

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.

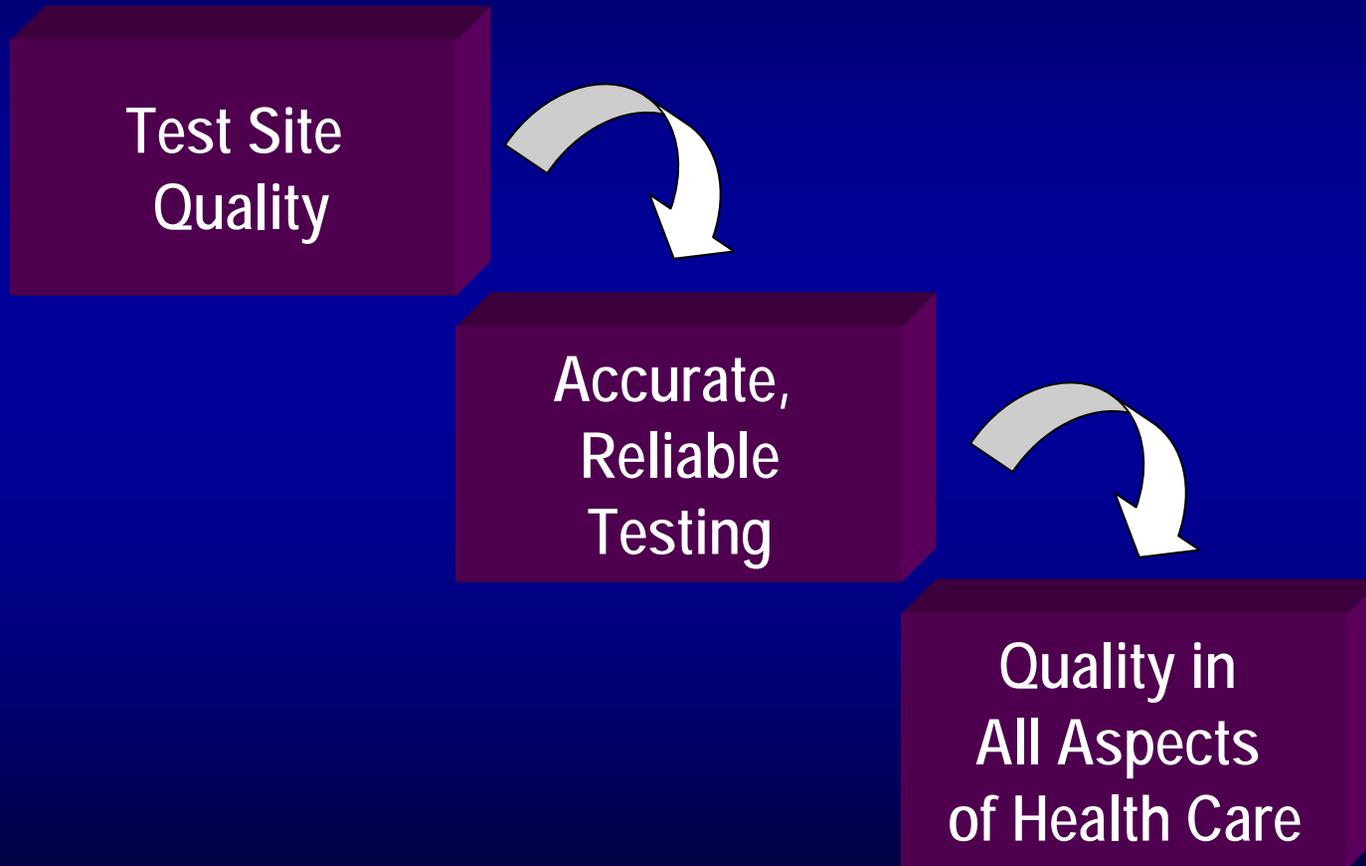


Discussion – Dining Out: A Quality Experience

- Think about your expectations for quality.
- What might you expect for a quality experience at a restaurant?



Why Quality?

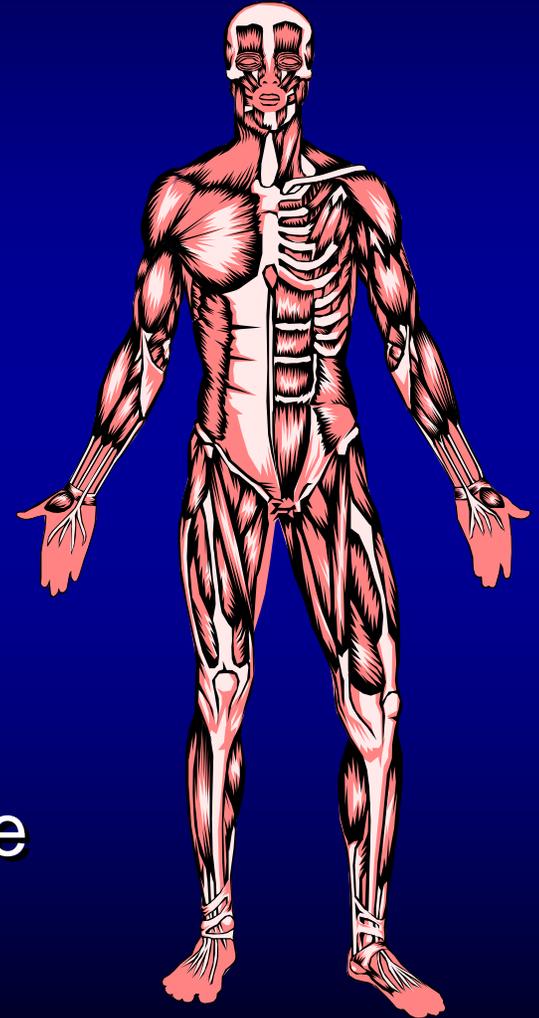


A Systems Approach to Quality

- 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.

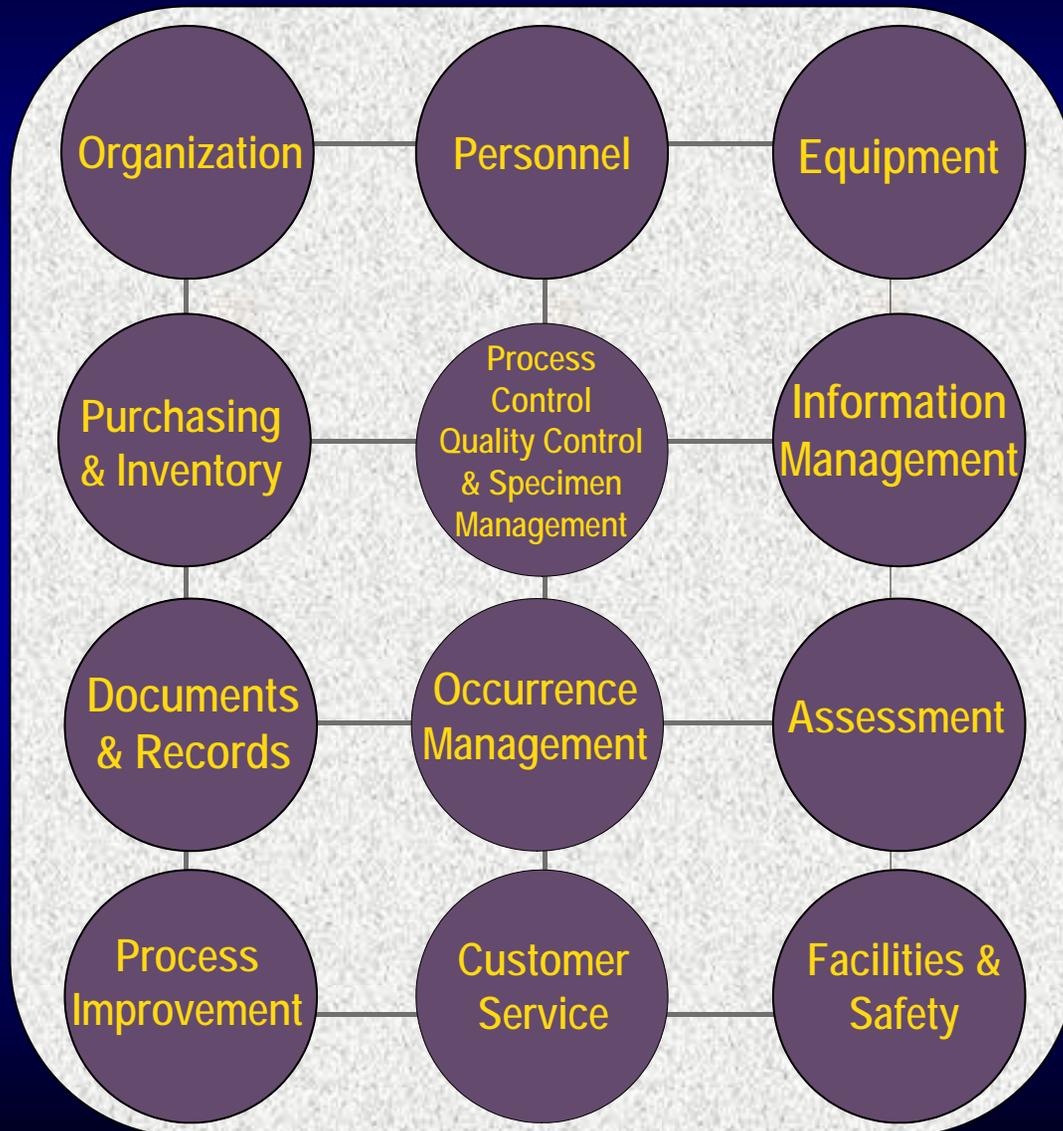
In other words... all activities which contribute to quality of tests, directly or indirectly.

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



◇ 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



Purchasing and Inventory

Procurement

Receiving

Storage

Inventory
management

Record
keeping



Process Control





Documents and Records

Standardized forms

Document approval

Document distribution

Document storage/retrieval

Document destruction



Information Management

Information
flow

Data collection
& management

Patient privacy &
confidentiality

Computer
skills



Occurrence Management

Written
procedures for
addressing errors

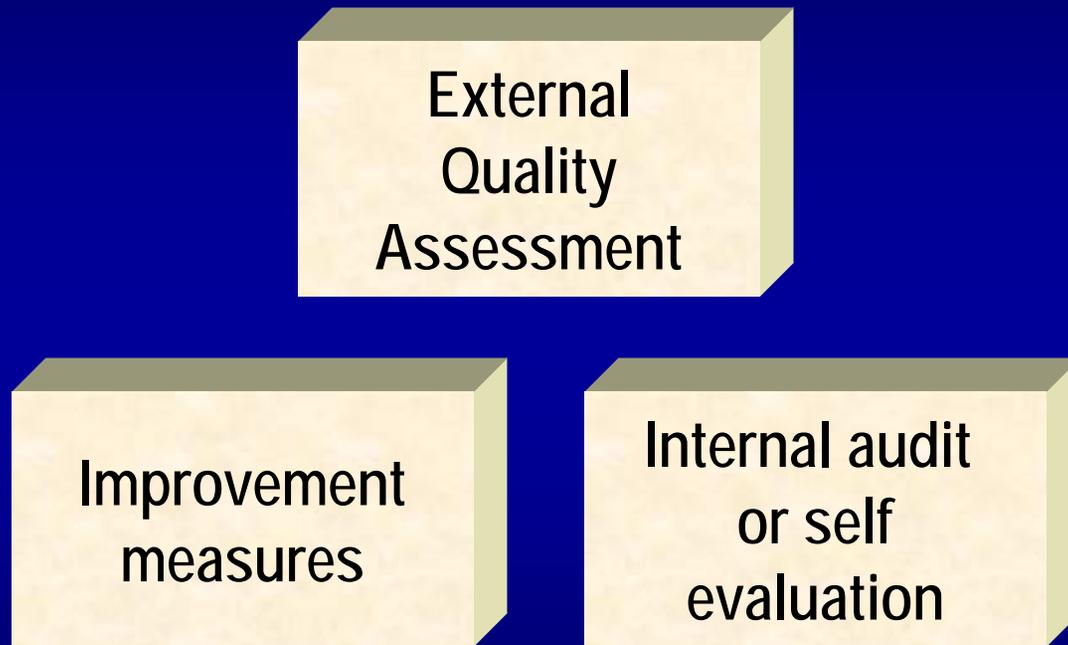
Corrective
actions

Occurrence
records

Occurrence
reporting



Assessment





Process Improvement

On-going
data
collection

Improvement
measures



Customer Service

Monitoring
Customer
satisfaction

Process
improvement

Rewards



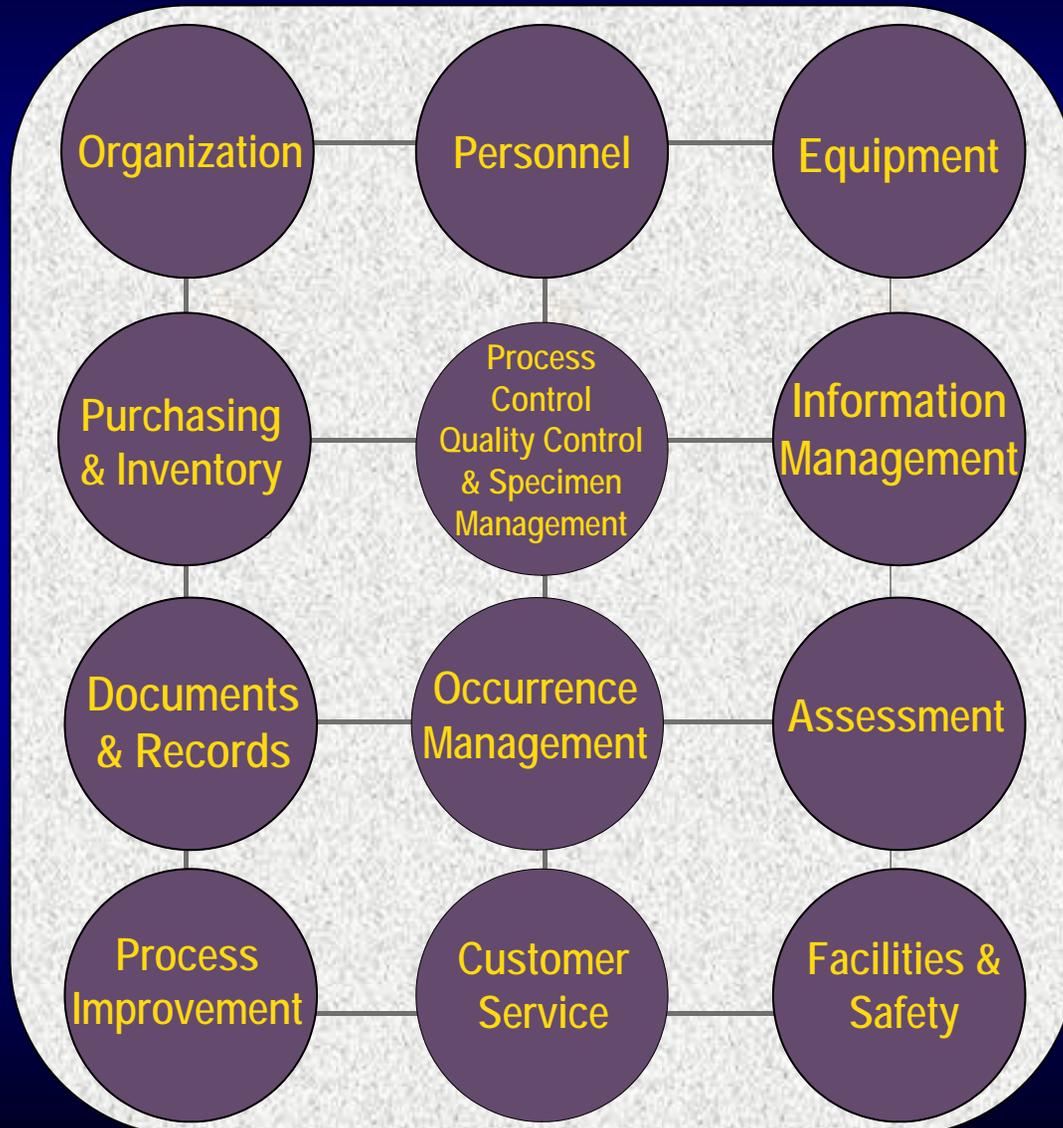
Facilities and Safety

Testing and
storage
areas

Safety practice

Safety
procedures
& records

The Lab Quality System



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!

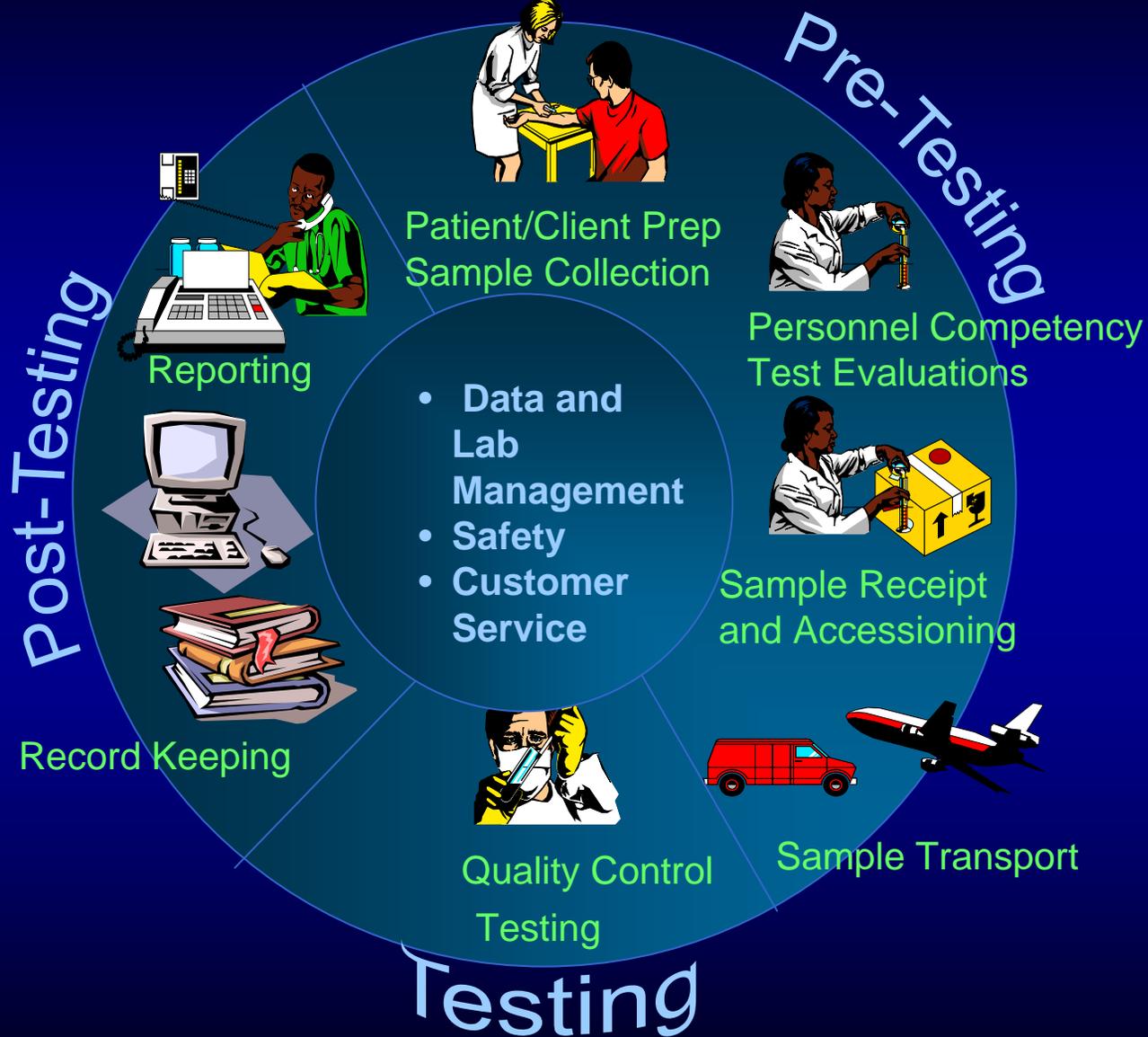
- Laboratory management and program staff establish quality assurance procedures.
- Test site personnel implement the quality assurance procedures.

Quality Assurance vs. Quality Control

	Quality Assurance	Quality Control
Definition	Activities to ensure <u>process</u> are adequate for a system to achieve its objectives	Activities to evaluate a <u>product</u> or work <u>result</u>
Examples	<ul style="list-style-type: none">• Establish standard procedures for sample collection• Define criteria for acceptable samples	<ul style="list-style-type: none">• Analyze known QC sample to determine if a test is valid• Decide if a sample is acceptable for testing



The Quality Assurance Cycle



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.