HIV Rapid Test Quality Assurance: System Implementation Requirements to Ensure Accurate Testing

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2nd Serial NDOH/PEPFAR Dissemination Workshop - Draft
What we talk about when we talk about QA of HIV RT

• The First 90 and Rapid Test Performance: False positives a problem?

• The Guides: Do’s and Don’ts: Are we aligned to WHO Guidance?

• From Guides to Practice: Implementing the RTQII Plan

• Assessment of Tools: The spider’s web

• Closing the Circle: Not quite but a step in the right direction
HIV Positive

Engage, counsel, monitor, support

HIV Care (Pre-ART)

Retain, counsel, monitor, support

ART

Adherence and viral suppression

UNDETECTABLE

HIV TESTING

- Improved HIV rapid tests (e.g., oral tests)
- Home- and community-based counseling and testing
- HIV testing by community and lay health workers
- Provider-initiated HIV testing and counseling and integration with primary care
- Targeted mobile testing for hard-to-reach groups at schools, taxi ranks, farms, workplaces

PRE-ART REGULAR CLINIC CARE

- Strong referral and linkage to care
- Free HIV care and treatment
- Point-of-care CD4 count testing
- Rapid diagnosis and treatment of TB
- Regular visits, TB and PCP prophylaxis
- Support tools (mobile messages, patient-held appointment cards)

EARLY ART RETENTION IN CARE

- Timely and/or earlier ART initiation
- Adapted adherence support
- Decentralization, primary care integration
- Task-shifting
- Non-toxic robust drugs; once-daily fixed-dose combinations
- Viral load monitoring
- Out-of-clinic care

LONG-TERM ART AND UNDETECTABLE VIRAL LOAD

- Simplified clinical and refill schedules
- Community-based, peer-supported ART
- Viral load–triggered adherence support
- Reliable drug supply, multiple month refills
- Defaulter tracing

IN-COUNTRY TOT

RTQII Training
- Implementing Partners
- Provincial RTC
- District Trainers

PARTICIPANT TRAINING

Training
- District Coordinators
- Sub district Coordinators
- OPM
- Mentors
- Lab Advisors

QA IMPLEMENTATION

PT and IQC
- PT Data Management
- IQC Data Management
- Corrective Actions

SITE VISITS

SPI RT Checklist
- Quarterly
- M and E Checklist
- Biannually
- HTC Register
- QA data Collection
- QA Data Analysis
Stepwise Process for Improving the Quality of HIV Rapid Testing (SPI-RT) Checklist

SPI-RT Checklist

Version 2.0

9/14/2014
Purpose of an assessment

• Provides guidance on quality assurance (QA) practices for sites using HIV Rapid Test to diagnose HIV infection.
• Identify areas where improvement is needed
• Develop and implement a work plan to address gaps
• Implement quality assurance elements
• Monitor quality progress
• Maintain continuous quality improvement
Purpose of the Checklist

The SPI-RT checklist will:

• Provide a solid foundation for ensuring the quality of testing
• Specify detailed requirements to conduct an assessment
• Serve as a tool to evaluate a RT site against the requirement for quality improvement
• Act as guidelines for development of policies and procedures
Methods used to evaluate test site operations

- Review the RT site records
- Observe the RT site operations
- Ask open-ended questions
- Follow client specimen or result through the testing process
<table>
<thead>
<tr>
<th>Section</th>
<th>Section Name</th>
<th>Total Points</th>
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<tbody>
<tr>
<td>Section 1</td>
<td>Personnel Training and Certification</td>
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<tr>
<td>Section 2</td>
<td>Physical Facility</td>
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<td>Section 3</td>
<td>Safety</td>
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<td>Section 4</td>
<td>Pre-Testing Phase</td>
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<td>Post-Testing Phase</td>
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<td>Section 7</td>
<td>Document and Record</td>
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<tr>
<td>Section 8</td>
<td>External Quality assessment</td>
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<td><strong>TOTAL SCORE</strong></td>
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Five pre-certification levels for testing sites

- **Level 4**: >90%
  - Eligible for national site certification
- **Level 3**: 70% - 89%
  - Close to national site certification
- **Level 2**: 60% - 69%
  - Partially ready for national site certification
- **Level 1**: 40% - 59%
  - Needs improvement in specific areas
- **Level 0**: <40%
  - Need improvement in all areas and immediate remediation
## Eastern Cape: Site Data

<table>
<thead>
<tr>
<th>District</th>
<th>Number of sites</th>
<th>SPI RT Level 1</th>
<th>SPI RT Level 2</th>
<th>Average % Score per District</th>
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<tr>
<td>Amatole</td>
<td>13</td>
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<tr>
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<tr>
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<tr>
<td>Chris Hani</td>
<td>13</td>
<td>2</td>
<td>11</td>
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</tr>
<tr>
<td>Joe Gcabi</td>
<td>13</td>
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<td>OR Tambo</td>
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<td><strong>TOTAL</strong></td>
<td><strong>87</strong></td>
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</table>
% Score: Provincial (n= 87)
Common Deficiencies

Training and Certification
- No evidence of training documents on site
- Records of competency not available
- No refresher training available
- No National certification Program in place

Pre-testing
- No SOPs/Job aides in place for tests
- Current national algorithm not used
- Tests kits not labeled

Testing Phase
- Testing procedure not adhered to
- Job aids not available
- Timers available but not working
- QC Logs not reviewed by supervisor

Post-testing phase
- National standardized register not used (PHC Register used)
- No disinfection of testing area

External Quality Assessment
- EQA(PT) not implemented
Multi-Step Approach to QA

1. WHO PRQ/USAID-CDC
   Validated RT kits

2. Evaluation of rapid tests and testing algorithms for in-country use

3. Hands-on training of key trainers and subsequent roll out of training with emphasis on QA

4. Certification of testing personnel and testing sites

5. Implementation of standardized logbook IQC and PT program (QA)

6. Identification and training of local partners to scale up QA program

7. Collection and analysis of data and develop reports with NRL

8. Corrective actions including site visits and limited retesting where needed

9. Annual refresher training of the testing personnel conducted regionally

10. Implementation post-market surveillance
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