Module 12

Quality Control

Purpose	To help you 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
Learning Objectives	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 Outline	What is Quality Control (QC)? Benefits of QC in rapid testing Internal versus external quality control Troubleshooting invalid results Quality control records
Handouts	Exercise #1: Interpreting Rapid Test Results Exercise #2: Resolving Un-reportable Test Results Daily Record of Quality Control Results
Notes on Customization	Insert table of possible test outcomes based on country-specific algorithm.

What is Quality Control (QC)?

Quality Control is measures taken to monitor the quality of the test itself. Quality control ensures that the test is working correctly and the tester can report accurate test results with confidence.

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

If problems or errors occur, you must immediately take corrective actions before you give results to patients.

Sources of Controls

There are two types of quality control for HIV rapid testing: internal and external to the test kit.

Internal quality control:

- 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 device includes a true IgG control, it is important to test an external control sample.

External quality control:

- 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.

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.

Internal and External Quality Control

Internal Control

Included in testing device or as part of the kit

External Control

Control samples are often received in tubes called cryovials. This photo illustrates control samples neatly stored in a Styrofoam container.

Examples of Tests that Include Internal Control

Capillus, Determine, Hema-Strip, OraQuick, and Uni-Gold all include an internal control. But one of these tests does not have an internal control built into its test device. Do you know which one that is?

Capillus Kit Comes with Internal Control Samples

Capillus does not have internal control incorporated into its test device. 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. 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.

Sources of External Quality Control Samples

External controls may either be obtained from commercial manufacturers, or from another laboratory that has prepared validated quality control samples in-house.

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

For all controls, you must:

- Label vial with date when first used
- Test before expiry date
- Take care as to not contaminate the control materials.

Information Box

Regardless of where external control materials come from, it is important to understand the procedures and logistics for a regular and ongoing supply of controls to all testing sites.

You should know:

- 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

Frequency of Use: When Should You Test External Control Samples?

At a minimum, test your external control samples:

- Once a week
- When a new shipment of control materials or test kits are received at the testing site
- In the 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.

Invalid Results – What Do You Do?

If you get an invalid result, you must repeat the test. In addition, you should identify the cause of the problem, inform your supervisor, and take corrective actions.

Repeatedly invalid results may be due either problems with the test product or test procedures. In this case, you should continue with an approved alternative testing algorithm.

Troubleshooting Invalid Results

It is important to always follow the Standard Operating Procedure (SOP) for each type of test used, as the following may differ from kit to kit:

- 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.

Use the table below to help you troubleshoot invalid results.

Problem	Potential Cause	Action
No control line or band present	Damaged test device or controls	Repeat the test using new device and blood sample
	Proper procedure not followed	Follow each step of testing according to SOP Re-check buffer and/or specimen volumes Wait for the specified time before reading the test
	Expired or improperly stored test kits or controls	Check expiration date of kits or controls. Do not use beyond stated expiration date Check temperature records for storage and testing area
Positive reaction with negative external control, i.e. false positive	Incubation time exceeded	Re-test negative control using a new device and read results within specified time limit
Extremely faint control line	The control line can vary in intensity	No action required. Any visible line validates the results.

Possible HIV Test Outcomes: Parallel Algorithm

There are a variety of combinations of outcomes when following a parallel testing algorithm.

Parallel Testing Algorithm

TEST 1	TEST 2	TEST 3	HIV Status
Non-reactive	Non-reactive		Negative
Reactive	Reactive		Positive
Non-reactive	Reactive	Non-reactive	Negative
Reactive	Non-reactive	Non-reactive	Negative
Non-reactive	Reactive	Reactive	Positive
Reactive	Non-reactive	Reactive	Positive

If an invalid result is obtained at any point, corrective actions should be taken prior to reporting test results.

Exercises

#1: Interpreting Rapid Test Results

#2: Resolving Un-reportable Test Results

At the end of this module, you will find two exercise sheets. Read the instructions and write your answers in the space provided.

Maintaining Quality Control Records

Why are these records important? Because they help with trouble-shooting and provide proof of reliable test results.

How are the records maintained? By using standard worksheets.

When should you maintain QC records? Every time when you test QC materials. You should also record all invalid results and inform supervisor.

Quality Control Record: An Example

An example quality control record is provided for your reference at the end of this module.

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.

Periodic Review of Records

You should review QC results periodically in order to detect any problems early. This review involves:

- Daily 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

Keep in mind that if problems are detected, you must take corrective actions immediately.

Key message

- Always follow Standard Operating Procedures (SOPs) for each test performed.
- If problems or errors occur, you must immediately take corrective actions before you give results to patients.
- If an invalid result is obtained at any point, corrective actions should be taken prior to reporting test results.
- QC results must be documented and reviewed periodically for early detection of problems.

Module Review

Find out how much you have learned by answering these questions.

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?

_____

_____

_____

Module Review

Find out how much you have learned by answering these questions.

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?

_____

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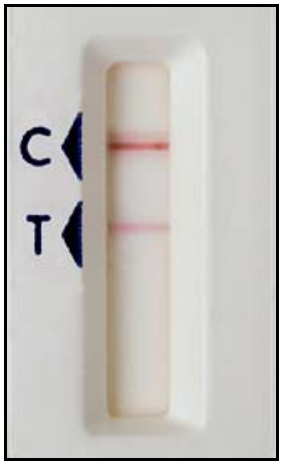
_____

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.**



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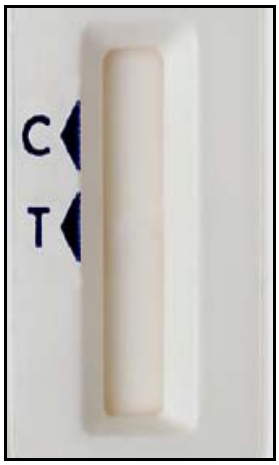

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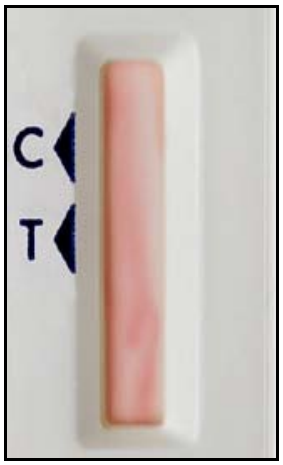

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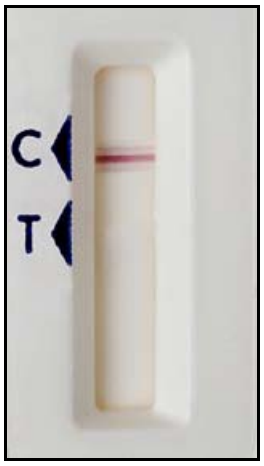

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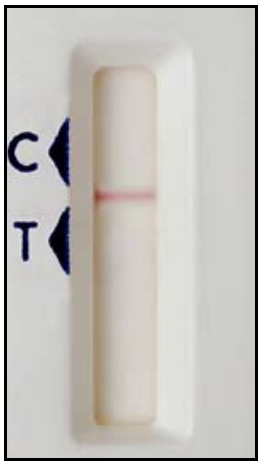

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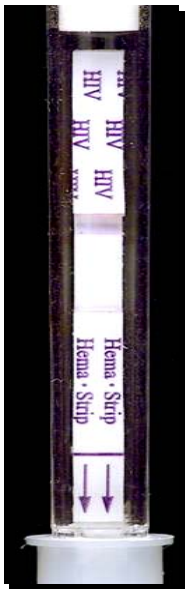
Exercise #2: Resolving Un-reportable Test Results

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.

Determine

Uni-gold

Hema-strip



Result: _____ **Result:** _____ **Result:** _____

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 Record of Quality Control Results

Kit: _____ Lot #:_____ Expiration Date: _____

Date	Negative Control Result	Neg Control Lot #	Acceptable? Y / N	Positive Control Result		Pos Control Lot #s		Acceptable? Y / N	Initials	Reviewed by & Date
				Low Pos	Pos	Low Pos	Pos			

Corrective Actions

Date	Action Taken	Initials	Reviewed by & Date