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-I. In this study we compared the recently FDA approved AVIOQ HTLV I/II Microelisa System (Avioq, Rockville, MD) with the MP Diagnostics HTLV 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% of 31 patient samples confirmed positive by Western blot for HTLV I (17), HTLV II (9) or HTLV III (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 III infections when using the HTLV Western blot for confirmation. Overall, the Avioq ELISA assay demonstrated good performance and reproducibility.

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 retested using the HTLV Western blot for positive or negative results.

Precision Studies

Within-run precision was evaluated by testing 3 replicates of each HTLV I, II samples with discrepant staining (table 2).

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 (rss) 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 were negative, 2 indeterminate, and 1 non specific staining (table 2).

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 epidemiologically 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 II Microelisa system to MP Diagnostics (MPD) HTLV III ELISA 4.0 (MP) assay. The Avioq HTLV III 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.

Table 1: Concordance between Avioq and MP ELISA

<table>
<thead>
<tr>
<th>Sample</th>
<th>Avioq</th>
<th>MP</th>
<th>ELISA 4.0</th>
</tr>
</thead>
<tbody>
<tr>
<td>74 Samples Tested</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Positive</td>
<td>34</td>
<td>33</td>
<td>0</td>
</tr>
<tr>
<td>Negative</td>
<td>0</td>
<td>5</td>
<td>36</td>
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</table>

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

<table>
<thead>
<tr>
<th>Sample</th>
<th>Avioq</th>
<th>MP</th>
<th>HTLV Blot 2.4 pattern</th>
<th>WB</th>
</tr>
</thead>
<tbody>
<tr>
<td>I/II</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HTLV I</td>
<td>F1-02</td>
<td>F1-02</td>
<td>F1-02</td>
<td>F1-02</td>
</tr>
<tr>
<td>HTLV II</td>
<td>F2-02</td>
<td>F2-02</td>
<td>F2-02</td>
<td>F2-02</td>
</tr>
</tbody>
</table>

CVs of within-run S/CoS of positive samples ranged from 1.0 to 34.8%, average is 13.4%.

Conclusions

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