**Overview**

**Useful For**
Qualitative screening detection of human T-cell lymphotropic virus types 1 and 2 (HTLV-1 and HTLV-2)-specific antibodies with confirmation and differentiation between HTLV-1 and HTLV-2 infection

**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>HTLLC</td>
<td>HTLV-1/-2 Ab Confirmation, CSF</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

**Testing Algorithm**
If human T-cell lymphotropic virus types 1 and 2 (HTLV-1/-2) antibody by EIA is reactive, then HTLV-1/-2 antibody confirmation by line immunoassay (LIA) will be performed at an additional charge.

**Method Name**
Enzyme Immunoassay (EIA)

**NY State Available**
Yes

**Specimen**

**Specimen Type**
CSF

**Specimen Required**

- **Collection Container/Tube:** Sterile vial

**Specimen Volume:** 1 mL

**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>
</tbody>
</table>

**Specimen Stability Information**

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
<th>Special Container</th>
</tr>
</thead>
<tbody>
<tr>
<td>CSF</td>
<td>Frozen (preferred)</td>
<td>30 days</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Refrigerated</td>
<td>14 days</td>
<td></td>
</tr>
</tbody>
</table>
Clinical and Interpretive

Clinical Information

Human T-cell lymphotropic virus types 1 and 2 (HTLV-1 and HTLV-2) are closely related exogenous human retroviruses. HTLV-1 was first isolated in 1980 from a patient with a cutaneous T-cell lymphoma, while HTLV-2 was identified from a patient with hairy cell leukemia in 1982.

HTLV-1 infection is endemic in southwestern Japan, Caribbean basin, Melanesia, and parts of Africa, where HTLV-1 seroprevalence rates are as high as 15% in the general population. In the United States, the combined HTLV-1 and HTLV-2 seroprevalence rate is about 0.016% among voluntary blood donors. About half of these infected blood donors are infected with HTLV-1, with most of them reporting a history of birth in HTLV-1-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-1 occurs from mother to fetus, sexual contact, blood transfusion, and sharing of contaminated needles. Two diseases are known to be caused by HTLV-1 infection: adult T-cell leukemia or lymphoma, and a chronic degenerative neurologic disease known as HTLV-1-associated myelopathy or tropical spastic paraparesis. Cases of polymyositis, chronic arthropathy, panbronchiolitis, and uveitis also have been reported in HTLV-1-infected patients.

HTLV-2 is prevalent among injection drug users in the United States and in Europe, and more than 80% of HTLV infections in drug users in the United States are due to HTLV-2. HTLV-2 also appears to be endemic in Native American populations, including the Guaymi Indians in Panama and Native Americans in Florida and New Mexico. HTLV-2-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-2 is transmitted similarly to HTLV-1, but much less is known about the specific modes and efficiency of transmission of HTLV-2. The virus can be transmitted by transfusion of cellular blood products (whole blood, red blood cells, and platelets). HTLV-2 infection has been associated with hairy-cell leukemia, but definitive evidence is lacking on a viral etiologic role. HTLV-2 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-1 or HTLV-2 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

A negative screening results indicate the absence of both human T-cell lymphotropic virus types 1 and 2 (HTLV-1- and HTLV-2)-specific IgG antibodies in spinal fluid.

A reactive screening test result is suggestive of infection with either HTLV-1 or HTLV-2. However, this result does not confirm infection (eg, low specificity), and it cannot differentiate between HTLV-1 and HTLV-2 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-1 or HTLV-2.

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 any specimen other than spinal fluid.

A negative test result does not exclude the possibility of exposure to human T-cell lymphotropic virus types 1 and 2 (HTLV-1 or HTLV-2). 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 >3,000 mg/dL)
- Grossly hemolyzed (hemoglobin level of >3,051 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 human T-cell lymphotropic virus types 1 (HTLV-1) viral lysate, a purified HTLV-2 viral lysate, and a recombinant HTLV-1 p21E antigen. With the addition of a diluted test sample containing antibodies to either HTLV-1 or HTLV-2, 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 antibody present in the sample is proportional to color development. (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
2 days

Maximum Laboratory Time
4 days

SpecimenRetention 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 modified from the manufacturer's instructions. Its performance characteristics were determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the U.S. Food and Drug Administration.

CPT Code Information
86790
86689 (if appropriate)

LOINC® Information

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<th>Test ID</th>
<th>Test Order Name</th>
<th>Order LOINC Value</th>
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<tbody>
<tr>
<td>HTLVC</td>
<td>HTLV-1/-2 Ab Screen, CSF</td>
<td>22361-0</td>
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<table>
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<th>Result LOINC Value</th>
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<td>604934</td>
<td>HTLV-1/-2 Ab Screen, CSF</td>
<td>22361-0</td>
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