Performance of the VITROS® Immunodiagnostic Products HIV Combo Assay™

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Method
Antibody detection in the VITROS® Immunodiagnostic Products HIV Combo Assay™ (VITROS® HIV Combo Assay™) is achieved using recombinant transmembrane envelope proteins for HIV-1 group M and O and HIV-2. Antigen detection is accomplished using monoclonal antibodies against HIV p24. Biotinylated antibodies or anti-p24 antibodies are pre-bound to MicroWells coated with streptavidin. Sample is added to the well in the first stage of the reaction and HIV antigen is captured by the biotinylated proteins. After wash, HRP conjugated envelope proteins or anti-p24 antibodies are added. Following final wash, bound HRP conjugates are detected using VITROS® signal reagent.

Assay Design

HIV p24 Antigen Sensitivity

A one-HIV p24 standard was diluted and tested on both the VITROS® HIV Combo Assay™ and a commercially available HIV Ag/Ab Combo assay. The AFSSAPS standard (Bk007 7220) was used.

Detection of HIV-1 Antibody Subtypes

A total of 83 HIV-1 group M subtype samples were tested on the VITROS® HIV Combo Assay™.

Seroconversion Sensitivity

Thirty-four commercially available HIV-1 seroconversion panels were tested using the VITROS® HIV Combo Assay™ and a commercially available 4th generation HIV assay.

Detection of HIV-1 Antigen Genotypes

A total of 52 specimens were evaluated on a VITROS® 3600 Immunodiagnostic System. These commercially available HIV-1 Group M specimens were run without dilution. The remaining 49 specimens were received as cell culture supernatants and diluted in HIV negative plasma. Antigen genotype sensitivity was determined using the AFSSAPS standard. The VITROS® HIV Combo Assay™ detected all 51 samples tested.

Precision

Total within lab precision for the VITROS® HIV Combo Assay™ was evaluated over 22 days consistent with CLSI EP05-A3 using one lot of positive and negative reference materials.

Conclusions

Ortho is developing a 4th-generation HIV assay that has demonstrated the following:

- Obtained within lab precision that ranged from 1.4% to 10.0%
- Seroconversion sensitivity consistent with a commercially available 4th-generation assay
- HIV p24 antigen sensitivity of 1.1 pg/mL when determined using the AFSSAPS standard
- Detection of all antigen genotypes (98.8% of samples at 200,000 HIV RNA copies/mL) and 100% of antibody subtype samples tested
- 100% specificity with clinical samples and 99.84% specificity with donor samples
- Developed to be used on random access VITROS® Systems