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**Materials and Methods**

**Assay design**

The LIAISON® XL MUREX recHTLV-I/II assay uses two steps chemiluminescence immunoassay (CLI A) technology for the qualitative determination of specific antibodies to Human T-cell Lymphotropic Virus (HTLV) type I and type II in human serum or plasma samples. This assay use a recombinant antigen (gp21) specific for transmembrane region of HTLV-I/II and two synthetic peptides (gp46) specific for outer envelope region of HTLV-I or HTLV-II (Fig 1a and 1b).

**Specimens**

During a 2 weeks period, all unselected serum samples (N=663) submitted to the laboratory for HTLV testing were examined by LIAISON® XL murex recHTLV-I/II assay. These samples were mainly provided from couples requesting inclusion in an assisted fertility program, donor’s organs and patients from French Overseas Departments (Martinique, Guadeloupe and French Guyana).

Samples that were discordant were tested by INNO-LIA HTLV I/II Score (Fujirebio Europe N.V, Gent, Belgium), a line immunoassay using antigens derived from HTLV I and HTLV II immunodominant proteins, for confirmation. Sensitivity was evaluated using 49 frozen HTLV-I positive serum specimens (confirmed by Immunoblot INNO-LIA HTLV I/II Score).

**Results**

Among 663 routine samples, 658 samples were negative with ARCHITECT and LIAISON® XL. 5 and 3 samples were reactive with ARCHITECT and LIAISON® XL respectively. The results are summarized in the following table 1. >>>

<table>
<thead>
<tr>
<th>LIAISON® XL murex recHTLV-I/II</th>
<th>ARCHITECT rHTLV- I/II</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>3</td>
</tr>
<tr>
<td>Negative</td>
<td>2</td>
</tr>
<tr>
<td>Total</td>
<td>5</td>
</tr>
</tbody>
</table>

Table 1: Results of Immunoblot INNO-LIA.

In addition, all 49 positive HTLV-I samples were detected by both assays.

**Conclusions**

The HTLV assay performance of LIAISON® (120 - 171 tests/h) and ARCHITECT (100 tests/h) were equivalent. LIAISON® XL murex recHTLV-I/II assay demonstrated very good specificity and sensitivity. It was appropriate for the large-scale screening of samples for HTLV-1/2 antibodies.