MAYO CLINIC LABORATORIES

Test Definition: HTLVI

Human T-Cell Lymphotropic Virus Types I and II Antibody Screen with Confirmation, Serum

Overview

Useful For

Qualitative detection of human T-cell lymphotropic virus types I and II (HTLV-I and HTLV-II)-specific antibodies with confirmation and differentiation between HTLV-I and HTLV-II infection

This test **should not be used** to screen blood, human cells, tissues, or solid-organ donors.

This test is **not intended fo**r use on cord blood specimens.

Reflex Tests

Test Id	Reporting Name	Available Separately	Always Performed
HTLVL	HTLV-I/-II Ab Confirmation, S	Yes	No

Testing Algorithm

If the human T-cell lymphotropic virus types I and II (HTLV-I/-II) antibody screen is reactive, then HTLV-I/-II antibody confirmation by line immunoassay will be performed at an additional charge.

Method Name

Enzyme Immunoassay (EIA)

NY State Available

Yes

Specimen

Specimen Type

Serum

Ordering Guidance

This test is for serum specimens only. For spinal fluid specimens, order HTLVC / Human T-Cell Lymphotropic Virus Types 1 and 2 (HTLV-1/-2) Antibody Screen with Confirmation, Spinal Fluid.

Necessary Information

Date of collection is required.

Specimen Required

Supplies: Sarstedt Aliquot Tube, 5 mL (T914)

Collection Container/Tube:
Preferred: Serum gel
Acceptable: Red top
Submission Container/Tube: Plastic vial
Specimen Volume: 1 mL Serum
Collection Instructions:
1. Centrifuge blood collection tube per collection tube manufacturer's instructions (eg, centrifuge within 2 hours of collection for BD Vacutainer tubes).
2. Aliquot serum into plastic vial.

Forms

If not ordering electronically, complete, print, and send 1 of the following forms with the specimen:
-Kidney Transplant Test Request
-Infectious Disease Serology Test Request (T916)

Specimen Minimum Volume

Serum: 0.6 mL

Reject Due To

Gross hemolysis	Reject
Gross lipemia	Reject
Gross icterus	Reject
Precipitated specimens	Reject
Heat-treated specimens	Reject

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum	Frozen (preferred)	28 days	
	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 also have been reported in patients with a HTLV-I infection.

In the United States and Europe, HTLV-II is prevalent among persons who inject drugs (PWID). In the United States, over 80% of HTLV infections in drug users are due to HTLV-II. HTLV-II appears to be endemic in American indigenous populations, including the Guaymi tribe 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 a PWID. 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 screening 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 test result is suggestive of infection with either HTLV-I or HTLV-II. However, this result does not confirm infection (eg, low specificity), and it cannot differentiate between HTLV-I and HTLV-II infection.

Specimens with reactive screening test results will be tested automatically by the line immunoassay (LIA) confirmatory test. Positive LIA results provide confirmatory evidence of infection with HTLV-I or HTLV-II.

A reactive screening result with a negative or indeterminate confirmatory test result suggests either a false-reactive screening test result or a seroconverting HTLV infection. Repeat testing in 1 to 2 months can clarify the final infection status. Persistently indeterminate confirmatory test results indicate absence of HTLV infection.

Cautions

A negative test result does not exclude the possibility of exposure to human T-cell lymphotropic virus types I and II. Levels of total antibodies to these viruses may be undetectable in early infection.

Performance characteristics have not been established for the following specimen characteristics:
-Grossly icteric (total bilirubin level of >20 mg/dL)
-Grossly lipemic (triolein level of >3000 mg/dL)
-Grossly hemolyzed (hemoglobin level of >3051 mg/dL)
-Containing particulate matter
-Cadaveric specimens

Clinical Reference

1. Yamano Y, Sato T. Clinical pathophysiology of human T-lymphotropic virus-type I-associated myelopathy/tropical spastic paraparesis. Front Microbiol. 2012;3:389
2. 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
3. Marrero Rolon RM, Yao JDC. Laboratory diagnosis of HTLV-1-associated myelopathy. Clin Microbiol Newsl. 2020;42(16):129-134. doi:10.1016/j.clinmicnews.2020.07.004

Performance

Method Description

The Avioq HTLV-I/II Microelisa System is an enzyme-linked immunosorbent assay in which the solid phase (microwells) is coated with a purified human T-cell lymphotropic virus types I (HTLV-I) viral lysate, a purified HTLV-II viral lysate, and a recombinant HTLV-I p21E antigen. With the addition of a diluted test sample containing antibodies to either HTLV-I or HTLV-II, complexes are formed by the interaction of the antibodies in the sample and the solid phase antigens. Following incubation, the sample is aspirated and the well is washed with buffer. Subsequently, antihuman immunoglobulin (goat) conjugated with horseradish peroxidase is added, which binds the antibody-antigen complex during a second incubation. Following a wash and incubation with TMB (tetramethylbenzidine) substrate, a blue color is produced. The enzyme reaction is stopped by the addition of a sulfuric acid solution, which changes the color to yellow. The amount of HTLV-I / HTLV-II specific antibodies present in the sample is proportional to the color intensity.(Package insert: Avioq HTLV-I/II Microelisa System. Avioq, Inc; 03/2024)

PDF Report

No

Day(s) Performed

Monday, Tuesday, Thursday, Friday

Report Available

1 to 4 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 has been cleared, approved, or is exempt by the US Food and Drug Administration and is used per manufacturer's instructions. Performance characteristics were verified by Mayo Clinic in a manner consistent with CLIA requirements.

CPT Code Information

86790
86689 (if appropriate)

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
HTLVI	HTLV-I/-II Ab Screen, S	29901-6

Result ID	Test Result Name	Result LOINC® Value
9539	HTLV-I/-II Ab Screen, S	29901-6