HIV RAPID DIAGNOSTIC TESTS: A TECHNICAL UPDATE

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Outline of this Brief

1. Why HIV RDTs are so important
2. HIV RDT technology update
3. Solutions
4. HIV RDT regulatory review
5. RDT quality assurance
6. Conclusions
1. OVERVIEW
WHERE ARE THE NEEDS?
WHAT ARE WE TRYING TO SOLVE WITH LAY PROVIDER AND SELF-TESTING?
Progress toward the first 90, 2015

43% of PLHIV still remain undiagnosed worldwide

Source: UNAIDS, 2016 – based on 2015 measure derived from data reported by 87 countries, which accounted for 73% of people living with HIV worldwide; 2015 measure derived from data reported by 86 countries. Worldwide, 22% of all people on antiretroviral therapy were reported to have received a viral load test during the reporting period.
Progress toward the first 90, 2015: Asia and the Pacific

- PLHIV diagnosed: 64%
- PLHIV on ART: 41%
- PLHIV on ART virally suppressed: 34%

Source: UNAIDS, 2016
WHO HIV Self-testing Guidance

• Outlines models, priorities, policy issues, & technical considerations

• Emphasizes potential for HIVST to reach key populations & high risk groups in all settings & men, young people and health workers in high prevalence settings.

• Encourages countries to conduct pilot programs

• Global WHO HIVST guidance in Dec 2016

• Current info available on HIVST.org
1\textsuperscript{st} generation = 35 days
2\textsuperscript{nd} generation = 28 days
3\textsuperscript{rd} generation = 21 days
4\textsuperscript{th} generation = 14 days

14 day difference between earliest time to detection between a 2\textsuperscript{nd} generation and 4\textsuperscript{th} generation test

Source: Adapted from Branson 2014 and UNITAID HIVST Technology Landscape 2016
What is the difference between Generations?

- 1\textsuperscript{st} generation – antibody detection tests that utilize viral lysate as the HIV-specific antigen and a generic Ig detector.
- 2\textsuperscript{nd} generation – antibody detection tests that utilize recombinant proteins as the HIV-specific antigen and a generic Ig detector.
- 3\textsuperscript{rd} generation – antibody detection tests that utilize synthetic peptides as the HIV-specific antigen to capture antibodies in a sandwich-style assay to allow multiple classes of Ig to be detected.
- 4\textsuperscript{th} generation – antibody (typically 3\textsuperscript{rd} generation format) and antigen (p24) detection combined in the same test.
HIV RDTs can perform well in the hands of self-testers

**Sensitivity** as high as 98.8% (95% CI 96.6 – 99.5%)

**Specificity** as high as 100% (95% CI 99.9 – 100%)

Source: Figueroa et al Poster WEPEC207; WHO forthcoming
Most scenarios have public health benefits even when performance is less than ideal

Example of HIVST among female sex workers in South Africa

National
- Population: 138,000
- Prevalence: 59.8% [Very High]
- Linkage to Health Services/Prevention: 15% [Moderate]
- Linkaged to Care: 50% [Low]
- % of Combination with Net Positive Benefit: 100%

Johannesburg
- Population: 7,697
- Prevalence: 72% [Very High]
- Linkage to Health Services/Prevention: 15% [Moderate]
- Linkaged to Care: 23% [Very Low]
- % of Combination with Net Positive Benefit: 75%
When linkage to care increases to just 50%

All scenarios have net-benefit for female sex workers in Johannesburg

**Johannesburg**
- Population: 7,697
- Prevalence: 72% [Very High]
- Linkage to Prevention: 15% [Middle]
- Linkage to Care: 23% [Very Low]
- % of Combination with Net Positive Benefit: 75%

If Linkage to Care improved to 50% [Low]
- % of Combinations with Net Positive Benefit: 100%

Source: Johnson 2016; WHO forthcoming
Key messages

• We are making progress toward 90-90-90, but we are far from finished
• A test does not have to have >99% sensitivity and >98% specificity to have public health impact
• There is a net benefit of increased HIV testing (using lay and self-testing) among populations that are at high risk, but that won’t test in conventional testing, even if sensitivity and specificity may be lower than in a lab
• The system as a whole has to be considered, not just one component in isolation
• Guidelines are coming, but will need country implementation plans – don’t be left behind!
2. TECHNOLOGY UPDATE

WHAT’S NEW WITH HIV RAPID DIAGNOSTIC TESTS?
## Finger stick tests for professional use in the market

### Assay name (manufacturer) | Sensitivity | Specificity | Approval status
--- | --- | --- | ---
ABON™ HIV 1/2/O Tri-Line Human Immunodeficiency Virus Rapid Test Device (ABON Biopharm (Hangzhou) Co. Ltd, China) | 100% | 99.7% | WHO PQ
Alere Determine HIV-1/2 (Alere Medical Co. Ltd, Japan) | 100% | 99.4% | WHO PQ
Alere HIV Combo (Alere Medical Co. Ltd, Japan) | 100% | 99.72% | CE marked
Anti-HIV 1/2 (Turk Lab, Turkey) | 100% | 10% | CE marked
DIAQUICK HIV 1&2 Ab Cassette (DIALAB GmbH, Austria) | 100% | 100% | CE marked
First Response™ HIV 1-2-0 Card Test (Premier Medical Corporation, Nani Daman, India) | 100% | 98.8% | CE marked
Genie Fast HIV 1/2 (Bio-Rad Laboratories, Marnes La Coquette, France and Steenvoorde, France) | 100% | 99.9% | CE marked
Hexagon HIV (Human Gesellschaft für Biochemica und Diagnostica mbH Germany) | 100% | 99.9% | CE marked
HIV 1/2 STAT-PAK® Dipstick (Chembio Diagnostic Systems Inc., USA) | 100% | 99.7% | WHO PQ
HIV 1/2 STAT-PAK™ (Chembio Diagnostic Systems Inc., USA) | 99.3% | 100% | WHO PQ
ImmunoComb® II HIV 1&2 BiSpot (Orgenics Ltd, Israel) | 100% | 99.4% | WHO PQ

### Assay name (manufacturer) | Sensitivity | Specificity | Approval status
--- | --- | --- | ---
INSTI HIV-1/HIV-2 Antibody Test (BioLytical Laboratories Inc., Canada) | 100% | 99.7% | WHO PQ
Multispot HIV-1/HIV-2 Rapid Test (Bio-Rad Laboratories, Marnes La Coquette, France and Steenvoorde, France) | 100% | 99.3% | FDA/ PMA
Multisure HIV Rapid Test (MP Biomedicals Asia Pacific, Singapore) | 100% | 99.12% | CE marked
ONE STEP Anti-HIV(1&2) Test (InTec PRODUCTS INC., Xiamen, China) | 99.8% | 99.23% | CE marked
Rapid Test for Antibody to Human Immunodeficiency Virus (HIV) (Colloidal Gold Device) (Beijing Wantai Biological Pharmacy Enterprise Co. Ltd, China) | 100% | 98.48% | WHO PQ
SD Bioline HIV Ag/Ab Combo (Standard Diagnostics Inc., Republic of Korea) | 100% | 99.1% | WHO PQ
SD BIOLINE HIV/Syphilis Duo (Standard Diagnostics Inc., Republic of Korea) | 100% | 99.5% | WHO PQ
SD BIOLINE HIV-1/2 3.0 (Standard Diagnostics Inc., Republic of Korea) | 99.8% | 99.9% | WHO PQ
SURE CHECK® HIV 1/2 Assay (Chembio Diagnostic Systems Inc., USA) | 99.8% | 99.9% | WHO PQ
Uni-Gold™ HIV (Trinity Biotech Manufacturing Ltd, Ireland) | 99.8% | 99.9% | WHO PQ
VIKIA HIV 1/2 (bioMérieux SA, France) | 99.4% | 99.9% | WHO PQ

Source: Table 1 UNITAID HIVST Technology Landscape 2016
## Finger stick tests for self-testing in the market

<table>
<thead>
<tr>
<th>Assay name (manufacturer)</th>
<th>Generation</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>Approval status</th>
<th>Approximate price per test (US$)</th>
</tr>
</thead>
<tbody>
<tr>
<td>autotest VIH (AAZ Labs, France)</td>
<td>2nd generation</td>
<td>100%</td>
<td>99.8%</td>
<td>CE marked; submitted WHO PQ</td>
<td>25–28 (to consumer)</td>
</tr>
<tr>
<td>Private sector version BioSURE HIV Self Test (BioSURE, United Kingdom)</td>
<td>2nd generation</td>
<td>99.7%</td>
<td>99.9%</td>
<td>CE marked</td>
<td>42–48 (to consumer)</td>
</tr>
<tr>
<td>Public sector version BioSURE HIV Self Test (BioSURE, United Kingdom)</td>
<td>2nd generation</td>
<td>99.7%</td>
<td>99.9%</td>
<td>CE marked</td>
<td>7.50–15 (to public sector)</td>
</tr>
<tr>
<td>INSTI HIV Self Test (bioLytical Laboratories, Canada)</td>
<td>3rd generation</td>
<td>100%</td>
<td>99.8%</td>
<td>CE marked</td>
<td>36 (to consumer)</td>
</tr>
</tbody>
</table>

Source: Table 3A UNITAID HIVST Technology Landscape 2016
### Finger stick tests for self-testing in the pipeline

<table>
<thead>
<tr>
<th>Assay name (manufacturer)</th>
<th>Generation</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>Approval status</th>
<th>Approximate price per test (US$)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atomo HIV Self-Test</td>
<td>3rd generation</td>
<td>NA</td>
<td>NA</td>
<td>No info</td>
<td>NA</td>
</tr>
<tr>
<td>(Atomo Diagnostics, Australia)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exacto® HIV Screening Test</td>
<td>3rd generation</td>
<td>NA</td>
<td>NA</td>
<td>Submitting dossier for CE mark</td>
<td>NA</td>
</tr>
<tr>
<td>(Biosynex Medtech, France)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HemaDiagnostics Self-Test</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>No info</td>
<td>NA</td>
</tr>
<tr>
<td>(Hema Diagnostics Systems LLC, USA)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>To be named</td>
<td>2nd generation</td>
<td>NA</td>
<td>NA</td>
<td>No info</td>
<td>NA</td>
</tr>
<tr>
<td>(Chembio Diagnostics Systems Inc., USA)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>To be named</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>No info</td>
<td>NA</td>
</tr>
<tr>
<td>(Alere, USA)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>To be named</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>No info</td>
<td>NA</td>
</tr>
<tr>
<td>(Trinity Biotech Manufacturing Ltd, Ireland)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Source: Table 4A UNITAID HIVST Technology Landscape 2016
Finger stick test continuum

Professional Use
- Sure Check
- Insti
- Determine
- Determine Combo
- Uni-Gold
- +17 others

Self-test
- Autotest
- BioSURE
- Insti

Pipeline
- Chembio
- Atomo
- Exacto
- Hema
- Alere
- Trinity

HEALTHY MARKETS
## Oral fluid tests for professional use in the market

<table>
<thead>
<tr>
<th>Assay name (manufacturer)</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>Approval status</th>
</tr>
</thead>
<tbody>
<tr>
<td>DPP® HIV 1/2 Assay*</td>
<td>100%</td>
<td>99.9%</td>
<td>WHO PQ</td>
</tr>
<tr>
<td>(Chembio Diagnostic Systems Inc., USA)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>OraQuick® HIV 1/2 Rapid Antibody Test*</td>
<td>99.1%</td>
<td>99.8%</td>
<td>WHO PQ</td>
</tr>
<tr>
<td>(OraSure Technologies Inc., USA)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Finger stick whole blood is an additional acceptable sample type for professional use.

Source: Table 1 UNITAID HIVST Technology Landscape 2016
Oral fluid tests for self-testing in the market

<table>
<thead>
<tr>
<th>Assay name (manufacturer)</th>
<th>Generation</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>Approval status</th>
<th>Approximate price per test (US$)</th>
</tr>
</thead>
<tbody>
<tr>
<td>OraQuick® In-Home HIV Test (OraSure Technologies Inc., USA)</td>
<td>2nd generation</td>
<td>91.7%</td>
<td>98.7%</td>
<td>FDA</td>
<td>40 (to consumer)</td>
</tr>
<tr>
<td>OraQuick® In-Home HIV Test (OraSure Technologies Inc., USA)</td>
<td>2nd generation</td>
<td>100%</td>
<td>99.8%</td>
<td>Completed CE procedure, pending CE certificate</td>
<td>NA</td>
</tr>
</tbody>
</table>

Source: Table 3B UNITAID HIVST Technology Landscape 2016
## Oral fluid tests for self-testing in the pipeline

<table>
<thead>
<tr>
<th>Assay name (manufacturer)</th>
<th>Generation</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>Approval status</th>
<th>Approximate price per test (US$)</th>
</tr>
</thead>
<tbody>
<tr>
<td>To be named (Sedia Biosciences, USA)</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>No info</td>
<td>NA</td>
</tr>
<tr>
<td>Aware™ HIV-1/2 OMT Oral HIV Self Test (Calypte BiomedicalCorporation, USA)</td>
<td>2nd generation</td>
<td>NA</td>
<td>NA</td>
<td>No info</td>
<td>NA</td>
</tr>
<tr>
<td>HIV Self-Test (OraSure Technologies, Bangkok, Thailand)</td>
<td>2nd generation</td>
<td>NA</td>
<td>NA</td>
<td>No info</td>
<td>Price available upon request</td>
</tr>
</tbody>
</table>

Source: Table 4B UNITAID HIVST Technology Landscape 2016
Oral fluid test continuum

Professional Use
- OraQuick
- DPP

Self-test
- OraQuick

Pipeline
- OraQuick
- Aware
- Calypte
Determine Combo

- 4th generation test
- Uses whole blood (large sample volume)
- 15 minutes
- Requires assay diluent (not currently provided in individual dose)
- Compact size can allow it to be discreet
- Storage up to 30C
- Commercially available for professional use
OraQuick

- 2nd generation test
- Oral fluid – no finger stick required, doesn’t require measuring sample or drops of assay diluent
- One step
- 20 minutes to results
- Assay diluent provided pre-measured in vial
- Bulky
- Currently available for professional use AND self-testing
autotest, BioSURE, SureCheck

- 2nd generation test
- Finger stick whole blood
- Small sample volume
- Premeasured buffer vial...adding test to vial ‘starts’ the test
- 15 minutes to results
- Potentially difficult to interpret test
- Currently available for professional use AND self-testing
Insti

- 3\textsuperscript{rd} generation test
- Finger stick whole blood, large 50uL sample volume
- Bulky
- Multiple steps, multiple pre-measured reagents
- Fast, results in under 2 minutes, no timed steps
- Currently available for professional use
Atomo

- 3rd generation test
- Bulky
- Integrated lancet
- Moving parts increase potential for breaking/malfunctioning
- Designed to help reduce errors with specimen delivery
- Integrated capillary tube to deliver correct sample volume, bubbles in sample collection are not a problem.
- Multiple steps, requires assay diluent (potential to integrate in second generation cassette)
- Limited use/data/commercial availability
- Potentially expensive platform
BIOLINE HIV/Syphilis Duo

- Similar form factor to rapid tests for many other diseases
- Generally cost effective when compared to two individual tests
- Potential to reach additional populations; integrate health services
- Several HIV/Syphilis tests available; other multiplex tests with 2 or more analytes are in development
- Approved for professional use in Vietnam
- Potential for lay applications
Key messages

• Technologies well-suited for lay and self-testing are available
• The tools can be effective in helping link people to treatment and PrEP
• Pipeline technologies should advance in 1-5 years
• Multiplexed technologies have the potential to integrate HIV and other public health programs resulting in benefits to test users
3. SOLUTIONS

APPLYING NOVEL TECHNOLOGIES IN NOVEL WAYS TO ADDRESS NEEDS
The HIV epidemic in Vietnam

- Low prevalence in the general population
- Higher prevalence in key populations

- Epidemic has similar components to North America and Europe
  - High quality self-testing has been implemented

- Resource constraints have similar components to areas of Asia and Africa
  - Affordable and acceptable self-testing has been successfully piloted
Matching the right tests with the intended uses

1. Lay provider testing
2. Self-testing
3. Screening/testing for pre-exposure prophylaxis (PrEP) eligibility
4. Partner notification
5. Recent exposure/incident testing
Lay provider HIV testing

- Testing modality needs to be responsive to client’s needs
- Testing may occur at a facility or in a non-traditional setting, likely with trained users
- Tests should be self-contained, easy to use, discreet, fast
- Client may have a strong preference for or against sample type (finger stick whole blood, oral fluid)
- Important to build a relationship/trust with the client
- Successful programs will see clients return for regular testing
- 2\textsuperscript{nd}, 3\textsuperscript{rd}, and 4\textsuperscript{th} generation tests may all be suitable in this environment
HIV self-testing (HIVST)

- There is a high probability the tester is naïve to using the test
- Needs to be easily available through distribution channels
- Conscious of cost
- Easy to use, intuitive, clear instructions, few steps, easy to interpret
- Must be of good quality, able to withstand environmental conditions at point of distribution and user-controlled storage
- Small, discreet packaging may be important to some users
- Linkage to counseling and care is important
Screening/testing for PrEP eligibility

- Likely to be conducted by a trained provider
- Requires high sensitivity – preferably 4th generation test
- A nucleic acid test is ideal, but no true point-of-care test is currently available
- Eclipse and window periods are a concern; repeat testing algorithm needed
Partner notification

- Referral of partners from confirmed positives
- Regular testing of discordant couples
- 4th generation tests are preferred, but structure of program may allow for 2nd or 3rd generation tests
- Integrate into lay provider or self testing programs
- Provide a pathway to PrEP for those who are eligible
Recent HIV exposure/incident testing

- Typically a very low proportion of test needs
- Rapid tests, even 4\textsuperscript{th} generation, may not be best suited for this
- Referral up the testing chain to a reference laboratory with nucleic acid testing capabilities may be best
- Should consider testing in conjunction with post-exposure prophylaxis
- Lay provider testing
- Self-testing
- Screening/testing for PrEP eligibility
- Partner notification
- Recent exposure/incident testing
• Lay provider testing
• Self-testing
• Screening/testing for PrEP eligibility
• Partner notification
• Recent exposure/incident testing

Finger stick
Venipuncture
Oral fluid
Key messages

- Lay and self-testing can have a net positive public health impact.
- HIV self-testing has been implemented in the US, UK, France, Hong Kong and other countries because it is safe and effective. It is a good public health policy that can reach key populations who are not testing for HIV through regular methods and avert new HIV infections.
- There are a variety of test options that meet intended uses and are effective at helping to achieve 90-90-90 targets.
4. REVIEW OF REGULATORY SITUATIONS FOR HIV SELF-TESTING
Currently 16 countries have policies which are supportive of HIVST

- Australia, Malawi, Rwanda, Spain and the United Republic of Tanzania report that policy is in place, but implementation has not yet begun.
- Brazil plans to introduce a product for HIVST in pharmacies in late 2016.
- South African Pharmaceutical Council lifted the ban on the sale of HIVST in May 2015, but the Ministry of Health has not provided official policy, criteria or standards.

What happens when HIVST is not [properly] regulated?

Implications of the on-line market for regulation and uptake of HIV self-testing in Australia

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School of Public Health, Faculty of Medicine and Biomedical Sciences, The University of Queensland, Herston, Australia

ABSTRACT
Self-Testing for HIV (HIVST) is widely recognised as a feasible and effective means of increasing rates of testing and detection of HIV, particularly in non-testing and infrequent testing populations. Currently in Australia, the only means of accessing this technology is to purchase unregulated products on-line. A search of available on-line distributors was purposefully performed from the perspective of an English-speaking individual, with no clinical background or specific understanding of HIV testing practices, seeking to determine their HIV status. Purchased kits were assessed against a structured extraction tool based on the Australian Therapeutic Goods Administration (TGA) HIV testing clinical performance guidelines. In total, eight HIVST kits were purchased from seven different distributors. Analysis of the purchased kits and linked websites revealed that none met the TGA’s requirements for HIV testing kits intended for home use; none also conformed to the additional recommendations for information, quality and links to services developed from this study’s review of HIVST associated literature. People seeking HIVST kits are able to purchase sub-standard products that ill serve their needs and do so at a time of great personal vulnerability. The fact that Australians are willing to purchase and use these sub-standard products indicates HIVST is in demand. Health policy and models of service are needed in order to ensure people have access to a safe and effective registered device at prices that enable equity of access to all Australians, particularly those most at risk of HIV. Other countries awaiting access to regulated HIVST devices also need to consider the potential implications. Collaboration between manufacturers, distributors, regulatory bodies, service providers and the community is needed globally in order to ensure HIVST is embedded into testing methods in a manner that does not disrupt but rather safely and effectively increases HIV testing rates.
Regulation in the balance

- Under regulation can result in low quality products, eroded public faith in the products and HIV testing/prevention/treatment systems, withdrawal of stakeholders, and risk to key populations and general public.
- Over regulation can result in high cost products, limited products available, prohibitively complex and long approval processes, rationing of products towards select populations, and risk to key populations and general public.
- Effective regulation results in consistent, high quality products that are affordable and accessible to those who can benefit the most.
Stringent regulatory authority (SRA) approval

- US FDA, Japanese MoH, European Union member approval, Canadian regulatory authority
- WHO pre-qualification (not a regulatory authority)
  - Approval generally included document review of design process, technical evaluation/review of the product, review of manufacturing, review of quality management system
  - Demonstrate that the product is as described (does what it is intended to do)
  - Demonstrate that the manufacturer is in control of the product
  - Regular audit/review schedule
Taking advantage of products with SRA

- Some countries take the position that allow products approved by a SRA or WHO PQ to complete an abbreviated registration process.
- This is appropriate if the product being registered is identical to that approved by the SRA or WHO PQ.
- Abbreviated review may still include a local product evaluation, requirements for notification of changes, and annual review requirements.
- Such a process can be efficient for the country and have a positive public health impact as it allows products to get to the public faster.
Product evaluations must be relevant

- Samples must be:
  - Representative of the population(s) of interest
  - Compatible with the test and product claims
  - Well pedigreed including gold standard
  - Of a statistically valid size
- Performance criteria must be linked to meaningful impact and set *a priori*
Key messages

- Regulating *in vitro* diagnostic tests is the responsibility of the government to assure products are safe and effective.
- In increasingly global environments, benefits and efficiencies can be gained from looking to peer regulators, such as SRAs and WHO PQ.
- Product evaluations must be carefully designed in a manner that can definitively answer if the test is safe and effective.
  - The right samples with the highest curation are important.
5. QUALITY ASSURANCE

QA IN VIETNAM: FOCUSING ON COMMUNITY-LEVEL TESTING
Examples of QA programs
HIVST QA in Vietnam

- It is perceived to add value to the CBOs – even if it means more work
- Implement soon – before ‘word of mouth’ advertising
  - (Positive and negative aspects)
- Consistent with current QA activities
  - WHO/CDC guidelines
  - Vietnam practice
- QA for CBOs needs to be easy, low cost, approachable, encourage continuous learning, provide value
- QA activities at the government level can have value
QA program details

- Training
- Regular re-training (certification by government)
- Continuing education
- CBO or site certification
- Quality assessment of RDTs: NICVB and local
- Feedback from confirmation testing
- Comment/Complaint/Problem reporting
- Access to technical assistance
- Post-marketing surveillance
Key messages

• QA is important in maintaining program quality
• QA provides value to CBOs and clients
• Systems that mirror existing QA activities for facility-based testing can be effective, but they need to be appropriate for the implementers
• Post-marketing surveillance of tests for lay and self-testing are important for assuring high quality products are available to test users
6. CONCLUSIONS
Early evidence from VAAC/Healthy Markets pilot

- Currently only ~30% of key populations test annually in conventional HIV testing sites.
- Current facility based testing yields a positivity rate of ~1%.
- Initial data indicate ~8% positivity in urban key populations and ~3% in rural populations. This is an important increase of yield.
- The majority (65%) of HIV lay testers had never tested before.
- Initial data from lay and self-testing indicate ~97% positives enroll in treatment.
Conclusions

• **Not enough.** Current HIV testing service approaches are not adequate to reach 90-90-90.
• **Catch up.** Public health response lags behind public demand.
• **It works.** Lay and self-testing are tools that have been shown to work to get people to know their status, identifying people living with HIV, and enrolling them to treatment.
• **How to do it.** WHO Guidance on HIVST is coming, but country and regional-level policy development and regulations are needed.
• **Get going.** Use what we have today and urgently work toward the infrastructure and product availability to implement programs for those who can benefit most.
Conclusions

- **Impact.** Lay and self testing increase the yield of identifying positives and enrolling them in treatment.
- **Appropriate regulation.** Safety and efficacy of the tests is critical. Too much or too little regulation can put populations at risk.
- **Support.** Organizations implementing lay and self-testing services need to be supported to have successful, sustainable programs.
- **Empower.** Individuals seeking to know their HIV status can take charge of their health and behavior by accessing services not previously approachable.
Discussion

• What other use cases of public health importance can be reasonably expected?
• In the evolving epidemic, which tests are important for PrEP initiation?
• How can multiplex diagnostic technologies integrate other public health priorities?
• What other technologies are needed to help end the epidemic?