Performance of the Alere Determine™ HIV-1/2 Ag/Ab Combo Rapid Test in the Miami Health Department STD Clinic: A Review of the First 9 Months of Use

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Project

To pilot the implementation of the first FDA approved rapid point-of-care (POC) 4th generation HIV-1/2 Ag/Ab Combo (Determine Combo) test into the practice of STD clinics in the state of Florida. Miami-Dade County ranks first in the number of diagnosed HIV and AIDS cases in Florida. FDOH Miami-Dade County Laboratory is AHCA/CLIA-certified for moderate complex and waived testing, performing approximately 5000 rapid HIV-1/2 tests annually in its high HIV-1 seroprevalence public health population.

Implementation

The Determine Combo detects and distinguishes HIV-1 p24 Antigen (Ag) from HIV-1 and HIV-2 Antibodies (Ab) and thus has the potential to improve diagnosis of acute HIV-1 infection. The transition from CLIA-waived Clearview Complete HIV-1/2 to Determine Combo involved laboratory staff training, test performance verification, PT (AAB) enrollment, CLIA and AHCA license upgrade and test performance monitoring. Per the established testing algorithm, POC reactive serum specimens were sent to the FBPHL-Miami for confirmation by Abbott Combo IA, Multispot HIV-1/HIV-2 differentiation and HIV-1 NAT for any discordant results. Determine Combo nonreactive results were reported as HIV-1/2 negative.

Results (see tables)

A total of 3,272 Determine Combo tests were performed from 12/2/2014 to 8/31/2015, 2.8% (91/3272) were preliminary HIV-1 Ab positive, 75.8% (69/91) were confirmed by the laboratory-based algorithm (table 1). The observed specificity of 99.32% (3203/3225) is within the Determine 95% CI (97.7-99.5%). In addition, 50 Determine Combo reactive specimens were also tested by Clearview Complete (table 2). More false-positive HIV-1 Ab results were observed with Determine Combo and there was an absence of p24 Ag detection in the first nine months of use.

Lessons Learned

- Determine Combo was successfully implemented.
- HIV-1 antibody specificity was comparable to package insert specifications for high risk population, but more data is needed to verify Ag sensitivity and specificity.
- The clinic linkage-to-care process was modified due to the Determine Combo HIV-1 Ab false positive frequency.
- Testing algorithm was modified to test Determine nonreactive specimens for acute infections by the Abbott Combo IA.
- Alere Determine is a higher cost to the clinic due to PT enrollment and additional license fee.
- Use of Determine with serum/plasma requires more specimen preparation and licensed technical staff to perform the test.

Study Period	(POC): Rapid Alere Determine HIV 1/2 Ag/Ab Combo Test			Confirmation by BPHL-Miami (Abbot IA 4th generation, IA Multispot, NAT)				Specificity %	Sensitivity %
	# of tests performed	Negative	Positive	Positive	False Positive	Negative	False negative		
12/2/2014 - 8/31/2015	3272	3181	91	69	22	3203*	N/A	99.32	N/A
9/1/2015 - 12/31/2015	1057	1033	24	21	5	1036	2	99.52	91.3

*- Non Reactive have not been confirmed by Abbott Combo IA for that period (12/2/2014-8/31/2015)

Test	Total #	Ab +	P24+	Negative	False-positives
Determine Combo Reactive	50	47	3		13
Clearview Complete	50	38	N/A	12	1
Abbott Combo IA	50	37		13	

- Orgenics, Alere manufacturing partner, opened investigation on test performance on false negative and false positive cases.

References

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2. B. Bennett, D. Neumann, S. Fordan, et al. 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. Journal of Clinical Virology 58S (2013) e29– e33.
3. Alere Determine™ HIV–1/2 Ag/Ab Combo package insert

Acknowledgements

Florida Department of Health in Miami-Dade County STD clinic and Laboratory staff, Florida Department of Health Bureau of Public Health Laboratories-Miami and Jacksonville staff.