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

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Conflict of Interest

- Paul Contestable, Kathleen Dermody, Adrienne Eckhardt and Charles Noeson are employees of Ortho Clinical Diagnostics
- This study was sponsored by Ortho Clinical Diagnostics

Background

- HTLV is a transfusion transmitted virus that blood donations in many countries are required to be screened for prior to transfusion.
- The VITROS® Immunodiagnostic Products Anti-HTLV I/II assay (VITROS® Anti-HTLV) has been designed to detect antibodies to HTLV Types I and II.

Aims

- 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).

Methods

Test Method

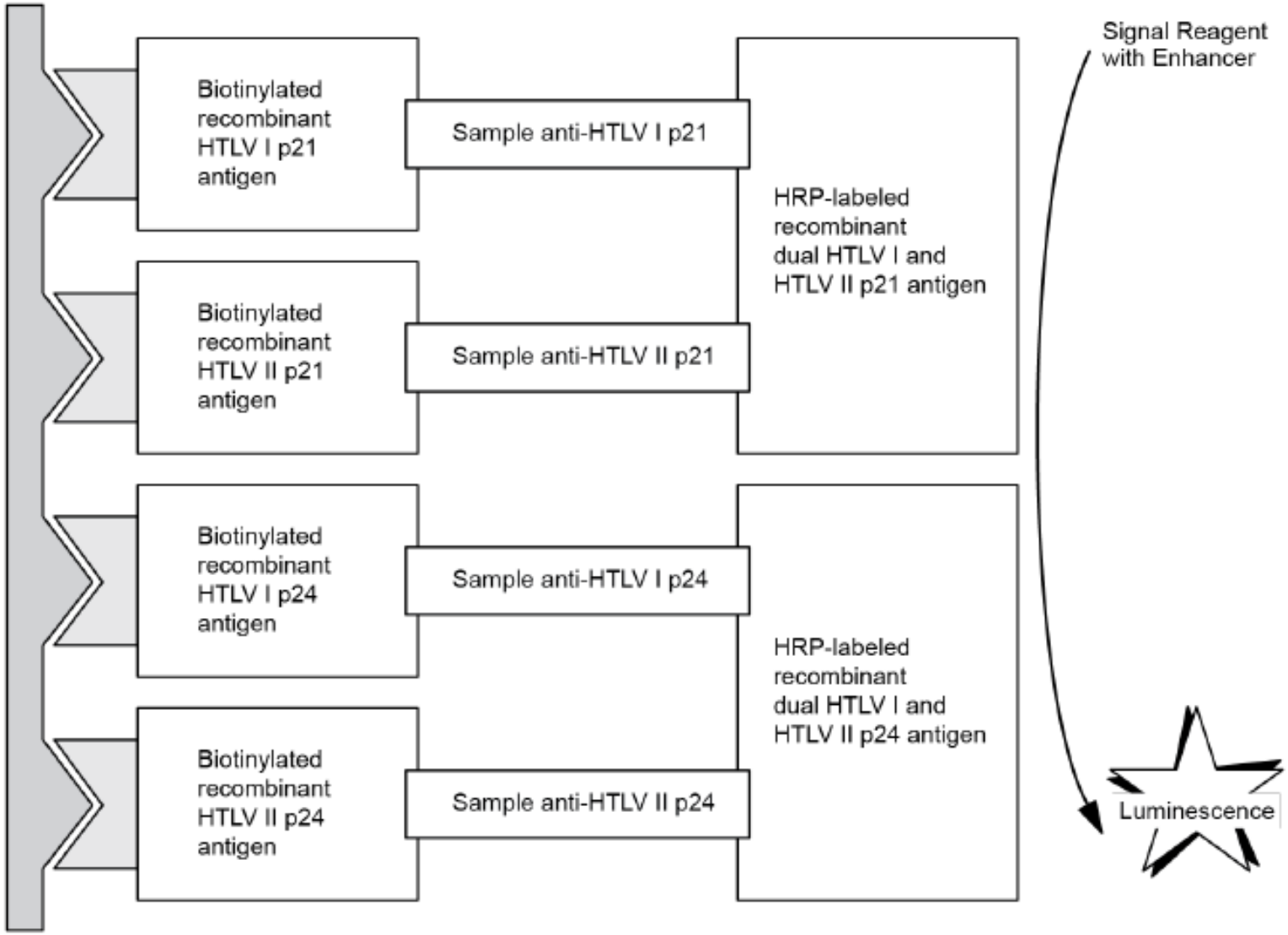
- Antibody detection in VITROS® Anti-HTLV is achieved using recombinant HTLV antigens coated onto the well.
- Sample is added to the coated wells in the first stage of the reaction, and HTLV antibody from the sample is captured.
- After washing, HRP conjugated recombinant HTLV antigens are added.
- Following 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.

Methods (cont.)

Test Algorithm

- 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 ARCHITECT 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 Description	N	CE Marked HTLV I/II Test		VITROS® HTLV I/II Test	
		Nonreactive	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 Description	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

N = Number of Samples, NR = Non-reactive, IR = Initially Reactive, RR = Repeatedly Reactive
* INNO-LIA HTLV I/II Score confirmatory test

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.