Introduction
This study was designed to assess the clinical and analytical performance of the VITROS Immunodiagnostic Products Anti-HTLV I/II assay (VITROS Anti-HTLV) on the VITROS ECi/ECiQ/3600 Immunodiagnostic Systems and the VITROS 5600 XT 7600 Integrated Systems. In addition, assay performance for VITROS Anti-HTLV I/II was compared to the Abbott ARCHITECT hTHTLV-II assay (ARCHITECT hTHTLV-II). The assay detects antibodies to HTLV Types I and II.

Method
Clinical testing was performed at two external sites and analytical testing was performed internally using two reagent lots.

Assay Architecture
Clinical specificity was evaluated using fresh samples from 5096 HTLV negative blood donors and frozen samples from 204 HTLV negative hospitalized patients. Samples were tested on the VITROS assay as well as the ARCHITECT hTHTLV-I/II assay. Discordant results were resolved by performing confirmatory testing with independent reference methods. Observed specificity in the blood donor population for VITROS Anti-HTLV was 99.94% (5093/5096, 95% CI: 99.83-99.99%) compared to 99.84% (5088/5096, 95% CI: 99.69-99.93%) for ARCHITECT hTHTLV-I/II. Overall specificity for VITROS Anti-HTLV was 99.92% (5296/5300, 95% CI: 99.81-99.98%) compared to 99.83% (5291/5300, 95% CI: 99.68-99.92%) for ARCHITECT hTHTLV-I/II.

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Clinical Sensitivity
Clinical sensitivity was evaluated using 434 HTLV positive samples tested on both VITROS Anti-HTLV and ARCHITECT hTHTLV-I/II. The sensitivity of VITROS Anti-HTLV was 100.0% (434/434, 95% CI: 99.2-100.0%) compared to 99.8% for ARCHITECT hTHTLV-I/II (433/434, 95% CI: 98.7-100.0%).

Conclusion
The VITROS Anti-HTLV III assay demonstrates excellent clinical sensitivity and specificity. VITROS Anti-HTLV III is intended to be used as an aid in diagnosis of HTLV infection and to screen donors of blood, blood components, cells, tissue and organs for the presence of HTLV infection.

Analytical Sensitivity
Analytical sensitivity was evaluated using 2 commercially available performance panels. Commercial panel results were concordant with the package insert. Results from one of the commercial panels are shown below.