Evaluation of the INSTI HIV-1/2 Test Performance Characteristics at the Point-of-Care Clinical Setting (FDOH-Miami-Dade STD Clinical Lab).

O.V. Ponomareva, M. Vasquez - Florida DOH in Miami- Dade County, Miami, FL
Berry Bennett – Florida DOH BPHL-Jacksonville, Jacksonville, FL

Project

A project was conducted to evaluate performance characteristics (accuracy, sensitivity and specificity) of the FDA approved, CLIA-waived INSTI HIV-1/2 Antibody Test and to compare them with performance of Alere Determine HIV-1/2 Ag/Ab Combo and Clearview Complete (rebranded later as SureCheck) Ab tests. Another objective was to determine if INSTI is simple enough to perform as a point-of-care test in a true clinical setting and if it benefits clients and providers with faster turnaround time. FDOH Miami-Dade County Laboratory is AHCA/CLIA-certified for moderate complex and waived testing, performing approximately 4000 rapid HIV-1/2 tests annually in its high HIV-1 seroprevalence public health population.

Implementation

A total of 400 INSTI kits and control materials were provided by BioLytical Laboratories, Inc. A panel of 70 known plasma samples with varying levels of HIV-1 viral load and HIV-1 Ab s/co values were provided by the BPHL-Jacksonville. 304 whole blood samples were collected by venipuncture for routine screening from patients with unknown HIV status visiting STD clinic. All study samples (whole blood and plasma panel) were tested by three tests in the following order: Alere Combo first, then Clearview Complete followed by INSTI. Blood samples were sent to BPHL-Miami for confirmation per CDC recommended diagnostic algorithm using Abbott Combo IA, Multispot HIV-1/HIV-2 differentiation assay and HIV-1 NAAT for discordant results.
Testing and required QC were performed following manufacturers product inserts and lab SOPs.
Sensitivity, specificity and accuracy are calculated for each test. Testing personnel are licensed laboratory technicians/technologists properly trained.

Results (see tables)

A total of 304 whole blood samples were tested in October-November 2016, 1.64% (5/304) were preliminary HIV-1 Ab positive by all three tests, and 100% (5/5) were confirmed by the laboratory-based algorithm at the BPHL-Miami. 299 non-reactive specimens (100%) were confirmed as negative. 100% (70/70) of plasma panel samples were tested as Ab positive. No p24 Ag was detected by Alere Combo. No false-negative or false-positive were detected by any of three tests. All three tests demonstrated 100% specificity, that is in concordance with INSTI product insert specifications and exceeds specificity for Alere Determine (99.2% for high risk group and 99.7% overall) and Clearview (99.9%).
Sensitivity was 100% for all 3 tests that exceeds package inserts specifications (99.9% for INSTI and Alere Determine and 99.7 for Clearview).

Three rapid HIV-1/2 Tests Performance Comparison Study

	Alere HIV 1/2 Ag/Ab combo			Clearview Complete HIV-1/2 Ab		INSTI HIV-1/2 Ab		Confirmation by BPHL-Miami		Total
HIV samples	**Neg**	**Ag React.**	**Ab React.**	**Negative**	**Reactive**	**Negative**	**Reactive**	**Negative**	**Positive**	
Whole Blood samples	299		5	299	5	299	5	299	5	**304**
Plasma panel samples	0	0	70	0	70	0	70	0	70	**70**
Total	**299**	**0**	**75**	**299**	**75**	**299**	**75**	**299**	**75**	**374**

Lessons Learned

- INSTI tests were easy to perform and interpret. Test procedure takes only 1-3 minutes and significantly improves patient and provider satisfaction.
- In addition the short processing time allows more patients to be prescreened in a very busy STD clinic.
- HIV-1 antibody specificity and sensitivity were in concordance or exceeded manufacturers' tests specifications, although more data is recommended to identify acute/early infection.
- All three tests demonstrated high degree of accuracy and provided a reliable way to perform rapid HIV testing in acute care settings.

- Based on study results non-reactive prescreened specimens may not require additional testing unless the provider/counselor determines that recent patient risk factors are consistent to a possible acute HIV-1 infection.
- All reactive samples may be tested by secondary HIV rapid test with highest specificity to expedite the linkage-to-care process. Final confirmation should be done by BPHL-Miami as per CDC recommended algorithm.

References

1. Centers for Disease Control and Prevention and Association of Public Health Laboratories. Laboratory Testing for the Diagnosis of HIV Infection: Updated Recommendations. Available at http://stacks.cdc.gov/view/cdc/23447. Published June 27, 2014. Accessed June 22, 2015.
    1. 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.
2. Alere Determine™ HIV–1/2 Ag/Ab Combo package insert
3. INSTI HIV-1/2 Ab package insert
4. Clerview Complete HIV-1/2 AB 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.