New Generation of Nucleic Acid Testing

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Disclaimer: The findings and conclusions in this presentation are those of the author and do not necessarily represent the views of the Centers for Disease Control and Prevention

Disclosure: No relevant financial relationships
Persons Living with Diagnosed or Undiagnosed HIV Infection
HIV Care Continuum Outcomes, 2009, 2010 and 2011
United States and Puerto Rico

National HIV Surveillance System: Estimated number of persons aged ≥13 years living with diagnosed or undiagnosed HIV infection (prevalence) in the United States at the end of the specified year. The estimated number of persons with diagnosed HIV infection was calculated as part of the overall prevalence estimate.

Medical Monitoring Project: Estimated number of persons aged ≥18 years who received HIV medical care during January to April of the specified year, were prescribed ART, or whose most recent VL in the previous year was undetectable or <200 copies/mL—United States and Puerto Rico.
Figure 1. Percentage of HIV-Infected People at Each Stage of the HIV Care Continuum, United States and Puerto Rico, 2012.

National HIV Surveillance System data were used to estimate the number of people 13 years of age or older who were living with diagnosed or undiagnosed HIV infection (prevalence) in the United States at the end of 2012. Data from the Medical Monitoring Project were used to estimate the number of people 18 years of age or older who received medical care for HIV infection between January and April 2012, the number who received prescriptions for antiretroviral treatment (ART), and the number whose most recent viral load in the previous year was undetectable or less than 200 copies per milliliter.
Original Investigation

Human Immunodeficiency Virus Transmission at Each Step of the Care Continuum in the United States

Jacek Skarbinski, MD; Eli Rosenberg, PhD; Gabriela Paz-Bailey, MD, MSc, PhD; H. Irene Hall, PhD; Charles E. Rose, PhD; Abigail H. Viall, MA; Jennifer L. Fagan, MA; Amy Lansky, PhD; Jonathan H. Mermin, MD, MPH
Early Diagnosis Benefits

- **Public Health- Decrease Transmission**
  - **Behavioral**
    - Transmission rate ~3.5 times higher in the unaware group compared to the people aware of status\(^1\)
    - Persons with acute HIV named 2.5 times as many partners and twice as many partners with undiagnosed HIV, compared with people with longstanding infection\(^2\)
    - Modeling data from US MSM suggests epidemic would be larger without behavior change\(^3\)
  - **Biologic- Greater infectiousness?**
    - Higher rates of transmission (10-26X) from individuals in acute/early stages of infection\(^4,5\)
    - SIV: plasma from acute infection 750 times more infectious per virion than plasma from chronic infection\(^6\)
    - Treatment as prevention works!\(^7\)

Early Diagnosis Benefits

- **Individual Benefit**
  - Multiple studies with indirect or antidotal evidence
  - Strategic Timing of Anti-Retroviral Treatment (START) study
    - First large-scale randomized clinical trial to establish that earlier antiretroviral treatment benefits all HIV-infected individuals
      - “The DSMB’s interim analysis found risk of developing serious illness or death was reduced by 53 percent among those in the early treatment group, compared to those in the deferred group”
HIV-2 Infection

- Remains uncommon in U.S., but
  - Does not respond to NNRTIs, some PIs (first line therapy)
  - Undetectable by HIV-1 viral load tests

- Misclassification by HIV-1 Western blot:
  - 54/58 (93%) HIV-2 patients tested had positive HIV-1 WB (NYC)*
  - 97/163 (60%) HIV-2 cases reported had positive HIV -1 WB (CDC)**

- HIV-2 often diagnosed after immunologic deterioration in patient with negative viral load

* Torian et al, Clinical Infectious Disease 2010
** MMWR July 2011
Objectives of Recommended Lab Algorithm

- Improve diagnosis of acute/early HIV infection
- Accurate diagnosis of HIV-2
- Decrease turn-around time for results
- No substantial change in cost for testing
HIV-1/2 antigen/antibody combination immunoassay

(+) indicates reactive test results
(-) indicates negative test results
NAT: nucleic acid test

HIV-1/2 antibody differentiation immunoassay

HIV-1 (+) HIV-2 (-)
HIV-1 antibodies detected

HIV-1 (-) HIV-2 (+)
HIV-2 antibodies detected

HIV-1 (+) HIV-2 (+)
HIV antibodies detected

HIV-1 (-) or Indeterminate
HIV-2 (-)

NAT (+)
Acute HIV-1 Infection

NAT (-)
Negative for HIV-1

NAT (+)
Negative for HIV-1 and HIV-2 antibodies and p24 antigen

Acute HIV-1 Infection

http://www.cdc.gov/hiv/testing/lab/guidelines/
Performance of the new HIV-1/2 Diagnostic Algorithm in Florida's public health testing population: A review of the first five months of utilization

Bennett et al J Clin Virol 2013
Evolution Continues

1st generation Indirect IA

- Labeled anti-human IgG
- anti-HIV IgG
- HIV particle proteins

2nd generation Indirect IA

- Labeled anti-human IgG
- anti-HIV IgG
- HIV synthetic or recombinant proteins

3rd generation Direct IA

- anti-HIV IgG
- anti-HIV IgM
- HIV synthetic or recombinant proteins

4th generation Antigen/Antibody

- anti-HIV IgG
- anti-HIV IgM
- labeled p24 monoclonal
- HIV synthetic or recombinant proteins
Alere Determine™ HIV-1/2 Ag/Ab Combo

Method: Lateral flow
Time to Results: 20 minutes
Storage Conditions: 2 - 30°C
Shelf Life: 9 months
Sample Type: Serum/plasma/whole blood
Distinguishes Ag/Ab reactivity

We do not know performance characteristics in the lab algorithm
Data collection is underway

CLIA waived for whole blood
Data from plasma suggests the assay detects infection ~ 3-5 days after instrumented Ag/Ab combo assays and possibly longer delays with whole blood  Masciotra et al JCV 2013
BioPlex® 2200 HIV Ag-Ab

Automated, random access, multiplex testing
Screens and differentiates antibodies to HIV-1 and HIV-2, and HIV-1 p24 antigen
Serum/plasma
Results out in ~ 1 hour
Sequence of HIV Assay Reactivity During Early HIV Infection relative to Western Blot*

*Assay sensitivity above is based on frozen plasma only. Whole-blood and oral fluid has not been characterized for early infection.

**Current data suggests that the Gen-Probe Aptima can detect HIV-1 RNA ~9-11 days after infection.

HIV Infection and Laboratory Markers

Eclipse Period
Infection undetectable
Very hard to calculate!

Acute HIV Infection

HIV RNA (plasma)
HIV p24 Ag
IgM
IgG

On the Horizon

• Rapid or simplified NAT for diagnosis and monitoring
Multiple assays on the same patient sample
Random access
Continuous sample/reagent loading
Quant and Qual tests
Sensitivity and Specificity?
Linear range for Quant?

*** HIV assays for Panther in development
**Alere™ Q System**

**Alere™ q HIV-1/2 Detect**

Sample: 25 μL fingerstick whole blood
Sealed system
PCR
Results in 50 minutes
Data Matrix: Expiry QC, assay type, lot Information

Kit shipped and stored at room temperature

**Alere™ q Analyzer**

Built in battery
Simple procedure with built in controls
Touch screen
Data storage of 1000 tests
Easily transportable, 17.2 lbs.
Specificity 100% (lower bound of 95% confidence interval [CI], 99.5%) and Sensitivity 96.8% (95% CI, 93.2%-98.8%)
Initial error rate of 6 %

<table>
<thead>
<tr>
<th>Alere q POC PCR (first test)</th>
<th>Positive</th>
<th>Negative</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>185</td>
<td>0</td>
<td>185</td>
</tr>
<tr>
<td>Negative</td>
<td>6</td>
<td>814</td>
<td>820</td>
</tr>
<tr>
<td>Error</td>
<td>11</td>
<td>49</td>
<td>60</td>
</tr>
<tr>
<td>Total</td>
<td>202</td>
<td>863</td>
<td>1065</td>
</tr>
</tbody>
</table>
Cepheid GeneXpert® System

Multiplex Real-Time PCR - Viral Load
Plasma 1ml ~ 2 hour run-time
Qualitative Dx test
Whole blood 100 uls?
AC power with potential for battery

GeneXpert Omni
Battery-operated
2.2 lbs
Wireless and web-enabled
Coming 2016?
Evaluation of the Xpert® HIV-1 Qual Assay

JA Jordan¹, S Carmona², A Tiam³, J Safrit⁷
GWU SPH, Washington, DC, ²NHLS, Johannesburg, S. Africa, ³NHLS, Lesotho, ⁷EGPAP, Lesotho

**Xpert® HIV-1 Qualitative Evaluation:**

<table>
<thead>
<tr>
<th>Category</th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;6 weeks - 18 months</td>
<td>250</td>
<td>62.2</td>
</tr>
<tr>
<td>&gt;18 months - 7 years</td>
<td>29</td>
<td>7.0</td>
</tr>
<tr>
<td>&gt;7 years</td>
<td>128</td>
<td>30.8</td>
</tr>
<tr>
<td>Total</td>
<td>415</td>
<td>100</td>
</tr>
</tbody>
</table>

**Demographics:**
- 415 eligible subjects;
- 223 (53.6%) females, 186 (44.8%) males;
- 505 specimens tested: 106 WB + 399 DBS

**Whole Blood Workflow:**
1. Collect 2100 µL whole blood and transfer to EDTA microtainer tube or lavender tube
2. Use the 1mL pipette to transfer 0.75 mL sample reagent into the cartridge
3. Use the transfer pipette to transfer 100 µL whole blood into the cartridge
4. Scan cartridge barcode
5. Load into GX and close door

**DBS Workflow:**
1. Collect DBS with 60-70 µL whole blood per spot
2. Transfer one DBS into the sample reagent bottle and mix. Incubate in Thermomixer at 56°C, 500 rpm for 15 min
3. Transfer all liquid into chamber 3 with the 1mL transfer pipette
4. Scan cartridge barcode
5. Load into GX and close door

**Results:**

<table>
<thead>
<tr>
<th>Whole Blood</th>
<th>Roche HIV-1 Qual - DBS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>POS</td>
</tr>
<tr>
<td>Xpert HIV-1 Qual - WB</td>
<td>54</td>
</tr>
<tr>
<td></td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>55</td>
</tr>
</tbody>
</table>

**WB Concordance:** 104/106 (98.1%)
- PPA: 98.2% (95% CI: 90.3-100.0)
- NPA: 98.0% (95% CI: 89.6-100.0)

**Specificity in HIV-1 sero-negative adult blood donors:**
- 100% specificity; 1104/1104 were HIV-1 negative, 95% CI: 99.6-100.0
- 512 WB and 502 DBS specimens were analyzed

**SUMMARY:**
- Excellent agreement between the Xpert® and Roche HIV-1 Qual assays

Xpert® HIV-1 Qual is applicable for near patient testing with results available in under 2 hours, with the potential for immediate confirmatory testing for:
- Early infant diagnosis
- Screening of high-risk sero-negative adults

*CE-IVD mark for in vitro diagnostic use. *Not available in the U.S.

Acknowledgement: Cepheid Inc. supported the HIV-1 Qual Study
Evaluation of the Xpert® HIV-1 Viral Load Assay

JA Jordan¹, AHB Wu², K Templeton³, JC Plantier⁴
¹GWU SPH, Washington, DC, ²UCSF, San Francisco, CA, ³NHS Lothian, Edinburgh, UK, ⁴Rouen University Hospital, Rouen Cedex, France

Xpert® HIV-1 Viral Load Evaluation:

**Unique features of this assay:**
- Single target – 3' end of the 5' LTR
- Accepts fresh and frozen plasma
- Uses both a low & high IQC, traceable to WHO international standard

**Demographics:**
- 724 eligible subjects
  - 205 (28.3%) females & 519 (71.7%) males
  - Average age 44.5 ± 11.3 years (range 18-83 yr)

**Inclusion Criteria:**
- Clinician ordered HIV-1 Viral Load (VL)
- ≥18 years of age
- Known ART status
- Plasma same freeze/thaw cycle

**Exclusion Criteria:**
- Previously enrolled in study
- Specimen not properly collected

**Results:**

**Assay Performance:**
Overall rate of assay success was 96.9%
Linear range: 40–10⁷ copies/mL (cp/mL)
Validated across Group M subtypes, Groups N & O

**Specificity in HIV-1 sero-negative blood band donors:**
- 100% specificity;
- 109/109 were HIV-1 negative,
- 95% CI: 96.7-100.0

**Results: All Eligible Specimens by Result Classification**

<table>
<thead>
<tr>
<th></th>
<th>Abbott RealTime-HIV-1 Assay</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV Detected ≥40 cp/mL</td>
<td>HIV Detected &lt;40 cp/mL</td>
</tr>
<tr>
<td>HIV Detected ≥40 cp/mL</td>
<td>390</td>
</tr>
<tr>
<td>HIV Detected &lt;40 cp/mL</td>
<td>87</td>
</tr>
<tr>
<td>HIV Not Detected</td>
<td>17</td>
</tr>
<tr>
<td>Total</td>
<td>494</td>
</tr>
</tbody>
</table>

Concordance=74.9%

**Specimens with HIV-1 VL Results for Either Assay Not Quantified by the Other:**

<table>
<thead>
<tr>
<th>No. Specimens</th>
<th>Xpert (cp/mL)</th>
<th>Abbott (cp/mL)</th>
<th>Values (cp/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>Not Detected</td>
<td>&gt;40</td>
<td>Abbott: 43, 44, 44, 81</td>
</tr>
<tr>
<td>2</td>
<td>&gt;40</td>
<td>Detected &lt;40</td>
<td>Xpert: 40, 43</td>
</tr>
<tr>
<td>1</td>
<td>&gt;40</td>
<td>Not Detected</td>
<td>Xpert: 51</td>
</tr>
<tr>
<td>24</td>
<td>Detected &lt;40</td>
<td>&gt;40</td>
<td>Abbott: 40-167 (median 64)</td>
</tr>
</tbody>
</table>

**Regression Analysis**

R²=0.9696, *Type unknown: US & European specimens thought to be B subtype

**Consecutive Specimens Collected Without Bias by Result Classification**

<table>
<thead>
<tr>
<th></th>
<th>Abbott RealTime-HIV-1 Assay</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV Detected ≥40 cp/mL</td>
<td>HIV Detected &lt;40 cp/mL</td>
</tr>
<tr>
<td>HIV Detected ≥40 cp/mL</td>
<td>97</td>
</tr>
<tr>
<td>HIV Detected &lt;40 cp/mL</td>
<td>24</td>
</tr>
<tr>
<td>HIV Not Detected</td>
<td>4</td>
</tr>
<tr>
<td>Total</td>
<td>125</td>
</tr>
</tbody>
</table>

Concordance=70.9%

**SUMMARY:**
Good overall agreement between Xpert® HIV-1 VL and Abbott RealTime HIV-1 Assays
- Slightly lower quantification with Xpert® at low end
- Slightly higher overall detection rate with Xpert®
- Xpert® allows flexibility for testing both frozen & fresh plasma specimens
- Xpert® allows for HIV-1 VL testing nearer the patient reducing TAT and loss to follow up

*CE-IVD mark for in vitro diagnostic use. *For Investigational Use Only in the U.S.

Acknowledgement: Cepheid Inc. supported HIV-1 VL Study
Isothermal amplification
Visual Read
Qualitative test for Dx
Semi-Quant for monitoring

SAMBA HIV Semiquantitative Test, a New Point-of-Care Viral-Load-Monitoring Assay for Resource-Limited Settings

Allyson V. Ritchie, Ines Ushiro-Lumb, Daniel Edemaga, Hrishikesh A. Joshi, Annemiek De Ruiter, Elisabeth Szumilin, Isabelle Jendrulak, Megan McGuire, Neha Goel, Pia I. Sharma, Jean-Pierre Allain, Helen H. Lee

Diagnostic Development Unit, Department of Haematology, University of Cambridge, Cambridge, United Kingdom; Barts and The London NHS Trust, London, United Kingdom; Médecins Sans Frontières, Paris, France; Department of Genitourinary Medicine and HIV, Guy’s and St Thomas’ NHS Foundation Trust, London, United Kingdom; Division of Transfusion Medicine, Department of Haematology, University of Cambridge, Cambridge, United Kingdom

<table>
<thead>
<tr>
<th>Sample source and SAMBA Semi-Q result (copies/ml)</th>
<th>No. with result with Roche TaqMan v2 (copies/ml)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>&lt;1,000</td>
</tr>
<tr>
<td>London</td>
<td></td>
</tr>
<tr>
<td>&lt;1,000</td>
<td>95</td>
</tr>
<tr>
<td>&gt;1,000</td>
<td>2</td>
</tr>
<tr>
<td>Malawi</td>
<td></td>
</tr>
<tr>
<td>&lt;1,000</td>
<td>146</td>
</tr>
<tr>
<td>&gt;1,000</td>
<td>4</td>
</tr>
<tr>
<td>Uganda</td>
<td></td>
</tr>
<tr>
<td>&lt;1,000</td>
<td>91</td>
</tr>
<tr>
<td>&gt;1,000</td>
<td>3</td>
</tr>
</tbody>
</table>

* Concordance between the two tests was 96.9% (473/488) overall, 97.8% (131/134) in London, 98.0% (196/200) in Malawi, and 94.8% (146/154) in Uganda.
Liat™ Analyzer Roche

Multiplex Real-Time PCR- Viral Load
30 min (500-1000cp/ml), 60 min (50 cp/ml)
Whole blood, plasma
Qualitative Dx
Whole Blood or plasma
AC power and battery
Integrated disposable cartridge contains all reagents for prep, amp & detection
Laboratory Evaluation of the Liat HIV Quant (IQuum) Whole-Blood and Plasma HIV-1 Viral Load Assays for Point-of-Care Testing in South Africa

Lesley Scott, Natasha Gous, Sergio Carmona, Wendy Stevens

Department of Haematology and Molecular Medicine, School of Pathology, Faculty of Health Science, University of Witwatersrand, Johannesburg, South Africa; National Health Laboratory Services, National Priority Program, Johannesburg, South Africa

TABLE 1 Evaluation matrix of the specimen numbers, specimen type, and comparator VL tests performed

<table>
<thead>
<tr>
<th>Purpose</th>
<th>Material</th>
<th>No. and type of specimens</th>
<th>Comparator assay</th>
</tr>
</thead>
<tbody>
<tr>
<td>Platform verification</td>
<td>Assessment-quality frozen plasma</td>
<td>10 HIV−, 25 HIV+</td>
<td>Roche CAP/CTMv2; Abbott RealTime HIV-1</td>
</tr>
<tr>
<td>Precision (intra- and intervariability)</td>
<td>4 ml whole blood (and plasma)</td>
<td>3 patient specimens (3, 4, and 5 log copies/ml) repeated 6 times; all tested on 3 instruments</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Linearity and variability of LDL</td>
<td>Clinical specimen plasma diluted into HIV-negative plasma</td>
<td>3 patient specimens (&gt;5.0 log) serially diluted 1:10 down to 3.0 log copies/ml and then diluted 1:2 to 2.0 log copies/ml (repeated 9 times); all tested on 3 Liat HIV Quant assay instruments</td>
<td>Roche CAP/CTMv2</td>
</tr>
<tr>
<td>Accuracy and misclassification</td>
<td>HIV+ clinical specimens</td>
<td>157 clinical specimens tested on the CAP/CTMv2 and Liat HIV Quant assay plasma assays; 94 (of 157) tested by Liat HIV Quant assay whole blood and 63 (of 157) tested by RealTime HIV-1</td>
<td>Roche CAP/CTMv2</td>
</tr>
</tbody>
</table>

*Ten of 17 HIV-negative panel members were tested, and all (n = 25) of the quantifiable panel members were tested on a Liat analyzer due to limited numbers of cartridges being available at the time of study.
No virological failure (downward misclassification) was missed.

Whole-blood assay has more variability than plasma.

Good reproducibility between and within repeat specimen testing for both whole blood and plasma.

Good linearity between 2.0 log copies/ml and 5.0 log copies/ml.

Increased variability in the viral load range of 2.0 log to 3.0 log copies/ml.

**TABLE 2** Liat HIV Quant plasma and whole-blood assay detection of HIV compared to detection by Roche CAP/CTMv2 on HIV-positive clinical specimens

<table>
<thead>
<tr>
<th>Category of plasma VL (n = 94)</th>
<th>Liat HIV Quant plasma assay</th>
<th>Liat HIV Quant whole-blood assay</th>
</tr>
</thead>
<tbody>
<tr>
<td>TND (log copies/ml)</td>
<td>TND</td>
<td>2.77</td>
</tr>
<tr>
<td>TND</td>
<td>TND</td>
<td>4.10</td>
</tr>
<tr>
<td>LDL (&lt;1.60) (log copies/ml)</td>
<td>TND</td>
<td>4.83</td>
</tr>
<tr>
<td>1.30</td>
<td>TND</td>
<td>3.29</td>
</tr>
<tr>
<td>1.30</td>
<td>TND</td>
<td>3.70</td>
</tr>
<tr>
<td>1.38</td>
<td>TND</td>
<td>4.08</td>
</tr>
<tr>
<td>1.60</td>
<td>2.61</td>
<td>3.38</td>
</tr>
<tr>
<td>1.60</td>
<td>2.37</td>
<td>3.46</td>
</tr>
<tr>
<td>2.0–2.99 log (log copies/ml)</td>
<td>2.17</td>
<td>4.83</td>
</tr>
<tr>
<td>2.19</td>
<td>TND</td>
<td>3.29</td>
</tr>
<tr>
<td>2.30</td>
<td>TND</td>
<td>3.70</td>
</tr>
<tr>
<td>2.48</td>
<td>2.41</td>
<td>4.08</td>
</tr>
<tr>
<td>2.92</td>
<td>2.92</td>
<td>3.38</td>
</tr>
<tr>
<td>2.99</td>
<td>3.01</td>
<td>4.13</td>
</tr>
<tr>
<td>3.0–6.99 log (n)</td>
<td>79</td>
<td>79</td>
</tr>
<tr>
<td>Overall misclassification (%)</td>
<td>5.3 (5/94)</td>
<td>15.9 (15/94)</td>
</tr>
<tr>
<td>Misclassification resulting in a change in patient management (%)</td>
<td>0</td>
<td>10.6 (10/94)</td>
</tr>
</tbody>
</table>

* Underlined results indicate clinical relevance for ART monitoring (>1.0 log copies/ml difference at values of >1,000 copies/ml) compared to the reported comparator results (≤1,000 copies/ml).
The Future of Testing

• Determine and Bio-Plex
  – Individual results for antigen and antibody
    • How does the Determine Rapid perform in the algorithm?
    • Should we modify the second step to reflex to NAT if antigen positive?

• Bio-Plex
  – Differentiation of HIV-1 and HIV-2 antibodies at screen
    • Maintain differentiation assay as second test?

• Geenius
  – Additional antibody interpretations, Untypable, HIV-2 Indeterminate
    • Additional need for NAT?

• Rapid NATs
  – Will they make screening for acute more cost effective and faster?
  – Commercial HIV-2 NAT?
  – Potential for Rapid/Rapid testing with high sensitivity during early infection?

• Studies ongoing stay tuned. 😊
HIV-1/2 antigen/antibody combination immunoassay

(+) HIV-1Ab HIV-2 Ab HIV Ab HIV- p24

HIV-1/2 antibody differentiation immunoassay

HIV-1 (+) HIV-2 (-) HIV-1 antibodies detected

HIV-1 (-) HIV-2 (+) HIV-2 antibodies detected

HIV-1 (+) HIV-2 (+) untypeable

HIV-1 (-) HIV-2 (-) indeterminate

NAT

NAT (+) Acute HIV-1 Infection

NAT (-) Negative for HIV-1

NAT (-) Negative for HIV-2
Conclusions

• New HIV Lab Algorithm officially recommended June 2014
• Data indicate HIV Lab algorithm can meet desired objectives
  • Identify infection earlier
  • More accurate diagnosis of HIV-2
  • Decrease Turn-around-time
  • No significant increase in cost

• Dx tests continue to evolve
  • Tests with greater differentiation capability (Bio-Plex, Geenius, Determine)
  • Rapid NATs?

• Modifications to HIV lab algorithm will happen once data are collected on new technology
No Test Is Perfect!

- Important that individuals being tested understand the limitations of the test used and the interpretation of their results
  - Message from the tester
  - Subject Information leaflet
http://www.cdc.gov/hiv/testing/lab/guidelines/

http://www.aphl.org/AboutAPHL/publications/Documents/ID_HIV-1-1-WesternBlotBrief_62015.pdf

Questions?

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The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.