Overview

Useful For
Diagnosis of chronic *Trypanosoma cruzi* infection (Chagas disease) via lateral flow assay

Testing Algorithm
If enzyme-linked immunosorbent assay result is positive or equivocal, then this test is performed at an additional charge.

Method Name
Only orderable as a reflex. For more information see CHAG / *Trypanosoma cruzi* IgG Antibody ELISA, Serum.

Immunochromatographic Strip Assay

NY State Available
Yes

Specimen

Specimen Type
Serum

Specimen Required
Only orderable as a reflex. For more information see CHAG / *Trypanosoma cruzi* IgG Antibody ELISA, Serum.

Collection Container/Tube:

Preferred: Serum gel

Acceptable: Red top

Submission Container/Tube: Plastic vial

Specimen Volume: 0.5 mL

Specimen Minimum Volume
0.2 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>
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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</td>
<td>14 days</td>
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</table>
Clinical and Interpretive

Clinical Information

Chagas disease (American trypanosomiasis) is an acute and chronic infection caused by the protozoan hemoflagellate, Trypanosoma cruzi, endemic in many areas of South and Central America. The parasite is usually transmitted by the bite of reduviid (or "kissing") bugs of the genus Triatoma but may also be transmitted by blood transfusion, organ transplantation, vertically from mother to fetus, and food ingestion. The acute febrile infection is frequently undiagnosed and often resolves spontaneously. Diagnosis of acute T. cruzi infection is most frequently confirmed by microscopic identification of trypomastigotes in fresh preparations of anticoagulated blood oruffy coat. Parasitemia decreases and is undetectable within 90 days of infection.

Chronic T. cruzi infections are often asymptomatic but may progress to produce disabling and life-threatening cardiac (cardiomegaly, conduction defects) and gastrointestinal (megaesophagus and megacolon) disease. These damaged tissues contain the intracellular amastigote of T. cruzi. The parasite is not seen in the blood during the chronic phase. Diagnosis of chronic T. cruzi infection relies on serologic detection of antibodies to this organism. However, no single serologic assay is sensitive and specific enough to be relied upon alone. Therefore, per current guidelines and the Centers for Disease Control and Prevention, serologic confirmation of chronic T. cruzi infection requires positivity on 2 tests utilizing 2 different methodologies or 2 different T. cruzi antigen preparations. When results are discordant, a testing by a third assay is recommended to resolve the initial results or, alternatively, repeat testing on a new sample may be required.

Reference Values

Only orderable as a reflex. For more information see CHAG / Trypanosoma cruzi IgG Antibody ELISA, Serum.

Negative Interpretation

Positive: Antibodies to Trypanosoma cruzi detected suggesting chronic T. cruzi infection. Diagnosis of chronic T. cruzi infection relies on the presence of appropriate exposure history and positive results by 2 distinct serologic assays. This patient was positive by both an anti-T. cruzi IgG enzyme-linked immunosorbent assay (ELISA) using purified, extracted T. cruzi antigens, and a lateral flow assay using recombinant T. cruzi antigens.(1)

Negative: No antibodies to T. cruzi detected. Chronic T. cruzi infection cannot be confirmed due to the discordant serologic results. Further testing (offered through the CDC) or repeat testing on a new sample is recommended.(1)

Cautions

False-positive results may occur in patients infected with Leishmania species or other Trypanosoma species, including Trypanosoma rangeli. Additionally, false-positive results with the T. cruzi lateral flow assay have been detected in patients with hepatitis C, toxoplasmosis, or syphilis.

A diagnosis of chronic Chagas disease requires both clinical evaluation (including exposure history) and laboratory results. Chagas disease should not be diagnosed based on a single serologic result alone.

A single negative result does not exclude the diagnosis of Chagas disease as antibodies to the pathogen may not yet detectable. Sensitivity of the assay may be decreased in significantly immunosuppressed patients.
Clinical Reference


Performance

Method Description
The Chagas DetectTM Plus Rapid Test is a qualitative, membrane-based immunoassay for the detection of antibodies to *Trypanosoma cruzi* in human serum and whole blood matrices (venous and capillary (finger prick) whole blood). The rapid test membrane is precoated with a recombinant antigen on the test line region and utilizes a separate control to assure assay flow and performance. During testing, the test sample is added to the sample pad and a proprietary blend of a stable liquid conjugate labeled with protein A is added to the sample pad. The conjugate and serum mixture migrates upward on the membrane (via capillary action) to react with recombinant *T cruzi* antigen on the membrane. If antibodies to the *T cruzi* antigen are present, a red line will appear at the test line. The red line at the control region should always appear if the assay is performed correctly. The presence of this red line verifies that proper flow has occurred and catastrophic failure of the conjugate has not occurred. (Package insert: Chagas Detect Plus Rapid Test. InBios; 01/30/2017)

PDF Report
No

Day(s) and Time(s) Test Performed
Monday; 9 a.m.

Analytic Time
Same day/1 day

Specimen Retention Time
2 weeks

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 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
86753

**LOINC® Information**

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<th>Order LOINC Value</th>
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<td>T. cruzi IgG, LFA, S</td>
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<table>
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