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 HIV 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]

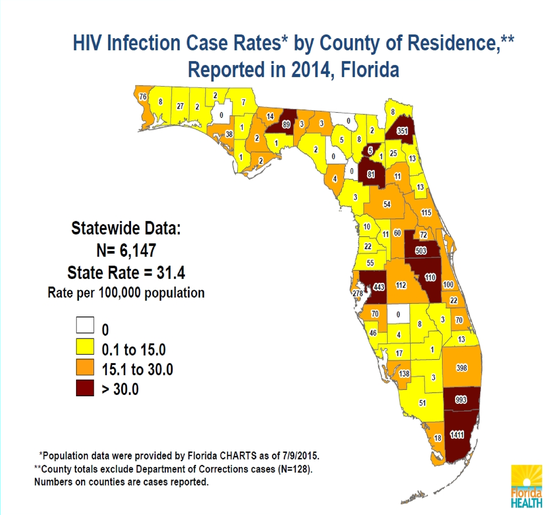

Fig. 1: Reported HIV Cases in Florida, 2014.

Objective

This prospective public health study was conducted to assess the sensitivity of the Alere Determine™ HIV-1/2 Ag/Ab Combo Rapid Test (Determine Combo) compared to an instrument-based HIV-1/2 Ag/Ab Combo Immunoassay (IA) on specimens from individuals who self-refer for HIV diagnosis at a Miami-Dade County STD clinic.

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)
- Sensitivity of the Determine Combo assay was defined as concordant positive results between the Determine Combo rapid test and the Abbott Combo IA, provided the differentiation IA and/or HIV-1 RNA NAT were also reactive.

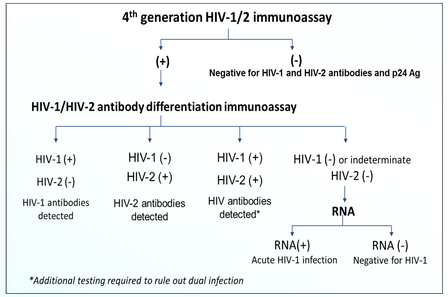

Fig. 2: Laboratory Testing for the Diagnosis of HIV Infection, Updated Recommendations: www.cdc.gov/hiv/testing/lab/guidelines

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 Multispot HIV-1 reactive (supplemental differentiation IA). Of 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 re-

Table 1

Number of Specimens Pre-screened by Determine Combo	Number (%) of Concordant Reactive Determine Combo and Abbott Combo	Number (%) of Algorithm-defined Acute HIV-1 Infections (FN Determine Combo)	Linkage to Care for Acute HIV-1 Cases (Days Post-diagnosis)	Number of Seronegative Partners Identified by Acute HIV-1 Cases
679	16 (2.3%)	2 (11.1%)	25 - 45	7 – 14

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% (16/18). 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 in lifetime treatment and medication cost per individual.[6] (Table 2)

Table 2: Potential Cost Saving by Testing and Educating Seronegative Partners

Index Patient	# Seronegative Partners	Lifetime Cost per Care	Total Cost Associated with Each Potential New Patient
1	7	$379,000	$2,653,000
2	14	$379,000	$5,306,000
Total Cost Averted	21	$379,000	$7,959,000

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