

Blood Systems Laboratories

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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. BSI performs an alternate manufacturer's licensed anti-HTLV-I/II EIA on all samples that test repeatedly reactive by the primary anti-HTLV-I/II test.

Anti-HTLV-I/II EIA: This enzyme-linked immunoassay (EIA) detects antibodies to HTLV-I and antibodies to HTLV-II.

Samples reactive by both anti-HTLV-I/II tests may be analyzed using a more specific supplemental assay.

Anti-HTLV-I/II Supplemental Assay: The InnoLIA HTLV-I/II Score assay detects and differentiates antibodies directed against HTLV-I and HTLV-II in human serum or plasma. This strip immunoblot assay uses recombinant and synthetic HTLV-I and HTLV-II proteins fixed to a nitrocellulose strip. Specific HTLV antibodies present in a specimen bind to these proteins and are subsequently detected using an enzyme immunoassay technique. Interpretation of results is based on the strength and pattern of reactivity with the HTLV proteins on the strip (see below). This test is not licensed by the FDA and is not for use in diagnostic procedures. Results are provided for investigational and research purposes only but may provide additional information for counseling of individuals with a repeat reactive screening assay.

Confirmation of HTLV antibody is determined using four HTLV proteins (p19 I/II, p24 I/II, gp46 I/II, and gp21 I/II). A streptavidin control is included on each test strip to monitor non-specific reactivity and must be nonreactive for results to be considered valid.

Positive: At least two bands (including p21 I/II) are reactive (greater than or equal to +/-)

OR

Three bands are reactive

NOTE: See below for differentiation and description of results reported for positive samples.

- Indeterminate:** Two bands (excluding p21 I/II) are reactive
OR
The p21 I/II band alone is reactive
- Negative:** No bands are reactive
OR
A single band (excluding p21 I/II) is reactive
- Invalid:** Streptavidin control band is reactive
- 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. In this case, the test is considered unreadable.

Differentiation between HTLV-I and HTLV-II antibody is determined using three discrimination proteins (gp46-I, p19-I, and gp46-II) and is based on the combined intensities of the reactivity for these three proteins. Only samples with an interpretation of Positive will be evaluated for discrimination between HTLV-I and HTLV-II.

HTLV-I Positive: Reactivity of gp46-I and p19-I is greater than gp46-II

HTLV-II Positive: Reactivity of gp46-I and p19-I is less than or equal to gp46-II
AND
GP46-II is greater than gp46-I

HTLV Positive – Untypable: Reactivity does not meet criteria for HTLV-I or HTLV-II

A positive result for this test is indicative of the presence of HTLV antibody. An indeterminate result may or may not indicate the presence of HTLV antibody and followup evaluation may be appropriate.

References:

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