

Module 12: Quality Control



The Lab Quality System



Lab workers



Health workers



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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 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



Control Band

External Control

Known positive and negative samples that are used to validate the reliability of the test system



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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



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Sources of External Quality Control Samples

Prepared by
Reference
Laboratory

Commercially
prepared

- Store according to instructions
- Date when opened
- Use before expiry date
- Do not contaminate





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

Problem

No control line or band present

Potential Cause

- Damaged test device or controls
- Proper procedure not followed
- Expired or improperly stored test kits or controls

Action

- 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





Troubleshooting Invalid Results – Cont'd

Problem

Positive reaction with negative external control, i.e. false positive

Extremely faint control line

Potential Cause

Incubation time exceeded

The control line can vary in intensity

Action

Re-test negative control using a new device and read results within specified time limit

No action required. Any visible line validates the results.



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Possible HIV Test Outcomes: Parallel 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



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?

- Troubleshooting
- Provides proof reliable test results

HOW?

- Use standard worksheets

WHEN?

- Each time QC materials are tested
- Record all invalid results and inform supervisor



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?

