

## 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 is **not intended for** screening blood, human cells, tissues, or solid-organ donors.

This test is **not intended for** 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 this screen is reactive, then 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, 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

**Collection Container/Tube:**

**Preferred:** Serum gel

**Acceptable:** Red top

**Submission Container/Tube:** Plastic vial

**Specimen Volume:** 1 mL

**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.

**Specimen Minimum Volume**

0.6 mL

**Reject Due To**

Gross hemolysis	Reject
Gross lipemia	Reject
Gross icterus	Reject
Heat-treated or precipitated specimens	Reject

**Specimen Stability Information**

Specimen Type	Temperature	Time	Special Container
Serum	Frozen (preferred)	28 days	
	Refrigerated	7 days	

**Clinical and 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.

HTLV-I infection is endemic in southwestern Japan, 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 HTLV-I-infected patients.

HTLV-II is prevalent among injection drug users in the United States and in Europe, and over 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 Indians 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

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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 (EIA). 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

This test is not offered as a screening or confirmatory test for serum specimens from blood, human cells, tissues, or solid organ donors.

A negative test result does not exclude the possibility of exposure to human T-cell lymphotropic virus types I and II (HTLV-I or HTLV-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. Araujo A, Hall WW: Human T-lymphotropic virus type II and neurological disease. *Ann Neurol.* 2004;56(1):10-19
2. Mahieux R, Gessain A: Adult T-cell leukemia/lymphoma and HTLV-I. *Curr Hematol Malig Rep.* 2007;2(4):257-264
3. Yamano Y, Sato T: Clinical pathophysiology of human T-lymphotropic virus-type I-associated myelopathy/tropical

spastic paraparesis. Front Microbiol. 2012;3:1-10

4. 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

## 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 (HRP) 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; 05/2019)

### PDF Report

No

### Day(s) Performed

Monday through Friday

### Report Available

1 to 4 days

### Specimen Retention Time

14 days

### Performing Laboratory Location

Rochester

## Fees and 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 Regional Manager. 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)

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**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