INTERPRETATION INFORMATION SHEET

Human T-Cell Lymphotropic Virus (HTLV) Serology

**Anti-HTLV-I/II ChLIA:** This chemiluminescent assay detects antibodies to HTLV-I and antibodies to HTLV-II as an aid in prevention of HTLV infection through transfusion. It does not discriminate between HTLV-I and HTLV-II antibodies. Additional supplemental testing may be performed for donor counseling purposes.

**Anti-HTLV-I/II EIA:** This enzyme immunoassay detects antibodies to HTLV-I and antibodies to HTLV-II as an aid in prevention of HTLV infection through transfusion. It does not discriminate between HTLV-I and HTLV-II antibodies. Additional supplemental testing may be performed for donor counseling purposes.

**MP Diagnostics HTLV Blot 2.4 Western blot assay:** This qualitative enzyme immunoassay is intended for confirming the presence of and differentiating antibodies to HTLV-I and HTLV-II in human serum and plasma. It is intended for use as a supplemental (additional, more specific) test for human serum and plasma samples with repeatedly reactive results by an FDA licensed HTLV-I/II donor screening test. This Western blot assay uses a combination of HTLV-I/II genetically engineered proteins (i.e., recombinant antigens) and HTLV-I viral proteins derived from native, inactivated viral particles (i.e., viral lysate). HTLV-I and HTLV-II differentiation is accomplished through the use of rgp46-I (a unique HTLV-I recombinant envelope protein) and rgp46-II (a unique HTLV-II recombinant envelope protein).

Interpretation of results is based on the presence or absence of reactivity with the major HTLV-I and HTLV-II gene products on each individual test strip. A sample control band is included on each test strip and must be reactive for results to be considered valid.

**HTLV-I Positive:**
*(Note: The non-major gag proteins (p26, p28, p32, p36, p53) may or may not be present and are not utilized in determining HTLV-I seropositivity)*

- Reactivity to p19, GD21 **and** rgp46-I; OR
- Reactivity to p19, p24 **and** GD21 (without rgp46-I), with reactivity to p19 which must be greater than or equal to reactivity of p24*

**HTLV-II Positive:**
*(Note: The non-major gag proteins (p26, p28, p32, p36, p53) may or may not be present and are not utilized in determining HTLV-II seropositivity)*

- Reactivity to p24, GD21 **and** rgp46-II; OR
- Reactivity to p19, p24 **and** GD21 (without rgp46-II), with reactivity to p24 which must be greater than the reactivity of p19*

**HTLV-I/II Positive:**
*(Note: The non-major gag proteins (p26, p28, p32, p36, p53) may or may not be present and are not utilized in determining HTLV-I/II seropositivity)*

- Reactivity to GD21, p19, p24, rgp46-I **and** rgp46-II
Indeterminate:
- Reactivity to HTLV specific bands that do not meet the criteria for HTLV-I positive, HTLV-II positive, HTLV-I/II positive or negative.

Negative:
- No reactivity to HTLV specific proteins; or
- Any combination of gag proteins excluding p24 (p19, p26, p28, p32, p36, p53); or
- Any single gag protein other than p19 or p24 (p26, p28, p32, p36, p53)

Unreadable:
- When the background is as dark or darker than the control band used to determine +/- reactivity, the laboratory cannot distinguish if there might be viral bands present.
- If a result cannot be interpreted due to background color development, the test is considered invalid and a fresh sample should be obtained for repeat HTLV antibody testing.
- In this case, the test result is reported as unreadable.

*In situations where relative reactivity of p19 and p24 is required for final interpretation, graded results will be noted as ++ instead of + for applicable protein bands.

### Interpretation Table

<table>
<thead>
<tr>
<th>HTLV-I/II EIA or ChLIA</th>
<th>MP HTLV Blot 2.4</th>
<th>Most likely interpretation</th>
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</thead>
<tbody>
<tr>
<td>Reactive</td>
<td>Positive</td>
<td>- HTLV antibody present, indicative of HTLV infection&lt;br&gt;- Recommend referral to physician&lt;br&gt;- Donor specimens interpreted as positive using +/- bands only should be retested using a fresh sample to confirm infection due to potential cross reactivity with higher levels of hemoglobin or from interfering medical conditions such as HIV, hemophilia and Sjogren's disease.</td>
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<tr>
<td>Reactive</td>
<td>Indeterminate</td>
<td>- May or may not be indicative of presence of HTLV antibodies&lt;br&gt;- Reactivity to any of the HTLV critical antigens in the strip (i.e., p19, p24, GD21, rgp46-II, and rgp46-I) is possible evidence of infection with HTLV.&lt;br&gt;- Individuals with indeterminate results should be followed to ascertain whether increased reactivity is demonstrated.</td>
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<tr>
<td>Reactive</td>
<td>Negative</td>
<td>- A seronegative result using the HTLV Blot 2.4 may be due to levels of anti-HTLV below the limit of detection in this assay; levels of anti-HTLV may be undetectable in early infection.&lt;br&gt;- A specimen that is reactive by a licensed HTLV screening test and seronegative by the HTLV Blot 2.4 does not exclude the possibility of infection with HTLV.</td>
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</tbody>
</table>

### References:
- Abbott Prism HTLV-I/HTLV-II, Instructions for use
- Avioq HTLV-I/II Microelisa System, Instructions for use
- MP Diagnostics HTLV Blot 2.4 Western blot assay, Instructions for use

### Revision History

<table>
<thead>
<tr>
<th>Revision</th>
<th>Implemented</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Rev 2</td>
<td>05/17/2016</td>
<td>Implementation of MP HTLV Blot 2.4</td>
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<tr>
<td>Initial Release</td>
<td>05/01/2013</td>
<td>Revision History added</td>
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HTLV-INT REV 2