COMPARISON OF THE AVIOQ HTLV I/II MICROELISA SYSTEM TO MP DIAGNOSTICS (MPD) HTLV I/II ELISA 4.0 ASSAY FOR DETECTION OF HTLV I/II

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Abstract (revised)

Introduction: Human T-cell Lymphotropic Virus type 1 (HTLV-I) is a retrovirus that is the etiological agent of adult T-cell leukemia (ATL) and tropical spastic paraparesis (HAM/TSP). Although HTLV-II has also been linked to leukemia and neurologic disorders, it is less pathogenic than HTLV-1.In this study we compared the recently FDA approved AVIOQ HTLV I/II Microelisa System (Avioq, Rockville, MD) with the MP Diagnostics HTLV I/II ELISA 4.0 assay (MP Diagnostics, Santa Ana, CA) for the detection of anti-HTLV I and HTLV II antibodies.

Materials and Methods: Seventy four (74) de-identified patient samples that had HTLV Western blot (HTLV Blot 2.4, MP Diagnostics Santa Ana, CA) confirmatory results available were tested using the MP and Avioq HTLV immunoassays.

Results: The Avioq assay detected 100% or 31 samples confirmed positive by Western blot for HTLV-I (17), HTLV II (9) or HTLV I/II (5) infections. Of the 74 samples tested, 33 samples were positive and 36 were negative by both assays. Five (5) samples were discrepant.

Conclusions: Avioq ELISA was 100% sensitive and specific for detecting HTLV I, HTLV II and HTLV I/II infections when using the HTLV Western blot for confirmation. Overall, the Avioq ELISA assay demonstrated good performance and reproducibility.

Background

Human T-cell Lymphotropic Viruses (HTLVs) are pathogenic type C retroviruses that may cause severe hematological and neurological diseases in infected individuals. HTLV-I has been etiologically associated with neoplastic conditions and a variety of demyelinating neurologic disorders.
HTLV-I infection is highly prevalent in Japan, Africa, Caribbean islands and South America. Recent epidemiological studies in the United States and Europe confirm the presence of a mixed prevalence of both HTLV-I and HTLV-II among different high-risk populations.
This study compared the Avioq HTLV I/II Microelisa system to MP Diagnostics (MPD) HTLV I/II ELISA 4.0 (MP) assay. The Avioq HTLV I/II Microelisa system was FDA approved on March 26, 2012 for the detection of antibodies to Human T- Lymphotropic Virus Type I (HTLV-I) and/or Human T-Lymphotropic Virus Type II (HTLV-II) in human serum or plasma.

Methods/ Design

Correlation Studies:
Seventy-four samples (74) de-identified patient samples that had HTLV confirmatory Western blot (MP Diagnostics HTLV BLOT 2.4) results available were tested by both the MP and the Avioq (Avioq, Research Triangle, NC) screening immunoassays, in singlicate. Samples with initially discrepant results between the two screening assays were retested with both assays for resolution.

Precision Studies
Within-run precision was evaluated by testing 3 negative, 4 HTLV-1 positive and 4 HTLV-2 positive samples in triplicate on one analytical run or ELISA plate.
Between run precision was evaluated by testing the same 11 samples in duplicate on four consecutive analytical runs.

Results

- All HTLV Western blot positive samples (n=31) were positive by Avioq.
- All HTLV Western blot negative samples (n=36) were negative by Avioq.
- Three (3) of the twenty five (25) samples that were indeterminate (ind) or non-specific staining (nss) by MP HTLV blot were positive by Avioq. Twenty two (22) were negative by Avioq.
- There were 5 discrepant samples between the Avioq and MP ELISA results, all were positive by MP and negative by Avioq. The HTLV Western blot results for the 5 discrepant samples:2 were negative, 2 indeterminate, and 1 non-specific staining (table 2).

Table 1: Concordance between Avioq and MP ELISA

74 Samples Tested		Avioq	
		Positive	Negative
MP	Positive	33	5
	Negative	0	36

Table 2: Western blot results for samples with discrepant ELISA results.

	Avioq		MP		MP HTLV Blot 2.4 pattern									WB
Sample	Qualitative	S/C	Qualitative	S/CO	p24	p26	p28	p32	p36	gp46	p53	rgp 46-II	rgp 46-I	result
HTLV-014	neg	0.5	pos	2.07	0	0	0	0	0	0	0	0	0	neg
HTLV-015	neg	0.21	pos	5.59	0	0	0	0	0	0	0	0	0	neg
HTLV-029	neg	0.18	pos	5.26	1	X	X	X	X	X	X	+/-	X	ind
HTLV-030	neg	0.49	pos	2.01	1	0	0	0	0	0	0	0	0	ind
HTLV-039	neg	0.11	pos	6.23	X	X	X	X	X	X	X	X	X	nss

WB explanation:
A positive result is defined by the presence of antibodies to two gene products (gag, p19 and/or p24 and env, gp46 and/or 61/68). There are 11 HTLV bands possible within the reading frame and all must be given a score. Each band is scored with an intensity of. 0 = absent, 1 = weak positive, 2 = strong positive, X = non-specific staining is potentially masking the band, +/- = the intensity of the band is present, but weaker than control band.

Fig. 1: Signal to Cutoff (S/CO) Correlation between Avioq and MP ELISA assay results.

The red lines indicate the cutoff S/CO for reporting a negative or positive result.

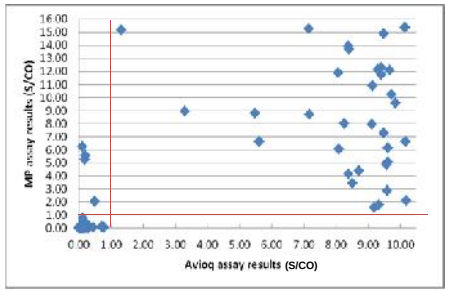
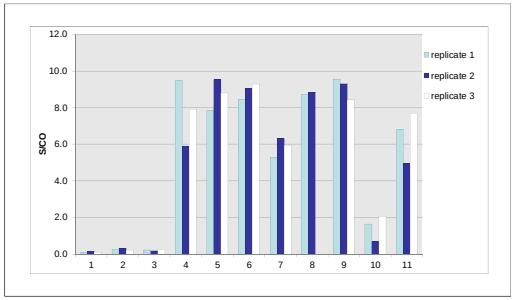
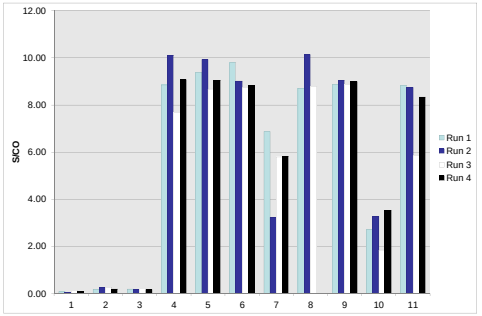


Fig. 2 : With-in run precision studies of Avioq HTLV samples.



CVs of within-run S/COs of positive samples ranged from 1.0 to 48.3%, average is 15.5%.

Fig. 3: Between run precision for the Avioq HTLV ELISA.



CVs of between-run S/COs of positive samples ranged from 1.1 to 33.7%, average is 13.4%.

Conclusions

Avioq ELISA was 100% sensitive and specific for detecting HTLV I, HTLV II and HTLV I/II infections when using the HTLV Western blot for confirmation. Overall, the Avioq ELISA assay demonstrated good performance and reproducibility.