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Organism specificity was achieved by testing 30 HIV-negative samples from three donor groups including five healthy blood donors, five healthy blood donors, five healthy blood donors, five healthy blood donors, five healthy blood donors, five healthy blood donors, and five healthy blood donors. In addition, four different concentrations of each analyte were tested for the BioPlex® 2200 HIV Ag-Ab assay, with its unique assay design and reporting capability. Four different concentrations of each analyte were tested for the BioPlex® 2200 HIV Ag-Ab assay, with its unique assay design and reporting capability.

Conclusion
The BioPlex® 2200 HIV Ag-Ab assay, with its unique assay design and reporting capability, demonstrated excellent assay performance including:

- High sensitivity (81.3%);
- High specificity (99.86%);
- Excellent HIV-1/HIV-2 Ab differentiation capability;
- High reproducibility; and
- Excellent HIV-1 Ag Ab-Ab differentiation capability.

In addition to known HIV-1 and HIV-2 positive samples, 239 HIV-1 group M Ab-negative samples were analyzed using the BioPlex® 2200 HIV Ag-Ab assay kit by the HIV-1 Ab assay. The results from a single sample aspiration testing demonstrated excellent assay performance with less than 0.4% reactive for each spiked analyte by the intended assay.

Purpose
To evaluate the performance of an automated HIV assay with enhanced sensitivity that can report antigen and antibody results simultaneously, and differentiated HIV-1 from HIV-2.

Methods
The BioPlex® 2200 HIV Ag-Ab assay is a fully integrated, automated, and discrete detection system for simultaneous HIV antigen and antibody detection. The assay uses a unique combination of four populations of dye-labeled microparticles to capture the HIV-1 p24 antigen and HIV-1 and HIV-2 antibodies.

- HIV-1 p24 antigen
- HIV-1 Ab
- HIV-2 Ab

Following incubation with serum or plasma, the beads are washed to remove unbound patient sample. After incubation with serum or plasma, the beads are washed to remove unbound patient sample. The BioPlex® 2200 HIV Ag-Ab assay is a high-throughput, high-sensitivity HIV-screening assay.

Results
The BioPlex® 2200 HIV Ag-Ab assay was developed to simultaneously detect and identify of multiple HIV analytes for each sample processed from a single sample aspiration. Each sample is analyzed using a mixture of seven bead populations: anti-p24 antibody, anti-p24 synthetic peptide, anti-HIV-1 group O antibody, anti-HIV-2 antibody, anti-HIV-1 group M antibody, and anti-HIV-1 group A/B/c/d antibody.

The BioPlex® 2200 HIV Ag-Ab assay demonstrated excellent assay performance with less than 0.4% reactive for each spiked analyte by the intended assay. The assay performed well on four different populations of microparticles and demonstrated excellent assay performance including:

- High sensitivity (81.3%);
- High specificity (99.86%);
- Excellent HIV-1/HIV-2 Ab differentiation capability;
- High reproducibility; and
- Excellent HIV-1 Ag Ab-Ab differentiation capability.

In addition to known HIV-1 and HIV-2 positive samples, 239 HIV-1 group M Ab-negative samples were analyzed using the BioPlex® 2200 HIV Ag-Ab assay kit by the HIV-1 Ab assay. The results from a single sample aspiration testing demonstrated excellent assay performance with less than 0.4% reactive for each spiked analyte by the intended assay.