Performance of the VITROS® Immunodiagnostic Products Anti-HTLV I/II Assay* in Two Clinical Laboratories

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Objective

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

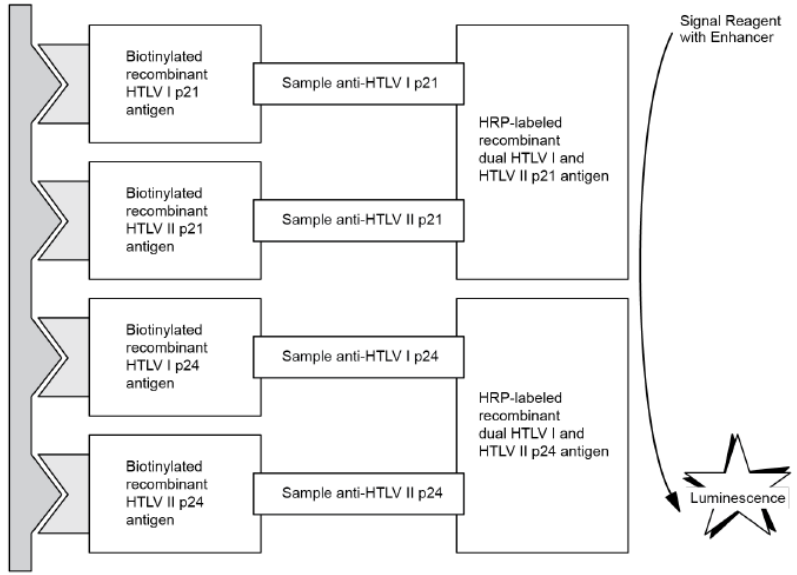
Methods

Antibody detection in VITROS Anti-HTLV is achieved using recombinant HTLV antigens coated onto the well. Sample is added to the coated wells in the first stage of the reaction and HTLV antibody from the sample is captured. After washing, HRP conjugated recombinant HTLV antigens are added. Following a final wash, bound HRP conjugates are detected using the VITROS signal reagent. The assay cut-off for VITROS Anti-HTLV is 1.00; values above the cut-off are Reactive for HTLV antibodies and values below 1.00 are Non-reactive.

Testing was performed at two sites using two reagent lots on a VITROS ECi/ECiQ Immunodiagnostic System, VITROS 3600 Immunodiagnostic System and VITROS 5600 Integrated System. Clinical sensitivity was evaluated using frozen patient samples. 434 HTLV positive samples were tested in triplicate on both VITROS Anti-HTLV and ARCHITECT rHTLV-I/II. 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 in singleton on each method. Samples that generated an initial result above the assay cut-off were retested in duplicate to determine final interpretation of result for that sample.

Data were analyzed to calculate the clinical sensitivity and clinical specificity for both methods. Discordant results were resolved by performing confirmatory testing with independent reference methods.

Assay Architecture



Clinical Sensitivity

Clinical sensitivity was evaluated using 434 HTLV positive samples tested on both VITROS Anti-HTLV and ARCHITECET rHTLV-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 rHTLV-I/II (433/434, 95% CI: 98.7-100.0%).

Sample Detection	N	CE Marked HTLV I/II Test		VITROS® HTLV I/II Test	
		Non-Reactive	Reactive	Non-Reactive	Reactive
Resolved HTLV Seropositive	434	1	433	0	434

Clinical Specificity

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 rHTLV-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 rHTLV-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 rHTLV-I/II.

Sample Detection	N	CE Marked HTLV I/II Test				VITROS® HTLV I/II Test			
		NR	IR	RR	Confirmed Positive**	NR	IR	RR	Confirmed Positive**
Blood Donor Samples	5096	5088	8	8	0	5093	4	3	0
Hospitalized Samples	207	203	4	4	3	203	4	4	3

** INNO-LIA HTLV I/II Score confirmatory test

N = Number of samples, NR = Non-reactive, IR = Initially Reactive, RR = Repeatedly Reactive

Conclusion

The VITROS Anti-HTLV I/II assay* demonstrates excellent clinical sensitivity and specificity. VITROS Anti-HTLV I/II 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.

* Product availability subject to local regulatory requirements. Not approved or cleared for US Market.

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