Abstract #25

Multi-Center Outcomes-Based Clinical Evaluation of the VITROS® Immunodiagnostic Products Anti-HIV 1+2 Assay* (VITROS Anti-HIV 1+2 Assay) in Subjects at High Risk, Low Risk or Positive for Infection with Human Immunodeficiency Virus Types 1 and/or 2 (HIV-1 and/or HIV-2).

Abstract Category:	New HIV Diagnostic Technologies Including Those That Are Not FDA Approved
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OBJECTIVE

This multi-center clinical study was conducted to establish the performance characteristics of the VITROS Anti-HIV 1+2 assay versus an FDA-licensed anti-HIV 1/2 reference assay.

METHODS

Samples obtained in the U.S. and internationally from individuals at high or low risk for HIV infection, without a known or previously determined HIV assay result, were tested with both assays. A pre-specified algorithm was used to determine the HIV antibody status (Positive, Negative or Not Determined) of the respective study subjects. Samples from individuals known to be HIV antibody positive were also tested with the VITROS assay. Sensitivity and specificity were calculated as the percentage of HIV Antibody Positive or Negative/Not Determined samples testing VITROS reactive or negative, respectively.

RESULTS

The sensitivity of the VITROS Anti-HIV 1+2 assay among samples from 2912 subjects at high risk for HIV infection obtained in the U.S. (N=2175), in the Ivory Coast (N=488) and from pregnant women in the U.S. (N=249) was 100% (85/85; 95% exact confidence interval (CI) 95.75% to 100.0%) versus 97.65% (83/85) for the reference assay. The specificity of the VITROS assay was 99.65% (2817/2827; CI = 99.35% to 99.83%) versus 99.22% (2805/2827) for the reference assay. The sensitivity of the VITROS Anti-HIV 1+2 assay among samples from 1444 U.S. subjects at low risk for HIV infection obtained from pregnant women (N=297), from pregnant women in the period around labor and delivery (N=49), from insurance applicants (N=999), and from pediatric subjects ages 2-17 years (N=99) was 100% (6/6; CI = 4.07% to 100.0%) versus 33.33% (2/6) for the reference assay. The specificity of the VITROS assay was 99.79% (1435/1438; CI = 99.39% to 99.96%) versus 99.58% (1432/1438) for the reference assay in low risk subjects. The sensitivity of the VITROS Anti-HIV 1+2 assay in samples from 1563 known HIV antibody positive subjects obtained in the U.S. (N=1121), from four geographic locations outside the U.S. (N=194), from mono-infected HIV-2 antibody positive subjects in the Ivory Coast (N=208) and from HIV antibody positive pediatric subjects, ages 2-16 years, in the U.S. (N=40) was 99.94% (1562/1563; CI = 99.64% to 100.0%). With all populations combined, the overall sensitivity of the VITROS Anti-HIV 1+2 assay was 99.94% (1653/1654; CI = 99.66% to 100.0%); overall specificity was 99.70% (4252/4265; CI = 99.48% to 99.84%). The VITROS and reference assays were in agreement in 14/20 HIV seroconversion panels. The VITROS assay was reactive one bleed earlier in 5/20 panels and one bleed later in 1/20 panels.

CONCLUSIONS

The VITROS Anti-HIV 1+2 assay is safe and effective for the in vitro qualitative detection of antibodies to HIV-1 and/or HIV-2 in human serum and plasma (EDTA, heparin or citrate) using the VITROS ECi/ECiQ Immunodiagnostic System. Performance was comparable to the FDA licensed reference assay. The results, in conjunction with other serological and clinical information, may be used as an aid in the diagnosis of infection with HIV-1 and/or HIV-2 in persons with signs or symptoms of, or at risk for, HIV infection.