Challenges and Success of Implementing the HIV Diagnostic Testing Algorithm: Reports from Four HIV Surveillance Programs

2016 HIV Diagnostic Conference
Outline

• Challenges of Implementing Public Health Reporting of the HIV Diagnostic Testing Algorithm

• Public Health Efforts and Successful Strategies
  – Educational efforts directed towards laboratories
  – Educational efforts directed towards clinicians
  – Roles of Health Department partner services and surveillance investigation

• Discussion
HIV-1/HIV-2 antibody differentiation immunoassay

1. HIV-1/2 Ag/Ab combo immunoassay/ HIV-1/2 immunoassay
   - (+) indicates reactive test result
   - (-) indicates non-reactive test result

2. HIV-1/HIV-2 antibody differentiation immunoassay

3. HIV-1 RNA assay
   - RNA (+): Positive for HIV-1
   - RNA (-): Negative for HIV-1

(+): Positive test result
(-): Negative test result

HIV Diagnostic Testing Algorithm

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

RNA assay

HIV-1 RNA assay
Main Challenges Related to Implementing Public Health Reporting of the Diagnostic Algorithm

- Incomplete reporting of components of the algorithm is common
- Partial execution of the algorithm is common; reliance on specific clinician order
- Referral of specimen necessitates linking results to determine final test result
- Alternate algorithms and laboratory-specific reporting nuances
- Inconsistently used LOINC or laboratory proprietary coding
- Initial screening outside of the laboratory
- Not all reports represent newly diagnosed persons
- Unclear or nonspecific reports to the ordering clinician
Educational Efforts Directed Towards Laboratories (1)

Broad dissemination of clear and concise educational materials and official guidelines

– New York State Laboratory Reporting of Communicable Diseases

– New York State HIV reporting guidelines, schematics and reporting grid

– CDC/APHL Laboratory Testing for the Diagnosis of HIV Infection
Educational Efforts Directed Towards Laboratories (2)

Comprehensive and standardized laboratory recruitment process with verification of permits, instruments, testing algorithms, LOINC, laboratory specific local codes, referral facility, review of NYS PHL reporting requirements, file format, anticipated testing volume
Educational Efforts Directed Towards Laboratories (3)

Twice annual count resolution and lab assessment distribution and reconciliation

Biennial permit renewal regulatory audit process
Educational Efforts Directed Towards Clinicians

1. The problems

2. What surveillance does to help

3. What labs could do to help
Problem 1: Confusion

- Physicians and testing sites confused about:
  - Proper/best HIV tests to order
  - Interpretation of HIV test results
  - Follow up process for discordant results

- Electronic ordering adds to confusion
  - Long lists of HIV tests
  - Type Differentiation tests looks like a screen

- Providers deal with multiple laboratories
Surveillance Helps

• Phone call to each physician/site when:
  – Improper tests ordered
  – NAT needed
• HIV Testing Guidance sent by email or fax following phone conversations
• Phone number listed above lab reporting section of case report
• Suggest attaching lab reports to case report
• Provide examples of how to report lab results in case report instructions
### Case Report Instructions: How to Report Labs

2. Example of reactive rapid Ag/Ab 4th gen test (Determine) followed by standard lab algorithm:

<table>
<thead>
<tr>
<th>Type of Test</th>
<th>Collection Date</th>
<th>Rapid Test</th>
<th>Positive or Reactive for Ag</th>
<th>Reactive for Ab</th>
<th>HIV-1 Ab Positive</th>
<th>HIV-2 Ab Positive</th>
<th>Indeterminate</th>
<th>Negative or Nondetectable</th>
<th>Manufacturer</th>
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<tbody>
<tr>
<td>HIV-1/2 Ag/Ab Lab IA (4th Gen Discriminating)</td>
<td>2/5/2016</td>
<td>Y</td>
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<tr>
<td>HIV-1/2 Ag/Ab Rapid IA (4th Gen Discriminating)</td>
<td>2/5/2016</td>
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<tr>
<td>HIV-1/2 Ag/Ab Lab IA (4th Gen)</td>
<td>2/5/2016</td>
<td>N</td>
<td>X</td>
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<tr>
<td>HIV-1/2 Ab IA (2nd or 3rd Gen)</td>
<td>2/5/2016</td>
<td>Y</td>
<td>N</td>
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<tr>
<td>HIV1/HIV 2 Type Differentiating IA</td>
<td>2/5/2016</td>
<td>Y</td>
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<tr>
<td>HIV-1 Western Blot</td>
<td>N</td>
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<td>HIV-1 RNA/DNA Qualitative NAAT</td>
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<td>OTHER:</td>
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<tr>
<td>Last Negative Test (prior to HIV diagnosis)</td>
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<td>Y</td>
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</tbody>
</table>

If HIV lab tests were NOT documented, is HIV diagnosis confirmed by a clinical care provider? Yes □ No □ Unc □
If YES, please provide date of documentation by care provider: / /
HIV Testing Guidance

SELECTING APPROPRIATE HIV DIAGNOSTIC TESTS
Guidance from the Michigan Department of Community Health/HIV Surveillance Program

With the release of improved HIV detection tests, we now have the ability to detect HIV infection earlier and identify patients in the acute phase when high levels of virus increase the likelihood of transmitting infection. Please follow the recommendations below for earlier detection of HIV and therefore the increased possibility of reducing transmission.

**Key Points:**
- Initial HIV screens should detect both antigen and antibody
- Two different reactive HIV tests may make an HIV diagnosis. If the second test is nonreactive or indeterminate, a third test must be run
- All initial reactive screening tests as well as all subsequent tests (regardless of the result) run must be reported to the health department

**Testing Steps:**

(See generations of assays explained later in document)

**Step 1: Initial screening test**
- Best: 4th generation antigen/antibody assay. Performed in lab or rapid test
- Good: 3rd generation antibody assay that detects both IgG and IgM
- Acceptable: 2nd generation IgG antibody assay. Includes most rapid tests that do not detect HIV antigen or IgM antibody

**Step 2: Supplemental test**
- Best: HIV-1/HIV-2 antibody type differentiating assay (e.g. Multispot, Geenius)
- Good: Western blot or IFA (now being phased out)
Problem 2: NAT Needed

• Reactive screen followed by negative supplemental test: need NAT

• Recommendation to submit fresh plasma often lost at bottom of lab report

• Labs should ideally reflex to FDA approved NAT, even if at another laboratory
Partner Services Feedback Form

Also used to request blood draws in discordant testing situations
What Labs Could Do to Help

- Utilize specimen processing staff to follow up when submitters order questionable tests
- Restrict stand-alone supplemental tests by special arrangement only.
- Reflex to FDA approved NAT in discordant testing situations even if at another laboratory.
  - Worries about contamination from running NAT on original serum have not born out.
- Coordinate with other labs, governmental agencies to standardize ordering and messaging
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