Sensitivity of the Alere Determine™ HIV-1/2 Ag/Ab Combo Rapid Test in a South Florida Population with a High Prevalence of HIV Infection
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Background
In 2014, Miami-Dade County ranked first in the number of reported HIV cases in Florida (Fig. 1) and first among the nation’s Metropolitan Statistical Areas (MSA) with an HIV infection case rate of 49.9 (Florida HIV/AIDS Surveillance). 1 Identifying acute HIV infections has the potential to avert additional HIV cases, especially as persons with acute HIV have named 2.5 times as many sex partners and twice as many partners with undiagnosed HIV compared to individuals with established infections. 2 In addition, transmission rates are higher (at least 10 times) in individuals during the acute stage of the infection. 3 4 Studies indicate that early HIV diagnosis, linkage and engagement into care are vital to realize improved personal health outcomes. 5

Methods
From September 8, 2015 to December 9, 2015:
Blood specimens were collected at Point of Care (POC) from individuals, regardless of their Determine Combo rapid test results.
Blood was submitted to the Florida Department of Health, Bureau of Public Health Laboratories, Miami, for comparative performance testing.
The new HIV Diagnostic Algorithm (CDC guidelines, June 27, 2014) was followed for this analysis, including the Abbott Laboratories ARCHITECT HIV Ag/Ab Combo Assay as the primary screening immunoassay. (Fig. 2)

Results
Of the 679 specimens pre-screened by a Determine Combo rapid test, 16 (2.3%) were concordant positive Determine Combo (Ag or Ab reactive), Abbott Combo and BioRad Laboratories Multipot HIV-1 reactive (supplemental differentiation IA). The remaining 663 Determine Combo negative specimens, 661 were Abbott Combo nonreactive and two were found to be Determine Combo false negative (FN) results by the algorithm-defined acute HIV-1 infection protocol (Abbott Combo reactive and 1 RNA NAT were also reactive).

Conclusion
The sensitivity of the Determine Combo rapid test used to pre-screen individuals in this high prevalence public health population was found to be 88.9% (1615). The package insert claim for serum sensitivity is 99.9% with a CI of 99.4%-100%. The detection of two algorithm-defined acute HIV-1 infections with FN Determine Combo results in a relative short time period strengthens our public health recommendation to seek additional laboratory-based HIV-1/2 Ag/Ab Combo IA testing for individuals with symptoms consistent with recent HIV infection or disclosure of recent high risk behaviors.

Discussion
Laboratory-based HIV testing algorithms, designed to identify acute as well as established infections, combined with timely antiretroviral therapy (ART), and targeting the uninfected MSM (men having sex with men) population, has the potential to reduce HIV incidence. Acute and early infections will impact HIV incidence, avert new infections and could save $379,000 per lifetime treatment and medication cost per individual. 6

Table 1: Potential Cost Saving by Testing and Educating Seronegative Partners

<table>
<thead>
<tr>
<th>Index Patient</th>
<th>Seronegative Partners</th>
<th>Lifetime Cost per Care</th>
<th>Total Cost Associated with Each Potential New Patient</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>7</td>
<td>$379,000</td>
<td>$12,653,000</td>
</tr>
<tr>
<td>2</td>
<td>14</td>
<td>$379,000</td>
<td>$5,308,000</td>
</tr>
<tr>
<td>3</td>
<td>21</td>
<td>$379,000</td>
<td>$7,959,000</td>
</tr>
</tbody>
</table>

Acknowledgements:
The authors wish to thank Melinda Waters and Lory Maddox, Florida Bureau of Public Health Laboratories, Miami, for statistical contributions.

References:
2) Moore, Z. et al. Number of Named Partners and Number of Partners Newly Diagnosed with HIV Infection Identified by Persons Newly Diagnosed with HIV Infection. AIDS Patient Care and STDs. 2006:November 44, 11.

Questions? Contact: lab.info@fdh.state.fl.us

Table 1: Number of Seronegative Partners Identified by Acute HIV-1 Infections

<table>
<thead>
<tr>
<th>Determine Combo</th>
<th>Algorithm-defined Acute HIV-1 Infections (Ag/Ab Reactive)</th>
<th>Acute HIV-1 Cases Identification</th>
</tr>
</thead>
<tbody>
<tr>
<td>679</td>
<td>661 (0.9%)</td>
<td>658 (98.5%)</td>
</tr>
<tr>
<td>2</td>
<td>16 (2.3%)</td>
<td>2 (11.1%)</td>
</tr>
</tbody>
</table>

Number of Acute HIV-1 Infections Identified by Algorithm-defined acute HIV-1 infection protocol (Abbott Combo reactive and 1 RNA NAT were also reactive) 21
Number of Acute HIV-1 Infections Identified by Determine Combo nonreactive and two were found to be Determine Combo false negative (FN) results by the algorithm-defined acute HIV-1 infection protocol (Abbott Combo reactive and 1 RNA NAT were also reactive) 2 of 2 (11.1%)