*Abstract #37*

# Development of an Anti-HIV 1+2 Assay for Use on a Random Access System


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## OBJECTIVE

Development of a chemiluminescent immunoassay for the in vitro qualitative detection of antibodies to Human Immunodeficiency Virus types 1 and/or 2 (anti HIV 1 and anti HIV 2) in human serum and plasma (heparin, EDTA or citrate) on the VITROS® ECi/ECiQ Immunodiagnostic System with Intellicheck®.

## METHODS

An immunometric bridging technique is used. This involves a two-stage reaction; in the first stage HIV antibody present in the sample binds with 4 HIV recombinant antigens coated on a microwell. Unbound sample is removed by washing. In the second stage 4 horseradish peroxidase (HRP)-labeled recombinant HIV antigens are added in the conjugate reagent. The conjugate binds specifically to any anti-HIV (IgG and IgM) captured on the well in the first stage. Unbound conjugate is removed by washing. The bound HRP conjugate is measured by a luminescent reaction following addition of a signaling reagent. The amount of HRP conjugate bound is directly proportional to the level of anti-HIV 1+2 present.

## RESULTS

Overall % positive agreement was determined to be 99.94% (1653/1654, with a 95% exact confidence interval of 99.66% to 100%) Overall % negative agreement was determined to be 99.70% (4252/4265, with a 95% exact confidence interval of 99.48% to 99.84%) From a genotype panel containing 25 naturally occurring plasma specimens from diverse geographic locations and including Group M (subtypes A, B, C, D, E, F, and G), Group O and HIV-2; all panel members were correctly detected by the VITROS® Anti-HIV 1+2 Assay. Seroconversion sensitivity was determined by testing 20 sero-conversion panels in both the VITROS® Anti-HIV 1+2 Assay and another commercially available method. The VITROS® Anti-HIV 1+2 Assay demonstrated earlier detection by at least 1 bleed and an average of 4 days for 25% of the panels tested. Assay precision is good with %CVs at the cut-off falling at <5% within occasion and <10% across both calibration interval and reagent lots. The assay was evaluated in full random access mode. This requires a single calibration every 28 days, quality controls run once every 24 hours and achieves a time to first result in under 50 minutes. Each test on the VITROS® ECi/ECiQ Immunodiagnostic System is also monitored by Intellicheck® Technology that enhances fluid detection verifications to reduce the risk of an incorrect result to near zero and generates an IntellireportTM that provides real-time status reporting on the quality of every patient result.

## CONCLUSIONS

In addition to the excellent clinical performance, the VITROS® Anti-HIV 1+2 Assay has the advantages of a random access system with exact control of each step of the test process and the security of Intellicheck® Technology.