The Route to Implementation of the New HIV Diagnostic Algorithm in New York State

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NYSDOH HIV Testing Programs

- **Wadsworth Center**
  - HIV rapid test confirmation, special services
  - Very limited initial screening/routine testing for HIV

- **NYSDOH Anonymous Counseling and Testing**
  - Rapid testing sites

- **Major portion of NYS-funded HIV testing occurs via medical providers and CBOs**
  - Supports contracts for lab testing

What is the NYS PHL’s role in this process?
Clinical Laboratory Reference System

- Licensure of clinical labs and blood banks that perform testing on residents/for providers of NYS
- Clinical Laboratory Evaluation Program (CLEP)
- CLEP requirements $\geq$ CLIA $\rightarrow$ NYS exempt by CMS
  - Certifies lab directors/asst. directors
  - Issues laboratory standards for clinical testing
  - Conducts on-site inspections
  - Operates a PT program
  - Evaluates lab-developed tests
- Maintain lists of permitted labs, tests performed
Implementation: Planning the Trip

- **March 2010 HIV Diagnostics Conference**
  - The New CDC/APHL HIV Diagnostic Testing Algorithm was proposed

- **NYSDOH HIV Algorithm Workgroup Convened**
  - Established in January 2011
  - Participants from NYSDOH HIV policy, prevention, education, surveillance and laboratory programs

- **Anticipated changes to HIV testing procedures were disseminated**
  - Each program tasked with identifying issues/concerns
  - Action items compiled, prioritized and tracked
# The Planning Grid

## Planning for the Introduction of New HIV Testing Algorithms

**Respondent:** Monica Parker, Wadsworth Laboratories

<table>
<thead>
<tr>
<th>ITEMS/ISSUES</th>
<th>ACTION STEPS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Policy</strong></td>
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<td><strong>Procedures</strong></td>
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<td><strong>Reimbursement</strong></td>
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<tr>
<td><strong>Law (?)/ Regulations</strong></td>
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<tr>
<td>- Clinical laboratory standards for HIV are outdated. These include standards</td>
<td>- WB is not specified as a confirmatory test, but the term 'antibody screening' occurs in several places.</td>
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<tr>
<td>for expedited maternal testing</td>
<td>New methods are not restricted to antibody screening and language should be updated.</td>
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<tr>
<td>- Some language in Subpart 58.8 (HIV Testing) of Part 58 (Clinical Laboratories</td>
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<td>and Blood Banks) is not current</td>
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<tr>
<td><strong>Surveillance</strong></td>
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<tr>
<td>- Current HIV case definition specifies laboratory criteria as positive result</td>
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<td>from an HIV antibody screening test confirmed by a positive result from a</td>
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<td>supplemental HIV antibody test (WB or IFA)</td>
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<td>- Currently positive WB and NAT trigger lab reporting, but not positive Multispot</td>
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<tr>
<td><strong>Staff training</strong></td>
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<td><strong>Provider education</strong></td>
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<tr>
<td><strong>Monitoring/QA</strong></td>
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<tr>
<td>Laboratory proficiency testing (PT) program needs updating. Current system is</td>
<td>Wadsworth will need access to appropriate PT samples and have a system for verifying results for methods</td>
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<tr>
<td>based on antibody screening/WB supplemental only</td>
<td>specified in proposed algorithm</td>
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<tr>
<td><strong>Other</strong></td>
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Supporting Documents

- New algorithm was affirmed in publications
  - Criteria for Laboratory Testing and Diagnosis of HIV; Approved Guideline M53-A (June 2011)
  - Special Issue of JCV (Dec 2011)

- CDC issued notice to surveillance programs (Nov 2011)
We’re On Our Way!
Initial Steps

Jan 2012: Letter from NYSDOH
- Distributed to clinicians, lab directors and other relevant stakeholders
- Described new multi-test algorithm

Email: hivtesting@health.state.ny.us
- Set up to field questions from the public
- Wide variety of questions received
- Highlighted aspects that needed clarification

http://www.health.ny.gov/diseases/aids/testing/algorithm.htm
Directions

Some recurring themes emerged
- Applicability of Multispot to the POC setting
- How rapid tests fit into algorithm
- Ability to use viral load test in algorithm
- MS package insert, interpretation issues

Concerns from laboratories that use of new algorithm would conflict with regulations and standards for HIV testing

How to fulfill PT requirements
Focus group tasked with developing detailed guidance for laboratories

- Which tests can be used in new algorithm
- When and if validation is needed
- How to report test results to providers
- How to report test results to DOH for public health reporting
Regulatory Actions

- Reworked the NYS clinical laboratory permit categories
- Eliminated HIV-specific lab standards that could impede use of the algorithm
- Modified NYS PT reporting format to accommodate new tests
- HIV reporting regs amended
- HIV lab testing regs under revision
Public Health Reporting Actions

- LOINC code for HIV-1/HIV-2 antibody differentiation test was requested from Regenstrief Institute.
- Guidance on reportable HIV test results for labs is being revised – New guidance on reporting:
  - combinations of test results
  - negative test results in some cases
- NYSDOH Electronic Clinical Laboratory Reporting System (ECLRS) was examined for compatibility with multi-test reporting.
Surveillance Program Actions

- Outreach to early adopters
- Education of labs and surveillance staff
  - Changes being implemented in reporting
  - Preferred LOINCS for reporting outcomes of the multi-test algorithm
    - HIV-1/HIV-2 differentiation test
- Review of permitted lab list to identify add’l labs that need to comply with reporting
  - Some labs that did not report previously, may now be required to do so
Communication Efforts

- Interim guidelines for new algorithm (in prep)
  - Includes clarification related to rapid testing
- Step-by-step description of algorithm
  - Results and interpretations for the Multispot test
- Guidelines for reporting to providers
  - Final interpretation statements for provider reports
- Instructions for reporting new combinations of HIV test results to DOH
  - Initial and supplemental results together or able to be linked by DOH
  - Link to MS LOINC info
Speed Bumps and Traffic Jams

- Language in current MS package insert
- NYS opted for *interim* guidelines in NYS until official recommendations are released
- For some labs, LIMS doesn’t allow reporting more than one test result
  - Compliance with PH reporting → expense for labs
- Incomplete execution of multi-test algorithm
  - Specimen handling requirements
- Restrictions on use of viral load tests
Next Steps

- Distribute Interim Guidance to Labs
- Update the NYS Communicable Disease Reporting Guidelines
  - Last update was 2010
- ECLRS survey
Are we there yet?
Contact Info

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