

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	<p>At the end of this module, you will be able to:</p> <ul style="list-style-type: none"> • 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

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

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

Teaching Guide

Slide Number	Teaching Points
1	<p><u>Module 5: Assuring the Quality of HIV Rapid Testing</u></p> <p>DISPLAY this slide before you begin the module. Make sure participants are aware of the transition into a new module.</p>
2	<p><u>Learning Objectives</u></p> <p>STATE the objectives on the slide</p>
3	<p><u>Content Overview</u></p> <p>EXPLAIN that these are the topics that will be covered in this module</p> <p>EMPHASIZE that this module provides an overview of the quality system and details on specific elements of the quality system.</p>
<p>Flipchart</p> 	<p>WRITE the content outline on a flipchart prior to training.</p> <p>REFER to it frequently to orient participants to where they are in the module.</p>
4	<p><u>What is “Quality”?</u></p> <p>STATE the definition on the slide</p> <p>EMPHASIZE that a service would include providing and interpreting an HIV Rapid Test.</p>

Slide Number	Teaching Points
<p>5</p> <p>Group Discussion</p> <p>5 minutes</p> <p>Flipchart</p> 	<p><u>“Dining Out”: A Quality Experience</u></p> <p>STATE Quality can be evaluated in anything we experience.</p> <p>EXPLAIN that you can better understand the concept of quality and quality systems, by thinking about what you might experience at a restaurant:</p> <p>ASK What you might expect for a quality experience at a restaurant.</p> <p>NOTE participants’ responses on a flipchart.</p> <p>STATE If your expectations as a customer are met by the restaurant, the restaurant has provided you with “quality” service.</p> <p>Simply put: Quality Management is having systems in place to continually evaluate:</p> <ul style="list-style-type: none"> • What is being done • How it is being done • What are opportunities for improvement • How to make changes for improvement • What is the impact of the change/improvement <p>ASK participants to keep the restaurant scenario in mind as they view and discuss the following slides.</p>
<p>6</p>	<p><u>Why Quality?</u></p> <p>EXPLAIN why quality is important:</p> <ul style="list-style-type: none"> • Quality at a testing site will result in accurate and correct performance of the HIV Rapid Test • 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

Slide Number	Teaching Points
7	<p><u>A Systems Approach to Quality</u></p> <p>STATE the approach we take to ensure lab quality is a systems approach.</p> <ul style="list-style-type: none"> • A systems approach examines all components in the system, not just focusing on any one component. • A systems approach places as much emphasis on identifying and describing the connections between system components as on identifying and describing the components themselves. <p>EXPLAIN the concept further by using the human body as an example.</p> <ul style="list-style-type: none"> • 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. • 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.
8	<p><u>Definition of A Lab Quality System</u></p> <p>READ the definition on the slide.</p> <p>STATE by adopting the systems approach to lab quality, a lab quality system would encompass all activities that contribute to quality directly or indirectly.</p>
9	<p><u>Benefits of a Quality System</u></p> <p>EXPLAIN the benefits of a quality system to the HIV rapid testing sites.</p>
10	<p><u>The Lab Quality System</u></p> <p>STATE a lab quality system has 12 components, each of which will be explained in further detail.</p> <p>POINT OUT the 12 components.</p>

Slide Number	Teaching Points
<p>Flipchart</p> 	<p>REFER to the flipchart from the discussion earlier. Relate each statement to a specific quality system essential. For example:</p> <ul style="list-style-type: none"> • You notice a government certificate of passed inspection posted near the entrance (<i>Assessment: external evaluation</i>) • The reservation you made has been recorded and honored (<i>Information Management; Documents & Records</i>) • You are treated courteously by a knowledgeable staff (<i>Personnel: training, supervision; Organization: standards, accountability</i>) • Your order was taken promptly and meal was served in a reasonable amount of time (<i>Process control</i>) • You ordered a menu item, and the restaurant had all the necessary ingredients to prepare the dish (<i>Inventory Management</i>) • The food was well presented, fresh and flavorful (<i>Inventory management, storage, procurement</i>) • Your overcooked steak was promptly replaced with a properly cooked steak (<i>Occurrence Management: correcting error; Equipment: maintenance, troubleshooting; Customer service</i>) • Before paying the bill, you were asked if your experience met your expectations and what would you have liked improved (<i>Process improvement; Organization: commitment to quality, standards</i>)
 <p><i>TIPS</i> 11-22</p>	<p>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.</p> <p>This module is highly conceptual and abstract. Try to provide as many concrete examples and analogies as possible.</p>
 <p><i>Customization</i> <i>Notes</i> 11-22</p>	<p>If a lab quality system has been established, provide specific in-country information for each component of the quality system.</p>

Slide Number	Teaching Points
11	<p><u>Organization</u></p> <p>EXPLAIN organization is the leadership or party responsible for establishing and managing the overall quality program. The quality system must start with the organization.</p> <p>To ensure total lab quality, organization needs to:</p> <ul style="list-style-type: none"> • Create quality policy and standards • Secure sufficient resources to maintain quality requirements • Clearly define roles and accountability • Cultivate a culture committed to quality <p>INDICATE this component is closely linked to other components such as personnel, equipment, process improvement, and customer service.</p>

Slide Number	Teaching Points
12	<p data-bbox="520 293 667 322"><u>Personnel</u></p> <p data-bbox="520 344 1358 477">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:</p> <ul data-bbox="520 501 1337 1440" style="list-style-type: none"> <li data-bbox="520 501 1337 566">• Human resource planning – What skills do you need? How many people do you need? When do you need them? <li data-bbox="520 591 1337 689">• 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. <li data-bbox="520 714 1337 813">• Retention – What is your plan to retain your people once they are hired? How are you going to address the issue of high turnover? <li data-bbox="520 837 1337 1032">• 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. <li data-bbox="520 1057 1337 1254">• Training – Upon assignment to a testing site, staff must be oriented to site policies 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. <li data-bbox="520 1279 1337 1440">• Performance management – This entails all the activities that ensure an employees on-the-job performance. It involves goal setting, performance coaching, feedback, monitoring, appraisal, and performance improvement measures.

Slide Number	Teaching Points
13	<p data-bbox="520 293 676 322"><u>Equipment</u></p> <p data-bbox="520 344 1362 510">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:</p> <ul data-bbox="520 535 1353 1160" style="list-style-type: none"> <li data-bbox="520 535 1295 629">• Selecting the right equipment. The purchasing contract should include installation and initial calibration; regular service; and training to operate the equipment. <li data-bbox="520 658 1353 752">• Setting up mechanism for regular preventative maintenance and routine calibration to ensure uninterrupted service and prolonged life span of the equipment. <li data-bbox="520 781 1289 842">• Ensuring readily available technical expertise for timely repair in case of equipment breakdown. <li data-bbox="520 871 1115 900">• Stocking up on parts that break frequently <li data-bbox="520 929 1094 958">• Establishing troubleshooting procedures <li data-bbox="520 987 1281 1048">• Creating a maintenance log and regularly reviewing all documentation <li data-bbox="520 1077 1313 1160">• Retiring equipment properly. This involves putting up signage, removing from premise, and salvaging reusable parts. <p data-bbox="520 1184 1362 1279">INDICATE this component is closely linked to other components such as personnel, purchasing and inventory, documents and records, and facilities and safety.</p>

Slide Number	Teaching Points
14	<p data-bbox="520 293 884 322"><u>Purchasing and Inventory</u></p> <p data-bbox="520 344 1350 477">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.</p> <p data-bbox="520 499 975 528">Purchasing and inventory involves:</p> <ul data-bbox="520 551 1350 1021" style="list-style-type: none"> <li data-bbox="520 551 1331 584">• Defining criteria for products and services to be purchased <li data-bbox="520 607 1286 674">• Establishing a system to receive, inspect, accept, store incoming materials <li data-bbox="520 696 943 730">• Maintaining proper inventory <li data-bbox="520 752 1305 819">• Developing a system to connect materials to appropriate patients, activities, or records <ul data-bbox="667 842 1350 1021" style="list-style-type: none"> <li data-bbox="667 842 1350 931">○ This is important in the event of notices from manufacturers of potential problems with specific kit lot #. <li data-bbox="667 954 1299 1021">○ You will know what lot # was used only if this information is recorded. <p data-bbox="520 1043 1358 1133">INDICATE this component is closely linked to other components such as organization, process control, documents and records, and facilities and safety.</p>

Slide Number	Teaching Points
15	<p><u>Process Control</u></p> <p>EXPLAIN process control.</p> <ul style="list-style-type: none"> • Process control refers to the activities and techniques performed to ensure: <ul style="list-style-type: none"> ○ Testing procedures are correctly performed ○ The environment is suitable for reliable testing ○ The test kit works as expected to produce accurate and reliable results • Process control concerns all aspects of the laboratory, not just the testing procedures. Examples include ensuring that: <ul style="list-style-type: none"> ○ Test methods are appropriately evaluated. ○ Testing sites have on hand up-to-date standard operating procedures. ○ All staff follow SOPs (Standard Operating Procedures) exactly as written. ○ Specimens are appropriately collected, handled/processed, stored, transported, and discarded. ○ QC (quality control) is performed and monitored. <p>INDICATE this component is closely linked to other components such as personnel, purchasing and inventory, assessment, and facilities and safety.</p>
16	<p><u>Documents and Records</u></p> <p>EXPLAIN document and records may be paper-based or computer-based. Regardless of the format, a system must be established in order to:</p> <ul style="list-style-type: none"> • Create standards for forms • Manage document revision, approval, and distribution • Manage patient test records • Maintain document storage, retrieval, and destruction <p>INDICATE this component is closely linked to other components such as purchasing and inventory, information management, assessment, and occurrence management.</p>

Slide Number	Teaching Points
17	<p><u>Information Management</u></p> <p>EXPLAIN information management refers to these activities:</p> <ul style="list-style-type: none"> • Manage incoming and outgoing information • Establish standards for gathering information • Ensure the privacy and confidentiality of patient information <p>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.</p> <p>INDICATE this component is closely linked to other components such as personnel, documents and records, and customer service.</p>
18	<p><u>Occurrence Management</u></p> <p>EXPLAIN occurrence management.</p> <ul style="list-style-type: none"> • 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. <ul style="list-style-type: none"> ○ 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. <p>INDICATE this component is closely linked to other components such as process control, documents and records, and customer service.</p>

Slide Number	Teaching Points
19	<p data-bbox="520 293 699 327"><u>Assessment</u></p> <p data-bbox="520 344 1362 445">EXPLAIN assessment is the periodic examining and monitoring of laboratory operations to established requirements. It involves external and internal evaluation.</p> <ul data-bbox="520 468 1342 927" style="list-style-type: none"> <li data-bbox="520 468 1315 600">• 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. <li data-bbox="520 622 1331 656">• There are two types of external evaluation or assessment. <ul data-bbox="576 678 1342 927" style="list-style-type: none"> <li data-bbox="576 678 1342 745">○ Testing sites may be routinely monitored in the form of supervisory visits. <li data-bbox="576 768 1321 927">○ 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. <p data-bbox="520 949 1362 1016">INDICATE this component is closely linked to other components such as organization, personnel, and process control</p>

Slide Number	Teaching Points
20	<p data-bbox="520 293 831 322"><u>Process Improvement</u></p> <p data-bbox="520 344 1342 374">EXPLAIN process improvement refers to activities designed to:</p> <ul data-bbox="520 400 1334 824" style="list-style-type: none"> <li data-bbox="520 400 1145 430">• Identify and eliminate causes of poor quality <li data-bbox="520 456 1318 707">• Reduce waste and improve efficiency by eliminating non-value added activities <ul style="list-style-type: none"> <li data-bbox="576 542 1318 707">○ 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? <li data-bbox="576 730 1334 824">○ But it doesn't always have to be formal. Opportunities for process improvement are everywhere if you pay attention. <p data-bbox="520 848 1214 913">DISCUSS the following examples to help participants understand the concept.</p> <ul data-bbox="520 940 1342 1290" style="list-style-type: none"> <li data-bbox="520 940 1342 1137">• 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? <li data-bbox="520 1162 1318 1290">• 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 <p data-bbox="520 1314 1305 1413">INDICATE component is closely linked to other components such as organization, personnel, documents and records, process control, and customer service</p>

Slide Number	Teaching Points
21	<p><u>Customer Service</u></p> <p>ASK participants, “who are your customers?”</p> <ul style="list-style-type: none"> • The patient/client is the ultimate customer. • However, we must not forget the clinician, program staff, and epidemiologists. These people are our internal customers. <p>EMPHASIZE everyone at the HIV rapid testing site has responsibility for providing good customer service, from the receptionist, counselor, and lab staff.</p> <ul style="list-style-type: none"> • 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 <p>INDICATE this component is closely linked to other components such as personnel, documents and records, process control, and process improvement</p>
22	<p><u>Facilities and Safety</u></p> <p>EXPLAIN it is important to:</p> <ul style="list-style-type: none"> • 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 <p>INDICATE this component is closely linked to other components such as organization, personnel, purchasing and inventory, occurrence management, process control, and customer service.</p>
23	<p><u>The Lab Quality System</u></p> <p>POINT OUT some components (highlighted in yellow) will be further explored in later modules.</p> <p>ASK if participants have any questions.</p>

Slide Number	Teaching Points
 <p>TIPS</p>	<p>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.</p> <p>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.</p>
<p>24</p> <p>Activity</p> <p>20 minutes</p>	<p><u>Activity: Are You “Positive” or “Negative?”</u></p> <p>CONSTRUCT the cabbage ball prior to the module. (NOTE: Instructions are located at the end of this module.)</p> <p>FOLLOW the procedure below when conducting the activity.</p> <p>INFORM participants of the activity.</p> <p>POINT OUT the instructions on the slide.</p> <p>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).</p> <p>START the activity by tossing the cabbage ball to any participant.</p> <p>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.)</p> <p>A participant:</p> <ul style="list-style-type: none"> ○ Catches the ball ○ Peels one statement off the ball ○ Reads the statement to the entire group and decides whether it is positive or negative ○ Tosses the ball to the next person ○ Walks to the appropriate corner based on the statement <p>(The process repeats)</p> <p>CONCLUDE the activity by answering any questions participants may have.</p> <p>If time allows, repeat this activity using new cabbage balls.</p>
<p>25</p>	<p><u>Who Is Responsible for Quality?</u></p> <p>STATE quality is everyone’s responsibility.</p>

Slide Number	Teaching Points
Transition	<p>STATE:</p> <ul style="list-style-type: none"> • We just had an overview of what the lab quality system encompasses. • Next we will talk about what you can do to contribute to lab quality. • But first, let's define some terms – QA and QC. • You play an important role in both.
26	<p><u>Quality Assurance vs. Quality Control</u></p> <p>EXPLAIN the difference between quality assurance (QA) and quality control (QC).</p> <p>STATE QC is part of QA.</p>
27	<p><u>The Quality Assurance Cycle</u></p> <p>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.</p> <p>EXPLAIN the 3 phases and the activities associated with each phase.</p>
28	<p><u>Why Do Errors Occur?</u></p> <p>STATE each bullet on the slide.</p> <p>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.</p>
	<p>ASK participants, “What are some errors that may occur during pre-testing, testing, and post-testing phase in the QA cycle?”</p> <p>NOTE participant responses on a flip chart.</p>
29	<p><u>Pre-testing Errors</u></p> <p>PRESENT the slide.</p> <p>ACKNOWLEDGE points that have been mentioned by the participants in the discussion.</p>
30	<p><u>Preventing and Detecting Errors – Before Testing</u></p> <p>PRESENT the slide.</p> <p>EMPHASIZE every tester is responsible for preventing and detecting errors.</p>

Slide Number	Teaching Points
31	<p><u>Testing Errors</u></p> <p>PRESENT the slide.</p> <p>ACKNOWLEDGE points that have been mentioned by the participants in the discussion.</p> <p>EXPLAIN “incorrect reagents used” (last bullet) refers to using buffers from a different kit.</p>
32	<p><u>Preventing and Detecting Errors – During Testing</u></p> <p>PRESENT the slide.</p> <p>EMPHASIZE every tester is responsible for preventing and detecting errors.</p>
33	<p><u>Post-testing Errors</u></p> <p>PRESENT the slide.</p> <p>ACKNOWLEDGE points that have been mentioned by the participants in the discussion.</p>
34	<p><u>Preventing and Detecting Errors – After testing</u></p> <p>PRESENT the slide.</p> <p>EMPHASIZE every tester is responsible for preventing and detecting errors.</p>
35	<p><u>Why is Quality System Important to Rapid Testing?</u></p> <p>REVIEW the points on the slide.</p>
36	<p><u>Summary</u></p> <p>ASK participants to answer the questions on the slide.</p> <p>ANSWER any questions participants may have.</p>

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 overheard 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.