4TH GENERATION TESTING UPDATE

Implications for HIV Testing Providers
Caroline Campbell

OBJECTIVES:

- At the completion of this presentation, participants will be able to:
  - List three benefits of the new HIV testing algorithm
  - Identify and define the new “diagnostic window of detection” for serum samples
  - Recognize key test technology terms

HIV ANTIBODY TESTING

- Most people develop detectable HIV antibodies 2-8 weeks after infection (average 25 days)
- Prior to October 2013, HIV testing algorithm used at the State Lab (DCLS):
  - EIA screen (3rd Generation)
  - Confirmed by Western Blot (WB)
p24 Antigen

- p24 is the antigen on HIV-1 that most commonly provokes an antibody response
- First marker of HIV-1 infection
- Can be detected at 2 weeks from infection
4TH GENERATION HIV AG/AB EIA TEST

- Combined antigen/antibody test

  - Can detect...
    - p24 antigen
    - HIV-1 antibodies
    - HIV-2 antibodies

  - But...cannot tell them apart

NEW HIV TESTING ALGORITHM

STEP 1

4th Gen EIA antigen/antibody

reactive

MULTISPOT HIV Ab TEST

- Supplemental test
  - used after a reactive 4th Gen EIA
- Replaces WB
  - More sensitive and specific than WB
  - Faster and less expensive than WB
- Will differentiate HIV-1 and HIV-2
NEW HIV TESTING ALGORITHM

**STEP 2**

- 4th Gen EIA (antigen/antibody)
  - Reactive
    - Multispot (antibody)
      - HIV 1 +
      - HIV 2 +
      - HIV 1 and 2 -

**What if you get a non-reactive result from Multispot antibody test?**

- HIV 1 +
- HIV 2 +
- HIV 1 and 2 -

NUCLEIC ACID AMPLIFICATION TEST FOR HIV-1 RNA

- Supplemental test
- Used after a reactive EIA and a non-reactive Multispot or indeterminant Multispot
- Highly sensitive test which can detect the presence of viral RNA
- HIV-1 RNA/NAAT testing can detect acute HIV-1 infection

**STEP 3**

- 4th Gen EIA (antigen/antibody)
  - Reactive
    - Multispot (antibody)
      - HIV 1 +
      - HIV 2 +
      - HIV 1 and 2 -

- NAAT (HIV-1 RNA)
  - +
  - -
ACUTE PHASE

What is Acute Phase of HIV Infection?
Appearance of markers of HIV infection

- Absence of HIV-specific antibodies
- Depressed CD4 by NAT or p24 antigen
- Rapid rise in plasma viral load
- Acute viral syndrome: fever, rash, diarrhea, fatigue, headache

DIAGNOSTIC WINDOW OF DETECTION

- The time from infection to detection
- Varies depending on the test used

WINDOWS OF DETECTION

<table>
<thead>
<tr>
<th>Test</th>
<th>Window of Detection</th>
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<tbody>
<tr>
<td>4th Gen:</td>
<td></td>
</tr>
<tr>
<td>Conventional</td>
<td>2 weeks</td>
</tr>
<tr>
<td>3rd Gen:</td>
<td></td>
</tr>
<tr>
<td>Conventional</td>
<td>2-8 weeks (avg. 25 days)</td>
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<tr>
<td>Rapid HIV Test</td>
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POSSIBLE RESULTS FOR 4TH GENERATION EIA AND THE NEW TESTING ALGORITHM

WHAT DOES THIS MEAN FOR YOU?

QUESTIONS??