Using Reported HIV Diagnostic Testing Results to Identify Cases of Acute HIV Infection: Lessons Learned from New York State

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AIDS Institute

Outline

- Presentation Objectives
- Overview of Clinical Laboratory Reference System
- HIV Testing in New York State
- HIV Diagnostic Testing Algorithm
- Received Results of the HIV Diagnostic Testing Algorithm
- Detecting AHI from Reported Lab Data
- Ongoing Efforts and Next Steps

Presentation Objectives

1. Describe issues related to identifying cases of acute HIV infection (AHI) from laboratory results
2. Review specific challenges originating from incomplete reporting of the diagnostic testing algorithm and use of alternate algorithms
3. Outline a process to investigate possible cases of AHI from reported laboratory data
4. Discuss the continued role of the HIV-1 Western blot
5. Describe the continued need for surveillance investigation and medical record review

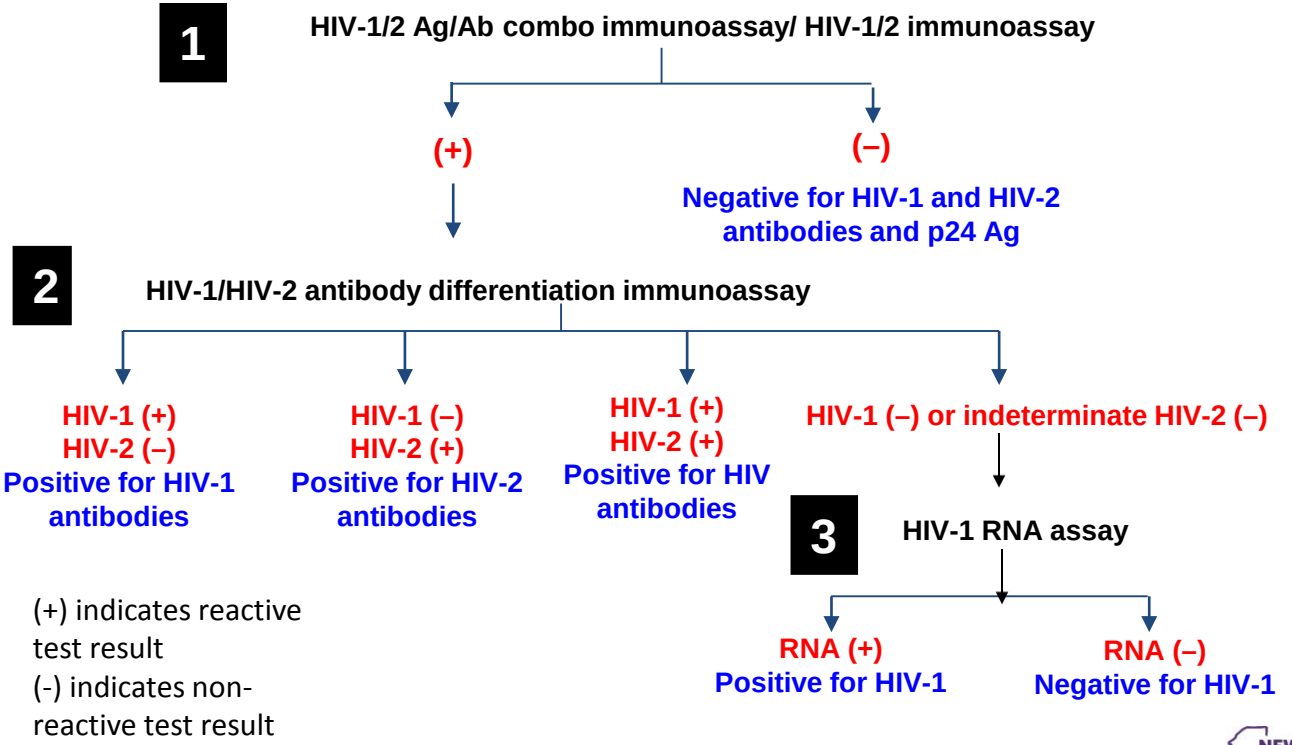
NYSDOH Clinical Laboratory Reference System

- Licensure of clinical labs and blood banks that perform testing on NYS residents or for NYS clinicians
- Clinical Laboratory Evaluation Program (CLEP) testing in NYS
  - Issues permits and certification to perform testing
- HIV-relevant permits testing in NYS
  - **Diagnostic immunology:** serology (antibody, antigen)
  - **Viral identification:** molecular identification tests (NAT, PCR, bDNA), genotyping or phenotyping, viral cultivation
  - **Cellular immunology:** Lymphoid immunophenotyping (CD4)

HIV Testing in New York State

- Annual reporting of >1.1 million test results via the NYSDOH Electronic Clinical Laboratory Reporting System (ECLRS)
- 111 labs are permitted and certified to conduct HIV-related testing in NYS
  - 69 labs report diagnostic test results
  - 21 additional labs are under recruitment for reporting of diagnostic test results
    - 11 are brand new to public health reporting
  - 4 labs use alternate algorithms that include the HIV Western blot (WB)
    - 18 labs submitted WB results in 2015
- Public health reporting of algorithm results began May 2013
  - Reporting was expanded to include all (positive, negative, indeterminate) results from supplemental HIV immunoassays (HIV-1 WB, HIV-2 WB or HIV-1 immunofluorescent assay)

HIV Diagnostic Testing Algorithm



(+) indicates reactive test result
(-) indicates non-reactive test result

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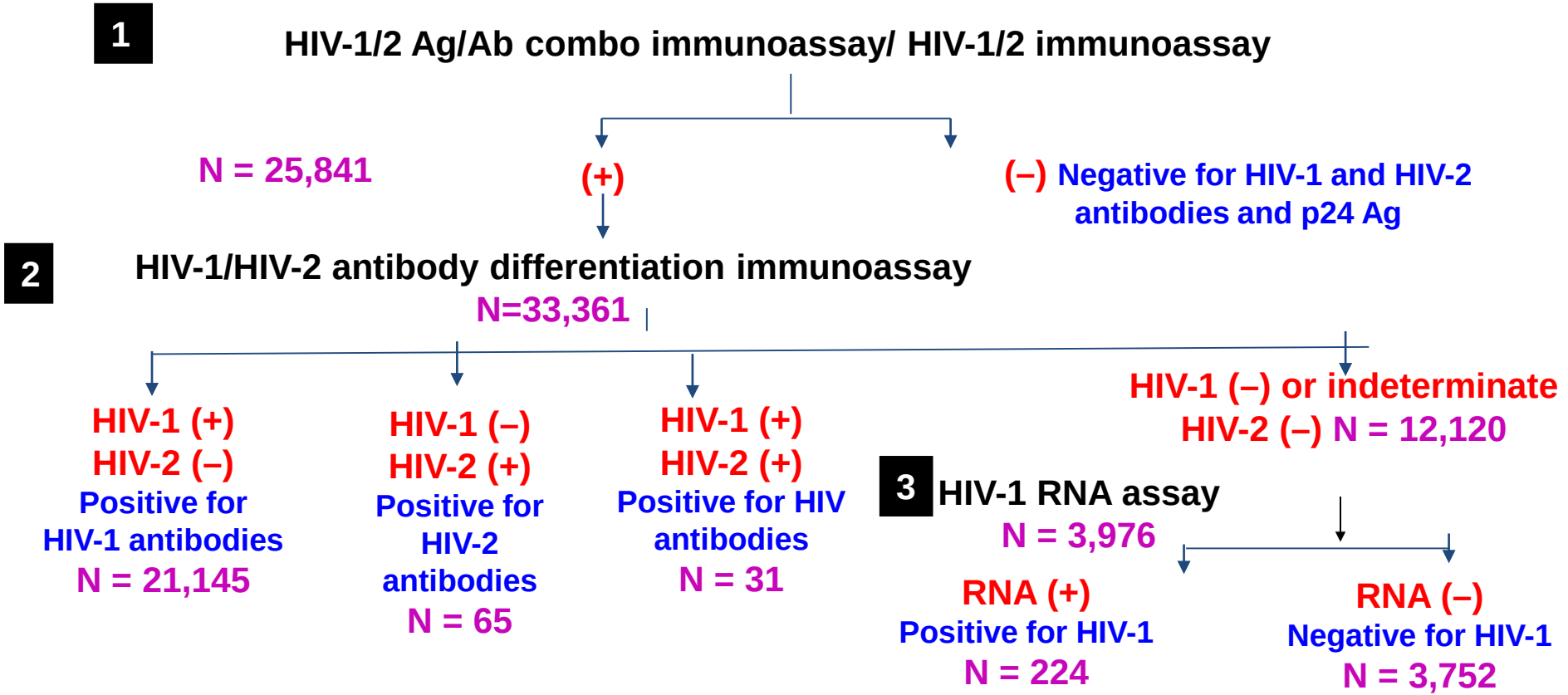
Received Results of the HIV Diagnostic Testing Algorithm, NYS, May 2013-Dec 2015



Received Results, May 2013-Dec 2015 (2)

- Repeat diagnostic testing of persons with established infection is widespread
  - 70% of reported confirmed algorithm/WB results

- Incomplete reporting of diagnostic test results is common
  - Of the 63,178 reported algorithm test results, only 20,636 (33%) complete sets were received
  - Of the 1,002 reported negative or indeterminate WB results, 47% were without the additional required testing

Yielding a total of <u>10,681</u> incomplete sets of results and, ultimately, unresolved HIV-infection status

Detecting AHI from Reported Lab Data

- Potential AHI is defined as a negative or indeterminate antibody result in conjunction with a detectable HIV-1 nucleic acid test result (RNA)
  - Step 2 HIV-1 negative/indeterminate/HIV-2 negative result AND Step 3 detectable (qualitative or quantitative) RNA

    OR
  - Indeterminate WB followed by detectable (qualitative or quantitative) RNA

- 239 cases met this definition
  - Algorithm based N=155
  - WB based N=84

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Detecting AHI from Reported Lab Data (2)

- Additional laboratory data was reviewed to clarify AHI status
  - Refuting evidence: concurrent or late AIDS diagnosis
  - Supporting evidence: high viral load (≥ 100K) proximate to the algorithm/WB result

- 40% (N=97) had supporting laboratory evidence of AHI
  - Only 22 (23%) had AHI or acute retroviral syndrome diagnosis documented in the medical record and captured by the public health investigation

- **Not possible to sort out based solely on reported lab data**

Ongoing Efforts and Next Steps

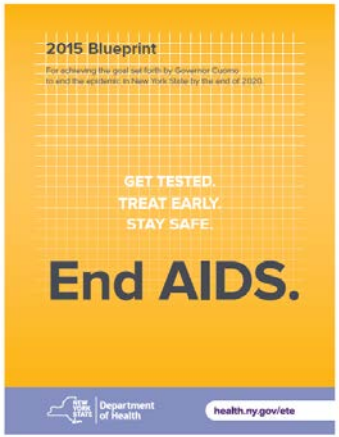
- Laboratory reporting
  - Partial execution of the algorithm, alternate algorithms and incomplete reporting of test results hinder the detection of AHI by surveillance programs
  - Underscores the existing problems with reporting within the referral/reference laboratory setting
  - Report to ordering clinician is neither clear or specific enough

- Changing testing technologies lead to the continual need to revise procedures and validate submission of new lab results
  - Geenius HIV 1-2 Supplemental assay
  - Bio-Rad Multispot HIV-1/HIV-2 Rapid Immunoassay retirement
  - Dwindling availability of WB
  - New tests coming to the market, including point-of-care NATs

Ongoing Efforts and Next Steps (2)

- eHARS solution to identify potential AHI cases
- Initial and ongoing staff education needs
- Education of providers regarding what they are ordering, what the test results mean and what follow up testing is required
- Ongoing evaluation of existing procedures and system

Questions?



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