Test Definition: HTLVL

Human T-Cell Lymphotropic Virus Types I and II (HTLV-I/-II) Antibody Confirmation, Serum

Overview

Useful For

Confirmatory detection of human T-cell lymphotropic virus types I and II (HTLV-I and HTLV-II)-specific IgG antibodies in human serum specimens that are consistently reactive by initial screening tests

Differentiating between HTLV-I- and HTLV-II-specific IgG antibodies

Method Name

Line Immunoassay (LIA)

NY State Available

Yes

Specimen

Specimen Type

Serum SST

Ordering Guidance

This confirmatory assay should be ordered only on serum specimens that are consistently reactive by an antihuman T-cell lymphotropic virus 1 and 2 (anti-HTLV-I/-II) screening immunoassay. For an evaluation that includes screening and confirmation, order HTLVI / Human T-Cell Lymphotropic Virus Types I and II Antibody Screen with Confirmation, Serum.

For testing spinal fluid specimens, order HTLLC / Human T-Cell Lymphotropic Virus Types 1 and 2 (HTLV-1/-2) Antibody Confirmation, Spinal Fluid.

Necessary Information

Date of collection is required.

Specimen Required

Supplies: Sarstedt Aliquot Tube, 5 mL (T914)
Collection Container/Tube: Serum gel
Submission Container/Tube: Plastic vial
Specimen Volume: 0.5 mL Serum
Collection Instructions:
1. Centrifuge blood collection tube per collection tube manufacturer's instructions (eg, centrifuge and aliquot within 2 hours of collection for BD Vacutainer tubes).
2. Aliquot serum into plastic vial.

Forms

If not ordering electronically, complete, print, and send Infectious Disease Serology Test Request (T916) with the specimen.

Specimen Minimum Volume

Serum: 0.2 mL

Reject Due To

Gross hemolysis	OK
Gross lipemia	OK
Gross icterus	OK

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum SST	Frozen (preferred)		
	Refrigerated	7 days	

Clinical & Interpretive

Clinical Information

Human T-cell lymphotropic virus types I and II (HTLV-I and HTLV-II) are closely related exogenous human retroviruses. HTLV-I was first isolated in 1980 from a patient with a cutaneous T-cell lymphoma, while HTLV-II was identified from a patient with hairy cell leukemia in 1982.

Human T-cell lymphotropic virus type I infection is endemic in southwestern Japan, the Caribbean basin, Melanesia, and parts of Africa, where HTLV-I seroprevalence rates are as high as 15% in the general population. In the United States, the combined HTLV-I and HTLV-II seroprevalence rate is about 0.016% among voluntary blood donors. About half of these infected blood donors are infected with HTLV-I, with most of them reporting a history of birth in HTLV-I-endemic countries or sexual contact with persons from the Caribbean or Japan. Smaller percentages report a history of either injection drug use or blood transfusion. Transmission of HTLV-I occurs from mother to fetus, sexual contact, blood transfusion, and sharing of contaminated needles. Two diseases are known to be caused by HTLV-I infection: adult T-cell leukemia or lymphoma and a chronic degenerative neurologic disease known as HTLV-I-associated myelopathy or tropical spastic paraparesis. Cases of polymyositis, chronic arthropathy, panbronchiolitis, and uveitis have also been reported in patients infected with HTLV-I.

Human T-cell lymphotropic virus type II is prevalent among injection drug users in the United States and Europe. More than 80% of HTLV infections in drug users in the United States are due to HTLV-II. HTLV-II also appears to be endemic in Native American populations, including the Guaymi in Panama and Native Americans in Florida and New Mexico. HTLV-II-infected blood donors most often report either a history of injection drug use or a history of sexual contact with an injection drug user. A smaller percentage of infected individuals report a history of blood transfusion. HTLV-II is

transmitted similarly to HTLV-I, but much less is known about the specific modes and efficiency of transmission of HTLV-II. The virus can be transmitted by transfusion of cellular blood products (whole blood, red blood cells, and platelets). HTLV-II infection has been associated with hairy-cell leukemia, but definitive evidence is lacking on a viral etiologic role. HTLV-II has also been linked with neurodegenerative disorders characterized by spastic paraparesis and variable degrees of ataxia.

Infection by these viruses results in the appearance of specific antibodies against the viruses that can be detected by serologic tests, such as enzyme immunoassay. For accurate diagnosis of HTLV-I or HTLV-II infection, all initially screening test-reactive results should be verified by a confirmatory test, such as Western blot or line immunoassay.

Reference Values

Negative

Interpretation

Negative confirmatory test results indicate the absence of both human T-cell lymphotropic virus types I and II (HTLV-I and HTLV-II)-specific IgG antibodies in serum.

A reactive screening (enzyme immunoassay) result with a negative or indeterminate confirmatory (line immunoassay) test result suggests either a false-reactive screening test result or a seroconverting HTLV infection. Repeat testing with a new specimen can clarify the final infection status. Persistently indeterminate confirmatory test results indicate absence of HTLV infection.

Positive results for HTLV-I antibodies indicate the confirmed presence of HTLV-I IgG antibodies in serum, based on 2 visible antibody bands that include gp21-I/-II band, or 3 or more bands, and the sum of the gp46-I and p19-I band intensity is greater than the gp46-II band intensity.

Positive results for HTLV-II antibodies indicate the confirmed presence of HTLV-II IgG antibodies in serum, based on 2 visible antibody bands that include gp21-I/-II band, or 3 or more bands, and the gp46-II band intensity is a) greater than the gp46-I band intensity and b) greater than or equal to the sum of the gp46-I and p19-I band intensity.

Indeterminate results indicate the presence of gp21-I/-II band only or combination of any 2 bands without a detectable gp21-I/-II band. Patients with indeterminate test results with known risk factors for HTLV-I or HTLV-II infection should undergo repeat confirmatory antibody testing with a new specimen to determine final infection status.

Differentiation of HTLV-I and HTLV-II infection is not possible (ie, nontypeable HTLV antibodies) when the band intensity pattern does not meet the criteria of positive HTLV-I or HTLV-II antibody band intensity pattern.

Unreadable results indicate the presence of nonspecific background reactivity that is inhibiting the visualization of specific bands on the test strip. Repeat testing with a new specimen is recommended.

Invalid results indicate that nonspecific band reactivity is present. Submit another serum specimen for retesting if clinically indicated.

Cautions

A negative line immunoassay result does not preclude the possibility of exposure to human T-cell lymphotropic virus

types I and II.

Results from this confirmatory assay should always be interpreted together with the reactive screening test result on a given specimen.

Clinical Reference

1. Gessain A, Mahieux R. Tropical spastic paraparesis and HTLV-I associated myelopathy: clinical, epidemiological, virological, and therapeutic aspects. Rev Neurol (Paris). 2012;168(3):257-269. doi:10.1016/j.neurol.2011.12.006
2. Mahieux R, Gessain A. Adult T-cell leukemia/lymphoma and HTLV-I. Curr Hematol Malig Rep. 2007;2(4):257-264. doi:10.3390/v8060161
3. Yamano Y, Sato T. Clinical pathophysiology of human T-lymphotropic virus-type I-associated myelopathy/tropical spastic paraparesis. Front Microbiol. 2012;3:389. doi:10.3389/fmicb.2012.00389
4. Marrero Rolon RM, Yao JDC. Laboratory diagnosis of HTLV-1-associated myelopathy. Clin Microbiol Newslett. 2020;42(16)129-134. doi:10.1016/j.clinmicnews.2020.07.004

Performance

Method Description

INNO-LIA HTLV I/II Score is a line immunoassay based on the enzyme immunoassay principle. The assay uses well-defined antigens derived from human T-cell lymphotropic virus types 1 and 2 (HTLV-1 and HTLV-2) immunodominant proteins. The antigens used are either recombinant proteins or synthetic peptides, highly purified and fixed on a nylon membrane strip. The sequences are selected to allow the detection of antibodies with a wide specificity to all known isolates of the HTLV strains. The antigenicity exhibited by these proteins and peptides is either common to both HTLV-1 and HTLV-2, or type-specific to 1 of the 2 viruses to allow confirmation and discrimination in a single assay. Two *gag* (p19-I/II, p24-I/II) and 2 *env* (gp46-I/II, gp21-I/II) bands are applied as non-type-specific antigens, which are used to confirm the presence of antibodies against HTLV-1/2. The type-specific antigens for HTLV-1 (*gag* p19-I, *env* gp46-I) and for HTLV-2 (*env* gp46-II) are applied to differentiate between HTLV-1 and HTLV-2 infections. In addition, 4 control lines are coated: 1 negative control (streptavidin), and 3 positive control lines: a strong (antihuman IgG), a moderate (human IgG), and a weak (human IgG) line.

A test sample is incubated in a test trough together with the multiple antigen-coated strip. Specific HTLV antibodies, if present in the sample, will bind to the HTLV antigen lines on the strip. Subsequently, goat-antihuman IgG labeled with alkaline phosphatase is added and will bind to any HTLV antigen-antibody complex previously formed. Incubation with a chromogenic substrate produces a dark brown color in proportion to the amount of specific antibodies present in the sample. The color development is stopped with sulfuric acid. If the sample contains no HTLV-specific antibodies, only a low background color develops.(Unpublished Mayo method)

PDF Report

No

Day(s) Performed

Tuesday

MAYO CLINIC LABORATORIES

Test Definition: HTLVL

Human T-Cell Lymphotropic Virus Types I and II (HTLV-I/-II) Antibody Confirmation, Serum

Report Available
2 to 15 days

Specimen Retention Time
14 days

Performing Laboratory Location
Mayo Clinic Laboratories - Rochester Superior Drive

Fees & Codes

Fees
- Authorized users can sign in to Test Prices for detailed fee information.
- Clients without access to Test Prices can contact Customer Service 24 hours a day, seven days a week.
- Prospective clients should contact their account representative. For assistance, contact Customer Service.

Test Classification
This test was developed and its performance characteristics determined by Mayo Clinic in a manner consistent with CLIA requirements. It has not been cleared or approved by the US Food and Drug Administration.

CPT Code Information
86689

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
HTLVL	HTLV-I/-II Ab Confirmation, S	55162-2

Result ID	Test Result Name	Result LOINC® Value
83277	HTLV-I/-II Ab Confirmation, S	22362-8
23898	HTLV-I/-II Bands	61112-9
23899	HTLV-I/-II Discrimination	77744-1