**Introduction**

The VITROS Anti-HIV 1+2 assay was previously evaluated as part of a diagnostic evaluation study for the VITROS Immunodiagnostic Products Anti-HIV 1/2 assay. The study was conducted to establish the performance characteristics of the VITROS Anti-HIV 1+2 assay in high and low risk populations.

**Materials and Methods**

**PRINCIPLES OF THE PROCEDURE**

The VITROS Anti-HIV 1+2 assay is performed using the VITROS Immunodiagnostic Products Anti-HIV 1/2 assay. The VITROS Anti-HIV 1+2 assay is an immunometric assay for the detection of HIV-1 and HIV-2 antibodies in serum or plasma. It uses a combination of antibodies to detect HIV-1 and HIV-2 antibodies in a single test.

**CLINICAL STUDY POPULATIONS - OVERVIEW**

Samples from 2912 subjects at high risk for HIV infection were tested in this clinical study. These samples were obtained from pregnant women in the U.S. (N=297), pregnant women in a high risk country (N=173), and pregnant women in a low risk country (N=972). The study was conducted to establish the performance characteristics of the VITROS Anti-HIV 1+2 assay in high and low risk populations.

**ASSIGNMENT OF HIV ANTIBODY STATUS TO STUDY SAMPLES**

The samples were assigned to one of the following categories:

- HIV Antibody Negative
- Antibody Status Not Determined
- HIV Antibody Positive

**STUDY POPULATION DESCRIBERS**

The study population was described in terms of the following characteristics:

- Antigenicity
- Antigenic Type
- Age
- Gender
- Race
- Ethnicity
- Occupation
- Sexual Orientation
- Risk Group

**RESULTS**

The performance of the VITROS Anti-HIV 1+2 assay was compared to the performance of the VITROS Anti-HIV 1/2 assay. The sensitivity of the VITROS Anti-HIV 1+2 assay in high risk populations was 100% (85/85; CI = 95.75% to 100%), and the specificity was 99.70% (4252/4265; CI = 99.48% to 99.84%).

**Discussion**

The performance of the VITROS Anti-HIV 1+2 assay was comparable to the performance of the VITROS Anti-HIV 1/2 assay in both high and low risk populations. The assay is suitable for use in clinical settings where a rapid and accurate diagnosis of HIV infection is needed.

**Conclusion**

The VITROS Anti-HIV 1+2 assay is an effective and reliable tool for the detection of HIV-1 and HIV-2 antibodies in serum or plasma. Its performance is comparable to that of the VITROS Anti-HIV 1/2 assay, making it a valuable addition to the diagnostic armamentarium.