid DBS Specimen**  
DISCUSS why this specimen is invalid – specimen appears scratched or abraded.  
DISCUSS what may have caused it – applying blood with a capillary tube or other device. |
| 25           | **Invalid DBS Specimen**  
DISCUSS why this specimen is invalid – specimen not dry before mailing.  
DISCUSS what may have caused it – mailing specimen before drying for a minimum of 4 hours. |
| 26           | **Invalid DBS Specimen**  
DISCUSS why this specimen is invalid – specimen appears clotted or layered.  
DISCUSS what may have caused it:  
- Touching the same circle on the filter paper to blood drop several times  
- Filling circle on both sides of filter paper  
  The volume of specimen will not be uniform between spots resulting in errors during the testing process. |
| 27           | **Invalid DBS Specimen**  
DISCUSS why this specimen is invalid – specimen appears hemolyzed, discolored, or contaminated.  
DISCUSS what may have caused it:  
- Squeezing or “milking” of area surrounding the puncture site  
- Allowing filter paper to come in contact with glove or ungloved hands or substances either before or after blood collection  
- Exposing blood spots to direct heat |
<table>
<thead>
<tr>
<th>Slide Number</th>
<th>Teaching Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>28</td>
<td>Invalid DBS Specimen</td>
</tr>
<tr>
<td></td>
<td>DISCUSS why this specimen is invalid. The specimen exhibits serum rings, in other words, serum becomes separate from cells.</td>
</tr>
<tr>
<td></td>
<td>DISCUSS what may have caused it:</td>
</tr>
<tr>
<td></td>
<td>• Not allowing alcohol to dry at puncture site before making skin puncture</td>
</tr>
<tr>
<td></td>
<td>• Allowing filter paper to come in contact with alcohol, hand lotion, etc.</td>
</tr>
<tr>
<td></td>
<td>• Squeezing area surrounding puncture site excessively</td>
</tr>
<tr>
<td></td>
<td>• Drying specimen improperly</td>
</tr>
<tr>
<td></td>
<td>• Applying blood to filter paper with a capillary tube</td>
</tr>
<tr>
<td>29</td>
<td>Invalid DBS Specimen</td>
</tr>
<tr>
<td></td>
<td>DISCUSS why this specimen is invalid – no blood.</td>
</tr>
<tr>
<td></td>
<td>DISCUSS what may have caused it – failure to obtain blood specimen.</td>
</tr>
<tr>
<td>30</td>
<td>DBS Collection: Demonstration</td>
</tr>
<tr>
<td>Demonstration</td>
<td>PROVIDE an overview of the steps.</td>
</tr>
<tr>
<td>10 Minutes</td>
<td>REFERENCE the fingerprick steps using the job aid.</td>
</tr>
<tr>
<td></td>
<td>REMIND participants of the tips</td>
</tr>
<tr>
<td></td>
<td>DEMONSTRATE the DBS procedure step by step.</td>
</tr>
</tbody>
</table>

**TIPS**

Depending on the number of participants you have and the number of instructors available, you may want to break the participants into smaller groups for the demonstration.

When demonstrating,

- Show each step slowly and methodically.
- Talk out loud as you perform, but keep your statements brief.
- Repeat the procedure a few times, making sure each time you do exactly the same thing so you don’t confuse participants.
- Share tips from your experience.
<table>
<thead>
<tr>
<th>Slide Number</th>
<th>Teaching Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>31 Practice</td>
<td>DBS Collection: Hands-on Practice</td>
</tr>
<tr>
<td>35 minutes</td>
<td>CONDUCT the practice session.</td>
</tr>
<tr>
<td></td>
<td>INFORM participants what they are going to do.</td>
</tr>
<tr>
<td></td>
<td>DISTRIBUTE to all participants the supplies required to perform DBS collection.</td>
</tr>
<tr>
<td></td>
<td>POINT OUT the instructions on the slide.</td>
</tr>
<tr>
<td></td>
<td>SIGNAL when it is time to switch (every 15 minutes).</td>
</tr>
<tr>
<td></td>
<td>MONITOR the practice and provide necessary assistance to participants.</td>
</tr>
<tr>
<td></td>
<td>DEBRIEF by:</td>
</tr>
<tr>
<td></td>
<td>• POINTING out the commonly-made mistakes you have observed during the practice session.</td>
</tr>
<tr>
<td></td>
<td>• ASKING participants to share their experience and key learning from the practice.</td>
</tr>
<tr>
<td></td>
<td>• REASSURING participants that they will improve as they gain more experience</td>
</tr>
<tr>
<td>TIPS</td>
<td>Be prepared to provide plenty of personal attention to participants during hands-on practice. This is particularly important when teaching people without health or lab background.</td>
</tr>
<tr>
<td></td>
<td>Set up the groups in such a way that you are able to monitor 3 or 4 groups at a time.</td>
</tr>
<tr>
<td>32 Exercise</td>
<td>Exercise: Valid vs. Invalid DBS</td>
</tr>
<tr>
<td>5 minutes</td>
<td>LAY on a table all the DBS samples collected from the hands-on practice.</td>
</tr>
<tr>
<td></td>
<td>ASK participants to examine these samples, determine whether each is valid or not, and write their answers on a piece of paper.</td>
</tr>
<tr>
<td></td>
<td>DISCUSS the answers as a group.</td>
</tr>
<tr>
<td>33 Summary</td>
<td>ASK participants to answer the questions on the slide.</td>
</tr>
<tr>
<td></td>
<td>ANSWER any questions participants may have.</td>
</tr>
</tbody>
</table>
Module 15: Documents and Records

**Purpose**
To help participants understand the role documents and records play in the quality system and the monitoring of programs.

**Pre-requisite Modules**
- Module 5: Assuring the Quality of HIV Rapid Testing

**Module Time**
30 minutes

**Learning Objectives**
At the end of this module, participants will be able to:
- Tell the difference between a document and a record
- Explain the rationale for following documents and keeping records
- Provide examples of documents and records kept at a test site
- Follow the procedures as prescribed in SOPs
- Describe how to properly keep and maintain test site documents and records
- Describe the types of information typically not found in a manufacturer’s product insert

**Module Overview**

<table>
<thead>
<tr>
<th>Step</th>
<th>Time</th>
<th>Activity/Method</th>
<th>Content</th>
<th>Resources Needed</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>3 min</td>
<td>Presentation</td>
<td>Module introduction</td>
<td>Slides 1-4</td>
</tr>
<tr>
<td>2</td>
<td>4 min</td>
<td>Presentation Exercise</td>
<td>Documents vs. records</td>
<td>Slide 5-7</td>
</tr>
<tr>
<td>3</td>
<td>10 min</td>
<td>Presentation Discussion</td>
<td>Documents</td>
<td>Slides 8-14; manufacturer product inserts</td>
</tr>
<tr>
<td>4</td>
<td>10 min</td>
<td>Presentation</td>
<td>Records</td>
<td>Slides 15-22</td>
</tr>
<tr>
<td>5</td>
<td>3 min</td>
<td>Presentation Q&amp;A</td>
<td>Summary Key messages</td>
<td>Slide 23-24</td>
</tr>
</tbody>
</table>

**Material/Equipment Checklists**
- PowerPoint slides or transparencies
- Overhead projector or computer w/LCD projector
- Prepared Flipchart – content outline
- Handout: Client Test Record (please be prepared to show a form used locally)
- Manufacturer product inserts from test kits (enough copies to pass around)
### In general, this module must be customized with in-country examples of documents and records and site-specific information on how to keep and maintain records.

<table>
<thead>
<tr>
<th>Slide Number</th>
<th>Teaching Points</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Customization Notes</strong></td>
<td>In general, this module must be customized with in-country examples of documents and records and site-specific information on how to keep and maintain records.</td>
</tr>
<tr>
<td>1</td>
<td><strong>Module 15: Documents and Records</strong></td>
</tr>
<tr>
<td></td>
<td>DISPLAY this slide before you begin the module. Make sure participants are aware of the transition into a new module.</td>
</tr>
<tr>
<td>2</td>
<td><strong>The Quality System</strong></td>
</tr>
<tr>
<td></td>
<td>REMIND participants that Documents and Records is a component of the Lab Quality System.</td>
</tr>
<tr>
<td></td>
<td>• Documents and Records is an essential component of the Quality System. As a matter of fact, it is the backbone of the quality system.</td>
</tr>
<tr>
<td></td>
<td>• Documents communicate the policies and procedures that should be followed at each test site. This is important for assuring consistency and accuracy at the test site.</td>
</tr>
<tr>
<td>3</td>
<td><strong>Learning Objectives</strong></td>
</tr>
<tr>
<td></td>
<td>STATE the objectives on the slide.</td>
</tr>
<tr>
<td>4</td>
<td><strong>Content Overview</strong></td>
</tr>
<tr>
<td></td>
<td>EXPLAIN the topics that will be covered in this module.</td>
</tr>
<tr>
<td></td>
<td><strong>Flipchart</strong></td>
</tr>
<tr>
<td></td>
<td>WRITE the content outline on a flipchart prior to training. REFER to it frequently to orient participants to where they are in the module.</td>
</tr>
<tr>
<td>Slide Number</td>
<td>Teaching Points</td>
</tr>
<tr>
<td>--------------</td>
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</tr>
</tbody>
</table>
| 5            | **What Are Documents and Records?**  
STATE the points on the slide and ADD the following information:  
- Documents are written instructions for HOW TO do a specific task  
- Blank forms are also considered documents. Forms are used to capture data or information from performing a procedure.  
- Records are generated when written instructions are followed. In other words, after data, information, or results are recorded onto a form, label, etc, then it becomes a record.  
- Documents and records may be paper or electronic. |
| Exercise 6-7 | **Exercise: Differentiate Between Documents and Records**  
DISPLAY slide 6.  
ASK participants to look at the list on the slide for a minute and think about which item is an example of documents versus records.  
Go through each item as a group soliciting answers.  
DISPLAY slide 7 to show the correct answers (items in yellow are examples of documents and items in white are records).  
ANSWER any questions participants may have before moving on. |
| 8            | **Documents Are the Backbone of the Quality System**  
STATE the points on the slide. |
| 9            | **Standard Operating Procedures (SOPs) Are Documents that...**  
EXPLAIN SOPs are one type of document. Using SOPs results in reliable and consistent results. |
<p>| 10           | Customize slide #10 by replacing the sample SOP page on the slide with a page from a real in-country SOP. |</p>
<table>
<thead>
<tr>
<th>Slide Number</th>
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</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td><strong>SOPs Are Controlled Documents</strong>&lt;br&gt;DESCRIBE “controlled documents.”&lt;br&gt;EXPLAIN that key features of SOPs include:&lt;br&gt;• Cover page&lt;br&gt;• Descriptive Title&lt;br&gt;• SOP number&lt;br&gt;• Version Number&lt;br&gt;• Date when SOP become effective&lt;br&gt;• Signature of person responsible for writing the SOP&lt;br&gt;• Signature of person authorizing the SOP</td>
</tr>
<tr>
<td>11-12</td>
<td><strong>Customization Notes</strong>&lt;br&gt;ADD the following in-country information about SOPs:&lt;br&gt;• Who develops&lt;br&gt;• How distributed&lt;br&gt;• Process for updating</td>
</tr>
<tr>
<td>11</td>
<td><strong>What SOPs Should You Keep at a Test Site?</strong>&lt;br&gt;EXPLAIN each test site should have on hand current/approved SOPs. These are typical SOPs kept at a test site.&lt;br&gt;READ the examples on the slide.</td>
</tr>
<tr>
<td>12</td>
<td><strong>What SOPs Should You Keep at a Test Site? – Cont’d</strong>&lt;br&gt;READ the examples on the slide.</td>
</tr>
<tr>
<td>13</td>
<td><strong>SOPs Must Be Followed</strong>&lt;br&gt;PROVIDE examples of consequences of not following SOPs.&lt;br&gt;• Not following safety precautions poses unnecessary risk to self, client and the environment&lt;br&gt;• Reporting inaccurate results – negative impact on client and family&lt;br&gt;• Breach of ethical conduct</td>
</tr>
<tr>
<td>Activity</td>
<td>PAS AROUND manufacturer product inserts (from test kits) for participants to examine.&lt;br&gt;DISCUSS what information is included in the inserts and what is not.</td>
</tr>
<tr>
<td>14</td>
<td><strong>Do Not Rely Solely on Manufacturer Product Inserts</strong>&lt;br&gt;CONCLUDE the activity by pointing out the information on the slide.</td>
</tr>
<tr>
<td>Slide Number</td>
<td>Teaching Points</td>
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<tr>
<td>--------------</td>
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</tr>
<tr>
<td><strong>15</strong></td>
<td><strong>Proper Record-Keeping Makes Quality Management Possible</strong></td>
</tr>
<tr>
<td></td>
<td>EXPLAIN the points on the slide.</td>
</tr>
<tr>
<td></td>
<td>- Communicate accurately and effectively - Record keeping enables sites to be timely in reporting to program managers and site supervisors</td>
</tr>
<tr>
<td></td>
<td>- Minimize error – All records must be written.</td>
</tr>
<tr>
<td></td>
<td>- Monitor quality system – Records allow for periodic review of testing operations. Only through the review of records can improvements be identified.</td>
</tr>
<tr>
<td><strong>16</strong></td>
<td><strong>What Records Should You Keep at a Test Site?</strong></td>
</tr>
<tr>
<td></td>
<td>STATE the list on the slide.</td>
</tr>
<tr>
<td><strong>17</strong></td>
<td><strong>Tips for Good Record Keeping</strong></td>
</tr>
<tr>
<td></td>
<td>STATE the points on the slide.</td>
</tr>
<tr>
<td></td>
<td>- <strong>Understand the information to be collected.</strong> Before you record any information, make sure that you understand what is to be collected</td>
</tr>
<tr>
<td></td>
<td>- <strong>Record the information every time.</strong> Record on the appropriate form each time you perform a procedure.</td>
</tr>
<tr>
<td></td>
<td>- <strong>Record all the information.</strong> Make sure you have provided all the information requested on a form.</td>
</tr>
<tr>
<td></td>
<td>- <strong>Record the information the same way every time.</strong> Be consistent in how you record information.</td>
</tr>
<tr>
<td><strong>Customization Notes</strong></td>
<td>Customize slide #18 by replacing the sample client test record on the slide with a real in-country one.</td>
</tr>
<tr>
<td>Slide Number</td>
<td>Teaching Points</td>
</tr>
<tr>
<td>--------------</td>
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</tr>
<tr>
<td><strong>18</strong></td>
<td><strong>Client Test Records</strong>&lt;br&gt;POINT OUT types of information captured on test records and the proper way to complete the information:&lt;br&gt;• Client/Patient ID #&lt;br&gt;• Date of test&lt;br&gt;• Test 1 result&lt;br&gt;• Test 2 result&lt;br&gt;• Test 3 result&lt;br&gt;• Repeat results&lt;br&gt;• HIV Status&lt;br&gt;• Kit Name &amp; Lot #&lt;br&gt;• Person performing test&lt;br&gt;MENTION any commonly made mistakes</td>
</tr>
<tr>
<td><strong>19</strong></td>
<td><strong>Customization Notes</strong>&lt;br&gt;Customize slide #19 with in-country policy and information regarding record retention.</td>
</tr>
<tr>
<td><strong>19</strong></td>
<td><strong>How Long Should You Retain Client Records?</strong>&lt;br&gt;STATE points on the slide&lt;br&gt;DISCUSS importance of maintaining secure storage for all records</td>
</tr>
<tr>
<td><strong>20</strong></td>
<td><strong>Logbooks Are Cumulative Records of Test Site Operations</strong>&lt;br&gt;EXPAND the points on the slide:&lt;br&gt;• These photos of logbooks are common. Storage of logbooks and records should be kept in a manner that will minimize deterioration.&lt;br&gt;• Note also that although many sites used paper-based logbooks and records, they should be indexed so to allow for easy retrieval.&lt;br&gt;• Note the From and To Dates.</td>
</tr>
<tr>
<td><strong>21</strong></td>
<td><strong>Records Should be Permanent, Secure, Traceable</strong>&lt;br&gt;STATE facilities where records are kept should be secure to maintain patient/client confidentiality. Procedures and mechanisms should be that prevents unauthorized access.</td>
</tr>
<tr>
<td>Slide Number</td>
<td>Teaching Points</td>
</tr>
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<td>--------------</td>
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</tbody>
</table>
| **Customization Notes** | Customize slide #22 with specific in-country information related to the reporting processes:  
- What will be reported?  
- When will it be reported?  
- How will it be reported?  
- Whom will it be reported to?  
- How will the data be used? |
| 22 | **Information Recorded will Feed Into Monitoring and Evaluation Systems**  
EXPLAIN records must be kept permanent, secure, and traceable because they will be used for reporting and monitoring purposes.  
- Monitoring is the routine tracking of program information  
- Accurate facility records provide essential information for providing quality health care and monitoring PMTCT programs.  
- It is recommended that you analyze on a monthly basis the number of clients served and summarize the test results. |
| 23 | **Summary**  
ASK participants to answer the questions on the slide. |
| 24 | **Key Messages**  
STATE the key messages on the slide.  
ANSWER any questions participants may have. |
Module 16: Professional Ethics

Purpose
To provide participants with the necessary attitudes, motivation, and knowledge to apply ethical conduct to HIV rapid testing.

Pre-requisite Modules
Module 5. Assuring Quality of HIV Rapid Testing

Module Time
45 minutes

Learning Objectives
At the end of this module, you will be able to:
- Describe ethical issues related to HIV rapid testing
- Explain the importance of professional ethics
- Apply ethical conduct to HIV rapid testing
- Take appropriate actions to maintain client confidentiality

Module Overview

<table>
<thead>
<tr>
<th>Step</th>
<th>Time</th>
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<th>Content</th>
<th>Resources Needed</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2 min</td>
<td>Presentation</td>
<td>Module introduction</td>
<td>Slides 1-3; Prepared flipchart – content outline</td>
</tr>
<tr>
<td>2</td>
<td>30 min</td>
<td>Presentation Discussion Role-play</td>
<td>Ethical issues in HIV rapid testing; what and why important</td>
<td>Slides 4-12 Setup for role-play</td>
</tr>
<tr>
<td>3</td>
<td>10 min</td>
<td>Presentation Discussion</td>
<td>Applying ethics to HIV rapid testing</td>
<td>Slide 13-16</td>
</tr>
<tr>
<td>4</td>
<td>3 min</td>
<td>Q&amp;A</td>
<td>Summary Key messages</td>
<td>Slide 17-18</td>
</tr>
</tbody>
</table>

Material/Equipment Checklists:
- PowerPoint slides or transparencies
- Overhead projector or computer w/LCD projector
- Flipchart
- Handouts:
  - Guidelines for Ethical Behavior (ASCP)
  - Code of Ethics (IFBLS Code of Ethics)
### Teaching Guide

<table>
<thead>
<tr>
<th>Slide Number</th>
<th>Teaching Points</th>
</tr>
</thead>
</table>
| 1            | **Module 16: Professional Ethics**  
DISPAY this slide before you begin the module. Make sure participants are aware of the transition into a new module. |
| 2            | **Learning Objectives**  
STATE the objectives on the slide |
| 3            | **Content Overview**  
EXPLAIN the topics that will be covered in this module. |
| Flipchart    | WRITE the content outline on a flipchart prior to training.  
REFER to it frequently to orient participants to where they are in the module. |
| TIPS 4-6     | These three slides are introduced before ethics is defined (in slide #8). The intent is to provide the context and examples of the ethical dilemma that participants will likely face on their job. These examples will help them better grasp the abstract concept of ethics. Facilitate a discussion around each scenario. |
| 4            | **Scenario I**  
ASK a participant (or volunteer) to read the scenario on the slide.  
FACILITATE a discussion.  
ASK participants:  
- What are the issues here?  
- What is the right thing to do?  
- What are the consequences if you don’t do the right thing?  
- How hard is it for you to do the right thing?  
WRITE participant responses on the flipchart. |
<table>
<thead>
<tr>
<th>Slide Number</th>
<th>Teaching Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td><strong>Scenario II</strong></td>
</tr>
<tr>
<td>Flipchart</td>
<td>ASK a participant (or volunteer) to read the scenario on the slide.</td>
</tr>
<tr>
<td></td>
<td>FACILITATE a discussion.</td>
</tr>
<tr>
<td></td>
<td>ASK participants:</td>
</tr>
<tr>
<td></td>
<td>▪ What are the issues here?</td>
</tr>
<tr>
<td></td>
<td>▪ What is the right thing to do?</td>
</tr>
<tr>
<td></td>
<td>▪ What are the consequences if you don’t do the right thing?</td>
</tr>
<tr>
<td></td>
<td>▪ How hard is it for you to do the right thing?</td>
</tr>
<tr>
<td></td>
<td>WRITE participant responses on the flipchart.</td>
</tr>
<tr>
<td>6</td>
<td><strong>Scenario III</strong></td>
</tr>
<tr>
<td>Flipchart</td>
<td>ASK a participant (or volunteer) to read the scenario on the slide.</td>
</tr>
<tr>
<td></td>
<td>FACILITATE a discussion.</td>
</tr>
<tr>
<td></td>
<td>ASK participants:</td>
</tr>
<tr>
<td></td>
<td>▪ What are the issues here?</td>
</tr>
<tr>
<td></td>
<td>▪ What is the right thing to do?</td>
</tr>
<tr>
<td></td>
<td>▪ What are the consequences if you don’t do the right thing?</td>
</tr>
<tr>
<td></td>
<td>▪ How hard is it for you to do the right thing?</td>
</tr>
<tr>
<td></td>
<td>WRITE participant responses on the flipchart.</td>
</tr>
<tr>
<td>Slide Number</td>
<td>Teaching Points</td>
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</tr>
<tr>
<td><strong>7</strong></td>
<td><strong>What Could Be the Consequences of...</strong></td>
</tr>
<tr>
<td></td>
<td>SUMMARIZE the discussion using this slide.</td>
</tr>
<tr>
<td></td>
<td>REFER participants back to the points captured on the flipchart.</td>
</tr>
<tr>
<td></td>
<td>STATE the following key points, if not already captured:</td>
</tr>
<tr>
<td></td>
<td>• A false positive HIV result can lead to:</td>
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<tr>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• A false negative result can lead to:</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Each result you report is connected to a patient/client.</td>
</tr>
<tr>
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<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• You must strive to do the right things right.</td>
</tr>
<tr>
<td><strong>8</strong></td>
<td><strong>What Is Ethics?</strong></td>
</tr>
<tr>
<td></td>
<td>STATE the definition on the slide.</td>
</tr>
<tr>
<td><strong>9</strong></td>
<td><strong>Why is Ethics Important?</strong></td>
</tr>
<tr>
<td></td>
<td>STATE the text on the slide.</td>
</tr>
<tr>
<td></td>
<td>CONCLUDE In other words if we do not apply a code of ethics the patient or someone else will suffer.</td>
</tr>
<tr>
<td><strong>10</strong></td>
<td><strong>Scenario IV</strong></td>
</tr>
<tr>
<td></td>
<td>STATE the scenario on the slide.</td>
</tr>
<tr>
<td></td>
<td>FACILITATE a discussion.</td>
</tr>
<tr>
<td></td>
<td>ASK participants:</td>
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<td></td>
<td>WRITE participant responses on the flipchart.</td>
</tr>
<tr>
<td>Slide Number</td>
<td>Teaching Points</td>
</tr>
<tr>
<td>--------------</td>
<td>-----------------</td>
</tr>
</tbody>
</table>
| 11           | **Maintaining Confidentiality**  
STATE the points on the slide.  
ADD the following points:  
  - Prior to testing, clients should be informed about the purpose, advantages, and disadvantages of testing. This process ensures understanding of the Counseling-Testing process.  
  - Keeping information confidential means that it is kept a secret from everyone.  
EMPHASIZE People often violate ethics not because they mean to, but because they are careless. Therefore, we must be extra vigilant about ethical conduct. |
| 12 (TIPS)    | Prior to the module (preferably a day or two before):  
  - IDENTIFY appropriate people (volunteers from participants or other facilitators) to play the roles.  
  - PREPARE them for the task by explaining the intent, plot, and background of the role-play.  
  - HELP them develop their script or lines for a 3-5 minute play.  
  - PROVIDE ample time for them to rehearse. The better prepared they are, the more successful the role-play will be, and the more impact it has on the participants.  
  - SECURE props for role-play, e.g., dining table, chairs, glasses, beer bottles, notepad for taking orders.  
**Plot for the Role-Play**  
Two friends (Kathy and Judy) from different test sites met for dinner one evening at a local restaurant. Their conversation evolved from the usual discussion about family into a discussion about work. Kathy commented that she felt sorry for Sue, a very pretty lady, who is now 5 months pregnant and was just diagnosed with HIV. |
<table>
<thead>
<tr>
<th>Slide Number</th>
<th>Teaching Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>12</td>
<td><strong>Role-Play</strong></td>
</tr>
<tr>
<td></td>
<td>INTRODUCE the role-play and the characters in the role-play.</td>
</tr>
<tr>
<td></td>
<td>• You are going to watch a role-play.</td>
</tr>
<tr>
<td></td>
<td>• There are two roles – Kathy and Judy. They are both community counselors and each works at a different HIV rapid testing site. They are meeting for dinner at a restaurant.</td>
</tr>
<tr>
<td></td>
<td>• The role-play will take about 3-5 minutes.</td>
</tr>
<tr>
<td></td>
<td>DISCUSS the questions on the slide.</td>
</tr>
<tr>
<td></td>
<td>DEBREIF by summarizing key discussion points.</td>
</tr>
<tr>
<td>13</td>
<td><strong>Who is Responsible for Ethics?</strong></td>
</tr>
<tr>
<td></td>
<td>ELABORATE the points on the slide.</td>
</tr>
<tr>
<td></td>
<td>• Everyone at a testing site plays a part.</td>
</tr>
<tr>
<td></td>
<td>• Your testing site may not have all the categories of staff mentioned, nevertheless anyone who plays a part in testing or has access to the test results must adhere to ethical conduct.</td>
</tr>
<tr>
<td></td>
<td>• They may cheat in some way, damage specimens, falsify results, or inform other people about results. Equally they can decide to ensure that specimens are delivered, recorded, stored and reported with high quality.</td>
</tr>
<tr>
<td>Slide Number</td>
<td>Teaching Points</td>
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<td>--------------</td>
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</tr>
</tbody>
</table>
| 14           | **How Do We Apply Ethics To HIV Rapid Testing?**  
PROVIDE the following examples.  
  - Work done  
    - Use only kits approved for use in country  
    - Ensure quality outputs – Following SOPs as written. If a test procedure calls for 20 minutes incubation or wait time, DON’T take shortcuts. Wait the full time before recording and reporting test results  
    - Keep supplies and kits in safekeeping. Unauthorized use of test kits outside of the testing site is prohibited.  
      - If you have questions, ASK.  
      - DO NOT falsify results.  
  - Behavior of staff - Testing staff should conduct themselves in a professional manner. Examples of professionalism include:  
    - Dressing appropriately. If lab coat of apron is soiled, change to a clean one  
    - Turning cell phones off. It is disruptive and not considerate of clients to talk on the phone during the course of testing.  
    - Not discussing results of interaction with clients with others. Maintaining patient confidentiality is a MUST.  
  - Behavior of management – Management sets the example or expectations of how staff should conduct themselves.  

**Customization Notes**  
If the country already has in place national policy on ethics or code of conduct, cite the specific legislation and replace slides 15-16. If not, use these two slides to guide discussion.

**Transition**  
EXPLAIN A Code of Ethics is an expression of basic values - the principles and standards by which you should conduct yourself  
STATE A number of laboratory professional organizations have code of ethics, with common principles of conduct. The next 2 slides highlight principles from IFBLS and ASCP
<table>
<thead>
<tr>
<th>Slide Number</th>
<th>Teaching Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>15</td>
<td><strong>Flipchart</strong></td>
</tr>
<tr>
<td></td>
<td><strong>Code of Ethics (IFBLS)</strong></td>
</tr>
<tr>
<td></td>
<td>DISCUSS each point on the slide. ASK:</td>
</tr>
<tr>
<td></td>
<td>• What does this mean to you?</td>
</tr>
<tr>
<td></td>
<td>• What personal action will you take to demonstrate this conduct?</td>
</tr>
<tr>
<td></td>
<td>WRITE participant responses on the flipchart.</td>
</tr>
<tr>
<td></td>
<td>STRESS the last point:</td>
</tr>
<tr>
<td></td>
<td>• Be accountable… you must take personal responsibility for everything you do…. be able to answer for your conduct and moral obligations to choose to do right over wrong.</td>
</tr>
<tr>
<td>16</td>
<td><strong>Flipchart</strong></td>
</tr>
<tr>
<td></td>
<td><strong>Code of Ethics (ASCP)</strong></td>
</tr>
<tr>
<td></td>
<td>DISCUSS each point on the slide. ASK:</td>
</tr>
<tr>
<td></td>
<td>• What does this mean to you?</td>
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<tr>
<td></td>
<td>• What personal action will you take to demonstrate this conduct?</td>
</tr>
<tr>
<td></td>
<td>WRITE participant responses on the flipchart.</td>
</tr>
<tr>
<td></td>
<td>CONCLUDE the discussion by summarizing key points from the flipchart.</td>
</tr>
<tr>
<td>17</td>
<td><strong>Summary</strong></td>
</tr>
<tr>
<td></td>
<td>ASK participants to answer the questions on the slide.</td>
</tr>
<tr>
<td>18</td>
<td><strong>Key Messages</strong></td>
</tr>
<tr>
<td></td>
<td>STATE the key messages on the slide.</td>
</tr>
<tr>
<td></td>
<td>ANSWER any questions participants may have.</td>
</tr>
</tbody>
</table>
Capillus HIV Rapid Test
For use with whole blood, serum, or plasma
Store Kits: 2 - 8 °C

- Check kit before use. Use only items that have not expired or been damaged.
- Bring kit and previously stored specimens to room temperature prior to use.
- Always use universal safety precautions when handling specimens. Keep work areas clean and organized.

This outline is not intended to replace the product insert or your standard operating procedure (SOP).

1. Collect test items and other necessary lab supplies.
2. Label the device with client identification number.
3. Place slide on the black interpretation card. Ensure that slide is right side up.
4. Gently mix the latex reagent well ensuring that it is homogenous.
5. Use the dropper to draw the latex reagent up to the calibration mark. Avoid drawing up air bubbles.
6. Dispense the reagent into the mixing well, away from the capillary channel. Do not allow the dropper to touch the slide.
7. Collect 10 µl of specimen using a new disposable pipette tip with the pre-calibrated pipette.
8. Hold the pipette directly over the well and dispense the specimen directly into the latex solution.
9. Mix the specimen and latex by pumping the mixture in and out of the tip 3 times. Stir in a circular motion at least 5 times.
10. Initiate the capillary flow by moving the mixture to the opening of the channel.
11. Allow the latex mixture to flow through the entire channel and into the viewing window (about 3-7 min.) before reading the results.
12. Read and record the results and other pertinent info on the worksheet.

**Capillus HIV Rapid Test Results**

- **Reactive**
  - Latex Aggregation – white clumping
- **Non-reactive**
  - No Latex Aggregation – no white clumping

Use of trade names and commercial sources is for identification only and does not imply endorsement by WHO, the Public Health Service, or by the U.S. Department of Health and Human Services (2005).
Determine HIV Rapid Test
(For use with whole blood, serum, or plasma)
Store kit: 2 - 30°C

- Check kit before use. Use only items that have not expired or been damaged.
- Bring kit and previously stored specimens to room temperature prior to use.
- Always use universal safety precautions when handling specimens. Keep work areas clean and organized.

This outline is not intended to replace the product insert or your standard operating procedure (SOP).

1. Collect test items and other necessary lab supplies.
2. Use 1 strip per test and be sure to preserve the lot number on the remaining packet of strips.
3. Label the test strip with client identification number.
4. Pull off the protective foil cover.
5. Collect 50 µl of specimen using either a pasteur or precision pipette.
6. Apply the specimen to the absorbent pad on the strip.
7. For whole blood only add 1 drop of chase buffer to the specimen pad.
8. Wait 15 minutes (no longer than 60 minutes) before reading the results.
9. Read and record the results and other pertinent info on the worksheet.

Determine HIV Rapid Test Results

Reactive
2 lines of any intensity appear in both the control and patient areas.

Non-reactive
1 line appears in the control area and no line in the patient area.

Invalid
No line appears in the control area. Do not report invalid results. Repeat test with a new test device even if a line appears in the patient area.

Use of trade names and commercial sources is for identification only and does not imply endorsement by WHO, the Public Health Service, or by the U.S. Department of Health and Human Services (2005).
Finger Prick

Always use universal safety precautions.

1. Collect supplies.

2. Position hand palm-side up. Choose whichever finger is least calloused.

3. Apply intermittent pressure to the finger to help the blood to flow.

4. Clean the fingertip with alcohol. Start in the middle and work outward to prevent contaminating the area. Allow the area to dry.

5. Hold the finger and firmly place a new sterile lancet off-center on the fingertip.

6. Firmly press the lancet to puncture the fingertip.

7. Wipe away the first drop of blood with a sterile gauze pad or cotton ball.

8. Collect the specimen. Blood may flow best if the finger is held lower than the elbow.

9. Apply a gauze pad or cotton ball to the puncture site until the bleeding stops.

10. Properly dispose of all contaminated supplies.

Use of trade names and commercial sources is for identification only and does not imply endorsement by WHO, the Public Health Service, or by the U.S. Department of Health and Human Services (2005).
Hema-Strip HIV Rapid Test
For use with whole blood, serum, or plasma
Store Kits: 2° - 30° C

- Check kit before use. Use only items that have not expired or been damaged.
- Bring kit and previously stored specimens to room temperature prior to use.
- Always use universal safety precautions when handling specimens. Keep work areas clean and organized.

This outline is not intended to replace the product insert or your standard operating procedure (SOP).

1. Collect test items and other necessary lab supplies.
2. Label device with the client identification number.
3. Collect specimen. Touch specimen with device tip until tip is full.
4. Remove buffer vial – separate from top of device.
5. Place buffer vial on a flat surface.
6. Firmly press the device tip through the foil cover. Continue pushing device, usually 2 more times, to the bottom of vial until device and buffer vial snap together tightly.
7. Place the test device upright in a rack.
8. Wait 15 minutes before reading the results.
9. Read and record the results and other pertinent info on the worksheet.

Hema-Strip Rapid HIV Test Results

**Reactive**
2 lines of any intensity appear in both the control and client areas.

**Non-reactive**
1 line appears in the control area and no line in the client area.

**Invalid**
No line appears in the control area. Do not report invalid results. Repeat test with a new test device even if a line appears in the client area.

Use of trade names and commercial sources is for identification only and does not imply endorsement by WHO, the Public Health Service, or by the U.S. Department of Health and Human Services (2005).
OraQuick HIV Rapid Test
For use with whole blood, serum or plasma
Store Kits: 2 - 30°C

- Check kit before use. Use only items that have not expired or been damaged.
- Bring kit and previously stored specimens to room temperature prior to use.
- Always use universal safety precautions when handling specimens. Keep work areas clean and organized.

This outline is not intended to replace the product insert or your standard operating procedure (SOP).

1. Collect test items and other necessary lab supplies.
2. Set reusable stand on a flat, level surface. Partially remove device from package and label device and the developer vial with client identification number.
3. Carefully uncap the developer vial and place vial into the stand.
4. Collect approximately 5 µl of specimen using a new disposable loop.
5. Transfer the collected specimen to the vial.
6. Stir the specimen in the vial with the loop.
7. Insert the device pad completely into the vial with the result window facing forward.
8. Wait 20 minutes (no longer than 40 min.) before reading the results.
9. Read and record the results and other pertinent info on the worksheet.

OraQuick HIV Rapid Test Results

- **Reactive**
  - 2 lines of any intensity appear in both the control and test areas.

- **Non-reactive**
  - 1 line appears in the control area and no line in the test area.

- **Invalid**
  - No line appears in the control area. Do not report invalid results. Repeat test with a new test device even if a line appears in the test area.

Use of trade names and commercial sources is for identification only and does not imply endorsement by WHO, the Public Health Service, or by the U.S. Department of Health and Human Services (2005).
OraQuick HIV Rapid Test
For use with oral fluids
Store Kits: 2 - 30° C

- Check kit before use. Use only items that have not expired or been damaged.
- Bring kit and previously stored specimens to room temperature prior to use.
- Always use universal safety precautions when handling specimens. Keep work areas clean and organized.

This outline is not intended to replace the product insert or your standard operating procedure (SOP).

1. Collect test items and other necessary lab supplies.
2. Set reusable stand on a flat, level surface. Partially remove device from package and label device and developer vial with client identification number.
3. Carefully uncap the developer vial and place vial into the stand.
4. Instruct the client to use the pad end of the test device to swab completely across the outside of the upper and lower gums, one time around.
5. Insert the device pad completely into the vial with the result window facing forward.
6. Wait 20 minutes (no longer than 40 min.) before reading the results.
7. Read and record the results and other pertinent info on the worksheet.

OraQuick HIV Rapid Test Results

**Reactive**
2 lines of any intensity appear in both the control and test areas.

**Non-reactive**
1 line appears in the control area and no line in the test area.

**Invalid**
No line appears in the control area. Do not report invalid results. Repeat test with a new test device even if a line appears in the test area.

Use of trade names and commercial sources is for identification only and does not imply endorsement by WHO, the Public Health Service, or by the U.S. Department of Health and Human Services (2005).
HIV 1/2 Stat-Pak
For use with whole blood, serum, or plasma
Store Kits: 8 - 30°C

- Check kit before use. Use only items that have not expired or been damaged.
- Bring kit and previously stored specimens to room temperature prior to use.
- Always use universal safety precautions when handling specimens. Keep work areas clean and organized.

This outline is not intended to replace the product insert or your standard operating procedure (SOP).

1. Collect test items and other necessary lab supplies.
2. Remove device from package and label device with client identification number.
3. Collect approximately 5 µl of specimen using a new disposable loop or pipette.
4. Dispense the sample in the center of SAMPLE well.
5. Add 3 drops of buffer, holding vial vertically over the SAMPLE well.
6. Wait for 10 minutes before reading the results.
7. Read and record the results and other pertinent info on the worksheet.

HIV 1 / 2 Stat-Pak Test Results

**Reactive**
2 lines of any intensity appear in both the control and test areas.

**Non-reactive**
1 line appears in the control area and no line in the test area.

**Invalid**
No line appears in the control area. Do not report invalid results. Repeat test with a new test device even if a line appears in the test area.

Use of trade names and commercial sources is for identification only and does not imply endorsement by WHO, the Public Health Service, or by the U.S. Department of Health and Human Services (2005).
Uni-Gold HIV Rapid Test
For use with whole blood, serum, or plasma
Store Kits: 2 - 30°C

- Check kit before use. Use only items that have not expired or been damaged.
- Bring kit and previously stored specimens to room temperature prior to use.
- Always use universal safety precautions when handling specimens. Keep work areas clean and organized.

This outline is not intended to replace the product insert or your standard operating procedure (SOP).

1. Collect test items and other necessary lab supplies.
2. Remove device from package and label device with client identification number.
3. Collect specimen using the disposable pipette.
4. Add 2 drops (approx. 60µl) of specimen to the sample port in the device.
5. Add 2 drops (approx. 60µl) of the appropriate wash reagent to sample port.
6. Wait for 10 minutes (no longer than 20 min.) before reading the results.
7. Read and record the results and other pertinent info on the worksheet.

Uni-Gold HIV Rapid Test Results

**Reactive**
2 lines of any intensity appear in both the control and test areas.

**Non-reactive**
1 line appears in the control area and no line in the test area.

**Invalid**
No line appears in the control area. Do not report invalid results. Repeat test with a new test device even if a line appears in the test area.

Use of trade names and commercial sources is for identification only and does not imply endorsement by WHO, the Public Health Service, or by the U.S. Department of Health and Human Services (2005).
Venipuncture
For use with vacutainer tubes
Always use universal safety precautions.

1. Collect supplies.
2. Label tube with the client identification number.
3. Put tourniquet on client about 3-4” above venipuncture site.
4. Have client form a fist so veins are more prominent.
5. After palpating the path of the vein, clean the venipuncture site with alcohol using a circular motion. Allow the area to dry.
6. Assemble needle and vacuum tube holder.
7. Insert the collection tube into the holder until the tube reaches the needle.
8. Remove cap from needle.
9. Use your thumb to draw skin tight about 1-2” below the venipuncture site. Hold skin tight through Step 10.
10. Insert the needle, bevel side up, into the vein.
11. Push the vacutainer tube completely onto the needle. Blood should begin to flow into the tube.
12. Release the tourniquet.
13. Fill the tube until it is full or until vacuum is exhausted.
14. After opening client’s hand, place dry gauze over the venipuncture site.
15. Apply mild pressure to the pad and slowly remove the needle.
16. Apply bandage or continue applying mild pressure until bleeding has stopped.
17. Properly dispose of all contaminated supplies.

Use of trade names and commercial sources is for identification only and does not imply endorsement by WHO, the Public Health Service, or by the U.S. Department of Health and Human Services (2005).
Module 3: Slide 33
Exercise #1: Interpreting Individual HIV Rapid Tests

Instructions: Interpret the test results in the following examples. Write your interpretation of the test result on the line provided below each example.
Module 3: Slide 33
Exercise #2: Interpreting Individual HIV Rapid Tests

Instructions: Interpret the test results in the following examples. Write your interpretation of the test result on the line provided below each example.
Module 4: Slide 20

Exercise #1: Interpreting HIV Status Using Parallel Algorithm

A client has come in for an HIV Rapid Test. Following the parallel algorithm, you conducted three tests. The results are shown below.

- Interpret the HIV Rapid Test results for Test #1, Test #2, and Test #3
- Determine HIV Status

<table>
<thead>
<tr>
<th>Test</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>#1</td>
<td>________</td>
</tr>
<tr>
<td>#2</td>
<td>________</td>
</tr>
<tr>
<td>#3</td>
<td>________</td>
</tr>
</tbody>
</table>

Final HIV Status __________________________
Exercise #2: Interpreting HIV Status Using Serial Algorithm

A client came in for an HIV Rapid Test. Following the serial algorithm, you conducted two tests. The results are shown below.

- Interpret the HIV Rapid Test results for Test #1 and Test #2.
- Determine if a third test is needed. If not, what is the client’s HIV status?

<table>
<thead>
<tr>
<th>Test #1</th>
<th>Test #2</th>
</tr>
</thead>
<tbody>
<tr>
<td>![Test #1 Image]</td>
<td>![Test #2 Image]</td>
</tr>
</tbody>
</table>

Result: _____________  
Result: _____________

Is a third test needed?  ___Yes  ___No

If no, what is the HIV Status?  _______________
Exercise #1: Interpreting Rapid Test Results

Instructions: Read the test results in the following examples. Write your interpretation of the test result on the line provided below each example.
Module 12: Slides 17-18

Exercise #2: Resolving Un-reportable Test Results

A tester received discordant test results from test 1 (Determine) and test 2 (Uni-gold). The algorithm called for a third test (or tie breaker) to determine HIV status of patient. Review the third test and answer the questions below.

<table>
<thead>
<tr>
<th>Determine</th>
<th>Uni-gold</th>
<th>Hema-strip</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="Determine.png" alt="Image" /></td>
<td><img src="Uni-gold.png" alt="Image" /></td>
<td><img src="Hema-strip.png" alt="Image" /></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Result:</th>
<th>Result:</th>
<th>Result:</th>
</tr>
</thead>
</table>

Should you accept the results? ________________________

If not,

What should be your next steps?

________________________________________________________________

What might have caused the tiebreaker test to yield an invalid result?

________________________________________________________________

What corrective actions might you take?

________________________________________________________________
DAILY EVALUATION

DAY 1 2 3 4 5 (Please circle one)
Date: __________

Please tell us 3 things you liked about today’s session.

_____________________________________________________________________
_____________________________________________________________________
_____________________________________________________________________

Please tell us 3 things you would like to see improved about today’s session.

_____________________________________________________________________
_____________________________________________________________________
_____________________________________________________________________

Please provide specific feedback on training materials.

_____________________________________________________________________
_____________________________________________________________________
_____________________________________________________________________

Additional comments:

_____________________________________________________________________
_____________________________________________________________________
_____________________________________________________________________
## HIV Rapid Test Training

### End of Workshop Evaluation

**Date:** ____________

On a scale of 1 – 5 circle the one best answer that indicates your level of agreement.

<table>
<thead>
<tr>
<th>Question</th>
<th>Not at All</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. To what extent, before coming to the workshop, were you informed about the <strong>purpose</strong> of this workshop?</td>
<td>Not at All</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>2. Was the workshop content <strong>consistent</strong> with the stated objectives?</td>
<td>Not at All</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>3. To what extent did the <strong>workshop</strong> meet your expectations?</td>
<td>Not at All</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>4. To what extent do you expect this workshop will <strong>make a difference</strong> in the way you do your job?</td>
<td>Not at All</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>5. Overall, how would you rate the <strong>usefulness</strong> of this workshop?</td>
<td>Not Useful</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>6. To what extent did the workshop <strong>provide</strong> the following?</td>
<td>Very Poor</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

**A.** Applicable theoretical information

**B.** Practical examples

**D.** Time for discussion

**F.** Appropriate exercises for learning the content

Additional comments about these topics:

<table>
<thead>
<tr>
<th>Question</th>
<th>Very Poor</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>7. Overall, how would you rate the following aspects of the workshop?</td>
<td>Very Poor</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

**A.** Organization of the training

**B.** Organization of the training manual

**C.** Workshop content in the manual

Additional comments about these topics:

<table>
<thead>
<tr>
<th>Question</th>
<th>Not at All</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>8. To what extent do you feel confident about the following?</td>
<td>Not at All</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

**A.** Applying country testing algorithm

**B.** Performing HIV rapid testing

**C.** Interpreting HIV rapid test results

**D.** Reporting HIV status
HIV Rapid Test Training
End of Workshop Evaluation
Date: ____________

E. Troubleshooting HIV rapid tests 1 2 3 4 5
F. Applying safe work practices at test site 1 2 3 4 5
G. Using quality control materials 1 2 3 4 5
H. Identifying errors that may occur in the testing process 1 2 3 4 5
I. Managing stocks at HIV rapid test site 1 2 3 4 5
J. Collecting blood from a fingerprick 1 2 3 4 5
K. Collecting, handling, and shipping Dried Blood Spots 1 2 3 4 5
L. Conducting internal assessments of test site operations 1 2 3 4 5
M. Following written standard operating procedures (SOPs) 1 2 3 4 5
N. Keeping appropriate records 1 2 3 4 5
O. Practicing professional ethics including maintaining confidentiality 1 2 3 4 5

Additional comments about these topics:

9. What did you like most about this workshop?

10. What did you like least about this workshop?

11. If you were given the task of redesigning the workshop, what would you change?

12. Any other suggestions?
<table>
<thead>
<tr>
<th>Question #</th>
<th>MODULE # / Name</th>
<th>QUESTION</th>
<th>KEY</th>
</tr>
</thead>
</table>
| 1. | 1 - Overview of HIV Infection | Which of the following statements is INCORRECT about HIV and AIDS?  
   A. HIV is the virus that causes AIDS.  
   B. Everyone with AIDS is infected with HIV.  
   C. Everyone who is infected with HIV has AIDS.  
   D. Anyone infected with HIV, although healthy, can still transmit the virus to another person. | C |
| 2. | 1 - Overview of HIV Infection | Choose the MOST APPROPRIATE response to the question below.  
   When a client's HIV antibody test is non-reactive, what does it mean?  
   A. This person is infected.  
   B. This person is not infected.  
   C. This person is immune to HIV.  
   D. Antibodies against HIV were not detected in this person's body at the time of the test. | D |
| 3. | 1 - Overview of HIV Infection | Choose the INCORRECT response to the question below.  
   When a client's HIV antibody test is reactive, what does it mean?  
   A. This person is infected.  
   B. Seroconversion has occurred.  
   C. This person is immune to HIV.  
   D. This person has antibodies against HIV. | C |
| 4. | | Depending on the rapid tests used in the country, the following questions may need to be modified. | |
| 5. | 3 - Overview of HIV Testing Technologies | What is the result of the rapid test?  
   A. Reactive  
   B. Non-reactive  
   C. Invalid  
   D. None of the above | A |
<table>
<thead>
<tr>
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<th>MODULE # / Name</th>
<th>QUESTION</th>
<th>KEY</th>
</tr>
</thead>
</table>
| 6. | 3 - Overview of HIV Testing Technologies | What is the result of the rapid test?  
A. Reactive  
B. Non-reactive  
C. Invalid  
D. None of the above | B |
| 7. | 3 - Overview of HIV Testing Technologies | What is the result of the rapid test?  
A. Reactive  
B. Non-reactive  
C. Invalid  
D. None of the above | C |
| 8. | 3 - Overview of HIV Testing Technologies | What is the result of the rapid test?  
A. Reactive  
B. Non-reactive  
C. Invalid  
D. None of the above | A |
| 9. | 3 - Overview of HIV Testing Technologies | What is the result of the rapid test?  
A. Reactive  
B. Non-reactive  
C. Invalid  
D. None of the above | B |
<table>
<thead>
<tr>
<th>Question #</th>
<th>MODULE # / Name</th>
<th>QUESTION</th>
<th>KEY</th>
</tr>
</thead>
</table>
| 10.        | 4 – HIV Testing Strategies and Algorithms | Your country follows a serial testing algorithm. A tester performs 3 tests and the following test results are obtained:  
- Test 1: Reactive  
- Test 2: Non-Reactive  
- Test 3: Invalid  
Which statements best describes your next steps in reporting the results?  
A. HIV status should be reported as positive  
B. Tester should repeat Test 1, and report client as negative if Test 1 is non-reactive  
C. Tester should review standard operating procedures  
D. B & C  
E. Unable to determine | D |
| 11.        | 4 – HIV Testing Strategies and Algorithms | What is the final HIV status given the following test results:  
- Test 1: Reactive  
- Test 2: Non-reactive  
- Test 3: Reactive  
A. Positive  
B. Negative  
C. Reactive  
D. Can’t determine | A |
| 12.        | 4 – HIV Testing Strategies and Algorithms | Given question # 11 above, which type algorithm is followed:  
A. Serial  
B. Parallel  
C. Combination, since outcome of tests resulted in different results  
D. None of the above | B |
<table>
<thead>
<tr>
<th>Question #</th>
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<th>QUESTION</th>
<th>KEY</th>
</tr>
</thead>
<tbody>
<tr>
<td>13.</td>
<td>5 - Quality Systems</td>
<td>Which of the following statements is an example of Quality Assurance?</td>
<td>E</td>
</tr>
<tr>
<td></td>
<td>Overview</td>
<td>A. Checking the expiration date of a test kit</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>B. Testing a new shipment of test kits using known positive and negative</td>
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<td></td>
<td></td>
<td>specimens</td>
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<td></td>
<td></td>
<td>C. Participating in an external quality assessment (EQA) program, if</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>you are not too busy</td>
<td></td>
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<td></td>
<td></td>
<td>D. Reporting accidental sharps injuries only to your co-workers.</td>
<td></td>
</tr>
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<td></td>
<td></td>
<td>E. A &amp; B</td>
<td></td>
</tr>
<tr>
<td>14.</td>
<td>5 - Quality Systems</td>
<td>Which of the following statements best describe an action(s) to assure</td>
<td>E</td>
</tr>
<tr>
<td></td>
<td>Overview</td>
<td>staff competence?</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>A. Reporting an accidental spill incidence</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>B. Providing training on testing procedures</td>
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<td></td>
<td></td>
<td>C. Only verbally communicating rules to follow at the test site</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>D. Having staff read all workplace polices and procedures</td>
<td></td>
</tr>
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<td></td>
<td></td>
<td>E. B &amp;D</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>F. B &amp;C</td>
<td></td>
</tr>
<tr>
<td>15.</td>
<td>5 - Quality Systems</td>
<td>Which factor(s) may compromise the quality of HIV rapid testing?</td>
<td>A</td>
</tr>
<tr>
<td></td>
<td>Overview</td>
<td>A. Recording a reactive result that is visible after 5, although the</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>manufacturer requires the test to be read between 10-20 minutes.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>B. Checking the expiration date of the test kit prior to use</td>
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<td></td>
<td></td>
<td>C. Discarding a lancet found on the floor in the waste container</td>
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<tr>
<td></td>
<td></td>
<td>designated for “sharps”</td>
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<td></td>
<td></td>
<td>D. Testing quality control samples once per week</td>
<td></td>
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<tr>
<td>Question #</td>
<td>MODULE # / Name</td>
<td>QUESTION</td>
<td>KEY</td>
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</tr>
</tbody>
</table>
| 16.        | 6 - Safety     | Which of the following statements about sharp containers is CORRECT?  
A. These containers are used to collect sharps for re-use.  
B. Keep all containers in a centralized location to avoid accidental contamination.  
C. Shake the containers often to create more space.  
D. Seal and remove the containers when they are ¾ full. | D |
| 17.        | 6 - Safety     | Which of the following actions is NOT a safety practice?  
A. Pipetting by mouth.  
B. Disposing of sharps into a sharps container immediately after use.  
C. Keeping supplies locked in a secure area.  
D. Washing hands before and after testing each client. | A |
| 18.        | 6 - Safety     | What does this sign mean?  
A. Poisons  
B. Bio-hazard  
C. Recycling  
D. Electrical shock possible | B |
<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>19.</td>
<td>6 - Safety</td>
<td>Which of the following is NOT a safety practice?</td>
<td>A</td>
</tr>
<tr>
<td></td>
<td></td>
<td>A. Pipette by mouth.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>B. Dispose of sharps after each test.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>C. Keep supplies locked in a secure area.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>D. Wash hands before and after testing each client.</td>
<td></td>
</tr>
<tr>
<td>20.</td>
<td>6 - Safety</td>
<td>Which statement best describes how to prepare a 10% (vol/vol) bleach solution?</td>
<td>C</td>
</tr>
<tr>
<td></td>
<td></td>
<td>A. Mix 5 parts water with 5 parts bleach.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>B. Mix 1 part water with 9 parts bleach</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>C. Mix 1 part bleach with 9 parts water</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>D. Mix 1 part bleach with 10 parts water</td>
<td></td>
</tr>
<tr>
<td>21.</td>
<td>7 – Preparation for Testing: Kits and Supplies</td>
<td>Which of the following item(s) is essential for conducting HIV rapid testing?</td>
<td>E</td>
</tr>
<tr>
<td></td>
<td></td>
<td>A. Lancets</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>B. Test Kits</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>C. Sharps containers</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>D. Gloves</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>E. All of the above</td>
<td></td>
</tr>
<tr>
<td>22.</td>
<td>8 - Blood Collection: Fingerprick</td>
<td>Choose the CORRECT answer?</td>
<td>E</td>
</tr>
<tr>
<td></td>
<td></td>
<td>When performing finger prick to collect blood for testing…</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>A. When cleaning the finger with alcohol, start in the center and work outward to prevent contamination.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>B. After pricking the finger, you should not collect the 1st drop of blood.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>C. After puncturing the finger, you should collect the first drop of blood to be sure you have enough blood for testing.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>D. You should have the client stand to help facilitate blood flow after puncturing.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>E. A &amp; B</td>
<td></td>
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<tr>
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<td>QUESTION</td>
<td>KEY</td>
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<td>---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
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</tbody>
</table>
| 23.        | 9 –Performing HIV Rapid Tests | Which of the following statement(s) is CORRECT? Before performing a rapid test, you must examine the test kit to make sure that…   
  A. The test device has not been previously opened or damaged.  
  B. The test kit has not expired.  
  C. You have adequate supplies and reagents before beginning testing.  
  D. The test kit has been stored appropriately according to manufacturer specifications.  
  E. All of the above                                                                 | E   |
| 24.        | 8 - Blood Collection: Fingerprick | Choose the CORRECT answer.  
  When preparing your client for rapid test, you should:  
  A. Keep the clients standing during finger prick to ensure the blood does not clot.  
  B. Put your client at ease by describing what happens during the rapid HIV test.  
  C. Inform the client that the results will be sent to his/her family at no extra charge.  
  D. **None** of the above is correct.                                                                 | B   |
| 25.        | 9 – Performing HIV Rapid Tests | Three tests are performed on the blood samples from a patient. The following are the results.  
  • Test 1: Non-reactive  
  • Test 2: Reactive  
  • Test 3: Non-reactive  
  What is the HIV status of the patient?  
  A. Positive  
  B. Negative  
  C. Invalid  
  D. Unable to determine                                                                 | B   |
<table>
<thead>
<tr>
<th>Question #</th>
<th>MODULE # / Name</th>
<th>QUESTION</th>
<th>KEY</th>
</tr>
</thead>
</table>
| 26.        | 9 – Performing HIV Rapid Tests | Three tests are performed on the blood samples from a patient. The following are the results obtained.  
- Test 1: Invalid, after repeated testing  
- Test 2: Reactive  
- Test 3: Invalid  
What is the HIV status of the patient?  
A. Positive  
B. Negative  
C. Invalid  
D. Unable to determine status. | D |
| 27.        | 10 – Inventory: Managing stocks | Which of the following statements about principles of stock management is INCORRECT?  
A. All stock must be accounted for. Everything that comes in and goes out must be recorded.  
B. Never order more supplies than your storage space can hold.  
C. Never order more supplies than you can use before their expiration dates.  
D. Observe the “First in, first out” rule. | D |
| 28.        | 10 – Inventory: Managing stocks | To ensure uninterrupted service at the test site, you must always maintain an adequate stock of supplies and kits. Use the information below to help you determine when to re-order.  
On average, you use three boxes of pipette tips (100 per box) each week. It usually takes three weeks to receive items you have ordered. You need to place an order when you have only ___________ boxes of pipette tips remaining in the inventory.  
A.  3  
B.  6  
C.  9  
D. 12 | C |
<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>29.</td>
<td>10 – Inventory: Managing stocks</td>
<td>When you re-order, how many boxes of pipette tips should you get to ensure continuous supply? Assume that storage space is not a problem.</td>
<td>C</td>
</tr>
<tr>
<td></td>
<td></td>
<td>A. 3</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>B. 6</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>C. 9</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>D. 12</td>
<td></td>
</tr>
<tr>
<td>30.</td>
<td>11 – Use and Care of Equipment</td>
<td>Which of the following equipment care activities is your responsibility at the test site?</td>
<td>D</td>
</tr>
<tr>
<td></td>
<td></td>
<td>A. Recording the temperature of refrigerators daily</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>B. Immediately reporting problems to your site supervisor</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>C. Keeping food items out of the laboratory refrigerator</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>D. All of the above</td>
<td></td>
</tr>
<tr>
<td>31.</td>
<td>12 – Quality Control</td>
<td>Which of the following statements about external quality control samples is INCORRECT?</td>
<td>A</td>
</tr>
<tr>
<td></td>
<td></td>
<td>A. It is performed by external people during their on-site visit.</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>B. The quality control material could have either been purchased commercially or made by your reference laboratory.</td>
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<tr>
<td></td>
<td></td>
<td>C. Should be stored according to standard operating procedures to maintain sample integrity.</td>
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<td></td>
<td></td>
<td>D. It is performed periodically.</td>
<td></td>
</tr>
<tr>
<td>32.</td>
<td>12 – Quality Control</td>
<td>Which of the following statement is INCORRECT about internal quality control when the control is integrated into the test device itself (e.g., procedural control).</td>
<td>B</td>
</tr>
<tr>
<td></td>
<td></td>
<td>A. The internal quality control is read every time a rapid test is performed.</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>B. Test results must not be reported if a faint line appears in the control band region of the test device.</td>
<td></td>
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<td>C. Test results must not be reported if internal controls yield in an invalid result</td>
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<td></td>
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<td>D. All of the above</td>
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<td>Question #</td>
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</tbody>
</table>
| 33.        | 12 -Quality Control                  | Which of the following statements about *external quality control* is INCORRECT?  
A. It is performed by external people during their on-site visit.  
B. The quality control material can be prepared commercially or made in-house.  
C. It is performed with known positive and negative specimens to ensure testing reliability.  
D. It is performed periodically. | A   |
| 34.        | 13 – External Quality Assessment     | Which of these terms is best described by the definition below:  
“*A process by which specimens are randomly selected from the routine workload at a test site and sent to the reference laboratory for validation of results.*”  
A. External quality control (QC)  
B. Proficiency testing  
C. On-site evaluation  
D. Re-testing | D   |
| 35.        | 13 – External Quality Assessment     | Which statement below describes a process where testing operations are evaluated by an external person or agency?  
A. External quality control (QC)  
B. Proficiency testing  
C. On-site evaluation  
D. Re-testing | C   |
| 36.        | 14 – Blood Collection: Dried Blood Spots | When collecting Dried Blood Spots through a finger prick, which of the following techniques is CORRECT?  
A. Press the filter paper against the puncture site.  
B. Apply blood to only one side of the filter paper.  
C. Apply blood repeatedly until a circle is filled.  
D. Apply the first drop of blood to the filter paper. | B   |
<table>
<thead>
<tr>
<th>Question #</th>
<th>MODULE # / Name</th>
<th>QUESTION</th>
<th>KEY</th>
</tr>
</thead>
</table>
| 37.        | 15 – Documents and Records | Keeping records secure means:  
A. Locking all record books at the end of the day to maintain confidentiality  
B. Limiting access to the testing area  
C. Protecting records from environmental hazards  
D. All of the above | D |
| 38.        | 15 – Documents and Records | Which of the items below is considered a document?  
A. Standard Operating Procedure (SOP)  
B. Temperature readings from refrigerator  
C. Log of specimens referred to reference laboratory for testing  
D. Quality control results | A |
| 39.        | 15 – Documents and Records | Which of the items below is considered a record?  
A. Photo illustration of test procedure  
B. Summary of test results  
C. Blank form for capturing refrigerator temperatures  
D. Standard Operating Procedure | B |
| 40.        | 16 – Professional Ethics | Which of the following statements is a breach of professional ethics?  
A. Given a parallel testing algorithm, reporting positive HIV status as result of performing one HIV rapid test.  
B. Taking a test kit from the workplace to test a relative at home  
C. Noting the expiration date of a test kit after results have been reported  
D. All of the above | D |
Workshop Goal

You will gain the knowledge and skills to perform HIV rapid tests accurately and reliably in a safe and professional manner in an era of expanding programs.

Accuracy
Reliability
Quality
Safety

Lab workers  Health workers  Counselors
This Workshop Has 16 Modules

1. Overview of HIV Infection
2. Integration of HIV Rapid Testing in Programs
3. Overview of HIV Testing Technologies
4. HIV Testing Strategies and Algorithms
5. Assuring the Quality of HIV Rapid Testing
6. Safety at the HIV Rapid Testing Site
7. Preparation for Testing – Supplies and Kits
8. Blood Collection: Finger prick
This Workshop Has 16 Modules

9. Performing HIV Rapid Tests
10. Inventory
11. Use and Care of Equipment
12. Quality Control
13. External Quality Assessment
15. Documents and Records
16. Professional Ethics
How Will You Learn?

- Lecture
- Paper-based exercise
- Hands-on practice
- Energizer/Game
- Discussion
- Video
- Role-play
Certification Criteria

• Successful completion of the workshop:
  ▪ Daily attendance
  ▪ Passing score of 80% on written post-test
  ▪ Passing score of 100% on final practical examination

• 100% accuracy of first 50 specimens tested under direct supervision.
Workshop Agenda
Let’s Introduce Ourselves

Please tell us the following:

• Your name
• Job position
• Organization
• Expectations for the workshop
Module 1: Overview of HIV Infection
Learning Objectives

At the end of this module, you will be able to:

• Describe the difference between HIV infection and AIDS
• Discuss the HIV epidemics globally, regionally, and locally in terms of number of people affected
• Define the terms: antibody and antigen
• Explain how “window period” may affect HIV testing results
• Describe the progression of HIV infection
Content Overview

- What is HIV?
- What is AIDS?
- The HIV pandemic
- HIV transmission
- Window period
- Stages of HIV infection
What is HIV?

- **H**uman: Infecting human beings

- **I**mmunodeficiency: Decrease or weakness in the body’s ability to fight off infections and illnesses

- **V**irus: A pathogen having the ability to replicate only inside a living cell
Types of HIV Virus

- **HIV 1**
  - Most common in sub-Saharan Africa and throughout the world
  - Groups M, N, and O
  - Pandemic dominated by Group M
    - Group M comprised of subtypes A - J

- **HIV 2**
  - Most often found in West Central Africa, parts of Europe and India
Structure of HIV

- Envelope
- Core p24
- Reverse Transcriptase
- RNA
What is AIDS?

- **Acquired**: To come into possession of something new
- **Immune Deficiency**: Decrease or weakness in the body’s ability to fight off infections and illnesses
- **Syndrome**: A group of signs and symptoms that occur together and characterize a particular abnormality

AIDS is the final stage of the disease caused by infection with a type of virus called HIV.
HIV vs. AIDS

- HIV is the virus that causes AIDS
- Not everyone who is infected with HIV has AIDS
- Everyone with AIDS is infected with HIV
- AIDS is result of the progression of HIV Infection
- Anyone infected with HIV, although healthy, can still transmit the virus to another person
How is HIV Transmitted?

- Unprotected sexual contact with an infected partner
- Exposure of broken skin or wound to infected blood or body fluids
- Transfusion with HIV-infected blood
- Injection with contaminated objects
- Mother to child during pregnancy, birth or breastfeeding
HIV: A Global Pandemic

Adults and children estimated to be living with HIV/AIDS (2003): 34 – 46 million total

- Western Europe: 520,000 – 680,000
- North Africa & Middle East: 470,000 – 730,000
- Sub-Saharan Africa: 25.0 – 28.2 million
- Eastern Europe & Central Asia: 1.2 – 1.8 million
- East Asia & Pacific: 700,000 – 1.3 million
- South & South-East Asia: 4.6 – 8.2 million
- Australia & New Zealand: 12,000 – 18,000
- North America: 790,000 – 1.2 million
- Caribbean: 350,000 – 590,000
- Latin America: 1.3 – 1.9 million

Lab workers
Health workers
Counselors
HIV Epidemic in Sub-Saharan Africa


- Number of people living with HIV and AIDS
- % HIV prevalence, adult (15–49)

Source: UNAIDS/WHO, 2004
HIV Epidemic: Local Facts & Impact

• Insert -
  - Local HIV/AIDS Facts
  - Local Impact
Basic Terms

- **Antigen**: A substance which is recognized as foreign by the immune system. Antigens can be part of an organism or virus, e.g., envelope, core (p24) and triggers antibody production.

- **Antibody**: A protein (immunoglobulin) made by the body’s immune system to recognize and attack foreign substances.
Testing for Viral Infection and Immune Response

- Viral infection
  - Viral Load
  - p24 Antigen
- Immune response
  - Antibody (IgG, IgM)
  - Cellular response (CD4)
Evolution of Antibodies

SeroLogic Profile of HIV-1 Infection

- Anti-HIV Env
- Anti-HIV Core
- HIV Ag
- IgM
- relative concentration
- HIV-1 infection
- weeks
- months
- time
- years

Lab workers  Health workers  Counselors
Window Period

- Time from initial infection with HIV until antibodies are detected by a single test
- Usually 3-8 weeks before antibodies are detected
- May test false-negative for HIV antibodies during this time period
- Can still pass the virus to others during this period
Disease Progression

- Severity of illness is determined by amount of virus in the body (increasing viral load) and the degree of immune suppression (decreasing CD4+ counts).
- As the CD4 count declines, the immune function decreases.
WHO HIV/AIDS Classification System

- **Stage I**: Asymptomatic
- **Stage II**: Minor Symptoms
- **Stage III**: Moderate Symptoms
- **Stage IV**: AIDS

![Graph showing the progression of HIV/AIDS stages](image-url)
Can Disease Progression Be Delayed?

- Prevention and early treatment of opportunistic infections (OIs)
- Antiretroviral therapy
- Positive living
Summary

• What is HIV? What is AIDS? How does HIV relate to AIDS?
• What are the means by which HIV is transmitted?
• What is “window period?” How does it affect HIV test results?
• What is an antibody? Antigen?
• How does HIV infection progress?
• How can the disease progression of HIV/AIDS be delayed?
Module 2: Integration of HIV Rapid Testing in HIV Prevention and Treatment Programs
Learning Objectives

- Recognize the need for HIV testing and counseling (T&C) in HIV prevention programs
- Describe the role of HIV rapid testing in supporting prevention and counseling programs
- State the advantages of using HIV rapid tests in specific settings (e.g., VCT and PMTCT programs)
- Describe the programs/settings where HIV rapid tests are used in your country
Content Overview

• Need for expanding access to HIV testing
• Testing and counseling as an integral part of HIV prevention, care and support services
• Client counseling and HIV rapid testing are a formidable combination in any HIV prevention strategy
HIV/AIDS Program Strategy

“Innovative solutions must be found to dramatically increase the number of individuals who are tested and know their status.”

• Development, implementation, and evaluation of new, highly efficient and effective models

• Scaling up of current testing and counseling services
Current Status of HIV Testing

- 95% of the 40 million HIV infected people worldwide do not know they are infected
- Only 5-10% of population in many countries have ever had an HIV test; less than 10% of all pregnant women have received an HIV test
- Where HIV testing is more widely available, no more than 10% of health care facilities offered testing and counseling in 2002
HIV Testing Occurs in a Variety of Settings

Prevent HIV Infections

TB Clinics
Hospitals
STI Clinics

T&C
ANC
Blood Banks
Surveillance

Provide ARV treatment to HIV-infected persons
Provide care to HIV-affected persons

Lab workers
Health workers
Counselors
HIV T&C As An Entry Point to HIV Prevention, Care and Support Services

- Care & Support
- Home-based Care
- PMTCT
- Opportunistic Infection (OI)
- HIV Treatment
- Support Groups
- Community-based Care
- Future Planning
- HIV Prevention Services

Lab workers  Health workers  Counselors
Testing and Counseling

Self-initiated HIV testing and prevention counseling, primarily offered in free-standing sites

- Rapid testing can be used to advantage
- Opportunity for pre-test and post-test counseling
- Persons voluntarily seeking testing and counseling are most ready for change and prevention messages
- Immediate test results hasten care/treatment for HIV infected persons
- As demand for testing increases, VCT model may not meet country’s need
Clinic-Based HIV Testing and Counseling

Persons attending clinics (ANC, STI, TB) are routinely offered HIV testing and counseling

- HIV Rapid testing easy to implement
- Right to refuse HIV test offered (i.e., opt out)
- High rates of HIV infected persons identified
- Linkage to treatment and care facilitated
Community-Based

Testing and Counseling

Outreach provided through churches, workplace, youth programs, military, etc.

- People Living with HIV/AIDS (PLWHA) are essential to supporting community-based programs
- Often includes training of lay persons in community to offer testing and counseling
- Difficulties: supervision; quality assurance; confidentiality; linkage to care and treatment
Couples Testing and Counseling

Intervention in which sexual partners are counseled as a couple (e.g., VCT, PMTCT sites)

- HIV T&C of discordant couples is a highly effective prevention intervention
- Facilitates disclosure and joint planning for risk reduction
- Increases utilization of care and treatment may increase if the partner knows about and supports the infected person
- Allows for planning and care of children based on serostatus of both parents
HIV T&C As An Entry Point to HIV Prevention, Care and Support Services

- Care & Support
- Home-based Care
- PMTCT
- Opportunistic Infection (OI)
- HIV Treatment
- Support Groups
- Community-based Care
- HIV Prevention Services
- Future Planning

Lab workers • Health workers • Counselors
Mother-to-Child HIV Infections

- 2,000 new infections each day worldwide
- Over 90% are in resource-poor settings
- About 90% of HIV-positive pregnant women in resource-poor settings have no access to testing and do not know their HIV-status
Preventing Mother to Child Transmission (PMTCT)

PMTCT is part of a comprehensive approach that consists of 4 elements:

- **Element 1**: Primary prevention of HIV infection in women
- **Element 2**: Prevention of unintended pregnancies among women infected with HIV
- **Element 3**: Prevention of HIV transmission from HIV infected mothers to their infants
- **Element 4**: Provision of treatment, care and support to women infected with HIV, their infants and their families
Core Interventions for PMTCT

Transmission risk can be reduced by at least 50% through feasible, affordable interventions

- HIV Rapid testing and counselling
- Antiretroviral treatment
- Safer delivery practices
- Safer infant-feeding practices
Core PMTCT Interventions Depend on a Woman Knowing Her HIV Status

HIV testing and counselling (T&C) services:

- Play a vital role in identifying women who are HIV-positive
- Reduce the risk of mother-to-child transmission
- Provide comprehensive HIV/AIDS treatment & care to mother, infant and family members
- Help HIV-negative and HIV-positive women take risk-reduction steps
Rationale for Promoting HIV Rapid Tests for PMTCT

- Blood samples can be tested at antenatal clinic (ANC) or labour and delivery (L&D) ward
- Increase number of women that receive test results & counselling services
- Immediate availability of interventions for pregnant HIV-positive women
- Reduce HIV transmission to infants by testing pregnant women with unknown HIV status before or just after delivery and initiating ARV intervention
- Eliminate need to track down results from an outside lab
- Reduce risk of specimen mix-up or misplacement
Current International Recommendations for Testing and Counseling in PMTCT

- Group pre-test information and individual pre-test counseling at ANC clinic
- Routinely recommending HIV testing and counseling for pregnant women at ANC and at L&D
- **Rapid testing** with same-day result at ANC and at L&D
- Individual post-test counseling and encouraging partner testing

Summary

- What are venues for HIV testing and counseling?
- What are the advantages of using HIV rapid testing at these venues?
- What are special advantages of using HIV rapid testing in PMTCT?
Module 3:
Overview of HIV Testing Technologies
Learning Objectives

At the end of this module, you will be able to:

• Discuss settings where HIV testing will be part of service delivery during an era of expanded services
• Discuss the spectrum of testing technologies for HIV
• Explain the advantages and disadvantages of HIV rapid tests
• Accurately recognize individual test result as reactive, non-reactive, or invalid
Content Overview

- Expansion of HIV rapid testing
- Spectrum of HIV diagnostic tests
- Challenges with HIV testing
- Spectrum of HIV testing technologies
- Advantages and disadvantages of HIV rapid testing
- Three formats of rapid tests
- Reading individual test results
HIV Testing Occurs in a Variety of Settings

Prevent HIV Infections

Provide care to HIV-affected persons

Provide ARV treatment to HIV-infected persons

Lab workers

Health workers

Counselors
Expansion of Testing Services

- Integrate HIV laboratory services and diagnostics fully into national health laboratory structures
- Facilitate testing in non-traditional settings
- Consider all our testing options

Lab workers  Health workers  Counselors
Use of HIV Testing Technologies in the Continuum of Care

Use HIV rapid diagnostic test to identify an HIV infection

Initiate treatment with ARVs minimal diagnostics required

Monitor effectiveness of ARVs with diagnostics (viral load, CD4) and safety with basic laboratory tests
Spectrum of HIV Tests

- HIV diagnosis (Antibody/Antigen testing)
  - Enzyme Immunoassays (EIAs)
  - Rapid tests
  - Western blot (WB)
- Early diagnosis in infants
  - p24
- Initiation and monitoring of ART
  - CD4
  - Viral Load
Challenges of HIV Testing

- Early detection of seroconversion
- Early detection in infants born to HIV positive mothers
- Effect of HIV subtypes on test performance
- Impact of other health conditions on test performance
- Product specific equipment
- Technical skill
Enzyme Immunoassays (EIAs)

- Quantitative assay to measure HIV antibodies
  - Most detect antibodies to HIV-1 and HIV-2
  - Antigens coated in microwells
  - HIV Antigen / Antibody reaction is detected by color change
  - Intensity of color reflects amount of antibody present in serum
- Some assays can detect both HIV antibody and HIV antigen (close window period)
- Issues:
  - Skilled lab technician
  - Large volume testing
  - Properly maintained equipment required
After several incubation and wash steps, a color reaction occurs if HIV antibody is present. An automated reader gives a measurement of optical density (presence of color) for each well.
HIV Rapid Tests

- Qualitative assay to detect HIV antibodies
- Most detect HIV 1 and HIV 2
- As reliable as EIAs
- Issues:
  - Small volumes
  - Validation of use
  - Appropriate training
Western Blot / Line Immunoassays

- Used as supplemental test for confirmation (only difficult cases)
- Detects antibodies to specific HIV antigens on cellulose strip
- Issues:
  - Multiple standards for performance and interpretation
  - Expensive
  - Limited commercial availability
**HIV p24 Antigen**

- **Core protein of the virus**
- **EIA detects p24 antigen before antibody can be detected**
  - Detected 2 to 3 weeks after HIV infection
  - Detected about 6 days before antibody tests become reactive
- **Used for:**
  - Diagnosis of pediatric HIV-1 infections
  - Blood bank safety (high incidence countries)
- **Issues:**
  - Level 4 complexity
  - Properly maintained equipment required
CD4 T-Lymphocyte

- CD4 T-lymphocyte counts used for:
  - Determining clinical prognosis
  - Assessing criteria for antiretroviral therapy
  - Monitoring therapy

- Manual and automated methods

- Issues:
  - Requires high level of technical skill for test performance and interpretation
  - Properly maintained equipment
Viral Load

- Quantitative molecular assay measures amount of HIV in blood products
- Used to:
  - Predict disease progression
  - Assist with deciding when to initiate anti-retroviral therapy
  - Monitors response to anti-retrovirals
- Issues:
  - Expensive
  - Labor-intensive
  - Special facilities
Complexity of HIV Tests Varies*

- **Level 1**: No additional equipment and little or no laboratory experience needed
- **Level 2**: Reagent preparation or a multi-step process is required; Centrifugation or optimal equipment
- **Level 3**: Specific skills such as diluting are required
- **Level 4**: Equipment and trained laboratory technician are required

*WHO Reports
HIV Rapid Tests provides excellent tool for expansion of services
HIV Rapid Tests: Advantages

- Increases access to prevention (VCT) and interventions (PMTCT)
- Supports increased number of testing sites
- Same-day diagnosis and counseling
- Robust and easy to use
- Test time under 30 minutes
- Most require no refrigeration
- None or one reagent
- Minimal or no equipment required
- Minimum technical skill
HIV Rapid Tests: Disadvantages

- Small numbers for each test run
- Quality Assurance/Quality Control at multiple sites
- Test performance varies by product
- Refrigeration required by some products, e.g., Capillus
- Reader variability in interpretation of results
- Limited end-point stability of test results
Body Fluids Used for HIV Rapid Testing

- Serum
- Plasma
- Whole blood
- Oral fluids
Three Formats of HIV Rapid Tests

- Immunoconcentration (flow-through device)
- Immunochromatography (lateral flow)
- Particle agglutination
How Immunoconcentration Works

HIV antibody links to bound HIV peptide antigens forming the color spot

Internal Control

HIV-1 peptide

HIV-2 peptide
Tests Based on Immunoconcentration

Flow-Through Devices:
- Multi-Spot
- Genie II

Top view
Side view
Reading Results: Genie II

Non-reactive

Reactive

Lab workers
Health workers
Counselors
How Immunochromatography Works

IgG Antibodies
HIV antibodies

Colloidal gold conjugated to HIV antigen

HIV antigen

Anti-IgG/gold antibodies

Add Sample

Conjugate

Test Line

Control line

Lab workers
Health workers
Counselors
Tests Based on Immunochromatography

Lateral Flow Devices

- Determine
- Hema-Strip
- OraQuick
- Unigold
Reading Results: Determine

Non-Reactive

Reactive

Sample Pad  Test line  Control line

Lab workers  Health workers  Counselors
Reading Results: OraQuick

Non-Reactive

Reactive

Lab workers  Health workers  Counselors
How Particle Agglutination Works

Anti-HIV antibodies bind to the antigen-coated latex particles.
Tests Based On Agglutination

Agglutination devices:
• Capillus
• Serodia
Reading Results: Capillius

Lab workers
Health workers
Counselors

Non-reactive
Weak Reactive
Strong Reactive
There Are Only Three Possible Outcomes for Single HIV Antibody Tests

Reactive or “Positive”
- Test band
- Control band

Non-reactive or “Negative”
- Control band only

Invalid
- No control band present
- Test has failed. Repeat with new device.
Exercise: Interpreting Individual HIV Rapid Test Results

- Refer to Participant Manual
- Work alone to determine individual test results
- 3 Minutes
Key Messages

- HIV rapid tests can be as reliable as EIA
- All tests require attention to training, supervision, and monitoring at points of service.
- As testing is expanding and decentralized, training, supervision, and monitoring must follow accordingly and become all the more important.
Summary

- Where is HIV rapid testing likely to occur during an era of expansion of services?
- What is the intended use for: EIAs, Western Blot, p24 Antigen, CD4, Viral Load
- What are rapid tests?
- Why use rapid tests?
- How do you read a result – reactive, non-reactive or invalid?
Module 4: HIV Testing Strategies and Algorithms
Learning Objectives

At the end of this module, you will be able to:

• Discuss the process for developing a national testing algorithm
• Explain how sensitivity, specificity, positive/negative predictive value relate to development of an HIV rapid testing algorithm
• Explain the HIV rapid testing algorithm approved in your country
• Determine HIV status following a particular algorithm
Content Overview

- Testing strategies and algorithms
- Developing national testing algorithm
- Measuring performance of HIV rapid tests
- Interpreting HIV status
Strategies and Algorithms

• **Strategies** – Testing approach used to meet a specific need, such as:
  - Blood Safety
  - Surveillance
  - Diagnosis

• **Algorithms** – The combination and sequence of specific tests used in a given strategy
Strategies and Algorithms (Cont.)

- For a given strategy, multiple algorithms may be used depending on the needs of testing settings.
- The number of algorithms should be limited.
HIV Testing Strategies

- **Parallel testing**
  - Samples are tested simultaneously by two different tests

- **Serial testing**
  - Samples tested by a first test
  - Result of first test determines whether additional testing is required
Testing Algorithms Should be Developed at National Level

Key Steps:

- Identify appropriate tests
- Develop algorithm
- Build consensus
- Develop policy
- Bring into national scale
- Review testing algorithms annually
Timeline for Developing National Testing Algorithm

**Phase I**
- Determine Capacity
- Literature Review
- Situation Analysis
- Needs Analysis
- Proposal
- Ethical Review
- Procurement

**Phase II**
- (6 months)
- Establish Panels
- Evaluation
- Analysis of Data
- Algorithm Decision
- Publish Findings
- Site Selection
- Training of Staff
- On Site Evaluation
- Algorithm Approval

**Phase III**
- (> 3 months)
- Monitoring
- Pilot Manuals
- Monitor Performance
- Publish Algorithm

---

Lab workers
Health workers
Counselors
Advantages of National Testing
Strategies and Algorithms

Facilitates:

- Country-level standardization
- Procurement and supply management
- Training
- Quality assurance
Key Factors in Determining a Country’s Algorithm

- Test performance in country
- Test availability in country
- Program needs
- Ease of use
- Type of specimen
- Cost
- Potential need to differentiate between HIV 1 & HIV 2
Evaluating Test Performance: Basic Terms

- **Sensitivity (Se)** of a test is its capacity to correctly identify people that are infected with HIV.
- **Specificity (Sp)** of a test is its capacity to correctly identify people that are not infected with HIV.
- **Positive Predictive Value (PPV)** is the probability that a person who tests reactive is indeed infected with HIV.
- **Negative Predictive Value (NPV)** is the probability that a person who tests negative is not infected with HIV.
### Calculating Sensitivity, Specificity, PPV, & NPV

<table>
<thead>
<tr>
<th>Test result</th>
<th>Actual HIV status (Gold Standard)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>HIV infected</td>
<td>HIV -uninfected</td>
</tr>
<tr>
<td>Positive</td>
<td>A</td>
<td>B</td>
</tr>
<tr>
<td>Negative</td>
<td>C</td>
<td>D</td>
</tr>
<tr>
<td>Total</td>
<td>A+C</td>
<td>B+D</td>
</tr>
</tbody>
</table>

- **Sensitivity** = \( \frac{A}{A+C} \)
- **Specificity** = \( \frac{D}{B+D} \)
- **Positive Predictive Value** = \( \frac{A}{A+B} \)
- **Negative Predictive Value** = \( \frac{D}{C+D} \)
Calculating Sensitivity, Specificity, PPV, & NPV (Cont’d)

<table>
<thead>
<tr>
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<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>HIV infected</td>
<td>HIV -uninfected</td>
</tr>
<tr>
<td>Positive</td>
<td>A (370)</td>
<td>B (2)</td>
</tr>
<tr>
<td>Negative</td>
<td>C (4)</td>
<td>D (624)</td>
</tr>
<tr>
<td>Total</td>
<td>A+C (374)</td>
<td>B+D (626)</td>
</tr>
</tbody>
</table>

Sensitivity = $\frac{A}{A+C} = \frac{370}{374} = 98.9\%$

Specificity = $\frac{D}{B+D} = \frac{624}{626} = 99.7\%$

PPV = $\frac{A}{A+B} = \frac{370}{372} = 99.5\%$

NPV = $\frac{D}{C+D} = \frac{624}{628} = 99.4\%$
HIV Rapid Test Performance

- No test is 100% sensitive
- No test is 100% specific

Note: Performance of tests and subsequent algorithm must be determined in context of population
How Prevalence Affects PPV & NPV

PPV = \frac{(\text{Prevalence}) \times (\text{Se})}{(\text{Prevalence}) \times (\text{Se}) + (1-\text{Prevalence}) \times (1-\text{Sp})}

NPV = \frac{(1-\text{Prevalence}) \times (\text{Sp})}{(1-\text{Prevalence}) \times (\text{Sp}) + (\text{Prevalence}) \times (1-\text{Se})}
How Prevalence Affects PPV & NPV (Cont’d)

PPV for 10% prevalence population:

\[
\frac{(10/100) \times (98.9/100)}{(10/100) \times (98.9/100) + (1-10/100) \times (1-99.7/100)} = 97.3\%
\]

PPV for 1% prevalence population:

\[
\frac{(1/100) \times (98.9/100)}{(1/100) \times (98.9/100) + (1-1/100) \times (1-99.7/100)} = 76.9\%
\]
Testing Algorithm Describes the Sequence of Tests to be Performed

• An HIV Positive Status should be based upon the outcome of 2 or more tests
• When two test results disagree (one is reactive, the other non-reactive), the finding is called “discordant.” In this case, a third test must be performed.

Always follow the sequence of the tests in the algorithm
Ideal Algorithm

- Tests need to be:
  - Highly sensitive
  - Highly specific

- Tests should not share the same false negatives and false positives

- 3rd test (if needed)
* Develop appropriate algorithm diagram (parallel or serial) and insert names of HIV tests that represent test 1, 2 or 3.
Exercise: Interpreting HIV Status Using Testing Algorithm

- Refer to Participant Manual
- Work alone to determine HIV status
- 3 Minutes
### Possible HIV Test Outcomes: Parallel Algorithm

<table>
<thead>
<tr>
<th>TEST 1</th>
<th>TEST 2</th>
<th>TEST 3</th>
<th>HIV Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-reactive</td>
<td>Non-reactive</td>
<td></td>
<td>Negative</td>
</tr>
<tr>
<td>Reactive</td>
<td>Reactive</td>
<td></td>
<td>Positive</td>
</tr>
<tr>
<td>Non-reactive</td>
<td>Reactive</td>
<td>Non-reactive</td>
<td>Negative</td>
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<td>Non-reactive</td>
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<td>Positive</td>
</tr>
<tr>
<td>Reactive</td>
<td>Non-reactive</td>
<td>Reactive</td>
<td>Positive</td>
</tr>
</tbody>
</table>

- **Non-reactive** means the test result is negative, indicating no HIV infection.
- **Reactive** means the test result is positive, indicating HIV infection.
- **Positive** HIV status indicates a positive result across all tests.
- **Negative** HIV status indicates a negative result across all tests.
Summary

• Explain the importance of a tests’ Se, Sp, PPV, NPV

• Explain the testing algorithm adopted by MoH. What rapid tests are used and in what order?
Module 5: Assuring the Quality of HIV Rapid Testing

A Systems Approach to Quality
Learning Objectives

At the end of this module, you will be able to:

• Explain the systems approach to lab quality and its benefits
• Identify the essential elements of a lab quality system and how they apply to HIV rapid testing
• Recognize key factors that may compromise the quality of HIV rapid testing
• Describe your responsibilities in preventing and detecting errors before, during, and after testing
Content Overview

• The approach we take to achieve quality
• Essential elements of a lab quality system
• Quality assurance procedures at the HIV rapid testing site
• How you can contribute to quality before, during, and after testing
What Is “Quality?”

• The ability of a product or service to satisfy stated or implied needs of a specific customer

• Achieved by conforming to established requirements and standards.
Discussion –
Dining Out: A Quality Experience

• Think about your expectations for quality.

• What might you expect for a quality experience at a restaurant?
Why Quality?

Test Site Quality

Accurate, Reliable Testing

Quality in All Aspects of Health Care
A Systems Approach to Quality

• Considers all components within a system
• Identifies the connection and relationship (e.g., cause and effect) among the components

Example: the human body system
A headache may be caused by disorder of other components in the system
Definition of A Lab Quality System

The organizational structure, responsibilities, processes, procedures, and resources for implementing quality management of the laboratory or testing site.

In other words... all activities which contribute to quality of tests, directly or indirectly.
Benefits of a Quality System

- Monitors all parts of the testing system
- Detect and reduce errors
- Improve consistency between testing sites
- Help contain costs
The Lab Quality System

- Organization
- Personnel
- Equipment
- Purchasing & Inventory
- Process Control
- Quality Control & Specimen Management
- Information Management
- Documents & Records
- Occurrence Management
- Assessment
- Process Improvement
- Customer Service
- Facilities & Safety

Lab workers
Health workers
Counselors
Organization

Quality policy & standards

Sufficient resources

Clearly defined roles & accountability

A culture committed to quality
Personnel

- Human resource planning
- Hiring
- Retention
- Training
- Supervision
- Performance management
Equipment

Selection

Acquisition

Installation & initial calibration

Maintenance, service & repair

Troubleshooting

Disposition

Lab workers  Health workers  Counselors
Purchasing and Inventory

- Procurement
- Receiving
- Storage
- Inventory management
- Record keeping
Process Control

- Standard operating procedures
- Specimen management
- Quality control
Documents and Records

- Standardized forms
- Document approval
- Document distribution
- Document storage/retrieval
- Document destruction

Lab workers  Health workers  Counselors
Information Management

- Information flow
- Data collection & management
- Patient privacy & confidentiality
- Computer skills
Occurrence Management

- Written procedures for addressing errors
- Corrective actions
- Occurrence records
- Occurrence reporting
Assessment

- External Quality Assessment
- Improvement measures
- Internal audit or self evaluation

Lab workers  Health workers  Counselors
Process Improvement

On-going data collection

Improvement measures

Lab workers
Health workers
Counselors
Customer Service

- Monitoring Customer satisfaction
- Process improvement
- Rewards

Lab workers, Health workers, Counselors
Facilities and Safety

- Testing and storage areas
- Safety practice
- Safety procedures & records
The Lab Quality System

- Organization
- Personnel
- Equipment
- Purchasing & Inventory
- Process Control
- Quality Control & Specimen Management
- Information Management
- Documents & Records
- Occurrence Management
- Assessment
- Process Improvement
- Customer Service
- Facilities & Safety

Lab workers  Health workers  Counselors
Activity: Are You “Positive” or “Negative?”

Participants take turns tossing the cabbage ball. When you catch the ball,

• Peel a statement off the ball
• Read out loud your statement to the group
• Based on the statement, go to:
  ▪ The Positive Circle or
  ▪ The Negative Circle
Who Is Responsible for Quality?

EVERYONE!

- Laboratory management and program staff establish quality assurance procedures.
- Test site personnel implement the quality assurance procedures.
# Quality Assurance vs. Quality Control

<table>
<thead>
<tr>
<th>Definition</th>
<th>Quality Assurance</th>
<th>Quality Control</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Quality Assurance</strong></td>
<td>Activities to ensure process are adequate for a system to achieve its objectives</td>
<td>Activities to evaluate a product or work result</td>
</tr>
</tbody>
</table>
| **Examples** | • Establish standard procedures for sample collection  
• Define criteria for acceptable samples | • Analyze known QC sample to determine if a test is valid  
• Decide if a sample is acceptable for testing |
The Quality Assurance Cycle

- Data and Lab Management
- Safety
- Customer Service

Patient/Client Prep
Sample Collection

Personnel Competency
Test Evaluations

Sample Receipt and Accessioning

Sample Transport

Testing

Lab workers
Health workers
Counselors
Why Do Errors Occur?

Some causes include:

- Individual responsibilities unclear
- No written procedures
- Written procedures not followed
- Training is not done or not completed
- Checks not done for transcription errors
- Test kits not stored properly
- QC, EQA not performed
- Equipment not properly maintained

Errors can occur throughout the testing process
Pre-testing Errors

Examples include:

- Specimen mislabeled or unlabeled
- Specimen stored inappropriately before testing
- Specimen transported inappropriately
- Test kits stored inappropriately
Preventing and Detecting Errors – Before Testing

- Check storage and room temperature
- Select an appropriate testing workspace
- Check inventory and expiration dates
- Review testing procedures
- Record pertinent information, and label test device
- Collect appropriate specimen
Testing Errors

Examples include:

- Country algorithm not followed
- Incorrect timing of test
- Results reported when control results invalid
- Improper measurements of specimen or reagents
- Reagents stored inappropriately or used after expiration date
- Dilution and pipetting errors
- Incorrect reagents used
Preventing and Detecting Errors – During Testing

• Perform and review Quality Control (QC)
• Follow safety precautions
• Conduct test according to written procedures
• Correctly interpret test results
Post-testing Errors

Examples include:

- Transcription error in reporting
- Report illegible
- Report sent to the wrong location
- Information system not maintained
Preventing and Detecting Errors – After testing

- Re-check patient/client identifier
- Write legibly
- Clean up and dispose of contaminated waste
- Package EQA specimens for re-testing, if needed
Why is Quality System Important to HIV Rapid Testing?

- Ensures that quality is the foundation of everything we do
- Sets the standard for level of quality
- Meets/exceeds customer expectations
- Provides means to prevent, detect and correct problems
- Becomes the core of a monitoring, evaluation, & improvement system
- Reduces costs

Even the simplest Rapid Test is not foolproof
Summary

- Why do errors occur?
- What are some common errors that might occur with HIV rapid testing?
- Where is QA applied in a PMTCT or VCT testing site?
- What are some steps to take before, during, and after testing to assure the quality of results?
- Describe the impact that errors will have on the patient/client.
Module 6: Safety At the HIV Rapid Testing Site
The Lab Quality System

Organization

Personnel

Equipment

Purchasing & Inventory

Process Control
Quality Control & Specimen Management

Information Management

Documents & Records

Occurrence Management

Assessment

Process Improvement

Customer Service

Facilities & Safety

Lab workers

Health workers

Counselors
Why Is Safety Important?

• Coming in contact with human blood or blood products is potentially hazardous.
• Safety involves taking precautions to protect you and the client against infection.
What Else Needs Protection?

• Other people who may come in contact with testing by-products
• Protect integrity of test products
• Protect environment from hazardous material
Learning Objectives

At the end of this module, you will be able to:

- Adhere to personal health and safety practices
- Maintain a clean and organized workspace
- Disinfect and dispose of infectious materials
- Take appropriate actions following accidental exposure to potentially infectious specimen
- Follow written safety procedures and keep proper safety records
Content Overview

• General safety practices
  - Work habits (personal, work space, material)
  - Proper disposal of sharps and waste
  - Disinfection of work areas

• Safety documentation
Universal or Standard Precautions

Every specimen should be treated as though it is infectious.
Apply Safety Practices Throughout the Testing Process

- **Before Testing (Pre-analytical)**
  - Specimen collection
  - Specimen preparation
  - Specimen transport

- **Testing (Analytical)**
  - Testing

- **After Testing (Post-analytical)**
  - Disposal
Develop Personal Safe Work Habits

- Wash hands before and after testing each patient
- Wear a fresh pair of gloves with each patient
- Wear lab coat or apron
- Dispose of contaminated sharps and waste immediately after testing
Develop Personal Safe Work Habits (Cont’d)

- Pipetting by mouth is **strictly forbidden**
- Never eat, drink or smoke at the test site
- Keep food **out** of the laboratory/testing site refrigerator
Maintain Clean & Orderly Work Space

• Keep work areas uncluttered and clean
• Disinfect work surfaces daily
• Restrict or limit access when working
• Keep supplies locked in a safe and secure area
• Keep emergency eye wash units in working order and within expiry date

Biohazard
Take Precautions to Avoid Needle Stick Injury

What can cause needle stick injury?

- Lack of concentration
- Inexperience
- Lack of concern for others
- Improper disposal of sharps
Drop Used Sharps in Special Containers
Do’s and Don’ts: Sharps and Waste Containers

- Do Not break, bend, re-sheath or reuse lancets, syringes or needles
- Do Not shake sharps containers to create space
Do’s and Don’ts: Sharps and Waste Containers

What’s wrong with this picture?
Never Place Needles or Sharps in Office Waste Containers
Sharps Containers Must Be:

- Placed near workspace
- Closed when not in use
- Sealed when ¾ full

Lab workers  Health workers  Counselors
Policy for Handling Sharps

- User responsible for disposal of sharps
- Must dispose of sharps after each test
- Must place sharps in sharps boxes
- Do not drop sharps on the floor or in the office waste bin
- Place sharps container near your workspace
- Seal and remove when box is \( \frac{3}{4} \) full
- Incinerate all waste
Incineration of Waste

- Incineration is burning of contaminated waste to destroy and kill micro-organisms.
- Incineration:
  - Is effective against potential re-use
  - Protects environment
  - Must be supervised
Disinfect Work Areas with Bleach

Disinfection

• Kills germs and pathogens
• Keeps work surface clean
• Prevents cross-contamination
• Reduces risks of infection
Different Cleaning Jobs Require Different Bleach Solutions*

General lab use - *Hypochlorite Solutions*

<table>
<thead>
<tr>
<th>Spills</th>
<th>General Disinfection</th>
</tr>
</thead>
<tbody>
<tr>
<td>10% (1 part + 9 parts)</td>
<td>1% (1 part + 99 parts)</td>
</tr>
</tbody>
</table>

You should have 10% bleach readily available at your test site.

* WHO Laboratory Biosafety Manual
Making a 10% Bleach Solution

Referred to as a 1/10, 1:10, or 5,000 ppm bleach solution

1 Part Bleach + 9 Parts Water =

Label Container
1:10
Initials
Exp. Date
Health Warnings

Water Fill Line
Bleach Fill Line
In Case of a Spill or Splash

- Wear clean disposable gloves
- Immediately and thoroughly wash any skin splashed with blood
  - **Large spills** - Cover with paper towels and soak with 10% household bleach and allow to stand for at least 5 minutes
  - **Small spill** - Wipe with paper towel soaked in 10% bleach
- Discard contaminated towels in infectious waste containers
In Case of an Accident

- What types of accidents can happen?
  - Potential Injury, i.e., needlesticks, falls
  - Environmental, i.e., splashes or spills
  - Equipment damage
- What should you do?
  - Report to supervisor immediately
  - Assess & take action
  - Record using form
  - Monitor situation
Action Plan for Implementing Safety Practices

• Identify hazards
• Establish and implement safety polices and procedures
• Conduct safety specific training
  ▪ Must be a priority
  ▪ Communication is key
• Perform regular audits or assessments
Safety References
Summary

- What is safety? Why is it important?
- What does bio-hazard mean?
- What is the universal precaution you must take when dealing with specimens?
- What are some examples of safety practices related to personal habits? Work space?
- What are the rules related to handling sharps and waste?
- How do you prepare a 10% bleach solution?
- What do you do if there is a spill?
- What do you do when an accident occurs?
Module 7:
Preparation for Testing –
Supplies and Kits
Learning Objectives

At the end of this module, you will be able to:

• List and identify all the supplies required for HIV rapid testing

• List and identify all the components of test kits for HIV rapid testing
Memory Game: Supplies & Materials

How To Play:

• **Spend 3 min. browsing through the display and learn the items**

• **Spend 1 min. writing down as many items as possible (without looking)**

  ▪ **Tally up the total number of items you write down**

  ▪ **The person who remembers the most items wins.**
Supplies & Materials Checklist

- HIV Rapid testing kits
- Alcohol
- Cotton Gauze / Wool
- Sterile Lancets
- Sharps bin or Disinfectant jar for lancets
- Pen for marking or labeling
- Gloves
- Aprons or laboratory coats
- Timer, clock, or wrist watch with minute hand
- Transfer pipettes, pipette tips
Supplies & Materials Checklist (Cont’d)

• Paper towels (for bench coating, cleaning, and hand washing)
• Soap for hand washing
• Leak-proof bag for containing or moving labeled biohazard waste for incineration
• Disinfectant e.g. Jik, Chlorox
• Band-Aids or plasters

• Note: Some supplies may be obtained locally, some may be obtained through central stores or externally
Don’t forget:

- Positive and Negative controls
- Register or book for recording results
- Spray bottle for making bleach solution
- Standard Operating Procedures

- Thermometers
Gloves

- Single use disposable gloves
- Latex or polypropylene
- Without evidence of holes or tearing
Alcohol

Lab workers  Health workers  Counselors
Cotton Gauze or Cotton Balls

Single-use, hazardous waste disposal
Sterile Lancets

Single-use, hazardous waste disposal
Pipette

Transfer Pipette

Automatic Pipette

Lab workers

Health workers

Counselors
Timer

Lab workers

Health workers

Counselors
Standard Operating Procedures and Forms

Lab workers
Health workers
Counselors
Labeling Pens and Writing Pens

- Labeling Pens
- Writing Pens
Sharps Bins / Disinfectant Jar
Proper Disposal of Contaminated Materials
Waste Disposal
Household Bleach and Container

Lab workers
Health workers
Counselors
Examine Test Kits

• Display test kits used in-country
• Examine the different components found in each of the Rapid Test kits, e.g.,:
  ▪ Desiccant packet – This is not used when performing the test. It only serves to keep the packet contents dry before use. It should be discarded when the test kit packet is opened.
  ▪ Buffer solution – Required by some kits
Organize Your Work Area
Summary

- What are these items used for:
  - Gloves
  - Alcohol swabs
  - Cotton balls or gauze
  - Sterile lancets
  - Pipette
  - Timer
  - Standard operating procedures
  - Marking pens
  - Sharps disposal bins
  - Disinfectant jar
  - Bleach

- What are the components of the following test kits:
  - Test kit 1
  - Test kit 2
  - Test kit 3
Module 8: Blood Collection – Finger Prick
Learning Objectives

At the end of this module, you will be able to:

• Explain the preparation tasks required for rapid tests

• Put a client at ease while collecting blood

• Collect blood from a finger prick accurately and confidently
Content Overview

- Preparation for testing
- Educating your client
- Performing a finger prick
Video: Initial Steps

The video will help you answer these questions:

- What are the pre-test preparation steps?
- What safety precautions should you use?
- What should you look for in examining kits before use?
- How do you put your client at ease while performing the test?
Video: Finger Prick

The video will help you answer these questions:

- How do you …
  - Position the hand?
  - Decide which finger to use?
  - Clean the fingertip?
  - Use a lancet?
  - Ensure blood flow from your client’s fingertip?

- Do you …
  - Use a previously used lancet on a client?
  - Collect the first drop of blood?
Pre-collection Safety Precautions
Finger Prick – Getting Started

1. Collect supplies
2. Position hand palm-side up. Choose whichever finger is least calloused.

3. Apply intermittent pressure to the finger to help the blood to flow

4. Clean the fingertip with alcohol. Start in the middle and work outward to prevent contaminating the area. Allow the area to dry.

5. Hold the finger and firmly place a new sterile lancet off-center on the fingertip
Finger Prick – Collecting Blood

6. Firmly press the lancet to puncture the fingertip

7. Wipe away the first drop of blood with a sterile gauze pad or cotton ball

8. Collect the specimen. Blood may flow best if the finger is held lower than the elbow.

9. Apply a gauze pad or cotton ball to the puncture site until the bleeding stops
Finger Prick - Proper Disposal

10. Properly dispose of all contaminated supplies"
Instructor-Led Demonstration
Role Play: Rehearsing Finger-Pricking a Client

Purpose
To practice:
• Educating clients (what do you do to put them at ease)
• Performing a finger prick (rehearse the action without actually pricking the finger)

Total Time
10 Minutes

Process
• Work in pairs
• Decide roles
  ▪ Tester
  ▪ Client
• The tester practices on the client (3 min)
• Switch roles; repeat the process (3 min)
• Exchange feedback on each other’s performance (3 min)
Hands-on Practice: Transfer Pipette

**Purpose**
- To practice using a pipette efficiently

**Materials required**
- Transfer pipette
- A cup of water

**Process**
- Work alone
- Use the pipette to draw and release sufficient amount of water until you become efficient

**Time**
5 minutes
Hands-On Practice: Finger Prick

**Purpose**
To practice finger-prick on other people using a lancet, pipette, and other supplies

**Total Time**
45 Minutes

**Process**
- Work in groups of 3
- Decide roles: tester, client, observer
- The tester practices on the client while the observer provides feedback. *(15 minutes)*
- Switch roles and repeat the process until everyone has taken on each role once.

Do not practice on your own fingers!
Summary

• What do you check in a test kit before use?
• How do you put a client at ease while collecting blood?
• What supplies do you need for a finger prick?
• What are the steps when performing a finger prick?
• What safety precautions should you follow?
Module 9: Performing HIV Rapid Tests
Demonstration and Practice
Learning Objectives

At the end of this module, you will be able to:

• Perform 3 HIV rapid tests according to SOP
  • Insert Test 1 name
  • Insert Test 2 name
  • Insert Test 3 name
• Perform multiple tests simultaneously
• Accurately interpret individual test results
• Accurately determine HIV status
Content Overview

Overview of Testing Procedures

Workspace Setup

Demo + Practice (individual tests on known samples)

Video Presentation and Discussion

Practice (Multi-test algorithm with blind samples)

Optional hands-on session

Lab workers
Health workers
Counselors

A dry room
B practical room
Capillus
Capillus: Getting Ready

1. Collect test items and other necessary lab supplies

2. Label the device with client identification number

3. Place slide on the black interpretation card. Ensure that slide is right side up.
Capillus: Reagent Preparation

4. Gently mix the latex reagent well ensuring that it is homogenous.

5. Use the dropper to draw the latex reagent up to the calibration mark. Avoid drawing up air bubbles.

6. Dispense the reagent into the mixing well, away from the capillary channel. Do not allow the dropper to touch the slide.
7. Collect 10 µl of specimen using a new disposable pipette tip with the pre-calibrated pipette.
Capillus: Applying Specimen to Test Slide

8. Hold the pipette directly over the well and dispense the specimen directly into the latex solution.

9. Mix the specimen and latex by gently pumping the mixture in and out of the tip 3 times. Stir in a circular motion at least 5 times.

10. Initiate the capillary flow by moving the mixture to the opening of the channel using the pipette.
11. Allow the latex mixture to flow through the entire channel and into the viewing window (about 3-7 min.) before reading the results.

12. Read and record the results and other pertinent info on the worksheet.
Capillus – Test Interpretation

Non-reactive

Reactive
Determine

Lab workers

Health workers

Counselors
**Determine: Getting Ready**

1. Collect test items and other necessary lab supplies

2. Use 1 strip per test and be sure to preserve the lot number on the remaining packet of strips

3. Label the test strip with client identification number

4. Pull off the protective foil cover
Determine: Collecting Specimen

5. Collect 50 µl of specimen using a precision pipette or 1 drop using a plastic transfer pipette
6. Apply the specimen to the absorbent pad on the strip

7. For whole blood only add 1 drop of chase buffer to the specimen pad
Determine: Getting Results

8. Wait 15 minutes (no longer than 60 minutes) before reading the results

9. Read and record the results and other pertinent info on the worksheet
Determine - Test Interpretation

- Reactive
- Non-reactive
- Invalid
Hema-Strip

Lab workers  Health workers  Counselors
Hema-Strip: Getting Ready

1. Collect test items and other necessary lab supplies

2. Label device with the client identification number
Hema-Strip: Collecting Specimen

3. Collect specimen directly from the finger-stick. Touch specimen with device tip until tip is full.
Hema-Strip: Buffer Preparation

4. Remove buffer vial – separate from top of device

5. Place buffer vial on a flat surface
6. Firmly press the device tip through the foil cover. Continue pushing device, usually 2 more times, to the bottom of vial until device and buffer vial snap together tightly.

7. Place the test device upright in a rack.
Hema-Strip: Getting Results

8. Wait 15 minutes before reading the results

9. Read and record the results and other pertinent info on the worksheet
Hema-Strip: Test Interpretation

Reactive

Non-reactive

Invalid

Lab workers

Health workers

Counselors
OraQuick
OraQuick: Getting Ready

1. Collect test items and other necessary lab supplies

2. Set reusable stand on a flat, level surface. Partially remove device from package and label device and the developer vial with client identification number.

3. Carefully uncap the developer vial and place vial into the stand
4. Collect approximately 5 µl of specimen using a new disposable loop

4. Instruct the client to use the pad end of the test device to swab completely across the outside of the upper and lower gums, one time around
OraQuick: Transferring Specimen (Blood Only)

5. Transfer the collected specimen to the vial
6. Stir the specimen in the vial with the loop
OraQuick: Inserting Test Device Into Buffer Vial

7. Insert the device pad completely into the vial with the result window facing forward
8. Wait 20 minutes (no longer than 40 min.) before reading the results

9. Read and record the results and other pertinent info on the worksheet
OraQuick: Test Interpretation

Reactive  Non-reactive  Invalid

Lab workers  Health workers  Counselors
Uni-Gold
Uni-Gold: Getting Ready

1. Collect test items and other necessary lab supplies

2. Remove device from package and label device with client identification number
Uni-Gold: Collecting Specimen

3. Collect specimen using the disposable pipette
Uni-Gold: Adding Specimen and Reagent to Test Device

4. Add 2 drops (approx. 60µl) of specimen to the sample port in the device

5. Add 2 drops (approx. 60µl) of the appropriate wash reagent to sample port
Uni-Gold: Getting Results

6. Wait for 10 minutes (no longer than 20 min.) before reading the results

7. Read and record the results and other pertinent info on the worksheet
Uni-Gold: Test Interpretation

Reactive  Non-reactive  Invalid

Lab workers  Health workers  Counselors
Activity: Workspace Setup

Instructions:

- Identify your Workspace in the practical room
- Gather test kits and supplies
- Obtain reactive and non-reactive specimens from instructor
- Arrange all items at your work station

Activity time: 10 minutes
Hands-On Practice: Individual Tests

Instructions:
• Use safety precautions
• Practice with blood provided by your instructor only
• Raise your hand if you need additional supplies
• Show your test results to instructor after you are done

Total time: 15 minutes per test
Video Presentation and Discussion
Video: Capillus

Key learning points

- What preparation is required for the test kit before testing?
- What are the components in the test kit?
- What are controls for? How do you use them?
- What information needs to be recorded, and where?
- How should you position the slide? Why do you place the slide on a black interpretation card?
- How do you collect blood? What device do you use?
- How long do you set the timer?
- How many results are possible? How do you read them?
**Video: Determine**

Key learning points

- What preparation is required for the test kit before testing?
- What are the components in the test kit?
- What do you need to preserve when tearing test strip form the packet?
- What information needs to be recorded, and where?
- How do you collect blood? What device do you use?
- Which step can you omit when using serum or plasma?
- How long do you set the timer?
- How many results are possible? How do you read them?
Video: Hema-Strip

Key learning points

- What preparation is required for the test kit before testing?
- What are the components in the test kit?
- When you open the test packet, what do you need to check?
- What information needs to be recorded, and where?
- How do you collect blood? What device do you use?
- How long do you set the timer?
- How many results are possible? How do you read them?
Video: OraQuick

Key learning points

• What preparation is required for the test kit before testing?
• What are the components in the test kit?
• What information needs to be recorded, and where?
• How do you collect blood? What device do you use?
• How do you collect oral fluids? What device do you use?
• How long do you set the timer?
• How many results are possible? How do you read them?
Video: Uni-Gold

Key learning points

- What preparation is required for the test kit before testing?
- What are the components in the test kit?
- What information needs to be recorded, and where?
- How do you collect blood? What device do you use?
- How long do you set the timer?
- How many results are possible? How do you read them?
Video: Multiple HIV Tests

Key learning points

- What are the advantages of performing more than one test at a time?
- Why must you keep two test kits separate when performing both at the same time?
- Do you collect blood at the same time or separately when performing multiple tests?
- How do you set the timer when two tests require different wait time?
- When is a tie-breaker used? How does it determine HIV status?
Country Algorithm

- Display approved country algorithm here
## Possible Outcomes in a Parallel Algorithm

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<td>Non-reactive</td>
<td></td>
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<td>Reactive</td>
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<td>Positive</td>
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<td>Non-reactive</td>
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<td>Non-reactive</td>
<td>Negative</td>
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<td>Negative</td>
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<tr>
<td>Reactive</td>
<td>Non-reactive</td>
<td>Reactive</td>
<td>Positive</td>
</tr>
</tbody>
</table>
Hands-On Practice: Multi-Test Algorithm

Conduct test 1 and test 2 simultaneously following the multi-test algorithm. Perform the algorithm using the 5 designated blind specimens and determine HIV status of each.

Specimen

<table>
<thead>
<tr>
<th>Specimen</th>
<th>Test 1 - Test 2 - Test 3</th>
<th>HIV Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
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<td>5</td>
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</tr>
</tbody>
</table>
Hands-On Practice: Multi-Test

Algorithm (Cont’d)

Instructions:

• Collect supplies and obtain panel of blind specimens
• Organize your workspace
• Complete one algorithm before starting the next
  • Don’t forget – Use safety precautions
  • Practice on blood provided by your instructor only
  • Raise your hands if you need additional supplies
• Record results on worksheet
• Keep test devices - instructor will check results before discarding of devices

Total time: 2 hours
Summary

• Describe the key learning from performing:
  - (In-country test 1)
  - (In-country test 2)
  - (In-country test 3)

• Describe the key learning from performing the multi-test algorithm
Module 10: Inventory

Managing Stocks at the HIV Rapid Testing Site
The Lab Quality System

- Organization
- Personnel
- Equipment
- Purchasing & Inventory
- Process Control & Specimen Management
- Information Management
- Documents & Records
- Occurrence Management
- Assessment
- Process Improvement
- Customer Service
- Facilities & Safety

Lab workers, Health workers, Counselors
Learning Objectives

At the end of this module, you will be able to:

• Maintain proper records
• Maintain proper level of consumables
• Use first-expiry-first-out concept when managing stocks
• Inspect delivery of supplies before acceptance
• Identify lot numbers and expiry dates
• Keep kits and supplies in proper storage
Content Overview

• What is stock management?
• Record keeping
• Re-order levels
• Receipt of consumables
• Storage of consumables
Stock Management Means...

Properly maintaining adequate supplies to ensure uninterrupted service
Stock at a Rapid Test Site

Includes...

Insert photo of stockroom

Supplies at Workstation
Stock Management Leads to High Quality Testing

- Ensures availability of materials and kits, when needed
- Avoids the use of expired kits
- Minimizes wastage
How Do You Manage Stock?

You own a sundry shop. You buy the merchandise from suppliers and sell them for a profit. To keep a profitable business, you must always have the right items available for customer purchase everyday.

What must you do to maintain adequate stocks?
Stock Management Involves Knowing. . .

- What and how much supplies/consumables you have
- When to order
- What and how much has been ordered, when it was ordered
- Where to store stock
- When and how much fresh stock was received, and by whom
Stock Management Involves...

- Performing a “stock count”
- Maintaining proper inventory records
- Determining when to re-order
- Determining how much to re-order
- Placing orders properly
- Inspecting delivery of new orders
- Ensuring proper storage of stock
Perform a “Stock Count”

What is it?  Physically counting each item in the stock

When is it done?  Recommended at the beginning of each month

Who does it?  A designated person

All items must be accounted for. Everything that comes in and goes out must be recorded.
Maintain Proper Inventory Records

**Stock Card**
- Simple, heavy weight cards
- Kept for each item in stock

**Stock Book**
- Contains listing of all items in the store
- Update monthly after physical count
- Use information from stock cards
- Also called register
Stock Card: An Example

- Item Name: ___________ Unit: ___________
- Manufacturer: ________________________
- Minimum Stock (Re-Order Level): ___________

<table>
<thead>
<tr>
<th>Date</th>
<th>Received From</th>
<th>Issued To</th>
<th>Quantity Received</th>
<th>Quantity Issued</th>
<th>*Balance</th>
<th>Lot #</th>
<th>Signature</th>
</tr>
</thead>
<tbody>
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</tbody>
</table>
## Stock Book: An Example

<table>
<thead>
<tr>
<th>Item Name</th>
<th>Qty (units) Requested</th>
<th>Date Requested</th>
<th>Qty Received</th>
<th>Date Received</th>
<th>Lot #</th>
<th>Expiry Date</th>
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</table>
Reconciling Stock with Records

Ideal

# Tests Performed = Stock Depletion

Reality

# Test Performed + loss = Stock Depletion

What should be done to minimize loss?

Lab workers
Health workers
Counselors
Determine When to Re-order

Re-order when stock reaches minimum level

Terminology:

- **Minimum stock** - Amount of stock required to support testing operations until additional supplies are received.
- **Lead time** – Time between placing an order and receiving it.
- **Maximum usage** – number of test kits used in a given time period.
Calculating Minimum Stock Level

Minimum Stock Level = Maximum lead time in weeks \times Maximum Usage

Example:

Maximum lead time = 12 weeks
Maximum usage/wk = 3 kits
Minimum stock level = 12 \times 3 = 36 kits

When only 36 kits are left, place an order.
Exercise: Calculating Minimum Stock Level

- On average, you use 5 Uni-Gold kits a week.
- It normally takes 12 weeks to receive the order you placed.
- You should order more Uni-Gold kits when you have ____ kits left in the inventory.
Determine How Much to Re-order

Establish proper full stock level. Re-order to reach that level.

- Consider stock consumed, borrowed, expired, wasted, pilferage
- Never order more than your storage space can hold
- Never order more supplies than you can use before they are expired
- Consider maximum usage plus minimum stock level
Determine Full Stock Level

Maintain stocks that cover maximum usage plus minimum stock level

Maximum usage /wk = 70 tests
# tests / month = 70 x 4
280 tests used per month

Assuming 20 tests per kit, how many kits are used per month?
280 / 20 = 14

Lead time = 12 weeks or 3 months
Minimum stock level = 14 kits x 3 months = 42 kits
Full stock level = 42 + 14 = 56

You must always have 56 kits in stock at the beginning of each re-order cycle.
Exercise: Determine Full Stock Level

<table>
<thead>
<tr>
<th>Maximum usage /wk = 80 tests</th>
<th>Lead time = 12 weeks or 3 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>How many tests are used per month?</td>
<td>Minimum stock level = ______ kits</td>
</tr>
<tr>
<td>______ tests/month</td>
<td>Full stock level = ______ kits</td>
</tr>
<tr>
<td>Assuming 15 tests per kit, how many kits are used per month?</td>
<td>You must always have ______ kits in stock at the beginning of each re-order cycle (3 months).</td>
</tr>
<tr>
<td>______ kits/month</td>
<td></td>
</tr>
</tbody>
</table>

Determine:

- What is the minimum stock level?
- How many test kits should you have in the beginning of each re-order cycle?
Place Orders Properly

- Describe ordering system that is in place
- Provide specific instructions for placing orders
- Instruct trainees on how to complete specific forms related to inventory/stock management.
- Describe contingency plan when stock is not available
  - National contingency plan
  - Site contingency plan
- Describe communications / feedback systems to central level
  - How to cease standing deliveries
  - Why should you cease orders
  - What information should be fed back to central procurement or stores, e.g., updated consumption rates during scale up
Inspect Delivery of New Orders

Upon receipt:

• Verify contents of order received with requisition
• Check integrity of received supplies
• Date each item received
• Note expiration date
• Store new shipment behind existing shipment
• Create or update records
Examine Lot Number & Expiry Date

- Lab workers
- Health workers
- Counselors
Ensure Proper Storage of Inventory

- Keep in a clean, organized, and locked storeroom
- Store according to manufacturer’s instructions
- Place in well ventilated room
- Store away from direct sunlight
- Place items on shelves
- Organize existing and new shipments by expiration dates

First expiry, first out
Summary

• What does inventory management mean?
• What information is recorded in inventory record-keeping?
• How do you determine minimum stock level?
• How do you determine proper full inventory level?
• What does “First Expiry First Out” mean?
• What procedure should you follow when receiving new kits and supplies?
• How should kits and supplies be stored?
Key Messages

• Maintain an adequate inventory at all times to ensure uninterrupted service.
• Don’t let any item run out before re-order.
• Never order more than your storage space can hold. Never order more supplies than you can use before they are expired.
• All items in the inventory must be accounted for and recorded.
• Always inspect new shipment before accepting.
Module 11: Use and Care of Equipment

At the HIV Rapid Testing Site
The Lab Quality System

- Organization
- Personnel
- Equipment
- Purchasing & Inventory
- Process Control
- Quality Control & Specimen Management
- Information Management
- Documents & Records
- Occurrence Management
- Assessment
- Process Improvement
- Customer Service
- Facilities & Safety

Lab workers  Health workers  Counselors
Learning Objectives

At the end of this module, you will be able to:

• Specify your responsibilities related to equipment
• Routinely monitor the temperatures of refrigerators and freezers
• Confirm auto pipettes deliver specified volumes
• Properly use and maintain centrifuges
Content Overview

- Rationale for using properly maintained equipment
- Your responsibilities for equipment
- Use and care of equipment at the HIV rapid testing site
  - Refrigerator and Freezer
  - Pipette
  - Centrifuge
Functioning Equipment is Vital to Quality Service

Functioning Equipment produces reliable test results, lowers repair costs, prevents delays in testing, and maintains productivity.

Total Quality

Lab workers, Health workers, Counselors
Equipment at HIV Rapid Testing Site

- Refrigerator & freezer
  - Separates cells from serum/plasma

- Pipette
  - Collects or transfers specimen to test device

- Centrifuge
  - Collects or transfers specimen to test device

- Lab workers
- Health workers
- Counselors
Management Responsibilities: Ensure Test Site Readiness

Before equipment use:

- Assign oversight responsibility
- Update laboratory equipment inventory record
- Develop and implement written protocols for operating procedures
- Establish maintenance program including routine function checks and trouble-shooting
- Establish maintenance log
- Provide training for all operators
Your Responsibilities: Execute at Test Site

- Follow written operational procedures
- Conduct routine maintenance, including function checks
- Take corrective actions
- Keep records

Do not use malfunctioning equipment
Function Checks Verify that Equipment is Working Properly

Performed routinely
- Daily, weekly, monthly
- After adjustment or repair

Example:
- Monitoring refrigerator temperatures
- Verifying pipette accuracy
- Checking centrifuge speed
Refrigerator and Freezer: Use and Care

- Keep organized
- Periodically clean inside and outside
- Ensure door is completely sealed when closing
- CAUTION! – DO NOT store food items or beverages in laboratory refrigerator or freezer
Refrigerator & Freezer: Temperature Checks

Monitor daily

• Refrigerator: 2°C to 8°C
• Freezer: -20°C, -40°C, or -80°C
# Refrigerator & Freezer: Temperature Log

<table>
<thead>
<tr>
<th>Date</th>
<th>Temp Observed</th>
<th>Initials</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
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</tbody>
</table>
Types of Pipettes

- Precision pipettes (Not disposable)
  - Precise and accurate volumes (e.g., 50 µl for Determine)
  - Use disposable, single-use, pipette tips

- Graduated plastic bulb pipettes (Disposable)
  - Dispenses approximate volume
  - Easy to use
Pipette: Use and Care

• Select the appropriate pipette for the volume required
• Ensure that the pipettor, tips, and specimen are at the same temperature
• Firmly attach tip
Pipette: Use and Care (Cont’d)

- Hold the pipette vertically when aspirating
- Place tip just below the sample
- Avoid air bubbles
- Discard contaminated tips in appropriate container after completion of task

DO NOT RE-USE
- Pipette tips
- Graduated plastic bulb pipettes
Precision Pipettes Require Performance Checks

• Performed periodically
• Required supplies:
  ▪ Pipette
  ▪ Pipette tips
  ▪ Analytical balance
  ▪ Weigh boats
  ▪ Distilled or deionized water
Pipette: Steps for Checking Reproducibility

1. Pipette a series of 10 samples into a weigh boat on an analytical scale
2. Record weight of each sample to calculate calibration results
3. Verify calculated results are within limits

<table>
<thead>
<tr>
<th>Range</th>
<th>Max/Min</th>
<th>Accuracy</th>
</tr>
</thead>
<tbody>
<tr>
<td>10 µl</td>
<td>± 1.0 µl</td>
<td>10%</td>
</tr>
<tr>
<td>100 µl</td>
<td>± 10.0 µl</td>
<td>10%</td>
</tr>
<tr>
<td>200 µl</td>
<td>± 20.0 µl</td>
<td>10%</td>
</tr>
</tbody>
</table>

4. If the results are not within limits, remove from service until appropriate adjustment can be made
5. Decontaminate pipette and scale after use
## Pipette: Troubleshooting

<table>
<thead>
<tr>
<th>Problem</th>
<th>Potential Cause</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leakage</td>
<td>• Tip(s) incorrectly attached</td>
<td>• Attach firmly</td>
</tr>
<tr>
<td></td>
<td>• Foreign articles between the tip and cone</td>
<td>• Clean tip cones</td>
</tr>
<tr>
<td></td>
<td>• O-ring damaged</td>
<td>• Change the O-ring</td>
</tr>
<tr>
<td></td>
<td>• Incorrect operation</td>
<td>• Follow manufacturer’s instructions carefully</td>
</tr>
<tr>
<td></td>
<td>• Tip incorrectly attached</td>
<td>• Firmly attach tip</td>
</tr>
<tr>
<td>Inaccurate dispensing</td>
<td>• Follow manufacturer’s instructions carefully</td>
<td></td>
</tr>
</tbody>
</table>

- Lab workers
- Health workers
- Counselors
Centrifuge: Use and Care

- Always operate with the lid closed
- Balance contents before turning on
- Check for vibration
- Do not open the lid until the rotor has come to a complete stop
- Keep lids on tubes when spinning
Centrifuges: Function Checks

- Proper balance
- Lubrication
- Rotor function
Centrifuge: Routine Maintenance

• Clean interior, condenser coils, fan, and screens
• Investigate unusual noises or vibrations
• Inspect for evidence of wear, cracks in fitting, corrosion, uneven wear, or signs of fatigue:
  ▪ Head, shaft head and coupling
  ▪ Rotor
  ▪ Brushes and bearings
  ▪ Power supply
  ▪ Motor and lubricant
  ▪ Gaskets, seals, mounts and lubricants
• Calibrate speed
Centrifuge Safety

- Increase the speed slowly until optimal speed is reached
- Disconnect the centrifuge from the electrical source before preventive maintenance, cleaning or inspection
- Take caution when removing spills and broken specimen tubes after a run
- If tubes are broken, keep the door closed and allow to sit undisturbed for 30 minutes before attempting to clean
- Use tweezers to remove broken glass
Keep a Log for All Maintenance Activities

<table>
<thead>
<tr>
<th>Model no.</th>
<th>Serial no.</th>
</tr>
</thead>
</table>

**Generic Maintenance Form**

<table>
<thead>
<tr>
<th>MONTH:</th>
<th>YEAR:</th>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Daily Maintenance (Activity)</th>
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<th>2</th>
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<th>5</th>
<th>6</th>
<th>7</th>
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<tbody>
<tr>
<td>Weekly Maintenance (Activity)</td>
<td>1</td>
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<tr>
<td>Monthly Maintenance (Activity)</td>
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</tbody>
</table>
Exercise: Create a Maintenance Activity List

Purpose:
- Use what you have learned in this module and create a maintenance checklist specific to your test site

Process:
- Work in groups of 3-4 (or by test site)
- Create a list of maintenance activities on a daily, weekly, monthly, and yearly basis
- Activity time; 10 minutes
Summary

• Why is it important to keep equipment in optimal condition?

• Describe proper use and care for:
  - Refrigerator and freezer
  - Pipettes
  - Centrifuges

• What are some routine maintenance activities performed on:
  - Refrigerator and freezer?
  - Pipettes?
  - Centrifuges?

• Describe your responsibilities for equipment at the test site.
Module 12: Quality Control
The Lab Quality System

- Organization
- Personnel
- Equipment
- Purchasing & Inventory
- Process Control
- Quality Control & Specimen Management
- Documents & Records
- Occurrence Management
- Process Improvement
- Customer Service
- Information Management
- Assessment
- Facilities & Safety

Lab workers  Health workers  Counselors
At the end of this module, you will be able to:

- Differentiate between internal and external controls
- Use external quality controls at designated frequencies
- Analyze common problems associated with invalid test results
Content Overview

• What is Quality Control (QC)?
• Benefits of QC in rapid testing
• Internal versus external quality control
• Troubleshooting invalid results
• Quality control records
What Is Quality Control (QC)?

• Measures taken to monitor the quality of the test itself

• QC for HIV Rapid Testing includes:
  • Testing of samples with known results to verify if the procedure is working properly
  • Interpreting the presence or absence of control bands/lines within the device itself

• If an error occurs, do not release or report results until you have corrected the error.
Sources of Controls

- **Internal to the test Kit**
  - Control samples provided with the test kit with known reactivity
  - Region within the device, also termed procedural or in-built control

- **External to the test Kit**
  - Control samples not included with the test kit provided an external source that has been validated for use with a specific test kit
Internal and External Quality Control

**Internal Control**
Included in testing device or as part of the kit

**External Control**
Known positive and negative samples that are used to validate the reliability of the test system

- **Control Band**

Lab workers  Health workers  Counselors
Examples of Tests that Include Internal Control

- Capillus
- Determine
- Hema-Strip
- OraQuick
- Uni-Gold

Which test does not have internal control built into its device?
Capillus Kit Comes with Internal Control Samples

Positive and Negative Control Samples
Sources of External Quality Control

Samples

- Prepared by Reference Laboratory
  - Store according to instructions
  - Date when opened
  - Use before expiry date
  - Do not contaminate

- Commercially prepared
Frequency of Use: When Should You Test External Control Samples?

- Minimum once a week, beginning of the week
- New shipment of test kits
- Beginning a new lot number
- Environmental conditions exceed range needed for stability of kits
Invalid Results – What Do You Do?

- Repeat test
- If repeatedly invalid:
  - assume problem with test product or procedure
  - continue with alternative testing algorithm
- Identify cause of problem
- Inform supervisor
- Take corrective actions
# Troubleshooting Invalid Results

<table>
<thead>
<tr>
<th>Problem</th>
<th>Potential Cause</th>
<th>Action</th>
</tr>
</thead>
</table>
| No control line or band present |  • Damaged test device or controls  
  • Proper procedure not followed  
  • Expired or improperly stored test kits or controls |  • Repeat the test using new device and blood sample  
  • Follow each step of testing according to SOP  
  • Re-check buffer and/or specimen volumes  
  • Wait for the specified time before reading the test  
  • Check expiration date of kits or controls. Do not use beyond stated expiration date  
  • Check temperature records for storage and testing area |

Keywords: Lab workers, Health workers, Counselors
## Troubleshooting Invalid Results – Cont’d

<table>
<thead>
<tr>
<th>Problem</th>
<th>Potential Cause</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive reaction with negative external control, i.e. false positive</td>
<td>Incubation time exceeded</td>
<td>Re-test negative control using a new device and read results within specified time limit</td>
</tr>
<tr>
<td>Extremely faint control line</td>
<td>The control line can vary in intensity</td>
<td>No action required. Any visible line validates the results.</td>
</tr>
</tbody>
</table>
### Possible HIV Test Outcomes: Parallel Algorithm

<table>
<thead>
<tr>
<th>TEST 1</th>
<th>TEST 2</th>
<th>TEST 3</th>
<th>HIV Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-reactive</td>
<td>Non-reactive</td>
<td>Non-reactive</td>
<td>Negative</td>
</tr>
<tr>
<td>Reactive</td>
<td>Reactive</td>
<td>Non-reactive</td>
<td>Positive</td>
</tr>
<tr>
<td>Non-reactive</td>
<td>Reactive</td>
<td>Reactive</td>
<td>Negative</td>
</tr>
<tr>
<td>Reactive</td>
<td>Non-reactive</td>
<td>Non-reactive</td>
<td>Negative</td>
</tr>
<tr>
<td>Non-reactive</td>
<td>Reactive</td>
<td>Reactive</td>
<td>Positive</td>
</tr>
<tr>
<td>Reactive</td>
<td>Non-reactive</td>
<td>Reactive</td>
<td>Positive</td>
</tr>
</tbody>
</table>
Exercise #1: Interpreting Rapid Test Results

• Refer to the handout in your participant manual
• Read the test results and write your interpretation in the space provided.
• Time: 3 minutes
Exercise #2: Resolving Unreportable Test Results

Determine

Uni-gold

Hema-strip

Lab workers    Health workers    Counselors
Exercise #2: Resolving Un-reportable Test Results – Cont’d

• Should you accept the results?
• If not,
  • What should be your next steps?
  • What might have caused the tiebreaker test to yield an invalid result?
  • What corrective actions might you take?
Maintaining Quality Control

Records

**WHY?**
- Trouble-shooting
- Provides proof reliable test results

**HOW?**
- Use standard worksheets

**WHEN?**
- Each time QC materials are tested
- Record all invalid results and inform supervisor
Quality Control Record: An Example

Daily Record of Quality Control Results

<table>
<thead>
<tr>
<th>Date</th>
<th>Negative Control Result</th>
<th>Neg Control Lot #</th>
<th>Acceptable? Y / N</th>
<th>Positive Control Result</th>
<th>Pos Control Lot #</th>
<th>Acceptable? Y / N</th>
<th>Initials</th>
<th>Reviewed by &amp; Date</th>
</tr>
</thead>
<tbody>
<tr>
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</tbody>
</table>

Corrective Actions

<table>
<thead>
<tr>
<th>Date</th>
<th>Action Taken</th>
<th>Initials</th>
<th>Reviewed by &amp; Date</th>
</tr>
</thead>
<tbody>
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</tbody>
</table>

Lab workers  Health workers  Counselors
Periodic Review of Records

- Review of internal control results before accepting test results
- Review of external control results by test performer
- Weekly or monthly review of external quality control results by testing site supervisor
- Periodic audits or assessments
Summary

• What is quality control?
• What is an internal quality control?
• What is an external quality control?
• How often and when should external controls be used?
Summary – Cont’d

• What would you do if your external control tested invalid?

• Give examples of problems encountered with QC results, why they occurred, and how to correct them.

• Why is it important to maintain records of QC results?
Module 13: External Quality Assessment (EQA)

On-site Evaluation and Re-Testing
The Quality System

- Organization
- Personnel
- Equipment
- Purchasing & Inventory
- Process Control
- Quality Control & Specimen Management
- Information Management
- Documents & Records
- Occurrence Management
- Assessment
- Process Improvement
- Customer Service
- Facilities & Safety

Lab workers, supervisors, managers, workers, testers, counselors
Learning Objectives

At the end of this module, you will be able to:

• Assess operations at test site to determine if quality requirements are met
• Take corrective actions following External Quality Assessment (EQA)
• Keep appropriate records related to EQA
• Avoid common problems associated with EQA specimen management
Content Overview

• What is EQA and why is it important?
• EQA Responsibilities
• EQA Methods
  ▪ Proficiency Testing
  ▪ On-Site Evaluation
  ▪ Re-testing
• How to implement EQA
External Quality Assessment (EQA): Definition

Objective assessment of a test site’s operations and performance by an external agency or personnel
Why EQA?

- Allows comparison of performance and results among different test sites
- Provides early warning for systematic problems associated with kits or operations
- Provides objective evidence of testing quality
- Indicates areas that need improvement
- Identifies training needs
EQA: Conducted at All Levels of Testing

NRL = National Reference Lab
PL = Provincial or Intermediate Lab
TS = Test Site (Point of Service)
Management Responsibilities:

Overview

- Determines policies for EQA (WHO, WHAT, WHEN, HOW)
- Assigns responsibility
- Establishes and maintains a system for assessment visits
  - Schedules visits
  - Conducts evaluations
- Receives EQA results and supports corrective action measures
- Monitors and maintains records
- Investigates deficiencies
- Manages corrective action efforts
- Communicates outcomes
Testing Personnel’s Responsibilities: Overview

- Participate in the EQA program
- Take corrective actions
- Maintain EQA records
- Communicate outcomes to supervisors
EQA Methods

- Proficiency Testing
- On-site Evaluation
- Re-checking/Re-testing
What is Proficiency Testing?

- Panels of specimens are sent to multiple test sites by reference laboratory
- Test sites perform tests and report results
- Results indicate quality of personnel performance and test site operations
- Results are often compared across several testing sites
What is On-site Evaluation?

Periodic site visits to systematic assessment of lab practices

- Focuses on how the lab monitors its operations and ensures testing quality
- Provides information for internal process improvement
What is On-site Evaluation? – Cont’d

- Also referred to as audits, assessments, or supervisory visits
- Learn “where we are”
- Part of every lab quality system
- Measures gaps or deficiency
- Collect information for:
  - Planning & implementation
  - Monitoring
  - Continuous improvement
What is Re-testing?

- The process by which a random selection of specimens are collected from the routine workload at the test site and sent to the reference laboratory for validation
- Used to detect errors
EQA Should Lead to Corrective Actions

“Corrective Action”
An action taken to correct a problem or deficiency

Examples:
• Production of an incorrect result
• Not following procedures
Problems May Occur Throughout the Testing Process

**Pre-Testing**
- Specimen compromised during preparation, transport, or after receipt by improper storage or handling

**Testing**
- Reagents, test methods, QC
- Competency of staff

**Post-Testing**
- Report format
- Interpretation
Take Corrective Actions

- Use problem-solving team:
  - Investigate root causes
  - Develop appropriate corrective actions
- Implement corrective actions
- Examine effectiveness
- Record all actions and findings
Sample of Corrective Action Form

CORRECTIVE ACTION FORM

This Corrective Action is a result of:

- Occurrence: Date: Time:
- Internal Assessment: Date: Time:
- External Assessment: Date: Time:

Description of Problem or Finding: *(What happened and Why)*

- 
- 
- 
- 

Reported by: (Staff Name) ____________________________

Corrective Action Taken: *(What was done to prevent re-occurrence?)*

- 
- 
- 
- 

- Lab workers
- Health workers
- Testers
- Counselors
How To Implement EQA

Proficiency Testing

On-site Evaluation

Re-checking/Re-testing

Lab workers or Managers, Workmen, Testers, Counselors
On-Site Evaluation Process

1. Pre-Evaluation Preparation
2. Entrance Interview
3. Information Gathering
4. Outcome Assessment
5. Exit Conference
6. Reporting

Preparation
Entrance Interview
Observation of facilities, process, procedures
Outcome Assessment
Exit Conference
Reporting
### Site Visit Checklist – Assessment of Quality System

<table>
<thead>
<tr>
<th>Quality System Essential</th>
<th>Yes</th>
<th>No</th>
<th>Assessor’s comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Organization</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Is there a quality policy manual present and accessible?</td>
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<tr>
<td>• Does the policy manual address all elements of the quality system?</td>
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<tr>
<td>• Does the site have a designated quality officer?</td>
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<tr>
<td>• Is the site manager aware of all quality system efforts?</td>
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<tr>
<td><strong>Personnel</strong></td>
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<td></td>
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</tr>
<tr>
<td>• Do testing staff members possess certificates indicating successful participation in HIV rapid test training?</td>
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<tr>
<td>• Has the staff been oriented to the patient/client flow at the test site?</td>
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<tr>
<td>• Does staff demonstrate professionalism?</td>
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<tr>
<td>• Is number of staff adequate for the site workload?</td>
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<tr>
<td>• Approximately how many tests does each staff member perform per month?</td>
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</tr>
<tr>
<td><strong>Documents and Records</strong></td>
<td></td>
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</tr>
<tr>
<td>• Are standard operating procedures for all aspects of the testing process written, up-to-date, and accessible to staff?</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>• Is the handwriting legible?</td>
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</tr>
<tr>
<td>• Do worksheets include appropriate information?</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>• Are external quality control records up-to-date, easily reviewed?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Are corrective actions recorded?</td>
<td></td>
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<tr>
<td>• Are results interpreted and recorded according to the SOP and VCT/PMTCT protocol?</td>
<td></td>
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</tr>
<tr>
<td><strong>Purchasing and Inventory</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Are kits and reagents stored properly?</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>• Is staff following “first expired, first out” method when managing inventory stock?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Is there a policy for re-ordering kits and supplies?</td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>
Tester Responsibilities: Ensuring a Productive Site Visit

• Before Visit:
  ▪ Record keeping is essential. Get organized
  ▪ Confirm date of visit
  ▪ Review written policies and procedures
  ▪ Conduct internal assessment in preparation of site visit

• During Visit
  ▪ Participate in visits – cooperate
  ▪ Ask questions of site assessors

• After Visit
  ▪ Take corrective actions, where necessary

Remember – visits are instructive, not punitive
On-site Evaluation:

1. Pre-Evaluation Preparation

- Assign Responsibility
  - Laboratory management
  - Quality Manager
- Use Integrated team approach
- Determine who will conduct on-site evaluations
  - Select auditors with necessary skills:
    - Attention to detail
    - Ability to communicate effectively
    - Diplomacy
  - Provide appropriate training
- Schedule site visits
On-site Evaluation:

Pre-Evaluation Preparation:

• Determine site visit frequency:
  - Established sites - At least twice per year
  - New Sites - Quarterly
• For efficiency, cluster evaluations geographically
• Schedule in advance
  - Announced or unannounced visits
On-site Evaluation:

2 Entrance Interview

The entrance interview sets the tone for the entire visit

- Be prepared, positive and courteous
- Introduce evaluation team - show identification
- Provide overview of process in terms of what will be done
  - Review of facility
  - Record review
  - Observation
  - Interview with testing staff
  - Use of proficiency panel
  - Exit interview
On-site Evaluation:

Information Gathering

- Observe physical layout of the site
- Evaluate testing operations
  - Specimen collection
  - Observation of test performance
  - Quality control
  - Inventory of kits
  - Record-keeping
- Use quality systems checklist
- Conduct in an instructional, not punitive, manner.
On-site Evaluation:

4 Outcome Assessment

Evidence of implementation & maintenance of quality system?

- Conclude visit
  - No deficiencies

- Ensure visit is sufficient to objectively document evidence
- Expand visit or observation
- Reference deficiencies

 Supervisors or Managers

La workers or Managers

Counselors
On-Site Evaluation:

5 Exit Conference

Review findings with supervisory and testing staff

- Make positive statements first – acknowledge staff cooperation and support
- Address negative findings – allow test site to discuss findings and provide additional information
- Provide instructions and timeframe for submitting plan for correcting problems
On-site Evaluation:

6 Reporting

- Include information:
  - Site Name & Location
  - Date of Visit
  - Assessment Team Members
  - Major Findings
  - Recommendations for corrective actions
- Submit completed checklist and report to relevant authorities
Example: Assessment Report
Role Play: On-site Evaluation Visit

- **Objective:** To experience situations which may compromise test results that an evaluator may observe
- **Volunteers to play the following roles:**
  - Patient/Client
  - Quality Manager
  - Laboratory Manager
  - Person performing tests
- **Rest of the group will observe**
- **Role play time:** 20 minutes
Issues to Consider Prior to Implementing a Re-testing Program

- What is the purpose of re-testing?
- Is re-testing feasible?
- Does technical capacity exist at reference lab?
- Can turnaround of re-testing be accomplished in a timely manner allowing for immediate corrective actions?
- What type of specimen should be collected for re-testing?
- How should EQA specimens be labeled and recorded?
- When should specimens be shipped/transported to reference laboratory?
- Which laboratory should re-test specimens submitted by test sites?
# Statistical Basis for Re-testing:
## Error Detection

<table>
<thead>
<tr>
<th>Volume (Per Site)</th>
<th>1%* error</th>
<th>5%* error</th>
<th>Retesting Feasibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very low 50 spec</td>
<td>Re-test 48 (96%)</td>
<td>Re-test 31 (62%)</td>
<td>No</td>
</tr>
<tr>
<td>Low 500 spec</td>
<td>Re-test 225 (45%)</td>
<td>Re-test 56 (11%)</td>
<td>Possible</td>
</tr>
<tr>
<td>High 5000 spec</td>
<td>Re-test 290 (5.8%)</td>
<td>Re-test 59 (1.2%)</td>
<td>Yes</td>
</tr>
</tbody>
</table>

*95% Confidence
## Re-testing: Example Sampling Plan

<table>
<thead>
<tr>
<th>Volume (Per Site)</th>
<th>1%* error</th>
<th>5%* error</th>
<th>Retesting Feasibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low 500 spec</td>
<td>Re-test 225 (45%)</td>
<td>Re-test 56 (11%)</td>
<td>Possible</td>
</tr>
</tbody>
</table>

For monthly re-testing:

- Determine the number of specimens required to detect desired error detection rate
- For 1% error detection = 225 specimens/month
- Divide 225 by 4 = ~56 specimens/week = ~11 specimens/day
- Select number of specimens per day randomly – e.g., every 3\textsuperscript{rd} specimen

*95% Confidence
Re-testing Process

1. Determine specimen type
2. Determine sampling plan and time interval
3. Collect specimens
4. Store specimens until transport
5. Package and transport specimens along with paperwork to designated laboratory
6. Compare re-test results with site results
7. Take Corrective actions, if needed
Tester Responsibilities: Re-testing

- Follow written policies and procedures
- Collect appropriate specimen
- Record keeping is essential
- Take necessary precautions to avoid transcription errors
- Package and transport EQA specimens to designated reference laboratory
- Take necessary corrective actions
**Specimen Requirements**

- **Dried Blood Spots (DBS)**
  - 100 µl collected on labeled filter paper
  - Store refrigerated in appropriately packaged re-sealable plastic bag
- **Serum or Plasma**
  - 0.5 ml aliquot in labeled cryovial
  - Store at 2-8°C for up to 1 week
  - Store at -20°C or below if longer than 1 week
Example Specimen Transfer Log for Re-testing

[Insert Name of Referring Testing Site,
Contact Name
Address and Phone Number]

Date: ____________________________

Referring Testing Site ____________________________

<table>
<thead>
<tr>
<th>Specimen Tracking Number</th>
<th>Test Subject ID*</th>
<th>Final Result (Testing Site)</th>
<th>Date Specimen Collected</th>
<th>Specimen Type (DBS or Serum)</th>
<th>Collected by</th>
<th>Referral Lab Req(^*$) Completed ((\checkmark))</th>
<th>Date to referral lab</th>
<th>Date Conf Result Received</th>
<th>Result of Re-test</th>
</tr>
</thead>
<tbody>
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</table>

*ID = Identification
\(^*$\)Lab Req = Laboratory Requisition
Specimen Management:

Common Problems

• Transcription errors
  ▪ Mislabeling cryovial or DBS card
  ▪ From Lab register to specimen transfer log
  ▪ From reference lab to testing site
  ▪ Inadequate specimens
Summary

- Describe your responsibilities in EQA.
- What is proficiency testing? On-site evaluation? Re-testing?
- Explain the process for on-site evaluation.
- What are some issues to consider prior to implementing a re-testing program?
- Explain the process for re-testing.
- What are some common problems associated with specimen management?
Module 14: Blood Collection and Handling

Dried Blood Spot
What Is a Dried Blood Spot (DBS)?

- Whole blood collected on filter paper and dried
- Made directly from the client’s whole blood
- Used for re-testing at a reference laboratory
  - Testing site results are compared to reference laboratory results.
  - This is part of External Quality Assurance.
EQA Re-testing

Specimens collected for EQA could be dried blood spots (DBS) or serum/plasma

EQA is a process by which specimens:

• Are randomly selected from the routine workload at a test site
• Are sent to the reference laboratory for validation of results
Learning Objectives

At the end of this module, you will be able to:

• Collect dried blood spots (DBS)
• Package and store DBS in a way to maintain specimen integrity
• Maintain DBS records
• Distinguish between valid and invalid DBS
Content Overview

- Required supplies
- How to collect and dry DBS
- How to package and store DBS
- Valid and invalid DBS
- Hands-on practice
What Are Your Responsibilities?

- Collect valid specimens
- Label and store appropriately until transported for re-testing
- Ensure records are properly maintained
- Avoid transcription errors

A test result is only as good as the specimen collected
**EQA Specimen Transfer Log**

Example Specimen Transfer Log for Re-testing

[Insert Name of Referring Testing Site, Contact Name Address and Phone Number]

| Date: ______________________ |
| Referring Testing Site: ______________________ |

<table>
<thead>
<tr>
<th>Specimen Tracking Number</th>
<th>Test Subject ID*</th>
<th>Final Result (Testing Site)</th>
<th>Date Specimen Collected</th>
<th>Specimen Type (DBS or Serum)</th>
<th>Collected by</th>
<th>Referral Lab Req* Completed (Y/N)</th>
<th>Date to referral lab</th>
<th>Date Conf Result Received</th>
<th>Result of Re-test</th>
</tr>
</thead>
</table>

*ID – Identification

*Lab Req – Laboratory Requisition
Required Supplies for DBS

- Blood collection card (filter paper)
- Glycine weighing paper
- Sealable plastic bags
- Humidity cards
- Desiccant packs

Lab workers  Health workers  Counselors
How to Collect DBS

- Use Universal Safety Precautions
- Clearly label card with appropriate identification number
- Follow finger prick procedure
- Uniformly saturate entire circle

Two complete circles are better than five incomplete ones!!
How to Dry DBS

- Avoid touching or smearing the blood spots
- Allow the specimen to fully air dry horizontally (at least 3 hours) at room temperature
- Keep away from direct sunlight
- Do not heat, stack or allow DBS to touch other surfaces during the drying process
Dry Completely Before Packaging
How to Package DBS for Storage

1. Appropriately stack DBS
2. Insert into sealable plastic bag
3. Add desiccant packets
4. Add humidity cards
5. Label contents of bag and seal
1. **Stacking DBS**

Place filter paper between sheets of weighing paper

Fold weigh ends of weighing paper
2. Insert Into Sealable Plastic Bag
3. Add Desiccant Packets
4. Add Humidity Cards and Seal Bag
5. Label Outside of Plastic Bag with Contents
How to Store DBS

Keep packaged DBS (in sealable plastic bags) cool and dry until transported to reference laboratory

Avoid leaving in vehicle, as sun and heat will deteriorate DBS
How to Package DBS for Shipping

1. Insert bundled DBS into rip-resistant envelope
2. Include appropriate documentation
3. Insert both into brown envelop and seal for shipment
Example Specimen Transfer Log for Re-testing

[Insert Name of Referring Testing Site, Contact Name Address and Phone Number]

<table>
<thead>
<tr>
<th>Date:</th>
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<tbody>
<tr>
<td>Referring Testing Site</td>
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<table>
<thead>
<tr>
<th>Specimen Tracking Number</th>
<th>Test Subject ID*</th>
<th>Final Result (Testing Site)</th>
<th>Date Specimen Collected</th>
<th>Specimen Type (DBS or Serum)</th>
<th>Collected by</th>
<th>Referral Lab Req† Completed (y/n)</th>
<th>Date to referral lab</th>
<th>Date Conf Result Received</th>
<th>Result of Re-test</th>
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</table>

*ID = Identification
†Lab Req = Laboratory Requisition
Valid DBS Specimen

NAME ____________________________

DATE ____________________________

USA-N-0004

S&S® 903™ Lot #W001 A01707

Lab workers  Health workers  Counselors
Valid DBS Specimen

NAME  MB1KP1120
DATE  28/1/2002

S&S® 903 Lot #W001 A01692
Invalid DBS Specimen

Specimen quantity insufficient for testing
Invalid DBS Specimen

Specimen appears scratched or abraded
Invalid DBS Specimen

Specimen not dried sufficiently
Invalid DBS Specimen

Specimen appears clotted or layered
Invalid DBS Specimen

Specimen appears hemolyzed, discolored, or contaminated
Invalid DBS Specimen

Specimen exhibits serum rings
Invalid DBS Specimen

No Blood
DBS Collection: Demonstration

**Procedures**
- Fingerprick steps 1-7
- Apply pressure
- Allow a large drop of free-flowing blood to collect
- Quickly and gently touch the card with blood
- Let blood soak through
- Repeat until at least 2 circles are filled
- Fingerprick steps 9-10

**Tips**
- Do not press the filter paper against the puncture site.
- Apply blood to only one side of the filter paper.
- Do not apply blood more than once in the same collection circle.
- Do not “milk” the finger.

- Do not press the filter paper against the puncture site.
- Apply blood to only one side of the filter paper.
- Do not apply blood more than once in the same collection circle.
- Do not “milk” the finger.
**Purpose**
To practice collecting DBS from another person

**Total Time**
30 Minutes

**Process**
- Work in groups of 2
- Take turns practicing collecting DBS from your partner’s finger
Exercise: Valid vs. Invalid DBS

• **Objective**: To distinguish between valid and invalid DBS specimens

• **Process**: Examine the specimens collected from hands-on practice and determine whether each is valid or not.

• **Total time**: 3 minutes
Summary

• Describe the procedures for:
  ▪ Collecting DBS
  ▪ Drying DBS
  ▪ Packaging DBS for storage
  ▪ Storing DBS
  ▪ Packaging DBS for shipping
• Describe the criteria for valid DBS samples.
• What may have caused a DBS sample to be invalid?
Module 15: Documents and Records
The Lab Quality System
Learning Objectives

At the end of this module, you will be able to:

• Tell the difference between a document and a record
• Explain the rationale for maintaining documents and records
• Provide examples of documents and records kept at a test site
• Follow the procedures as prescribed in SOPs
• Describe how to properly keep and maintain test site documents and records
• Describe the types of information typically not found in a manufacturer’s product insert
**Content Overview**

- **What are documents and records?**
  - **Documents**
    - Why are they important?
    - What documents should you keep?
    - Why is it important to follow SOPs?
    - What is the proper way to keep and maintain documents?
  - **Records**
    - Why are they important?
    - What records should you keep?
    - What is the proper way to keep and maintain records?
What Are Documents and Records?

Documents
- WRITTEN policies, process descriptions, procedures, and blank forms
- Used to communicate information

Records
- Information captured on worksheets, forms, and charts
Exercise: Differentiate Between Documents and Records

- Country testing algorithm
- Safety manual
- Client test results
- Standard operation procedures (SOPs) for an approved HIV rapid test
- Manufacturer test kit inserts
- Summary of findings form on-site evaluation visit

- Report of corrective actions
- Temperature log (blank form)
- Quality control record (blank form)
- Daily maintenance log (completed)
- Stock cards and stock book (completed)
- EQA specimen transfer log (completed)
Exercise: Differentiate Between Documents and Records

- Country testing algorithm
- Safety manual
- Client test results
- Standard operation procedures (SOPs) for an approved HIV rapid test
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- Summary of findings form on-site evaluation visit

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- Temperature log (blank form)
- Quality control record (blank form)
- Daily maintenance log (completed)
- Stock cards and stock book (completed)
- EQA specimen transfer log (completed)
Documents Are the Backbone of the Quality System

Verbal instructions often are:

- Not heard
- Misunderstood
- Quickly forgotten
- Ignored

Policies, standards, processes, and procedures must be written down, approved, and communicated to all concerned.
Standard Operating Procedures (SOPs) Are Documents that... 

• Describe how to perform various operations in a testing site 
• Provide step-by-step instructions 
• Assure: 
  ▪ Consistency 
  ▪ Accuracy 
  ▪ Quality
SOPs Are Controlled Documents

- Must be approved for use in-country
- Must have document control features
- Must be kept up-to-date

---

**Document Type:** Standard Operating Procedure

<table>
<thead>
<tr>
<th>Document No.:</th>
<th>PR #</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Title:</strong> Test Procedure using Uni-Gold HIV Rapid Test Kit</td>
<td></td>
</tr>
</tbody>
</table>

1. **Purpose / Intended Use**

   The Trinity Biotech Uni-Gold™ HIV test is a single reagent assay for the detection of antibodies to human immunodeficiency virus types 1 and 2 in serum, plasma or whole blood.

2. **Procedure**

   - **SOP:**
     - **Document Control:**
     - **Revision No.:** 0
     - **Page 1 of 4

3. **Materials Required / Kit Contents:**

   - 20 Test Devices
     - Each test device contains colloidal gold labelled with synthetic HIV peptides, synthetic HIV peptides as test zone and a control line.

   - Wash Reagents (4ml)
     - Serum/Plasma Wash - Tris buffered wash containing detergent and preservative (0.1% sodium azide).
What SOPs Should You Keep at a Test Site?

- Daily routine schedule
- Country policies and algorithm
- Safety manuals
  - Safety Precautions
  - Preparation of 10% bleach solution
  - Post-HIV exposure prophylaxis management and treatment guidelines
- Blood collection:
  - Fingerprick, venipuncture, DBS
What SOPs Should You Keep at a Test Site?—Cont’d

- Test procedures
- EQA
  - Submission of EQA specimens to reference lab
  - Internal assessments
- Reordering of supplies and kits
- Equipment use and maintenance
SOPs Must Be Followed

• Why is it important to follow SOPs?
• What are the consequences if you don’t?
Do Not Rely Solely on Manufacturer Product Inserts

- Manufacturer product inserts do not provide specific information for test sites
- Examples include:
  - Materials required, but not in kit
  - Specific safety requirements
  - Sequence of tests in country algorithm
  - External quality control requirements
Proper Record-Keeping Makes Quality Management Possible

Record-keeping allows a test site to:

- Communicate accurately and effectively
- Minimize error
- Monitor quality system
- Assist management in:
  - Developing policy & plans
  - Monitoring and evaluating programs
What Records Should You Keep at a Test Site?

- Specimen transfer logs
- HIV request / client test result
- Lab / Test register
- Temperature logs
- Equipment maintenance logs
- Inventory records
**Tips for Good Record Keeping**

- Understand the information to be collected
- Record the information every time
- Record all the information
- Record the information in the same way every time

* PMTCT Generic Curriculum
Client Test Records

RAPID HIV TEST REQUEST FORM

Site Code: _______________ VCT Number: _______________ Age: _______________ Sex: M/F

Code name of counsellor/person collecting blood

Origin of sample (hospital department – please tick)

- Cervical smear
- General VCT
- Counseling area
- Medical Ward
- TB Ward
- Outpatients
- Paediatric ward

Purpose of testing (reason for test – please circle)

A. Screening
B. Follow-up testing
C. New client
D. MSM
E. CHC
F. TBL
G. ARV
H. Other

Laboratory/Test Site Report

RESULTS

<table>
<thead>
<tr>
<th>TEST</th>
<th>Lot No</th>
<th>Expiry Date</th>
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<tr>
<td>1st</td>
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TIEBREAKER

|
| EXPiry DATE
| LOT NUMBER |

FINAL RESULT

<table>
<thead>
<tr>
<th>TEST</th>
<th>Lot No</th>
<th>Expiry Date</th>
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CLIENT RESULT SHEET

Site Code: _______________ VCT Number: _______________ Lab Test Site no: _______________

Code name of counsellor/person collecting blood

Origin of sample (hospital department – please tick)

- Cervical smear
- General VCT
- Counseling area
- Medical Ward
- TB Ward
- Outpatients
- Paediatric ward

Result

HIV Antibody Test Result: _______________ Signed: _______________

- Fill completely and accurately
- Write legibly
- Sign & date

Insert sample in country client test record

Lab workers  Health workers  Counselors
How Long Should You Retain Client Test Records?

It depends on several factors:

- National policies
- Secure storage space at test site
Logbooks Are Cumulative Records of Test Site Operations

- Minimize deterioration
- Index to allow for easy retrieval

RECORDS

Lab workers  Health workers  Counselors
Records Should be Permanent, Secure, Traceable

- **Permanent:**
  - Keep books bound
  - Number pages
  - Use permanent ink
  - Control storage

- **Secure:**
  - Maintain confidentiality
  - Limit access
  - Protect from environmental hazards

- **Traceable:**
  - Sign and date every record
Information Recorded will Feed Into Monitoring and Evaluation Systems

• Provide in-country information:
  ▪ When will what be reported?
  ▪ How will it be reported?
  ▪ Whom will it be reported to?
  ▪ How will the data be used?
Summary

• What is the difference between a document and a record?
• What are some examples of documents and records?
• Name examples of information not found in a manufacturer product insert.
• What are some key features of SOPs?
• What are some tips for good record-keeping?
• How should records be maintained?
• How are test site records reported in your country?
Key Messages

- Written policies and procedures are the backbone of the quality system
- Complete quality assurance records make quality management possible
- Keeping records facilitates meeting program reporting requirements
Module 16: Professional Ethics
Learning Objectives

By the end of the module, you will be able to:

• Describe ethical issues related to HIV rapid testing
• Explain the importance of professional ethics
• Apply ethical conduct to HIV rapid testing
• Take appropriate actions to maintain client confidentiality
Content Outline

• What is ethics?
• Why is ethics important?
• Who is responsible for ethics?
• How is ethics applied to HIV rapid testing?
• Maintaining confidentiality
• Code of conduct
Scenario I

A pregnant woman comes for HIV testing. Your test site has just run out of the 2nd test in the algorithm. You tell her that she will have to come back in 2 days. She becomes very emotional and explains that she has traveled a long distance after finally deciding to get tested and won't be back in the area for a long time.

Feeling sorry for her, you proceed to perform test one, and report a resulting positive test to the client.
Scenario II

At the HIV rapid testing site, you discover that you just run out of the buffer for Test 1 of the algorithm. Rather than denying testing to clients, you decide to go ahead and perform Test 1 using the buffer from kits of Test 2.
Scenario III

Today is Monday. You discover that there are enough test devices to last through the entire week, but they will expire on Wednesday.

Since resources are tight and you don’t want to waste any test kits (it is only a couple of days past expiration anyway), you decide to use the test devices until the end of the week.
What Could Be the Consequences of…

• A false positive HIV result?
• A false negative result?
What Is Ethics?

“A set of principles of right conduct”
Why is Ethics Important?

“Decisions about diagnosis, prognosis and treatment are frequently based on results and interpretations of laboratory tests. Irreversible harm may be caused by erroneous tests.”

International Federation of Clinical Chemistry and Laboratory Medicine (IFCC)
Scenario IV

Rick, the tester, is excited about getting home at the end of his work day, because a relative he hasn’t seen in quite some time is scheduled to arrive. Right before he is ready to leave, he gets distracted by a phone call and forgets to lock up the lab register in the cabinet.
Maintaining Confidentiality

It is important to:
• Keep all client/patient information private
• Secure all records / logbooks
• Restrict access to testing areas

**Warning**
People often violate ethics not because they mean to, but because they are careless. As a matter of fact, they sometimes act with good intentions.
Role-Play

Watch the role-play and discuss:

• What happened?
• What were the ethical issues involved?
• What were the implications?
• What would you do if you were in this situation?
Who is Responsible for Ethics?

- EVERYONE!
  - Medical Laboratory Technician
  - Nurse Counselor
  - Clerk
  - Secretary
  - General Hand
  - Driver
How Do We Apply Ethics To HIV Rapid Testing?

- Work done
- Behavior of the staff
- Behavior of management
Code of Ethics (IFBLS)

Excerpts from International Federation of Biomedical Laboratory Science (IFBLS)

- Maintain **strict confidentiality** of patient information and test results
- Safeguard the **dignity and privacy** of patients
- Be accountable for the quality and integrity of clinical laboratory services
Code of Ethics (ASCP)

Excerpts from American Society for Clinical Pathology (ASCP)

- Treat patients and colleagues with respect, care and thoughtfulness
- Perform duties in an accurate, precise, timely and responsible manner
- Safeguard patient information as confidential, within the limits of the law
- Prudently use laboratory resources
Summary

• In your own words, what is ethics?
• Why is it important?
• Give examples of actions you can take to maintain client confidentiality.
• Give an example of a code of ethics to which you are willing to personally commit.
Key Messages

- Ethical issues are important. We must constantly remind ourselves of the code of conducts and ensure we do the right thing.
- Ethical issues are often hard to deal with because they create dilemmas.
- People often violate ethics not because they mean to, but because they are careless. As a matter of fact, they sometimes act with good intentions.