Participant Manual

MOH TT Certified
“Same-Visit”
HIV Testing Workshop

29 Nov-1 Dec 2005
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Materials Used in this Workshop

The materials used in this workshop were originally introduced at a meeting in Atlanta, Georgia on January 27-28, 2005. The meeting was entitled “Coordinating a Systematic Roll-Out of an HIV Rapid Test Training Package: Training for Quality HIV Rapid Testing in an Era of Expanding Services”. CAREC was represented at the meeting by Ms. Wendy Kitson-Piggott, Ms. Carol Trotman and Dr. Lynette Berkeley.

The materials introduced in Atlanta resulted from efforts coordinated among WHO, PAHO, CDC and USAID. The original materials were intended for customization to “site-specific” use. Site-specific materials must suit the training needs of national HIV rapid testing programs. In September 2004, The Ministry of Health of Trinidad and Tobago (MOH TT) requested CAREC technical assistance with introduction of “same visit” HIV testing. The customized materials in this binder are part of the CAREC response to that request.

The materials in your participant manual were customized during a series of conference calls. The goal of the customization process was to create materials optimally useful to the MOH TT “same-visit” rapid testing implementation. Those involved in the customization process are listed below. This workshop is the first use of the training package in the Caribbean Region.

The original materials included 16 Modules. This participant binder contains customized version of the Modules in their original order. Module 14 is intentionally omitted.

Customization Committee

Ms. Cameile Ali (consultant)
Dr. Lynette Berkeley (CAREC)
Ms. Rosemary Gonzales (NWRHA)
Dr. Stacy Howard (CDC)
Dr. Loris Hughes (CDC)
Ms. Peggy Mitchell (TPHL)
Dr. Cynthia Warner (CDC)
Ms. Robin Weaver (CAREC)
Dr. Katy Yao (CDC)
Status of HIV/AIDS
Trinidad & Tobago

Dr Nilesh Buddha
UN Volunteer, National Surveillance Unit
Ministry of Health, Trinidad & Tobago
Challenges of tracking HIV/AIDS

- HIV diseases can be asymptomatic for years
- Many infected do not know, are not counted
- Reported data reflect testing/ care seeking behaviour & access to testing/ treatment
- Stigma, fear of loss of confidentiality and of fatal disease – create barriers
- HIV & AIDS represent same viral infection, but are reported differently – challenging to standardize reports & analysis
Challenges… (contd)

• Different sources report HIV infections, AIDS cases & deaths
• Sensitive personal data, confidential, encoding-decoding, chances of duplication
• Marginalized populations (don’t want to be identified)
• Overseas/ private sector
Limitations

- HIV positive are *only* those cases which are reported/confirmed by TPHL/CAREC
- AIDS cases are
  - picked-up by NSU Surveillance Nurses from 5 public hospitals
  - classified by Medical Epidemiologist from TPHL forms
- Surveillance data do not represent HIV Incidence and Prevalence
Regional HIV and AIDS statistics and features, end of 2004

<table>
<thead>
<tr>
<th>Region</th>
<th>Adults &amp; children living with HIV</th>
<th>Adults &amp; children newly infected with HIV</th>
<th>Adult prevalence</th>
<th>Adult &amp; child deaths due to AIDS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sub-Saharan Africa</td>
<td>25.4 million [23.4 – 28.4 million]</td>
<td>3.1 million [2.7 – 3.8 million]</td>
<td>7.4 [6.9 – 8.3]</td>
<td>2.3 million [2.1 – 2.6 million]</td>
</tr>
<tr>
<td>North Africa &amp; Middle East</td>
<td>540 000 [230 000 – 1.5 million]</td>
<td>92 000 [34 000 – 350 000]</td>
<td>0.3 [0.1 – 0.7]</td>
<td>28 000 [12 000 – 72 000]</td>
</tr>
<tr>
<td>South and South-East Asia</td>
<td>7.1 million [4.4 – 10.6 million]</td>
<td>890 000 [480 000 – 2.0 million]</td>
<td>0.6 [0.4 – 0.9]</td>
<td>490 000 [300 000 – 750 000]</td>
</tr>
<tr>
<td>East Asia</td>
<td>1.1 million [560 000 – 1.8 million]</td>
<td>290 000 [84 000 – 830 000]</td>
<td>0.1 [0.1 – 0.2]</td>
<td>51 000 [25 000 – 86 000]</td>
</tr>
<tr>
<td>Latin America</td>
<td>1.7 million [1.3 – 2.2 million]</td>
<td>240 000 [170 000 – 430 000]</td>
<td>0.6 [0.5 – 0.8]</td>
<td>95 000 [73 000 – 120 000]</td>
</tr>
<tr>
<td>Caribbean</td>
<td>440 000 [270 000 – 780 000]</td>
<td>53 000 [27 000 – 140 000]</td>
<td>2.3 [1.5 – 4.1]</td>
<td>36 000 [24 000 – 61 000]</td>
</tr>
<tr>
<td>Eastern Europe &amp; Central Asia</td>
<td>1.4 million [920 000 – 2.1 million]</td>
<td>210 000 [110 000 – 480 000]</td>
<td>0.8 [0.5 – 1.2]</td>
<td>60 000 [39 000 – 87 000]</td>
</tr>
<tr>
<td>Western &amp; Central Europe</td>
<td>610 000 [480 000 – 760 000]</td>
<td>21 000 [14 000 – 38 000]</td>
<td>0.3 [0.2 – 0.3]</td>
<td>6 500 [ &lt;8 500]</td>
</tr>
<tr>
<td>North America</td>
<td>1.0 million [540 000 – 1.6 million]</td>
<td>44 000 [16 000 – 120 000]</td>
<td>0.6 [0.3 – 1.0]</td>
<td>16 000 [8 400 – 25 000]</td>
</tr>
<tr>
<td>Oceania</td>
<td>35 000 [25 000 – 48 000]</td>
<td>5 000 [2 100 – 13 000]</td>
<td>0.2 [0.1 – 0.3]</td>
<td>700 [ &lt;1 700]</td>
</tr>
<tr>
<td>TOTAL</td>
<td>39.4 million [35.9 – 44.3 million]</td>
<td>4.9 million [4.3 – 6.4 million]</td>
<td>1.1 % [1.0 – 1.3%]</td>
<td>3.1 million [2.8 – 3.5 million]</td>
</tr>
</tbody>
</table>
HIV/AIDS in T&T

<table>
<thead>
<tr>
<th>Daily in 2004</th>
<th>4 new cases of HIV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total HIV (1983 – 2004)</td>
<td>14536</td>
</tr>
<tr>
<td>Male:Female</td>
<td>60:40</td>
</tr>
<tr>
<td>Total AIDS</td>
<td>5365</td>
</tr>
<tr>
<td>Total deaths</td>
<td>3273</td>
</tr>
<tr>
<td>Median age of HIV +</td>
<td>Male – 35, Female – 29</td>
</tr>
<tr>
<td>15 – 24 year olds</td>
<td>15 %</td>
</tr>
<tr>
<td>Estimated PLWHA</td>
<td>3.2 % adults (28,000)</td>
</tr>
</tbody>
</table>
HIV/AIDS in T&T

- 70% of infections in 15-49 age group
- 45% of new infections occur in females
- In the 15-24 age group, 70% of the new infections occur in females
HIV/AIDS Surveillance in T & T

• Major reporting units: MRC, POSGH, EWMSC, QPCC/C, Pvt, SFGH, Tobago
• Less than 5% of total HIV/AIDS cases have data on occupation, education, condom usage, partner info, etc
• Data on ethnic origin ?
HIV in Age Group: 45-59 Years

45-59 Female

45-59 Male

Dr Nilesh Buddha, NSU, MoH, T&T
HIV in Age Group: 30-34 Years

- 30-34 Female
- 30-34 Male

Dr Nilesh Buddha, NSU, MoH, T&T
HIV in Age Group: 25-29 Years

Dr Nilesh Buddha, NSU, MoH, T&T
HIV in Age Group: 20-24 Years

- 20-24 Female
- 20-24 Male

Dr Nilesh Buddha, NSU, MoH, T&T
HIV in Age Group: 15-19 Years

- 15-19 Female
- 15-19 Male

Dr Nilesh Buddha, NSU, MoH, T&T
HIV positive in 2004, by age & sex

Dr Nilesh Buddha, NSU, MoH, T&T
Cumulative AIDS cases, by age & sex  

Dr Nilesh Buddha, NSU, MoH, T&T
HIV Positive
Exposure Category 2004

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AIDS Deaths by Year

- Men
- Women

Dr Nilesh Buddha, NSU, MoH, T&T
NSU Quarterly Reports

Dr Nilesh Buddha, NSU, MoH, T&T
Incidence

- HIV positive
- AIDS cases
- AIDS deaths
Recently Acquired HIV Infection Trend

Women, 15-24 Years of Age

Dr Nilesh Buddha, NSU, MoH, T&T
Cumulative (1983 - 2004), by age

Dr Nilesh Buddha, NSU, MoH, T&T
Counti-wise Incidence, 2004

Dr Nilesh Buddha, NSU, MoH, T&T
HIV Positive

Dr Nilesh Buddha, NSU, MoH, T&T

NSU  TPHL

0 500 1000 1500 2000 2500 3000

Dr Nilesh Buddha, NSU, MoH, T&T
HIV Positive Duplicates identified at NSU
HIV positive

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Positivity Rates
(% found positive among total samples received at TPHL)

Duplicates included
Duplicates excluded

Dr Nilesh Buddha, NSU, MoH, T&T
Dr Nilesh Buddha, NSU, MoH, T&T

HIV

- samples received
- positive numbers
- % positive

Dr Nilesh Buddha, NSU, MoH, T&T
2004, Major Providers

(samples sent for HIV test) (samples found positive)

(more than 80% of all tests performed & positive tests)

Dr Nilesh Buddha, NSU, MoH, T&T
% positive of total samples sent to TPHL for HIV testing in 2004

- MRC: 45%
- POSGH: 27%
- PV T: 18%
- SFGH: 6%
- QPCC&C: 4%

Total >80% of all positive in 2004

Dr Nilesh Buddha, NSU, MoH, T&T
Within one year of HIV diagnosis

Dr Nilesh Buddha, NSU, MoH, T&T

Deaths  AIDS  HIV
Monthly HIV/AIDS Admissions in 4 Public Hospitals

Data source: Active Surveillance Register, NSU

Dr Nilesh Buddha, NSU, MoH, T&T
Features

• Principle mode of transmission – Heterosexual, multiple sexual partners, unsafe sex
• Principle age at transmission – young females, adult males in all age groups
• Young men missed-out in VCT – remain continued source of infection
• Condom usage ? Substance abuse ? Ethnicity ?
• Occupation, education, socio-economic status ?
• ARV works, more resources will be required for sustained Care & Treatment
Features (contd)

- HIV/AIDS scenario at very crucial stage in 2005; sustained efforts in Prevention, Care & Treatment will yield very good returns
- Proximal causes – risky behaviours
- Solution – behavioral change communication (population-wide & high-risk targeted)
- Underlying causes – socio-economic (deprived, poor, disrupted families, uneducated, unemployed)
- Ultimate solution – social change, socio-economic rehabilitation of the marginalized

Dr Nilesh Buddha, NSU, MoH, T&T
How much persuasive?

• If u can’t find a woman, take a man
• Deputy is essential
• Rum till I die

Dr Nilesh Buddha, NSU, MoH, T&T
Public Health Axiom

• Population average determines numbers of deviant individuals (e.g., alcohol, blood pressure, smoking, high risk behaviour)
• We are all responsible for all
• Let’s think out of box
Population average has to change to reduce the high risk/ deviant individuals.
Small steps, big rewards

- Post-test Form of HIV+ at MRC
- Encoding Vs name-based, confidential reporting
- Ethnic data
- TPHL data analysis
- Explore possible synergies to avoid
  - Duplication & wastage of resources

Dr Nilesh Buddha, NSU, MoH, T&T
Big steps, big rewards

- AIDS notifiable disease
- Private sector involvement
- Behavioural studies, surveys
- TB & STD: co-morbidity
Surveillance Operational Guidelines

• Roles & responsibilities
  – National, Region, County

• Reporting
  – Who, whom, when, what
  – Flow chart & formats

• Data management
  – Security, confidentiality, coding

Dr Nilesh Buddha, NSU, MoH, T&T
Salient features

- Provider requests test
  - Public & private sector including laboratories
- TPHL reports positive test results to
  - Provider, CMOH and NSU
- County gets the post-test form filled-out and sends to NSU on weekly basis
- County reports monthly summary to RHA
- RHA plans & implements programmes
- NSU reports quarterly & annually

Dr Nilesh Buddha, NSU, MoH, T&T
Salient features

• NSU nurses fills-out post-test form of the AIDS cases found in the 4 major hospitals during active surveillance

• RHA to assume above responsibilities once its surveillance unit is functional

• Important: confidentiality & security at all levels
Module 2: Integration of HIV Rapid Testing in HIV Programs
Learning Objectives

- Recognize need for HIV counseling and testing in HIV prevention programs
- Recognize need for “same-visit” HIV testing in prevention programs
- Know the value of “same-visit” HIV testing for some sites (VCT, PMTCT etc.)
- Know where “same-visit” HIV testing will be used in T&T
Content Overview

- Need for expanded access to HIV testing
- Need for more people to “know their status”
- Need to integrate testing into counseling and referral programs
- Need to integrate testing into prevention, care and support services
HIV/AIDS Program Strategy

“Innovative solutions must be found to dramatically increase the number of individuals who are tested and know their status.”

- Implementation and evaluation of new and effective programmes
- Scale-up of current testing, counseling and referral services
Current Status of HIV Testing

• 95% of those infected with HIV do not "know their status"

• Only 5-10% of all people have ever had an HIV test

• Less than 10% of pregnant women have had an HIV test

• Less than 10% of health care facilities offered testing and counseling in 2002
HIV Testing Occurs in a Variety of Settings

- STI Clinics
- TB Clinics
- Hospitals
- Surveillance
- VCT
- PMTCT
- Blood Banks

Provide care to HIV-affected persons
Provide ARV treatment to HIV-infected persons

Prevent HIV Infections

Lab workers  Health workers  Counselors
HIV Testing as an “Entry Point” to other HIV Services

- Care & Support
- Home-based Care
- Future Planning
- PMTCT
- Opportunistic Infection (OI)
- HIV Prevention Services
- Community-based Care
- Support Groups
- HIV Treatment
Community-Based Counseling and Testing

- Members of the community are trained to provide counseling and testing

- Challenges: supervision; quality; confidentiality; linkage to care and treatment

- Support of community leaders is essential for success
Couples Counseling and Testing

- Facilitates disclosure and joint planning for risk reduction
- Increases utilization of HIV/AIDS services
- Allows for better family planning and care of children
Preventing Mother to Child Transmission (PMTCT)

- Prevention of HIV infection in pregnant women
- Prevention of unwanted pregnancies in HIV-infected women
- Prevention of HIV transmission from mothers to infants
- Provision of treatment and support to infected women and their families
Core Interventions for PMTCT

- “Same-visit” HIV testing and counseling
- Antiretroviral treatment
- Safer delivery practices
- Safer infant-feeding practices
Reasons for "Same-Visit" HIV Testing

• Clients can be tested on site
• More clients receive test results
• Immediate intervention (ART) is possible
• Reduce HIV transmission to infants
• Eliminate need to wait for lab test results
• Reduce chance of specimen “mix-up”
International Recommendations for Counseling and Testing in PMTCT

- Group pre-test information at ANC
- Individual pre-test counseling at ANC
- Routine HIV testing at ANC and at L&D
- “Same-day” testing at ANC and at L&D
- Individual post-test counseling
- Encouraging partner testing

Summary

• Where can HIV counseling and testing be offered?
• What are the advantages of using “same-visit” HIV testing?
• What are special advantages of using HIV rapid testing in PMTCT?
• How does HIV testing help to support access to treatment?
Module 3: Overview of HIV Testing Technologies
Learning Objectives

At the end of this module, you will be able to:

• Discuss integration of HIV testing into other HIV/AIDS programmes and services
• Discuss the various testing technologies for HIV
• Explain the advantages and disadvantages of HIV rapid tests
• Recognize individual HIV test results as positive, negative or invalid
Content Overview

• Expansion of HIV rapid testing
• Types of HIV tests
• Challenges in HIV testing
• Advantages and disadvantages of HIV rapid testing
• Types of HIV rapid tests
• Reading individual test results
HIV Testing Occurs in a Variety of Settings

Prevent HIV Infections

VCT
ANC
Blood Banks
Surveillance
TB Clinics
Hospitals
STI Clinics

Provide ARV treatment to HIV-infected persons
Provide care to HIV-affected persons

Lab workers
Health workers
Counselors
Expansion of Testing Services

- Integrate HIV testing services into national health systems
- Introduce testing into non-traditional settings
Use of HIV Testing in the Continuum of Care

- Use HIV testing to diagnose HIV infection
- Initiate treatment with ARVs
- Monitor effectiveness of ARVs with diagnostics (viral load, CD4)

Lab workers, Health workers, Counselors
Types of HIV Tests

• Serology (Antibody/Antigen testing)
  ▪ Enzyme Immunoassays (EIAs)
  ▪ Rapid tests
  ▪ Western blot (WB)

• Lymphocytes
  ▪ CD4 counts
  ▪ CD8 counts

• Nucleic Acid
  ▪ Viral Load
  ▪ PCR
Challenges in HIV Testing

- Maternal antibody present in infants
- “Window” between infection and antibody appearance
- Not all HIV subtypes can be detected with a single test
- Other health conditions
- Laboratory requirements
- Technical skill
Enzyme Immunoassays (EIAs)

- Detect HIV antibodies to both HIV-1 and HIV-2
- Detect both HIV antibody and HIV antigen (close window period)
- Require sophisticated laboratory
- Require well trained lab personnel
Enzyme ImmunoAssays (EIAs)

Samples placed in individual wells for testing

Automated reader determines result of test
HIV Rapid Tests

- Detect HIV antibodies to HIV 1 and HIV 2
- Results comparable to EIA results
- Suitable for non-lab settings
- Non-lab personnel can be trained to test using these devices
Western Blot Assays

- Detects antibodies to specific HIV antigens
- Difficult to interpret
- Multiple standards for performance in use
- Expensive
- Limited availability
CD4 Cell Counts

- Follow clinical progress
- Monitor therapy
- Require trained staff
- Require sophisticated equipment

Lab workers

Health workers
**HIV Viral Load**

- Molecular assay to measure HIV levels
- Used to monitor disease progression
- Used to monitor ARV response
- Requires sophisticated lab facility
- Requires highly trained personnel
- Expensive
HIV Test Complexity*

- **Level 1**: No laboratory facility or experience needed
- **Level 2**: Multi-step process is required; Centrifuge or other equipment required
- **Level 3**: Specific laboratory skills such as diluting are required
- **Level 4**: Sophisticated equipment and well-trained laboratory staff are required

*WHO Reports*
HIV Rapid Testing permits expansion of services

Lab workers  Health workers  Counselors
HIV Rapid Tests: Advantages

- Increased access to testing
- Expanded numbers of testing sites
- “Same-visit” HIV test results
- Permits testing in non-lab settings
- No refrigerated storage required
- WHO Level 1 test complexity
- Non-lab staff can be trained to use the tests
HIV Rapid Tests: Disadvantages

- Monitoring quality of testing is difficult
- Testing may be seen as “deceptively easy”
- Designing training for non-lab testers is challenging
- Positioning rapid testing within national medical systems is challenging
Body Fluids Used for HIV Rapid Testing

- Serum
- Plasma
- Whole blood
- Oral fluids
Three Formats of HIV Rapid Tests

• Immunoconcentration (flow-through device)
• Immunochromatography (lateral flow)
• Particle agglutination
**Immonoconcentration Principle**

HIV-antibody links to bound HIV-antigens forming colored spots

Internal Control

- HIV-1 peptide
- HIV-2 peptide
Immunoconcentration Tests

These devices are also called “Flow-Through” Devices.

Two brand names are:

- Multi-Spot
- Genie II
Reading Results: Genie II

Negative   Positive

Lab workers  Health workers  Counselors
Immunochromatography Principle

Lab workers
Health workers
Immunochromatography Tests

Lateral Flow Devices

- Determine
- Hema-Strip
- OraQuick
- Unigold
- Stat-Pak
Reading Results: Determine

Sample Pad  Test line  Control line

Negative
Positive
Positive

Lab workers  Health workers  Counselors

Test line

Sample Pad  Control line

Lab workers  Health workers  Counselors
Reading Results: OraQuick

Negative

Positive

Lab workers

Health workers

Counselors
Particle Agglutination Principle

Anti-HIV antibodies bind to the antigen-coated latex particles.
Agglutination Tests

- Capillus
- Serodia
Reading Results: Capillus

Lab workers
Health workers
Counselors
Results for HIV Rapid Tests

Positive
- Test band
- Control band

Negative
- Control band only

Invalid
- No control band present
- Repeat with new device.
Exercise: Interpreting Individual HIV Rapid Test Results

- Refer to Participant Manual
- Work alone to determine individual test results
- 3 Minutes
Key Messages

- HIV rapid tests are reliable
- HIV rapid tests require training, supervision, and monitoring
- No single test result can be used to diagnose HIV infection
Summary

- What are rapid tests?
- List three advantages of HIV rapid testing.
- What is WHO Level 1 test complexity?
- Why are HIV viral load tests needed?
- How many types of HIV rapid test results are possible?
Module 4:
HIV Testing Algorithms
Learning Objectives

At the end of this module, you will be able to:

• Define parallel and serial testing algorithms
• Define national testing algorithms
• Explain test selection for the MOH TT “same-visit” HIV rapid testing algorithm
• Describe the MOH TT testing algorithm
• Define HIV status using an algorithm
Content Overview

- Testing strategies
- Testing algorithms
- National algorithms
- MOH TT national testing algorithm
- Interpreting HIV test results
Strategies and Algorithms

- **Strategy** – Testing approach used:
  - Blood Safety
  - Surveillance
  - Diagnosis

- **Algorithm** – combination and sequence of tests used in a given strategy
HIV Test Performance

- No test is 100 % sensitive
- No test is 100 % specific
- No single HIV test result is sufficient to diagnose HIV infection
- A combination of results (an algorithm) is essential to diagnose HIV infection
Diagnostic Algorithms

- All diagnostic HIV testing is based on at least 2 test results*
- When the first two tests are concordant, the result can be reported
- When the first two tests are discordant, a third test must be performed
- The result of the third test is the algorithm result

*WHO recommendations
Ideal Algorithm Tests are:

- Highly sensitive
- Highly specific
- Based on different antigens
- Routinely available
- Easy to use
- Stored at room temperature
National Testing Algorithms

Advantages:
- Country-wide standardization
- Simplified procurement
- Simplified supply management
- Uniform training
- Quality monitoring
National Algorithm Development

- Select type of algorithm needed*
- Review available information
- Select tests for inclusion
- Develop protocol
- Pilot test selected algorithm
- Expand to national scale
- Review testing algorithms annually

*WHO recommendations
MOH TT Algorithm Selection*

• Algorithm should provide “same-visit” HIV test results
• Algorithm should be suitable for use in “non-lab” locations
• “Same-visit” test results can be obtained using “diagnostic” algorithms*
• Diagnostic algorithms require three tests
• Non-lab locations require use of HIV rapid tests

*WHO recommendations
MOH TT Algorithm Test Selection

- WHO evaluation
- CAREC evaluation
- Guyana evaluation
- Brazil evaluation
- Temperature for shipment/storage
- Ease of use
- Type of specimen (whole blood)
- Cost
- Procurement reliability
The Algorithm Is Important

Always follow the algorithm!
HIV Diagnostic Algorithms*

- Serial algorithms are suitable where prevalence of HIV exceeds 10%.

- Parallel algorithms are needed where prevalence of HIV is less than 10%.

- In TT, HIV prevalence is less than 10% and diagnosis requires a parallel algorithm.

*WHO definitions
Serial Testing

Algorithm

Blood Sample

Test 1

Negative
- Report Negative

Positive

Test 2

Positive
- Report Positive

Negative

Test 3

Positive
- Report Positive

Negative
- Report Negative
Parallel Testing Algorithm

Blood Sample

- Test 1
  - Both Positive
    - Report Positive
  - Both Negative
    - Report Negative
- Test 2
  - One Positive
    - One Negative
      - (Discordant)
  - Both Negative
    - Report Negative
- Test 3
  - Positive
    - Report Positive
  - Negative
    - Report Negative

Lab workers
Health workers
Counselors
MOH TT Algorithm

Blood Sample

Determine
Uni-Gold

Both Positive
Report Positive

Both Negative
Report Negative

One Positive One Negative
(Discordant)

Stat-Pak

Positive
Report Positive

Negative
Report Negative

Lab workers  Health workers  Counselors
HIV Testing Results:
Parallel Algorithm

<table>
<thead>
<tr>
<th>TEST 1</th>
<th>TEST 2</th>
<th>TEST 3</th>
<th>HIV Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negative</td>
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Lab workers  Health workers  Counselors
## HIV Testing Results: Parallel Algorithm

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- Lab workers
- Health workers
- Counselors
HIV Testing Results: Parallel Algorithm

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Lab workers  Health workers  Counselors
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# HIV Testing Results: Parallel Algorithm

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<th>TEST 1</th>
<th>TEST 2</th>
<th>TEST 3</th>
<th>HIV Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negative</td>
<td>Positive</td>
<td>Negative</td>
<td>Negative</td>
</tr>
</tbody>
</table>

- Lab workers
- Health workers
- Counselors
### HIV Testing Results: Parallel Algorithm

<table>
<thead>
<tr>
<th>TEST 1</th>
<th>TEST 2</th>
<th>TEST 3</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>Negative</td>
<td>Positive</td>
<td></td>
</tr>
</tbody>
</table>

Lab workers  HEALTH workers  Counselors
### HIV Testing Results: Parallel Algorithm

<table>
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<td>Positive</td>
</tr>
</tbody>
</table>

- **Lab workers**
- **Health workers**
- **Counselors**
### HIV Testing Results: Parallel Algorithm

<table>
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<th>TEST 1</th>
<th>TEST 2</th>
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<th>HIV Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negative</td>
<td>Positive</td>
<td>Positive</td>
<td></td>
</tr>
</tbody>
</table>
## HIV Testing Results: Parallel Algorithm

<table>
<thead>
<tr>
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<th>TEST 3</th>
<th>HIV Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negative</td>
<td>Positive</td>
<td>Positive</td>
<td>Positive</td>
</tr>
</tbody>
</table>

Lab workers  Health workers  Counselors
Questions?

- When can HIV be diagnosed with a single test?
- What is an algorithm?
- Why is the MOH TT algorithm parallel?
- What does it mean when test results are concordant? Discordant?
- What tests are in the MOH TT algorithm?
Module 5: 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 quality
• Identify the elements of quality in HIV rapid testing
• Recognize factors that compromise quality
• Describe your role in assuring quality in HIV testing
Content Overview

• How to achieve quality
• How to maintain quality
• Essential elements of a quality system
• Quality assurance in HIV rapid testing
• Your role in quality of HIV rapid testing
What Is “Quality”?
What Is “Quality”? 

- Reliable
- Reproducible
- Accurate
- Provides satisfaction
- Meets expectations
A Systems Approach to Quality

• Considers all components within a system
• Identifies the connections and relationships among the components

Example: the human body system
A pain in one component may be caused by a disorder in another component
Benefits of Quality Systems

- Monitors all components of testing
- Detects and corrects errors
- Improves reproducibility between testing sites
- Helps contain costs
T&T Quality Health Care System

- Organization
- Personnel
- Equipment
- Purchasing & Inventory
- Specimen Collection & Testing
- Data
- Documents & Records
- Corrective Action
- Monitoring
- System Improvement
- Client Satisfaction
- Facilities & Safety

Lab workers  Health workers  Counselors
Personnel

Planning  Hiring  Retention

Training  Supervision  Performance
Equipment

Selection

Maintenance

Security
Purchasing and Inventory

- Ordering
- Receiving
- Storing
- Tracking
- Records

- Lab workers
- Health workers
- Counselors
Spec Collection & Testing

- Specimen Management
- Standard Procedures
- Training
- Quality Control
- Result Reporting

Lab workers  Health workers  Counselors
Data

Collection

Management

Client Confidentiality

Computer skills

Lab workers

Health workers

Counselors
Documents and Records

- Standardized Forms
- Document Approval
- Document Distribution
- Document Storage
- Document Destruction

Lab workers  Health workers  Counselors
Corrective Action

- Error Identification
- Troubleshooting
- Improvement
- Record Keeping

Lab workers  Health workers  Counselors
Monitoring

- Internal Audit
- Improvement
- External Audit
System Improvement

Data Collection

Data Review

Data Utilization

Lab workers
Health workers
Counselors
Client Satisfaction

- Feedback
- Troubleshooting
- Resolution
Facilities & Safety

- Universal Precautions
- Safety Policy
- Confidentiality
- Standard Procedures
- Records
Quality Testing Systems

Quality system components include all activities, supplies, and personnel that contribute to test results.
Quality HIV Testing System

- Organization
- Personnel
- Equipment
- Inventory
- QC Sample Testing
- Data
- Record Keeping
- Specimen Collection & Testing
- Monitoring
- System Improvement
- Client Satisfaction
- Facilities & Safety

Lab workers
Health workers
Counselors
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?

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

EVERYONE!
Why Do Errors Occur?

- Responsibilities unclear
- Written procedures lacking
- Written procedures not followed
- Training incomplete
- Records improperly monitored
- Supplies stored improperly
- QC samples not tested
Preventing and Detecting Errors

- Record temperatures
- Review inventory
- Test QC samples
- Maintain QC Sample Log
- Use designated testing space
- Follow SOPs
- Complete records for each client
Testing Errors

• Algorithm not followed
• Individual test SOPs not followed
• Incorrect time for reading test
• Wrong buffer used for testing
• Expired reagents used for testing
• Finger-stick fails to give enough blood
• Incorrect information recorded
• Improper waste disposal
Quality in HIV Rapid Testing

- Makes test results uniform among testing sites
- Sets a standard for HIV testing
- Meets/exceeds customer expectations
- Provides approach to correcting problems
- Provides data for improvement of testing
- Reduces costs

No test is foolproof!
Summary

- Why do errors occur?
- What errors could occur in HIV rapid testing?
- Where is quality in a testing site?
- How can you reduce errors in testing?
- How will errors impact clients?
Module 6: Safety at the HIV Rapid Testing Site

Learning to “Think like a lab person” (Part 1)
Learning Objectives

At the end of this module, you will be able to:

- Follow personal health and safety practices
- Maintain a clean and organized workspace
- Dispose of infectious materials
- Describe what to do in the case of an accident
- Follow safety procedures and keep safety records
Content Overview

- Safety practices include how to:
  - Develop safety habits
  - Properly dispose of waste
  - Keep safety records
What is Safety?

Safety is taking precautions to protect you, the client and others against infection, accident or injury.
Why Is Safety Important?

We cannot wait until a serious accident or illness occurs before we implement safe practices.
Who Needs to be safe?

- The client
- The tester
- Others
Universal Safety Precautions

Every specimen should be treated as though it is infectious
Practice Personal Safe Work Habits

- Wash hands before and after testing each client
- Change gloves for each client
- Wear lab coat or apron
- Dispose of lancets in designated container
- Do not retrieve anything out of the disposal container/bag
Practice Personal Safe Work Habits (Cont’d)

- Do not put pens/pencils in your mouth. It is *strictly forbidden*
- Never eat, drink, apply make-up, remove or insert contact lenses, or smoke at the test site
- Do not store food/drink in the QC sample refrigerator
What is a Bio-Hazard?

An organism or substance capable of causing infection, disease or death.
Maintain Clean & Orderly Work Space

- Keep work areas uncluttered and clean
- Restrict or limit access when working
- Keep supplies locked in a safe and secure area
Drop Used Lancets in Special Containers
Disinfect Work Areas with Bleach

Disinfection

- Kills germs and pathogens
- Keeps work surface clean
- Prevents cross-contamination
- Reduces risks of infection
Different Cleaning Jobs Require Different Bleach Solutions*

General lab use - *Hypochlorite Solutions*

<table>
<thead>
<tr>
<th>Spills</th>
<th>General Disinfection</th>
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</thead>
<tbody>
<tr>
<td>10% (1 part + 9 parts)</td>
<td>1% (1 part + 99 parts)</td>
</tr>
</tbody>
</table>

You should have 10% bleach readily available at your test site.

*WHO Laboratory Biosafety Manual*
Making a 10% Bleach Solution

Referred to as a 1/10, 1:10

1 Part Bleach

9 Parts Water

= Water Fill Line

Bleach Fill Line

Label Container
1:10
Initials
Exp. Date
Health Warnings

Lab workers
Health workers
Counselors
In Case of a Spill or Splash

- Wear clean disposable gloves
- **Large spills** - Cover with paper towels and soak with 10% household bleach and allow to stand for at least 5 minutes
- **Small spill** - Wipe with paper towel soaked in 10% bleach
- Discard contaminated towels in infectious waste containers
Incineration of Waste

• Incineration is burning of contaminated waste to destroy and kill micro-organisms.

• Incineration:
  ▪ Prevents re-use
  ▪ Protects environment
  ▪ Must be conducted by authorized institutions
In Case of an Accident

What should you do?

- Assess & take action
- Report to manager immediately
- Record on standard form
Action Plan for Implementing Safety Practices

- Identify hazards
- Establish safety policies
- Implement safety procedures
- Keep proper safety records
Safety References
Learning Objectives

At the end of this module, you will be able to:

• List and identify all the supplies required for HIV rapid testing
• List and identify all the components of test kits for HIV rapid testing
Memory Game: Supplies & Materials

How To Play:

• Spend 3 minute browsing through the display and learn the items
• Spend 1 minute writing down as many items as possible (without looking)

- Tally up the number of items you list
- The person with the most items wins.
Materials & Supplies Checklist (Part 1)

- HIV rapid test kits
- Alcohol swabs
- Cotton
- Retractable Lancets
- Leak-proof bag for waste incineration
- Disinfectant
- Pen for writing

- Pen for labeling
- Timer or watch with minute hand
- Paper towels (for cleaning, hand washing and work area)
- Soap for hand washing
Materials & Supplies Checklist (Part 2)

- One positive QC sample
- One negative QC sample
- QC sample log
- Standard Operating Procedures
- Band Aids / plasters
- Thermometers
- Register for recording results
Gloves

- Single use disposable gloves
- Latex or polypropylene
- Without evidence of holes or tearing
Alcohol

Lab workers  Health workers  Counselors
Cotton Gauze or Cotton Balls

Single-use, hazardous waste disposal
Retractable Safety Lancets
Standard Operating Procedures and Forms

Lab workers

Health workers

Counselors
Labeling Pens and Writing Pens

- Labeling Pens

- Writing Pens

Lab workers
Health workers
Counselors
Waste Disposal
Examine Test Kits

- Display test kits used in-country
- Examine the different components found in each of the Rapid Test kits:
  - Desiccant packet – This is not used when performing the test.
  - Buffer solution – Required for whole blood testing.
  - Transfer pipette or loop
  - Testing device
Organize Your Work Area

Lab workers
Health workers
Counselors
Summary

- What type of lancets will be used for MOH TT “same-visit” testing?
- What are desiccant packs used for?
- What type of bag is needed for waste disposal?
- Which kit uses a loop for sample collection?
- How many QC samples are needed?
Module 8: Blood Collection – Finger Puncture
Learning Objectives

At the end of this session you will be able to:

• Apply the principle of the finger puncture
• Select the appropriate finger for the procedure
• Perform and collect finger puncture blood accurately and confidently
Content Overview

• Preparing for testing
• Educating your client
• Performing a finger puncture
Puncture Site Selection

Finger selection:
- Middle finger or Ring finger

Area of finger:
- Central fleshy portion of the finger, slightly to the side of the centre and perpendicular to the whorls of the fingerprint
Figure 10-9

Recommended site and direction of finger puncture.
Don’ts of Finger Puncture

- Do not puncture the side or the tip of the finger
- Do not puncture parallel to the grooves of the fingerprint
- Do not puncture the index finger
- Do not puncture the little finger
- Do not puncture the fingers of infants or very young children
Finger Puncture Procedure
Finger Puncture – Getting Started

1. Collect supplies
Finger Puncture – Finger Preparation

1. Choose whichever finger is least calloused.

2. Massage finger to increase blood flow.

3. Clean the fingertip with alcohol. Work from the middle out to reduce contamination. Allow the area to dry.

4. Grasp the finger and place a new sterile lancet on the side of the fingertip.
Finger Puncture – Collecting Blood

5. Firmly press the lancet to puncture the fingertip

6. Collect the sample. Blood may flow best when the finger is held lower than the elbow.

7. Apply a gauze pad or cotton ball to the puncture site until the bleeding stops

Lab workers  Health workers  Counselors
Finger Puncture - Proper Disposal

8. Properly dispose of all contaminated supplies

Lab workers  Health workers  Counselors
Instructor-Led Demonstration
Summary

• How do you put a client at ease while collecting blood?
• What supplies do you need for a finger puncture?
• What are the steps when performing a finger puncture?
• What safety precautions should you follow?
Module 9: Performing HIV Rapid Tests

Demonstration and Practice
Learning Objectives

• At the end of this module, you will be able to:
  - Define “Standard Operating Procedure” (SOP)
  - Perform MOH TT algorithm tests according to SOPs
    - Uni-Gold
    - Determine
    - Stat-Pak
  - Perform two tests simultaneously
  - Accurately interpret individual test results
  - Accurately determine HIV status
Content Overview

Overview of Testing Procedures

Workspace Setup

Demo + Practice
(individual tests on known samples)

Video Presentation and Discussion

Practice
MOH TT algorithm with blood and/or plasma samples

Lab workers  Health workers  Counselors
# Predictive Value: Single HIV Test

Test Specificity 99.8%

<table>
<thead>
<tr>
<th>HIV Prevalence</th>
<th>True +</th>
<th>False +</th>
<th>Positive Predictive Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>10%</td>
<td>100</td>
<td>2</td>
<td>98%</td>
</tr>
<tr>
<td>5%</td>
<td>50</td>
<td>2</td>
<td>96%</td>
</tr>
<tr>
<td>2%</td>
<td>20</td>
<td>2</td>
<td>91%</td>
</tr>
<tr>
<td>1%</td>
<td>10</td>
<td>2</td>
<td>83%</td>
</tr>
<tr>
<td>0.5%</td>
<td>5</td>
<td>2</td>
<td>71%</td>
</tr>
<tr>
<td>0.2%</td>
<td>2</td>
<td>2</td>
<td>50%</td>
</tr>
<tr>
<td>0.1%</td>
<td>1</td>
<td>2</td>
<td>33%</td>
</tr>
</tbody>
</table>
Determine

- Lab workers
- Health workers
- Counselors
Determine: Getting Ready

1. Collect test items

2. Use 1 strip per test
   Preserve the lot number

3. Label the test strip with client identification number

4. Remove protective foil cover

Lab workers
Health workers
Counselors
5. Collect 1 drop of blood using a plastic transfer pipette
Determine: Applying Sample and Buffer to Test Strip

6. Apply the sample to the absorbent pad on the strip

7. Add 1 drop of chase buffer to the specimen pad
Determine: Getting Results

8. Wait 15 minutes before reading the results

9. Read and record the results

Lab workers  Health workers  Counselors
**Determine - Test Interpretation**

- **Positive**
- **Negative**
- **Invalid**
Uni-Gold: Getting Ready

1. Collect test items

2. Remove device from package and label it
3. Collect specimen using the disposable pipette
Uni-Gold: Adding Sample and Reagent to Test Device

4. Add 2 drops of sample to the sample port

5. Add 2 drops of wash buffer to sample port
Uni-Gold: Getting Results

6. Wait for 10 minutes to read the results

7. Read and record the results
Uni-Gold: Test Interpretation

Positive

Negative

Invalid

Lab workers
Health workers
Counselors
Stat-Pak
Stat-Pak: Getting Ready

1. Collect test items

2. Remove device from package and label it
Stat-Pak: Collecting Specimen

3. Collect specimen using the calibrated loop
4. Add sample to center of SAMPLE well.

5. Add 3 drops of buffer. Drop buffer directly over SAMPLE well.
6. Wait for 10 minutes to read the results

7. Read and record the results
Stat-Pak: Test Interpretation

Positive  Positive

Lab workers  Health workers  Counselors
Stat-Pak: Test Interpretation

Positive
Lines of any intensity in both control and test areas.

Negative
Line in control area only.

Invalid
No line in control area. Do not report invalid results.

Lab workers 🌟 Health workers 🌟 Counselors 🌟
Activity: Workspace Setup

• Identify your workspace
• Gather test kits and supplies
• Obtain positive and negative samples from instructor
• Arrange all items at your work station

• Activity time: 10 minutes
Hands-On Practice: Individual Tests

Instructions:
• Use safety precautions
• Practice with samples provided by your instructor only
• Raise your hand if you need additional supplies
• Show your test results to instructor after you are done

Total time: 15 minutes per test
Video Presentation and Discussion
Video: Determine

- What preparation is required before testing?
- What are the components in the test kit?
- What must you preserve when separating test strips from the packet?
- What information needs to be recorded, and where?
- How do you collect blood? What device do you use?
- How long do you set the timer?
- How many results are possible? How do you read them?
Video: Uni-Gold

- What preparation is required before testing?
- What are the components in the test kit?
- What information needs to be recorded, and where?
- How do you collect blood? What device do you use?
- How long do you set the timer?
- How many results are possible? How do you read them?
Video: Multiple HIV Tests

- Why must you keep two test kits separate when performing both at the same time?
- Do you collect blood at the same time or separately when performing multiple tests?
- How do you set the timer when two tests require different wait time?
- When is the third test used?
- How does it determine HIV status?
MOH TT Algorithm

Blood Sample

Determine

Uni-Gold

Both Positive

Both Negative

One Positive
One Negative

( Discordant)

Stat-Pak

Positive

Negative

Report Positive

Report Negative

Report Positive

Report Negative

Lab workers

Health workers

Counselors
## Possible Outcomes in Parallel Algorithms

<table>
<thead>
<tr>
<th>TEST 1</th>
<th>TEST 2</th>
<th>TEST 3</th>
<th>HIV Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negative</td>
<td>Negative</td>
<td></td>
<td>Negative</td>
</tr>
<tr>
<td>Positive</td>
<td>Positive</td>
<td></td>
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<tr>
<td>Positive</td>
<td>Negative</td>
<td>Positive</td>
<td>Positive</td>
</tr>
</tbody>
</table>
Hands-On Practice: Parallel Algorithm

Conduct Determine, Uni-Gold and Stat-Pak tests simultaneously following the SOPs. Record the HIV status of each sample.

Specimen

1. Determine – Uni-Gold – Stat-Pak → HIV Status
2. Determine – Uni-Gold – Stat-Pak → HIV Status
3. Determine – Uni-Gold – Stat-Pak → HIV Status
5. Determine – Uni-Gold – Stat-Pak → HIV Status
Hands-On Practice: Parallel Algorithm

- Collect supplies
- Obtain panel of blind specimens
- Organize your workspace
- Complete one algorithm before starting the next
  - Use safety precautions
  - Practice only on samples provided
  - Raise your hand for additional supplies
- Record results on worksheet
- Do not discard test devices - instructor will check results
Summary

• Describe the key learning from performing:
  • (Uni-Gold)
  • (Determine)
  • (Stat-Pak)

• Describe the key learning from performing the multi-test algorithm
Module 10: Inventory

Managing Stock at the HIV Rapid Testing Site
Quality HIV Testing System

- Organization
- Personnel
- Equipment
- Inventory
- QC Sample Testing
- Data
- Record Keeping
- Specimen Collection & Testing
- Monitoring
- System Improvement
- Client Satisfaction
- Facilities & Safety

- Lab workers
- Health workers
- Counselors
Learning Objectives

At the end of this module, you will be able to:

• Maintain proper records
• Maintain proper level of consumables
• Use first-expiry-first-out concept when managing stock – Is “first in - first out” better?
• Inspect delivery of supplies before acceptance
• Identify lot numbers and expiry dates
• Store kits and supplies properly
Content Overview

What is stock management?

- Keeping record
- Re-ordering as needed
- Receiving consumables
- Storing consumables
Stock Management Means...

Properly maintaining adequate supplies to provide uninterrupted service
Stock at Rapid Test Site Includes...  

Inventory in Storage Area  
and  

Supplies at Workstation
Stock Management Leads to High Quality Testing

- Guarantees availability of supplies
- Reduces costs
- Avoids the use of expired kits
- Reduces waste
How Do You Manage Stock?

You own a doubles cart. Your wife prepares the doubles you sell them for a profit. To make money, you must always have what your customers want.

What must you do to maintain adequate stocks?
Stock Management Involves Knowing...

- What items you have.
- How many of each item you have.
- When to order.
- What you have ordered.
- How long it has been since you ordered.
- Where to store your stock.
- When new stock was received.
- Where new stock is located.
- Who received the new stock.
Stock Management Involves...

- Performing a “stock count”
- Maintaining proper inventory records
- Determining when to re-order
- Determining how much to re-order
- Placing orders properly
- Inspecting delivery of new orders
- Storing stock properly
**Perform a “Stock Count”**

<table>
<thead>
<tr>
<th>What is it?</th>
<th>Counting each item in the stock</th>
</tr>
</thead>
<tbody>
<tr>
<td>When is it done?</td>
<td>Recommended at the beginning of each month</td>
</tr>
<tr>
<td>Who does it?</td>
<td>A designated person</td>
</tr>
</tbody>
</table>

All items must be accounted for. Everything that comes in and goes out must be recorded.
Maintain Proper Inventory Records

**Stock Card**
- Simple, heavy weight cards
- Kept for each item in stock

**Stock Book**
- Contains listing of all items in the store
- Is updated after physical count
- Uses information from stock cards
- Is also called a Stock Register
**Stock Card: An Example**

- **Item Name:** ___________  **Unit:** ___________
- **Manufacturer:** ________________________
- **Minimum Stock (Re-Order Level):** ___________

<table>
<thead>
<tr>
<th>Date</th>
<th>Received From</th>
<th>Issued to</th>
<th>Quantity Received</th>
<th>Quantity Issued</th>
<th>*Balance</th>
<th>Lot #</th>
<th>Signature</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</table>

- Lab workers
- Health workers
- Counselors
## Stock Book: An Example

<table>
<thead>
<tr>
<th>Item Name</th>
<th>Qty (units) Requested</th>
<th>Date Requested</th>
<th>Qty Received</th>
<th>Date Received</th>
<th>Lot #</th>
<th>Expiry Date</th>
</tr>
</thead>
<tbody>
<tr>
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</table>
Reconciling Stock with Records

**Ideal**

\[
\text{# Tests Performed} = \text{Stock Depletion}
\]

**Reality**

\[
\text{# Test Performed} + \text{loss} = \text{Stock Depletion}
\]

What can be done to minimize loss?
Decide When to Re-order

Re-order when stock reaches minimum level

Terminology:

- **Minimum stock** - Amount of stock required to support testing operations until additional supplies are received
- **Lead time** – Time between placing an order and receiving it
- **Maximum usage** – number of test kits used in a given time period
Calculating Minimum Stock Level

Minimum Stock Level = Maximum lead time in weeks \times Maximum Usage

Example:
- Maximum lead time = 12 weeks
- Maximum usage/wk = 3 kits
- Minimum stock level = 12 \times 3 = 36 kits

When only 36 kits are left, place an order
Exercise: Calculate Minimum Stock Level

- On average, you use 5 Uni-Gold kits a week.
- Usually you need 12 weeks to receive your orders.
- You should order more Uni-Gold kits when you have ____ kits left in the inventory.
Decide How Much to Re-order

Establish proper full stock level. Re-order to reach that level.

- Review stock “use”. Include stock consumed, borrowed, expired, wasted, and pilfered.
- Never order more than you can store.
- Never order more than you can use before expiry.
- Know maximum usage AND minimum stock level
Decide Full Stock Level

Maintain stocks that cover maximum usage plus minimum stock level

Maximum usage /wk = 70 tests
# tests / month = 70 x 4

280 tests used per month

Assuming 20 tests per kit, how many kits are used per month?
280 / 20 = 14

Lead time = 12 weeks (3 months)
Minimum stock level = 14 kits x 3 months = 42 kits
Full stock level = 42 + 14 = 56

You must have 56 kits in stock at the beginning of each re-order cycle.
## Exercise: Decide Full Stock Level

<table>
<thead>
<tr>
<th>Maximum usage /wk = 80 tests</th>
<th>Lead time = 12 weeks or 3 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>How many tests are used per month?</td>
<td>Minimum stock level = _____ kits</td>
</tr>
<tr>
<td>___________ tests/month</td>
<td>Full stock level = ______ kits</td>
</tr>
<tr>
<td>Assuming 15 tests per kit, how many kits are used per month?</td>
<td>You must always have _____ kits in stock at the beginning of each re-order cycle (3 months).</td>
</tr>
<tr>
<td>___________ kits/month</td>
<td></td>
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</tbody>
</table>

**Calculate:**

- What is the minimum stock level?
- How many test kits should you have in the beginning of each re-order cycle?
Place Orders Properly

- Describe current ordering system
- Provide instructions for placing orders
- Instruct trainees to complete forms needed for inventory/stock management.
- Describe contingency plan for stock shortages
- Describe communications to suppliers
  - Learn how to stop standing deliveries
  - Know how to request delivery
  - Know what information to tell central procurement
Inspect Delivery of New Orders

Upon receipt:

- Verify contents of order received with requisition
- Check integrity of received supplies
- Date each item received
- Note expiration date
- Store new shipment behind existing shipment
- Create or update records
Examine Lot Number & Expiry Date
Proper Storage of Stock

- Store stock in clean, organized, and locked storeroom
- Store in well-ventilated space away from direct sunlight
- Store according to manufacturer’s instructions
- Record storeroom temperature daily
- Place items on shelves
- Organize existing and new shipments by expiration dates

First expiry, first out
Summary

• What does inventory management mean?
• What information is recorded in inventory record-keeping?
• How do you decide minimum stock level?
• How do you decide proper full inventory level?
• What does “First Expiry First Out” mean?
• What procedure should you follow when receiving new kits and supplies?
• How should kits and supplies be stored?
Key Messages

- Maintain adequate inventory at all times.
- Do not run out of anything before re-order.
- Never order more than you can store.
- Never order more than you can use before expiry.
- NOTIFY OVERAGE-redistribute before expiry.
- Account for all items in inventory.
- Inspect new shipments before acceptance.
Module 11: Refrigerators

QC Sample Storage at HIV Testing Sites
Quality HIV Testing System

- Organization
- Personnel
- Equipment
- Inventory
- QC Sample Testing
- Data
- Record Keeping
- Specimen Collection & Testing
- Monitoring
- System Improvement
- Client Satisfaction
- Facilities & Safety

Lab workers ♦ Health workers ♦ Counselors
Learning Objectives

At the end of this module, you will be able to:

• Monitor temperatures

• Keep temperature records
Content Overview

- Rationale for equipment maintenance
- Your responsibilities for equipment
- Refrigerators at HIV rapid testing sites
Functioning Equipment is Vital to Quality Service

- Produces reliable test results
- Lowers repair costs
- Prevents delays in testing
- Maintains productivity

Lab workers  Health workers  Counselors
Equipment at HIV Rapid Testing Sites

Refrigerator
# Temperature Log

## QS Sample Refrigerator

**Temperature Record**

Range (2 to 8 °C)

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Model No</th>
<th>Year</th>
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</table>

<table>
<thead>
<tr>
<th>Jan</th>
<th>Feb</th>
<th>Mar</th>
<th>Apr</th>
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</table>
Responsibilities at Test Site

- Record refrigerator temperatures (2°C to 8°C)
- Record storage area temperature (28°C or less)
- Record Testing room temperature (28°C or less)
- Report incorrect temperatures to your supervisor
- Take corrective actions
- Keep records for each day of testing

Stop testing if refrigerator fails!
Refrigerator Care

- Keep clean
- Close completely
- Report temperatures above 8°C or below 2°C
- DO NOT store food or beverages in the QC sample refrigerator
Summary

- Why keep temperature records?
- What is the proper temperature for the QC sample refrigerator?
- Why not store food in the QC refrigerator?
- What is the maximal permitted temperature for the storage area?
- What should you do when you record incorrect temperatures?
Module 12: Quality Control
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?
What Is Quality Control (QC)?

- Monitoring the quality of the test itself
- Reporting results that are correct
Controls for MOH TT HIV Rapid Testing

- **Internal**
  - Controls within the testing device

- **External**
  - Controls of *known* HIV status provided by an external source.
**Internal and External Quality Control**

**Internal Control**
Included in testing device

**External Control**
Known positive and negative samples used to check the testing process

[Diagram showing control bands and labeled sections for Lab workers, Health workers, and Counselors]
External Quality Control Samples

- Prepared by Reference Laboratory
- Commercially prepared
- Store according to instructions
- Date when opened
- Use before expiry date
- Do not contaminate
Use of External Control Samples in the MOH TT Testing System

• Each tester must test one positive and one negative control with each kit (Determine, Unigold and Stat-Pak):
  - At the start of each day of testing
  - At the beginning of a new lot number
# Quality Control Record: An Example

## QC SAMPLE LOG

<table>
<thead>
<tr>
<th>Date and Time</th>
<th>Tester</th>
<th>QC samples Lot #</th>
<th>Determine</th>
<th>Uni-Gold™</th>
<th>Stat-Pak</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td>Lot #</td>
<td>Ex Date</td>
<td>Result</td>
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<tr>
<td>Pos</td>
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</tbody>
</table>
QC Invalid Results – What Do You Do?

- Repeat test
- If the second test is invalid, STOP testing for the day.
- Identify cause of problem
- Inform manager
- Take corrective actions
## Troubleshooting Invalid Results

<table>
<thead>
<tr>
<th>Problem</th>
<th>Potential Cause</th>
<th>Action</th>
</tr>
</thead>
</table>
| No control line or band present | • Damaged test device or controls  
• Proper procedure not followed  
• Expired or improperly stored test kits or controls | • Repeat the test using new device  
• Follow each step of testing according to SOP  
• Re-check buffer and/or specimen volumes  
• Check expiry date of kits and QC samples. Do not use beyond stated expiry date  
• Check temperature records for storage and testing area |
### Troubleshooting Invalid Results – Cont’d

<table>
<thead>
<tr>
<th>Problem</th>
<th>Potential Cause</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive reaction with negative QC sample, i.e. false positive</td>
<td>Mixed up samples</td>
<td>Re-test negative control using a new device and read results within specified time limit</td>
</tr>
<tr>
<td>Extremely faint control line</td>
<td>The control line can vary in intensity</td>
<td>No action required. Any visible line validates the results.</td>
</tr>
</tbody>
</table>
Exercise #1: Interpreting Rapid Test Results

• Read the test results from the teaching aids we have just handed out.
• Write your interpretation on the index card provided.
Review of Quality Control

- Review of internal control results before accepting test results
- Review of external control results by tester
- Regular review of QC sample logs and other records by the Quality Monitor (site audits)
Module 13: Quality Monitoring

On-site Review and Auditing
Content Overview

- What is quality monitoring?
- Why is it important?
- Who will provide quality monitoring for MOH TT “same visit” HIV testing?
- Test site records
- Internal and external audits
- Verification panels
Review of Quality Control

- Review of internal control results before accepting test results
- Review of external control results by tester
- Regular review of QC sample logs and other records by the Quality Monitor (site audits)
Quality Monitoring Definition

Objective review of testing by an external agency or personnel
Why Quality Monitoring?

• To compare performance and results among test sites
• To provide early warning for systematic problems in testing
• To evaluate quality of testing
• To stop testing when appropriate
Monitoring Where Testers are Counselors

- Client confidentiality is top priority
- Monitoring must be indirect
- Internal auditing is by tester
- Site auditing is by quality monitors
- Quality monitors will provide feedback during the site audit
- Quality monitors have authority to stop testing
MOH TT Monitoring Components

- Temperature Records
- QC Sample Log
- Testing Records
- Verification Panels

- Supervisors or Managers
- Testers
What is a Site Audit?

A site audit is review of the testing process to collect information needed for process improvement.

Site audits may be:

- **Internal** - conducted by the person who is performing testing
- **External** – conducted by the Quality Monitor
Components of Site Audit

- Review temperature records
- Review QC sample log
- Review client test result records
- Verify inventory control records
- Observe cleanliness of testing site
- Observe cleanliness of QC refrigerator
- Request tester to complete verification panel (external audit only)
- Discuss review observations with tester
Management Responsibilities:

- Establish quality monitoring policy
- Assign responsibilities
- Respect Quality Monitor and/or Tester decisions about testing
- Correct deficiencies
- Communicate outcomes to all involved
Summary

- Quality Monitors are responsible for site audits
- Quality Monitors have authority to stop testing
- Effective Site Managers will respect and support decisions made by the Tester and the Quality Monitor
Module 15: Documents and Records

Learning to “Think like a lab person” (part 2)
Learning Objectives

At the end of this module, you will be able to:

• Explain differences between documents and records
• Explain the relationship between records and quality of testing
• List documents and records for quality testing at MOH TT testing sites
• Follow standard operating procedures (SOPs)
• Keep MOH TT testing site records accurately
Content Overview

• What are documents and records?
• Documents
  ▪ Why are they important?
  ▪ What documents should you keep?
  ▪ Why follow SOPs?
  ▪ What is the proper way to keep and maintain documents?
• Records
  ▪ Why are they important?
  ▪ What records should you keep?
  ▪ What is the proper way to keep and maintain records?
T&T Quality Health Care System

- Organization
- Personnel
- Equipment
- Purchasing & Inventory
- Specimen Collection & Testing
- Data
- Documents & Records
- Corrective Action
- Monitoring
- System Improvement
- Client Satisfaction
- Facilities & Safety

Lab workers  Health workers  Counselors
What Are Documents and Records?

Documents
- WRITTEN policies, process descriptions, procedures, and blank forms used to communicate information

Records
- Information on worksheets, forms, and charts (collected on documents)
Which Is Which?
Documents and Records

- MOH TT testing algorithm
- Reference manual
- Temperature logs (completed)
- SOPs for individual HIV rapid tests
- Manufacturer product inserts
- Temperature logs (blank)
- QC sample log (blank)
- Inventory cards (completed)
- Client record (completed)
- Client record (blank)
- Summary of findings from a site audit
Which Is Which?

Documents and Records

- MOH TT testing algorithm
- Reference manual
- Temperature logs (completed)
- SOPs for individual HIV rapid tests
- Manufacturer product inserts
- Temperature logs (blank)
- Inventory cards (completed)
- QC sample log (blank)
- Client record (completed)
- Client record (blank)
- Summary of findings from a site audit
Documents Are the Backbone of the Quality System

Verbal instructions often are:
- Not heard
- Misunderstood
- Quickly forgotten
- Ignored

Policies, standards, processes, and procedures must be written down, approved, and communicated to all concerned.
Standard Operating Procedures (SOPs) Are Documents that…

• Describe how to perform various operations in a testing site
• Provide step-by-step instructions
• Assure:
  ▪ Reliability
  ▪ Accuracy
  ▪ Quality
Use Test Site SOPs

- Manufacturer product inserts are not sufficient for testing.

- Test site SOPs include:
  - Materials required, but not in kit
  - Specific safety requirements
  - Sequence of tests for MOH TT testing
  - QC Samples testing procedure
SOPs Must Be Followed

• Why is it important to follow SOPs?

• What happens if you do not?
MOH TT Documents
What Documents Are Needed at MOH TT Testing Sites?

- MOH TT Testing Algorithm
- Temperature Logs
- Finger-stick blood draw procedure
- QC Sample Log
- Determine SOP
- Uni-Gold SOP
- Stat-Pak SOP
- HIV Test Report
- Inventory Cards
MOH TT Temperature Logs

Three Temperature Logs are needed at each MOH TT testing site:

- QC Sample Refrigerator
- Rapid Test Kit Storage Area
- Testing Area
### MOH TT Temperature Logs

** QS Sample Refrigerator Temperature Record**

*Range (2 to 8 °C)*

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<tr>
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</table>

- Fill accurately
- Write legibly
- Date
# MOH TT Temperature Logs

- Fill accurately
- Write legibly
- Date

## Kit Storage Temperature Record
(less than 28 °C)

<table>
<thead>
<tr>
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Year _______
# MOH TT Temperature Logs

- Fill accurately
- Write legibly
- Date

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**Testing Area Temperature Record**

(less than 28 °C)

Year _________
MOH TT Blood Collection Procedure

Each client will be asked to provide a sample of blood for testing.

Each blood sample should be collected the same way.

Collection should follow the Finger-Stick Blood Draw SOP
Blood collection from each client should follow the Finger Stick Blood Draw SOP.
MOH TT QC Sample Log

- Fill accurately
- Write legibly
- Date
- Sign

<table>
<thead>
<tr>
<th>Date and Time</th>
<th>Tester</th>
<th>QC samples Lot #</th>
<th>Determined Lot #</th>
<th>Ex Date</th>
<th>Result</th>
<th>Uni-Gold Lot #</th>
<th>Ex Date</th>
<th>Result</th>
<th>Stat-Pak Lot #</th>
<th>Ex Date</th>
<th>Result</th>
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MOH TT Rapid Test SOPs

Three HIV Rapid Test SOPs are needed at each MOH TT testing site:

- Determine
- Uni-Gold
- Stat-Pak
MOH TT SOP: Determine Test

Determina HIV-1/2 SOP

Summary of the manufacturer’s working protocol for Determine® Rapid Tests.

**Procedure**

1. Check the expiration date. Do not use expired kits.
2. Remove the protective kit cover from the test device.
3. Label test device with the appropriate patient/client identification.
4. Apply two drops of whole blood to the sample pad marked by an arrow symbol.
5. Wait one minute until blood is absorbed into the sample pad.
6. Apply 1 drop of Chase Buffer to the sample pad.
7. Wait at least 15 minutes (up to 60 minutes) and read the result.
8. Record results on the worksheet.

**Interpretation of Test Results**  (Only three results are possible with this test):

- **Positive** (Two bands)
  
  Red bands appear in both the control window (labeled 'C') and the patient window (labeled 'P') of the strip. Any visible red color in the patient window should be interpreted as positive.

- **Negative** (One Band)
  
  One red band appears in the control window of the strip (labeled 'C') and no red band appears in the patient window of the strip (labeled 'P').

- **Invalid** (No Band)
  
  If there is no band in the control window of the strip the test is invalid. Even if a red band is present in the patient window of the strip, the result is invalid and should be repeated.

- **Approved for use in-country**
- **Must be kept up-to-date**
- **Must be followed precisely**
MOH TT SOP: Uni-Gold Test

Uni-Gold® HIV SOP

Summary of the manufacturer’s working protocol for Uni-Gold® HIV Rapid Tests.

Procedures
1. Check the expiration date. Do not use expired kits.
2. Remove the protective kit cover from test device.
3. Label test device with the appropriate patient/client identification.
4. Apply two drops of whole blood to the sample well.
5. Apply 2 drops of Wash Reagent to the sample well.
6. Read results after 10 minutes (up to 20 minutes).
7. Record results on the worksheet.

Interpretation of Test Results (Only three results are possible with this test):

Positive (Two bands)
Red bands appear in both the control area (labeled ‘C’) and the test area (labeled ‘T’) of the device. Any visible red color in the test area should be interpreted as positive.

Negative (One Band)
One red band appears in the control area of the device (labeled ‘C’) and no red band appears in the test area of the device (labeled ‘T’).

Invalid (No Band)
If there is no band in the control area of the device, the test is invalid. Even if a red band is present in the test area of the device, the result is invalid and should be repeated.
MOH TT SOP: Stat-Pak Test

HIV1/2 Stat Pak SOP

Summary of the manufacturer’s working protocol for HIV1/2 Stat-Pak Rapid Tests.

Procedure
1. Check the expiration date. Do not use expired kits.
2. Remove the protective kit cover from the device.
3. Label the device with the appropriate patient/client identification.
4. Collect blood sample with the 5 µl loop provided.
5. Touch the loop to the center of the sample well and wait 3 seconds.
6. Slowly add three drops of buffer to the sample well.
7. Read results after 10 minutes (up to 20 minutes).
8. Record results on the worksheet.

Interpretation of Test Results (Only three results are possible with this test):

Positive (Two bands)
Red bands appear in both the control area (labeled ‘C’) and the test area (labeled ‘T’) of the device. Any visible red color in the test area should be interpreted as positive.

Negative (One Band)
One red band appears in the control area of the device (labeled ‘C’) and no red band appears in the test area of the device (labeled ‘T’).

Invalid (No Band)
If there is no band in the control area of the device, the test is invalid. Even if a red band is present in the test area of the device, the result is invalid and should be repeated.

- Approved for use in-country
- Must be kept up-to-date
- Must be followed precisely
**MOH TT HIV Rapid Test Report**

- Fill accurately
- Write legibly
- Date
- Sign

**HIV RAPID TEST REPORT**

<table>
<thead>
<tr>
<th>Client Name</th>
<th>Client ID</th>
<th>Client DOB</th>
<th>Client Gender M( ) F( )</th>
<th>Testing Location</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Rapid test</th>
<th>Determined</th>
<th>Uni-Gold™</th>
<th>Stat-Pak</th>
<th>Result</th>
<th>HIV Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lot #</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exp date</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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Lab workers  
Health workers  
Counselors
MOH TT Records
What Records Are Essential at MOH TT Test Sites?

- Temperature Logs
- QC Sample Logs
- Client test results
- Inventory records
Proper Record-Keeping Results in Quality Testing

Record-keeping allows a test site to:

- Communicate accurately and effectively
- Quickly identify problems
- Minimize error
- Monitor quality system
- Assist management in:
  - Developing policy & plans
  - Monitoring and evaluating programs
Tips for Good Record Keeping

- Understand the information to be collected
- Record the information every time
- Record all the information
- Record the information in the same way every time

* PMTCT Generic Curriculum

Lab workers  Health workers  Counselors
How Long Should You Retain Client Test Records?

It depends on several factors:

- National policies
- Secure storage space at test site
Records Should be Permanent, Secure, Traceable

• Permanent:
  ▪ Keep books bound
  ▪ Number pages
  ▪ Use permanent ink
  ▪ Control storage

• Secure:
  ▪ Maintain confidentiality
  ▪ Limit access
  ▪ Protect from environmental hazards

• Traceable:
  ▪ Sign and date every record
Information Recorded will Feed Into Monitoring and Evaluation Systems

• Provide in-country information:
  ▪ When will what be reported?
  ▪ How will it be reported?
  ▪ Whom will it be reported to?
  ▪ How will the data be used?
Summary

- What is a document?
- What is a record?
- List records used at MOH TT testing sites.
- What are SOPs?
- Why are SOPs important?
- What are some tips for good record-keeping?
- How should records be maintained?
Key Messages

• Written policies and procedures are the backbone of the quality system
• Complete quality assurance records make quality management possible
• Keeping records facilitates meeting program reporting requirements
Module 16: Professional Ethics
Learning Objectives

By the end of the module, you will be able to:

• Describe ethical issues related to HIV rapid testing
• Explain the importance of professional ethics
• Apply ethical conduct to HIV rapid testing
• Take appropriate actions to maintain client confidentiality
Content Outline

- What is ethics?
- Why is ethics important?
- Who is responsible for ethics?
- How is ethics applied to HIV rapid testing?
- Maintaining confidentiality
- Code of conduct
Scenario I

A pregnant woman comes for HIV testing. Your test site has just run out of the 2nd test in the algorithm. You tell her that she will have to come back in 2 days. She becomes very emotional and explains that she has traveled a long distance after finally deciding to get tested and won't be back in the area for a long time.

Feeling sorry for her, you proceed to perform test one, and report a resulting positive test to the client.
Scenario II

At the HIV rapid testing site, you discover that you just run out of the buffer for Test 1 of the algorithm. Rather than denying testing to clients, you decide to go ahead and perform Test 1 using the buffer from kits of Test 2.
**Scenario III**

Today is Monday. You discover that there are enough test devices to last through the entire week, but they will expire on Wednesday.

Since resources are tight and you don’t want to waste any test kits (it is only a couple of days past expiration anyway), you decide to use the test devices until the end of the week.
What Could Be the Consequences of…

- A false positive HIV result?
- A false negative result?
What Is Ethics?

“A set of principles of right conduct”
“Decisions about diagnosis, prognosis and treatment are frequently based on results and interpretations of laboratory tests. Irreversible harm may be caused by erroneous tests.”

International Federation of Clinical Chemistry and Laboratory Medicine (IFCC)
Scenario IV

Rick, the tester, is excited about getting home at the end of his work day, because a relative he hasn’t seen in quite some time is scheduled to arrive. Right before he is ready to leave, he gets distracted by a phone call and forgets to lock up the lab register in the cabinet.
Maintaining Confidentiality

It is important to:

• Keep all client/patient information private
• Secure all records / logbooks
• Restrict access to testing areas

Warning

People often violate ethics not because they mean to, but because they are careless. As a matter of fact, they sometimes act with good intentions.
Role-Play

Watch the role-play and discuss:

- What happened?
- What were the ethical issues involved?
- What were the implications?
- What would you do if you were in this situation?
Who is Responsible for Ethics?

• EVERYONE!
  - Medical Laboratory Technician
  - Nurse Counselor
  - Clerk
  - Secretary
  - General Hand
  - Driver
How Do We Apply Ethics To HIV Rapid Testing?

- Work done
- Behavior of the staff
- Behavior of management
Code of Ethics (IFBLS)

Excerpts from International Federation of Biomedical Laboratory Science (IFBLS)

- Maintain strict confidentiality of patient information and test results
- Safeguard the dignity and privacy of patients
- Be accountable for the quality and integrity of clinical laboratory services
Code of Ethics (ASCP)

Excerpts from American Society for Clinical Pathology (ASCP)

• Treat patients and colleagues with respect, care and thoughtfulness
• Perform duties in an accurate, precise, timely and responsible manner
• Safeguard patient information as confidential, within the limits of the law
• Prudently use laboratory resources
Caribbean Association of Medical Technologists
(CASMET)

CODE OF ETHICS

On entering at this time into the practice of Medical Technology, I accept with full realization of its implication, the responsibility associated with my duties.

I am aware that since the Physician or Surgeon relies upon my work in the diagnosis and treatment of disease, even an apparent trivial error may affect seriously the health or even the life of a Patient. Every procedure, therefore, must be carried out with thoughtfulness and accuracy.

Knowing these things I recognize that my integrity and that of my profession must be pledged to the absolute reliability of my work.

I am aware of the need for co-operation and friendly understanding between my fellow workers and myself and for the patience, humanity and tact which must be exercised toward the patient who by reason of his illness is particularly needful of my skill and kindness.

I realize that the knowledge obtained concerning persons in the course of my work is privileged and confidential and that since the Physician or Surgeon has the ultimate responsibility in diagnosis and treatment, my results may be made known only to him or another having duly constituted authority.

To these principles I hereby subscribe, promising to conduct myself at all times in a manner appropriate to the dignity of my profession.
Features of CASMET Code of Ethics

Testing is

- Thoughtful and accurate
- Reliabile
- Confidential
Summary

• In your own words, what is ethics?
• Why is it important?
• Give examples of actions you can take to maintain client confidentiality.
• Give an example of a code of ethics to which you are willing to personally commit.
Key Messages

- Ethical issues are important. We must constantly remind ourselves of the code of conducts and ensure we do the right thing.

- Ethical issues are often hard to deal with because they create dilemmas.

- People often violate ethics not because they mean to, but because they are careless. As a matter of fact, they sometimes act with good intentions.