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

<table>
<thead>
<tr>
<th>Test ID</th>
<th>Reporting Name</th>
<th>Available Separately</th>
<th>Always Performed</th>
</tr>
</thead>
<tbody>
<tr>
<td>HTLVL</td>
<td>HTLV-I/-II Ab Confirmation, S</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

Testing Algorithm
If human T-cell lymphotropic virus types I and II (HTLV-I/-II) antibodies by EIA are 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

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**

<table>
<thead>
<tr>
<th>Gross hemolysis</th>
<th>Reject</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gross lipemia</td>
<td>Reject</td>
</tr>
<tr>
<td>Gross icterus</td>
<td>Reject</td>
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</tbody>
</table>

**Specimen Stability Information**

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
<th>Special Container</th>
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<tbody>
<tr>
<td>Serum</td>
<td>Frozen (preferred)</td>
<td>28 days</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Refrigerated</td>
<td>7 days</td>
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</table>

**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 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 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**

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 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 immunoglobulins (goat) conjugated with horseradish peroxidase (HRP) are added, which bind 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 / or HTLV-II specific antibodies present in the sample is proportional to the color intensity. (Package insert: Avioq HTLV-I/II Microelisa System, Avioq, Inc., Research Triangle Park, NC, June 2017)

PDF Report
No

Day(s) and Time(s) Test Performed
Monday through Friday; Varies

Analytic Time
1 day

Maximum Laboratory Time
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 or approved by the U.S. 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

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<td>HTLV-I/-II Ab Screen, S</td>
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<th>Test Result Name</th>
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<td>9539</td>
<td>HTLV-I/-II Ab Screen, S</td>
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