HIV Testing
Evolution Continues

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Centers for Disease Control and Prevention

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

HIV Infection and Laboratory Markers

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 ~5-28 days after infection.
Objectives of Recommended Lab Algorithm

- Improve diagnosis of acute/early HIV infection
  - Public Health - Decrease Transmission
  - Individual Benefit - Decreased risk of Morbidity and Mortality with early treatment

- Accurate diagnosis of HIV-2
  - Does not respond to NNRTIs, some PIs (first line therapy)

- Decrease turn-around time for results

- No substantial change in cost for testing

HIV-1/2 antigen/antibody combination immunoassay

HIV-1/HIV-2 antibody differentiation immunoassay

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

http://www.cdc.gov/hiv/testing/lab/guidelines/
DATA AND TECHNOLOGY SINCE THE CURRENT ALGORITHM WAS RELEASED

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_
Bio-Rad Geenius™

Supplemental assay - Confirmation and differentiation of HIV-1 and HIV-2 antibodies in initially repeatedly reactive specimens

HIV confirmation and differentiation in less than 30 minutes
3 sample types: serum, plasma (5ul), whole blood (15 ul)
Software that uses a validated algorithm
Full traceability
Limited data on performance in the lab algorithm suggests comparable to Multispot
Delaney et al CROI 2015 abstract #621

ADVIA Centaur® HIV Ag/Ab Combo

Automated random access,
Detection of HIV p24 antigen and antibodies to HIV-1 (M+0) and HIV-2
Serum and plasma
Time to results ~ 1 hour
Platform useful for testing for multiple diseases
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

Random Access NAT
Hologic Panther System

Aptima HIV-1 Quant Assay*

Multiple assays on the same patient sample
Random access
Continuous sample/reagent loading

*“This assay is not intended to be used as a donor screening test for HIV-1 or as a diagnostic test to confirm the presence of HIV-1 infection.”
Coming Attractions

THE FOLLOWING PREVIEW HAS BEEN APPROVED FOR
RESTRICTED AUDIENCES ONLY
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The film advertised has been rated

Cepheid GeneXpert® System

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

Coming ?
**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

**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.
Future of the HIV Lab Algorithm

- **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. 😊**

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**HIV-1/2 antigen/antibody combination immunoassay**

- **Bio-Plex**
  - Determine

  - HIV-1Ab
  - HIV-2Ab
  - HIV Ab
  - HIV p24

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

- **Geenius**

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

- **New NATs?**

  - NAT (+)
  - Acute HIV-1 Infection
  - NAT (-)
  - Negative for HIV-1
  - Negative for HIV-2
Considerations for HIV POC Testing

- Locations/populations that lab testing is difficult or not feasible
  - Better to use POC than no test
- POC assays continue to improve and have good sensitivity and specificity for established infections but...
  - Be aware of assay limitations
    - Provide informed counseling messages
  - Oral Fluid assays will miss acute infections and some early infections \(^1,^2\)

\(^1\) Stekler et al, JCV 2013, \(^2\) Luo et al JCV 2013

Follow-up for Reactive Rapid Tests

- Current CDC Recommendation:
  - Lab testing algorithm beginning with a combination antigen/antibody IA should be used for specimens from persons with a preliminary positive rapid HIV test result
New Data For Time to Test Reactivity

- Desire to have time since infection/RNA reactive
  - Used same serconversion panel data and performed new estimates for time since RNA reactivity
    - Inter-test reactivity interval (ITRI)
  - Eclipse period simulated from published data
  - Why?
    - Valuable to testing providers for interpreting negative HIV test results
    - Counseling individuals on when to retest after an exposure.

Delaney et al. CID, 2016
http://cid.oxfordjournals.org/content/early/2016/11/03/cid.ciw666.full.pdf?keytype=ref&ijkey=P9Yzswu8ePE5WwP

HIV Infection and Laboratory Markers

Eclipse Period
Infection undetectable

HIV RNA (plasma)
HIV p24 Ag
IgM
IgG
Acute HIV Infection

Simulated Eclipse Period Probability Density Function

Delaney et al. CID, 2016

Test Window Periods

<table>
<thead>
<tr>
<th>Category (No. of Inclusive Tests)</th>
<th>Median (Interquartile Range; Days)</th>
<th>99th Percentile (Days)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antibody/antigen laboratory (4)</td>
<td>17.8 (13.0, 23.6)</td>
<td>44.3</td>
</tr>
<tr>
<td>IgG/IgM-sensitive laboratory (3)</td>
<td>23.1 (18.4, 28.8)</td>
<td>49.5</td>
</tr>
<tr>
<td>IgG-sensitive rapid screening (6)</td>
<td>31.1 (26.2, 37.0)</td>
<td>56.7</td>
</tr>
<tr>
<td>IgG-sensitive supplemental (2)</td>
<td>33.4 (28.5, 39.2)</td>
<td>58.2</td>
</tr>
<tr>
<td>Western blot (viral lysate) (1)</td>
<td>36.5 (31.0, 43.2)</td>
<td>64.8</td>
</tr>
</tbody>
</table>

Delaney et al. CID, 2016
Conclusions

• Current HIV Lab Algorithm officially recommended June 2014
• Data indicate HIV Lab algorithm met 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
• New data on Inter-test reactivity interval (ITRI) should improve interpretation of negative test results and counseling for retesting

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
HIV testing: Clinical Experience

Yun F (Wayne) Wang, MD, PhD.
Associate Professor, Pathology & Laboratory Medicine
Emory University School of Medicine
Director of Microbiology, Immunology & Molecular Diagnostics
Grady Health System
How many HIV tests?

**HIV Testing (old way)**

- **EIA**
- **WB**
- **PCR**
- **Rapid**
Rapid HIV diagnosis in the hospital emergency department and primary care clinic settings: successful experience and challenges

- Blood samples were collected during the course of clinical care and sent to the Grady clinical laboratory. Blood samples were processed on the track system.
- HIV 3rd generation EIA for HIV-1/2 antibody detection was performed using Ortho system. HIV 4th generation for HIV antigen and antibody detection was performed using Abbott Architect system.
- Rapid testing and reporting of HIV for the FOCUS program have been managed by using the updated HIV testing algorithm.
- The FOCUS team used laboratory results populated in the EMR to identify patients with HIV and link them to HIV-related medical care and support services.

YF Wang, B Shah, H. Freiman. 2016 HIV Diagnostics Conference

**Unique patients tested from July 9, 2013 – November 30, 2015**

<table>
<thead>
<tr>
<th></th>
<th>3rd Gen (EIA) 7/9/13-2/15/15 N=28,825</th>
<th>4th Gen (Ag/Ab) 2/16/15-11/30/15 N=24,288</th>
<th>Total 7/9/13-11/30/15 N=53,113</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients newly diagnosed with HIV</td>
<td>297 (1.0% of unique tested)</td>
<td>168 (0.7% of unique tested)</td>
<td>465 (0.9% of unique tested)</td>
</tr>
<tr>
<td>Patients with an acute HIV diagnosis</td>
<td>11 (3.7% of new HIV+)</td>
<td>13 (7.7% of new HIV+)</td>
<td>24 (5.2% of new HIV+)</td>
</tr>
</tbody>
</table>

HIV Confirmation Test

- Bio-Rad MultiSpot >> Geenius
- 11/2013 - 4/2014 evaluated
- 10/24/2014, FDA cleared.
- 5/2015 system, 7/2015 Re-evaluate
- 11/25/15 implemented

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**Geenius HIV 1/2**

**Sample ID:** 005  
**Cassette ID:** 125001214443  
**Kit Lot - Exp. Date:** 386012 - 2/15/2014  
**Order date:** 1/2014 10:16:11  
**Analysis date:** 1/2014 10:16:15  
**Test run by:** w wang  
**Test version:** 1.0.0.5  
**Rule(s):** HIV-1 Criteria - HIV-2 Criteria

**Image**

**Interpretation**

**Interpretation type:** Automatic

<table>
<thead>
<tr>
<th>#</th>
<th>Name</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>gp16</td>
<td>Absent</td>
</tr>
<tr>
<td>2</td>
<td>gp140</td>
<td>Absent</td>
</tr>
<tr>
<td>3</td>
<td>p31</td>
<td>Present</td>
</tr>
<tr>
<td>4</td>
<td>gp160</td>
<td>Present</td>
</tr>
<tr>
<td>5</td>
<td>p24</td>
<td>Present</td>
</tr>
<tr>
<td>6</td>
<td>gp41</td>
<td>Present</td>
</tr>
<tr>
<td>7</td>
<td>CTRL</td>
<td>Present</td>
</tr>
</tbody>
</table>

**Conclusion:** HIV-1 POSITIVE
Validation and Clinical Utility of Bio-Rad Geenius as Confirmatory Test for HIV Screening

- HIV 4th generation for HIV antigen and antibody detection was performed using Abbott Architect system.
- The Bio-Rad Geenius HIV-1/HIV-1 Supplemental Assay was evaluated and used in clinical setting for confirmation of HIV EIA screening in using the 4th generation test (Architect, Abbott) in a large urban hospital laboratory.
- Rapid testing and reporting of HIV for the FOCUS program have been managed by using the updated HIV testing algorithm, i.e., order HIV-1 RNA PCR for unconfirmed cases.
- HIV Ag/Ab testing replaced HIV EIA screening on February 16, 2015. Rapid confirmation using the Bio-Rad Geenius on November 2015.
- Signal cutoff (S/CO) result by Architect is 1.00.

Comparison Study for HIV Confirmation

<table>
<thead>
<tr>
<th></th>
<th>Geenius</th>
<th>Multispot</th>
<th>Total</th>
<th>S/CO</th>
<th>Range</th>
<th>Median</th>
<th>Average</th>
<th>&lt;100</th>
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<tr>
<td></td>
<td>Pos</td>
<td>Neg</td>
<td>Ind</td>
<td>Pos</td>
<td>Neg</td>
<td>Ind</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HIV-1 WB</td>
<td>82</td>
<td>82</td>
<td>82</td>
<td>23</td>
<td>1110</td>
<td>573</td>
<td>540</td>
<td>2.40%</td>
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<tr>
<td>HIV-1 Neg</td>
<td>12</td>
<td>12</td>
<td>12</td>
<td>1.5</td>
<td>40</td>
<td>2.6</td>
<td>7.5</td>
<td></td>
</tr>
<tr>
<td>HIV-1 Ind</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>3</td>
<td>1</td>
<td>4</td>
<td>25-134</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>96</td>
<td>98</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>


HIV Testing

[Diagram of HIV Testing Algorithm]
HIV Confirmation Test at Grady

**Focus HIV Testing**

- mHIV: Positive, S/CO = 390.98
- HIV Confirmatory Test:
  - HIV-1, Neg
  - HIV-2, Neg

**FOCUS HIV CONFIRMATION**

- HIV-1 Ab Confirmation: Negative
- HIV-2 Ab Confirmation: Negative
- HIV Assay Interpretation: Negative

**HIV-1 RNA-PCR, QUANT(Viral Load)**

- HIV RNA COPIES/mL: 6.85 log10 copies/mL
- Viral Load Comment: See Below

**Case 1**

- M 20, Emergency Room (Focus patient).
  - HIV EIA: Positive, S/CO = 390.98

- HIV Confirmatory Test:
  - HIV Negative: HIV-1, Neg; HIV-2, Neg

- True positive?

No follow-up, challenging to link the care
Testing: no follow-up, no clear answer. Need PCR

<table>
<thead>
<tr>
<th>Sex</th>
<th>Age</th>
<th>Conclusion</th>
<th>HIV-1</th>
<th>HIV-2</th>
<th>EIA S/CO</th>
<th>ER</th>
<th>HIV RNA (copy/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>M</td>
<td>19</td>
<td>HIV Neg</td>
<td>Neg</td>
<td>Neg</td>
<td>10.49</td>
<td>Yes</td>
<td>No F/U</td>
</tr>
<tr>
<td>M</td>
<td>20</td>
<td>HIV Neg</td>
<td>Neg</td>
<td>Neg</td>
<td>390.98</td>
<td>Yes</td>
<td>No F/U</td>
</tr>
<tr>
<td>M</td>
<td>19</td>
<td>HIV Neg</td>
<td>Neg</td>
<td>Neg</td>
<td>21.45</td>
<td>Yes</td>
<td>No F/U</td>
</tr>
<tr>
<td>M</td>
<td>44</td>
<td>HIV Neg</td>
<td>Neg</td>
<td>Neg</td>
<td>3.63</td>
<td>Yes</td>
<td>No F/U</td>
</tr>
<tr>
<td>F</td>
<td>39</td>
<td>HIV Neg</td>
<td>Neg</td>
<td>Neg</td>
<td>17.95</td>
<td>Yes</td>
<td>No F/U</td>
</tr>
<tr>
<td>M</td>
<td>51</td>
<td>HIV Neg</td>
<td>Neg</td>
<td>Neg</td>
<td>1.53</td>
<td>Yes</td>
<td>No F/U</td>
</tr>
<tr>
<td>M</td>
<td>21</td>
<td>HIV Neg</td>
<td>Neg</td>
<td>Neg</td>
<td>1.09</td>
<td>Yes</td>
<td>No F/U</td>
</tr>
<tr>
<td>M</td>
<td>50</td>
<td>HIV Neg</td>
<td>Neg</td>
<td>Neg</td>
<td>1.09</td>
<td>Yes</td>
<td>No F/U</td>
</tr>
<tr>
<td>F</td>
<td>33</td>
<td>HIV Neg</td>
<td>Neg</td>
<td>Neg</td>
<td>1.53</td>
<td>Yes</td>
<td>No F/U</td>
</tr>
</tbody>
</table>

(7/16-2/17)

Case 2

  HIV EIA: Positive, S/CO = 50.82

- HIV Confirmatory Test:
  HIV-1 Positive: HIV-1, Pos.; HIV-2, Neg.

- HIV-1 RNA PCR:
  > 10,000,000 copies/mL (>7 log10). CD4, 145 L

Real positive case, almost acute
Patient follow-up at HIV Clinic

HIV-1 RNAPCR:
- > 10,000,000 copies/ml
- 4.58 K copies/ml (10 days)
- 0.34 K copies/ml (1 month)
- <0.04 K copies/ml (3 months)
- <0.04 K copies/ml (5 months)

CD4:
- 145 L
- 336 (1 month)

Real positive case, patient responded to treatment!

HIV Test: True Positive Cases

<table>
<thead>
<tr>
<th>Sex</th>
<th>Age</th>
<th>Conclusion</th>
<th>HIV-1</th>
<th>HIV-2</th>
<th>EIA S/CO</th>
<th>HIV RNA (copy/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>M</td>
<td>41</td>
<td>HIV-1 Pos</td>
<td>Pos</td>
<td>Neg</td>
<td>101</td>
<td>&gt;10000000 (&gt;7 log10)</td>
</tr>
<tr>
<td>M</td>
<td>27</td>
<td>HIV-1 Pos</td>
<td>Pos</td>
<td>Neg</td>
<td>50.82</td>
<td>363K</td>
</tr>
<tr>
<td>F</td>
<td>48</td>
<td>HIV-1 Pos</td>
<td>Pos</td>
<td>Neg</td>
<td>86.17</td>
<td></td>
</tr>
<tr>
<td>F</td>
<td>21</td>
<td>HIV-1 Pos</td>
<td>Pos</td>
<td>Neg</td>
<td>106</td>
<td></td>
</tr>
<tr>
<td>M</td>
<td>62</td>
<td>HIV-1 Pos</td>
<td>Pos</td>
<td>Neg</td>
<td>1065</td>
<td>4.59 K</td>
</tr>
<tr>
<td>F</td>
<td>49</td>
<td>HIV-1 Pos</td>
<td>Pos</td>
<td>Neg</td>
<td>38.12</td>
<td></td>
</tr>
<tr>
<td>M</td>
<td>46</td>
<td>HIV-1 Pos</td>
<td>Pos</td>
<td>Inde</td>
<td>41.46</td>
<td>213.4 K</td>
</tr>
</tbody>
</table>

7/16-9/16
Case 3

- F 31, OB Clinic.
  HIV EIA: Positive, S/CO = 4.13

- HIV Confirmatory Test:
  **HIV-1 Indeterminate**: HIV-1, Indeterminate; HIV-2, Neg. gp41 (faint)

- HIV-1 RNA PCR: Not detected

Unconfirmed Cases, possible false positive EIA.

Case 4

- F, 17, Children's Hospital, Emergency Room.
  *Chlamydia trachomatis* NAT: positive; Wet-prep: Clue cell.
  HIV EIA: Positive, S/CO = 2.7.

- HIV Confirmation Test:
  **HIV Negative**: HIV-1, Neg.; HIV-2, Neg.

- HIV-1 RNA PCR: Not detected

Unconfirmed HIV Cases, possible false positive EIA
### HIV Results: Un-confirmed Cases (False Positive EIA)

<table>
<thead>
<tr>
<th>Sex</th>
<th>Age</th>
<th>Conclusion</th>
<th>HIV-1</th>
<th>HIV-2</th>
<th>EIA S/CO</th>
<th>ER</th>
<th>HIV RNA (copy/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>M</td>
<td>29</td>
<td>HIV-1 Indeterminate</td>
<td>Ind</td>
<td>Neg</td>
<td></td>
<td></td>
<td>Not detected</td>
</tr>
<tr>
<td>F</td>
<td>23</td>
<td>HIV Neg</td>
<td>Neg</td>
<td>Neg</td>
<td>27</td>
<td>Yes</td>
<td>Not detected</td>
</tr>
<tr>
<td>F</td>
<td>31</td>
<td>HIV-1 Indeterminate</td>
<td>Ind</td>
<td>Neg</td>
<td>4.13</td>
<td></td>
<td>Not detected</td>
</tr>
<tr>
<td>F</td>
<td>34</td>
<td>HIV Neg</td>
<td>Neg</td>
<td>Neg</td>
<td>1.13</td>
<td>No</td>
<td>Not detected</td>
</tr>
<tr>
<td>F</td>
<td>17</td>
<td>HIV Neg</td>
<td>Neg</td>
<td>Neg</td>
<td>2.7</td>
<td>Yes</td>
<td>Not detected</td>
</tr>
<tr>
<td>M</td>
<td>27</td>
<td>HIV Neg</td>
<td>Neg</td>
<td>Neg</td>
<td>1.84</td>
<td>No</td>
<td>Not detected</td>
</tr>
<tr>
<td>M</td>
<td>32</td>
<td>HIV Neg</td>
<td>Neg</td>
<td>Neg</td>
<td>1.34</td>
<td>No</td>
<td>Not detected</td>
</tr>
<tr>
<td>F</td>
<td>27</td>
<td>HIV Neg</td>
<td>Neg</td>
<td>Neg</td>
<td>2</td>
<td></td>
<td>Not detected</td>
</tr>
<tr>
<td>M</td>
<td>29</td>
<td>HIV Neg</td>
<td>Neg</td>
<td>Neg</td>
<td>2.59</td>
<td>Yes</td>
<td>Not detected</td>
</tr>
</tbody>
</table>

Possible False Positive EIA (4/16-1/17)

### Case 5

  - HIV Confirmation:
    - **HIV Negative**: HIV-1, Neg.; HIV-2, Neg.
  - HIV-1 RNA PCR: 1193.19 K copies/mL (6.08 log10)
  - Follow-up at HIV Pediatric Clinic: RNA, 43 K copies/mL (4.64 log10); CD4, 436

*Acute Infection, with STD; responded to treatment*
Case 6

- M 18, Emergency Room, viral pharyngitis, Group A Strep testing ordered in ER
  HIV EIA: Positive, S/CO = 18.01

- HIV Confirmation:
  HIV Negative: HIV-1, Neg.; HIV-2, Neg.

- HIV RNA PCR: > 10,000,000 copies/mL (>7 log10)

Acute Infection

Case 7

- M, 27, in patient, isolation, cough of blood; fever.
  HIV EIA: positive, S/CO = 43/ 31.15

- HIV Confirmation:
  HIV Negative: HIV-1, Neg.; HIV-2, Neg.

- HIV-1 RNA PCR:
  5340 K copies/mL (6.7 log10).
  HIV DNA PCR: Detected

- HIV-1 RNA PCR (Follow up in HIV Clinic):
  5340 K copies/mL (6.7 log10)
  11.7 K copies/mL (4.07 log10, 2 month);
  <0.04 K copies/mL (5 months).
  CD4, 154 > 355 (4 months).

Acute Infection, responded to treatment
### Acute HIV Infections: Confirmed Cases

<table>
<thead>
<tr>
<th>Sex</th>
<th>Age</th>
<th>Conclusion</th>
<th>HIV-1</th>
<th>HIV-2</th>
<th>Focus</th>
<th>EIA S/CO</th>
<th>ER</th>
<th>HIV RNA</th>
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<tbody>
<tr>
<td>M</td>
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(1/16-1/17)

### Case 8

- **M, 19 months**, Pediatric HIV Clinic.
  HIV EIA: positive, S/CO = 6.7

- HIV Confirmation:
  **HIV Negative**: HIV-1, Neg.; HIV-2, Neg.

- HIV DNA PCR:
  Not detected (14 days)
  Not detected (4 month)

  False positive EIA, long maternal antibody
Pediatric (maternal Antibody)

<table>
<thead>
<tr>
<th>Sex</th>
<th>Age (mo.)</th>
<th>Conclusion</th>
<th>HIV-1</th>
<th>HIV-2</th>
<th>EIA S/CO</th>
<th>HIV RNA (copy/mL)</th>
<th>HIV DNA</th>
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</table>

Maternal antibody: may be detected in 1.5 years (6/16-12/16)

Summary

- Early diagnosis and initiation of treatment for HIV are important for individual patient health and to reduce HIV transmission in the community.
- Implementing HIV-1/HIV-2 antigen-antibody EIA test with HIV confirmatory test provided a rapid turn-around time. HIV-1 RNA PCR needs to be used to confirm acute infection and rule out false positive EIA.
- Follow up for newly diagnosed patients with the linkage to care after discharged from the ED and primary care settings is challenging but can be achieved.
Thank You!
Band patterns

- p24, gp41
- p24, gp41
- p24, gp41
- p31, gp160, gp41
- p31, gp160, gp41
- gp160, gp41
- gp160 (f), gp41
- gp140(f), gp160, gp41

Thank you!

<table>
<thead>
<tr>
<th>Image</th>
<th>Interpretation</th>
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<tr>
<td>1</td>
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<tr>
<td>2</td>
<td>gp140</td>
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<td>p31</td>
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<td>6</td>
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Conclusion: HIV-1 POSITIVE (HIV-1 Positive/HIV-2 Indeterminate)
## EIA Results

<table>
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<tr>
<th>Initial Result (S/CO)</th>
<th>Retest Results (S/CO)</th>
<th>Final Result</th>
<th>Interpretation of Final Result</th>
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<tr>
<td>NR (&lt; 1.00)</td>
<td>No retest required (NA)</td>
<td>NR</td>
<td>HIV-1 p24 Ag and HIV-1/HIV-2 Ab not detected</td>
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<tr>
<td>R (≥ 1.00)</td>
<td>Both tests are NR (&lt; 1.00)</td>
<td>NR</td>
<td>HIV-1 p24 Ag and HIV-1/HIV-2 Ab not detected</td>
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<tr>
<td>R (≥ 1.00)</td>
<td>One or both tests are R (≥ 1.00)</td>
<td>R</td>
<td>Presumptive evidence of HIV-1 p24 Ag and/or HIV-1/HIV-2 Ab; perform supplemental confirmatory assay(s)</td>
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