Performance of the New HIV-1/2 Diagnostic Algorithm in Florida’s Public Health Testing Population: A Review of the First Five Months of Utilization

B Bennett¹, D Neumann², S Fordan¹, R Villaraza¹, S Crowe¹, and L Gillis², Florida Department of Health, Bureau of Public Health Laboratories, ¹Jacksonville, ²Miami, FL., USA

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Objectives

- Assess the performance of the new HIV-1/2 Diagnostic Algorithm after five months of utilization in our Florida public health testing population.

- Assess the laboratory reporting turn-around-time (TAT) using the new HIV-1/2 Diagnostic Algorithm.
Rationale for the Algorithm Transition

- Expectations to detect HIV-1 acute infections (AI) in addition to established infections.

- To reduce the number of HIV-1 inconclusive laboratory interpretations, 74 (2.6% of blood Western Blots) in 2011.

- Anticipated reduction in the HIV laboratory reporting turn around time for HIV-1 positive results.

- Projected minimum adverse impact on the laboratory HIV Prevention budget.

- Expedites HIV-2 assessments (no longer a reflex test after an indeterminate or negative Western blot).
Methods

- Between 4/16/12 – 9/16/12 a total of 51,953 routine clinical specimens were tested with the Abbott ARCHITECT HIV-1/2 Ag/Ab Combo chemiluminescent microparticle immunoassay (CMIA). Plasma and serum specimens were collected, stored and delivered to the laboratory per the assay package insert recommendations.

- Repeatedly reactive specimens were tested with the BioRad Multispot HIV-1/HIV-2 rapid test.

- Discordant specimens were tested with the Gen-Probe APTIMA HIV-1 RNA qualitative NAAT.

- Laboratory reporting TAT for HIV-1 positive results was a comparison of a three month reporting period pre and post algorithm transition. Assessing TAT for negative HIV-1 results was not a focus of this study.
FBPHL Blood-based HIV-1/2 Testing Algorithm (April 16, 2012)

HIV-1/2 Ag/Ab Abbott Immunoassay (CMIA)
- reactive
  - rpt.IA in duplicate
  - one or both reactive
  - HIV-1/2 Suppl. IA (Multispot HIV-1/HIV-2)
    - HIV-1 reactive
      - Report as HIV-1 Ab positive
    - HIV-2 reactive
      - Report HIV-2 Ab preliminary positive, forward to CDC
    - HIV-1/2 reactive
      - Rule out dual infection, see dilution protocol
    - HIV-1/2 nonreactive
      - Reflex to HIV-1 NAAT
- nonreactive
  - report as neg. HIV-1/2 Ab & p24 Ag
  - both nonreactive
HIV-1 APTIMA HIV-1 RNA NAAT

HIV-1 Repeatedly reactive

Positive for HIV-1 RNA
Report as acute HIV-1 infection.*

HIV-1 Non-reactive

Negative for HIV-1 RNA
and HIV-1/2 antibodies

* Additional action steps: Phone calls to the healthcare provider, DIS, Surveillance and Patient Care Program staff. Request a re-draw (PPT or plasma) to document seroconversion(?) and provide baseline viral load, genotype and CD4, if needed.
RESULTS (Sensitivity)

- Between 4/16/12 – 9/16/12 a total of 51,953 Abbott HIV-1/2 Combo CMIA's were performed.

- 992 specimens were CMIA repeatedly reactive of which
  - 920 (1.8%) were Multispot HIV-1 reactive
  - 2 were Multispot HIV-1/2 nonreactive, HIV-1 NAAT reactive (algorithm-defined acute cases)
  - Sensitivity = 100% (922/922)

- No HIV-2 cases identified.

- In comparison to
  - Abbott Combo package insert Ab sensitivity = 100% (99.63 - 100%)
  - FBPHL initial verification, Sept. – Nov. 2011, n = 1,287, sensitivity = 100% (31/31)
RESULTS (Specificity)

• 50,961 were CMIA nonreactive.

68 (0.14%) were Abbott r/r, Multispot HIV-1/2 & HIV-1 NAAT nonreactive

1 was Abbott r/r, Multispot HIV-1 reactive (Recombinant gp41 only), Western Blot nonreactive, HIV-1 NAAT nonreactive (no evidence of ART).

1 was Abbott r/r, Multispot HIV-1/2 nonreactive, HIV-1 NAAT reactive, subsequent (13 days later) blood draw Abbott CMIA nonreactive.

Abbott Specificity = 99.86% (50961/51031)
Algorithm Specificity = 99.99% (51030/51031)
PPV = 99.9% (922/923)

• In comparison to
  - Abbott Combo package insert specificity = 99.77% (99.62-99.88%)
  - FBPHL initial verification, Sept. – Nov. 2011, n= 1,287, specificity = 99.84% (1254/1256)
Jan – March only 22% were reported in ≤ 2 days compared to May – July 96%.
# Resolve of Multispot HIV-1/HIV-2 Recombinant HIV-1 gp41 Reactive Spot Only

1,245 HIV-1 reactive (recombinant & peptide gp41) results, April-Oct 2012.

<table>
<thead>
<tr>
<th>ID</th>
<th>Abbott HIV-1/2 Combo s/co</th>
<th>Multispot HIV-1/2 s/co</th>
<th>APTIMA HIV-1 RNA NAAT s/co</th>
<th>Viral load RNA copies</th>
<th>Follow up</th>
<th>Status</th>
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</thead>
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<tr>
<td>12050611</td>
<td>1.7, 1.9, 1.8</td>
<td>R</td>
<td>NR</td>
<td>0.13</td>
<td>&lt;75</td>
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<td>NR</td>
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</table>

*Performed off-site
Health Program Transition Process

• Collaboration between HIV Prevention, Surveillance and Patient Care Sections to ensure the proposed testing algorithm was acceptable under F.A.C. 64-D for proof of positivity, case reporting and Ryan White eligibility.

• Florida’s proprietary HIV database was updated to capture new elements of the algorithm and to revise HIV laboratory reports.

• The Florida HIV Testing Protocol was revised in Jan. 2012 and disseminated to select field staff for review and feedback.

• A series of webinars were conducted in April 2012 informing key stakeholders (EICs, case mgrs., DIS, C&T staff, etc.) on the new algorithm and protocol.

• The Nov. 2011 CDC Dear Colleague Letter to Surveillance Coordinators was beneficial in the conversion process.
Summary

• The Abbott HIV-1/2 Ag/Ab CMIA performance continued to be comparable to the package insert claims and our initial verification data.

• Two algorithm-defined HIV-1 acute infections were identified and linked to care in a timely manner.

• The laboratory reporting of HIV-1 positive results in ≤2 days of the specimen receipt increased from 22% to 96%.

• No blood-based HIV-1 inconclusive laboratory results were reported during the five month period.

• Collaboration between the laboratory, Prevention, Surveillance and Patient Care Program staff during the 4-6 months prior to the algorithm conversion provided a smooth transition.
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