

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	<ul style="list-style-type: none"> ▪ 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	<p>At the end of this module, participants will be able to:</p> <ul style="list-style-type: none"> • Differentiate between internal and external controls • Use external quality controls at designated frequencies • Analyze common problems associated with invalid test results

Module Overview

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

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**

Slide Number	Teaching Points
1	<p><u>Module 12: Quality Control</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>The Lab Quality System</u></p> <p>REMIND participants that quality control is one component of the laboratory quality system.</p>
3	<p><u>Learning Objectives</u></p> <p>STATE the objectives on the slide.</p>
4	<p><u>Content Overview</u></p> <p>EXPLAIN the topics that will be covered in this module.</p>
<p>Flipchart</p> 	<p>REFER to it frequently to orient participants to where they are in the module.</p>
5	<p><u>What is Quality Control (QC)?</u></p> <p>STATE that the primary benefit of quality control is that:</p> <ul style="list-style-type: none"> • It shows the tester that the test is working correctly. • Accurate test results can be reported with confidence. <p>HIGHLIGHT there are 2 levels of QC for HIV rapid testing:</p> <ul style="list-style-type: none"> • 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 <p>EMPHASIZE that if problems or errors occur, we must immediately take corrective actions <u>before</u> we give results to patients.</p>
 <p><i>TIPS</i></p>	<p>SHARE stories from personal or others' experiences about the consequences of negligence or lack of quality control.</p> <p>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.</p>

Slide Number	Teaching Points
6	<p><u>Sources of Controls</u></p> <p>STATE that there are two types of quality control for HIV rapid testing: internal and external to the test kit.</p> <p>EXPLAIN <u>Internal</u> quality control.</p> <ul style="list-style-type: none"> • Control samples with known reactivity may be included with the test kit that you would test as you would patient/client specimens. • 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. • Since it is not always known if the test devices include a true IgG control, it is important to test an external control sample. <p>EXPLAIN <u>External</u> quality control.</p> <ul style="list-style-type: none"> • 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. • This type of control should also be tested in the same manner as you would test a patient or client specimen. <p>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.</p>
7	<p><u>Internal and External Quality Control</u></p> <p>HIGHLIGHT the types of quality control previously discussed.</p> <p>POINT OUT the control band on the test device.</p> <p>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.</p>

Slide Number	Teaching Points
8	<p><u>Examples of Tests that Include Internal Control</u></p> <p>STATE that all the rapid tests listed on the slide have internal control as part of their kits.</p> <p>ASK, “One of these tests differ from the rest in that it does not have internal control incorporated into its test device.</p> <p>Which one is it?”</p> <p>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.)</p>
9	<p><u>Capillus Kit Comes with Internal Control Samples</u></p> <p>PROVIDE and EXPLAIN the correct answer: Capillus.</p> <ul style="list-style-type: none"> • 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	<p>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.</p>
 <i>Customization Notes</i> 10-11	<p>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.</p>
10	<p><u>Sources of External Quality Control Samples</u></p> <p>STATE that external controls may either be obtained from commercial manufacturers, or from another laboratory that has prepared validated quality control samples in-house.</p> <p>STATE It is important to <u>store controls appropriately</u>. 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</p> <p>EMPHASIZE the following points for both types of controls.</p> <ul style="list-style-type: none"> • Label vial with date when first used • Test before expiry date • Take care as to not contaminate the control materials.

Slide Number	Teaching Points
 <p><i>TIPS</i></p>	<p>When teaching laboratory technicians, consider adding the following content.</p> <p>STATE:</p> <ul style="list-style-type: none"> • 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. <p>EXPLAIN:</p> <ul style="list-style-type: none"> • 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
<p>11</p>	<p><u>Frequency of Use: When Should You Test External Control Samples?</u></p> <p>EXPLAIN the key points on the slide. At a minimum, controls should be tested:</p> <ul style="list-style-type: none"> • 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.
<p>12</p>	<p><u>Invalid Results – What Do You Do?</u></p> <p>EXPLAIN the key points on the slide.</p> <p>MAKE SURE everyone is aware of an alternate testing algorithm in the event of repeated invalid on any one test kit</p>
 <p><i>Customization Notes</i></p> <p>13-14</p>	<p>For these two slides, add any other problems, causes and actions that have been observed in your country, if necessary.</p>

Slide Number	Teaching Points
13	<p><u>Troubleshooting Invalid Results</u></p> <p>STATE the problems on the slide.</p> <p>ASK participants what may cause each problem.</p> <p>EXPLAIN what may cause the lack of reddish, pink, or purple line or dot in the control window</p> <p>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:</p> <ul style="list-style-type: none"> • Sample volume – This may differ from kit to kit, and might differ depending on the sample type (e.g. whole blood vs. serum). • Buffer volume – Some kits require different volumes of buffer. • Incubation time – This time may also differ from kit to kit. Always follow the time required by the manufacturer.
14	<p><u>Troubleshooting Invalid Results – Cont'd</u></p> <p>STATE the problems on the slide.</p> <p>ASK participants what may cause each problem.</p> <p>EXPLAIN what may cause positive band using negative control (i.e. false positive).</p> <p>ASK participants what may cause the next problem.</p> <p>EXPLAIN what may cause an extremely faint control line</p> <p>NOTE other potential problems, potential causes, and actions to take on a flipchart.</p>
 <i>Customization Note</i> 15	<p>For this slide, reflect possible test outcomes based on country specific testing algorithm.</p>
15	<p><u>Possible HIV Test Outcomes: Parallel Algorithm</u></p> <p>REMIND participants that there are a variety of combinations of outcomes when following a multi-test algorithm.</p>

Slide Number	Teaching Points
<p>16</p> <p>Activity</p> <p>5 minutes</p>	<p><u>Exercise #1: Interpreting Rapid Test Results</u></p> <p>READ the instructions on the slide.</p> <p>ALLOW 3 minutes for the exercise.</p> <p>DEBRIEF the exercise by discussing the correct answers.</p>
 <p><i>Customization Notes</i></p> <p>17</p>	<p>Consider replacing the three tests here with tests in your country's algorithm.</p>
<p>17</p> <p>Activity</p>	<p><u>Exercise #2: Resolving Un-reportable Test Results</u></p> <p>REFER to the exercise sheet in the participant manual.</p> <p>EXPLAIN the scenario for this exercise.</p> <ul style="list-style-type: none"> • 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.
<p>18</p> <p>Flipchart</p> 	<p><u>Exercise #2: Resolving Un-reportable Test Results</u></p> <p><u>(Cont'd)</u></p> <p>ASK participants to answer the questions in the exercise.</p> <p>ALLOW 3 minutes for the exercise.</p> <p>DEBRIEF the exercise by discussing the correct answers.</p> <p>NOTE their responses on a flipchart.</p> <p>ASK participants to think of the role of quality control in providing confidence with reporting results and determining actions to take.</p> <p>DEBRIEF the discussion by summarizing key learning points.</p>
<p>19</p>	<p><u>Maintaining Quality Control Records</u></p> <p>EXPLAIN the key points on the slide.</p>
 <p><i>Customization Notes</i></p> <p>20</p>	<p>If your country uses a different form from the example provided on the slide for recording and monitoring quality control results, insert it here.</p>

Slide Number	Teaching Points
20	<p><u>Quality Control Record: An Example</u></p> <p>EXPLAIN the following points:</p> <ul style="list-style-type: none"> • 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	<p><u>Periodic Review of Records</u></p> <p>STATE that QC results must be reviewed periodically. WHY? For early detection of problems</p> <ul style="list-style-type: none"> • 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	<p><u>Summary</u></p> <p>ASK participants to answer the questions on the slide.</p> <p>ANSWER any questions participants may have.</p>