

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

HTLV-I/II EIA or ChLIA	MP HTLV Blot 2.4	Most likely interpretation
Reactive	Positive	<ul style="list-style-type: none"> ▪ HTLV antibody present, indicative of HTLV infection ▪ Recommend referral to physician ▪ 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.
Reactive	Indeterminate	<ul style="list-style-type: none"> ▪ May or may not be indicative of presence of HTLV antibodies ▪ 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. ▪ Individuals with indeterminate results should be followed to ascertain whether increased reactivity is demonstrated.
Reactive	Negative	<ul style="list-style-type: none"> ▪ 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. ▪ 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.

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

Revision	Implemented	Reason
Rev 2	05/17/2016	Implementation of MP HTLV Blot 2.4
Initial Release	05/01/2013	Revision History added