Overview

Useful For
Diagnosis of chronic Trypanosoma cruzi infection (Chagas disease)

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>RCHAG</td>
<td>T. cruzi Ig, LFA, S</td>
<td>No</td>
<td>No</td>
</tr>
</tbody>
</table>

Testing Algorithm
If ELISA result is equivocal or positive, then the lateral flow assay will be performed at an additional charge.

Method Name
CHAG: Enzyme-Linked Immunosorbent Assay (ELISA)
RCHAG: Immunochromatographic Strip Assay

NY State Available
Yes

Specimen

Specimen Type
Serum

Specimen Required

Collection Container/Tube:
- Preferred: Serum gel
- Acceptable: Red top

Submission Container/Tube: Plastic vial

Specimen Volume: 0.5 mL

Forms
If not ordering electronically, complete, print, and send a Microbiology Test Request (T244) with the specimen.

Specimen Minimum Volume
0.2 mL

Reject Due To

<table>
<thead>
<tr>
<th>Condition</th>
<th>Action</th>
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</thead>
<tbody>
<tr>
<td>Gross hemolysis</td>
<td>Reject</td>
</tr>
<tr>
<td>Gross lipemia</td>
<td>Reject</td>
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</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>Serum</td>
<td>Frozen</td>
<td>14 days</td>
<td></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* is 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 also by food ingestion. The acute febrile infection is most often 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 CDC, 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

Negative

Reference values apply to all ages.

Interpretation

Positive:

Supplemental testing by a second *Trypanosoma cruzi* serologic assay, using an alternative method and/or different *T. cruzi* antigen, is required. Supplemental testing using an anti-*T. cruzi* lateral flow assay based on a recombinant *T. cruzi* antigen will be performed by reflex.(1)

Equivocal:

Supplemental testing by a second *T. cruzi* serologic assay, using an alternative method and/or different *T. cruzi* antigen, is required. Supplemental testing using an anti-*T. cruzi* lateral flow assay based on a recombinant *T. cruzi* antigen will be performed by reflex.(1)

Negative:

No antibodies to *T. cruzi* detected. Antibodies to *T. cruzi* may be absent during acute infection (<3 weeks from exposure), therefore, a negative result cannot be used to rule-out infection. Repeat testing in 2 to 3 weeks is
Test Definition: CHAG
T. cruzi IgG, ELISA, S

recommended if clinically indicated. Microscopic evaluation of a fresh blood smear is recommended for confirmation of acute T cruzi (<3 weeks since exposure) infection.

Cautions
False-positive results may occur in patients infected with Leishmania species or other Trypanosoma species, including Trypanosoma rangeli.

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 be detectable. Sensitivity of the assay may also be decreased in significantly immunosuppressed patients.

Clinical Reference

Performance

Method Description
The Hemagen Chagas kit is a qualitative indirect enzyme-linked immunosorbent assay using purified antigens extracted from cultured Trypanosoma cruzi that have been attached to the surface of microplate wells. The presence of antibodies in the test serum is detected by an enzyme catalyzed color change in added 3,3',5,5'-tetramethylbenzidine substrate.(Umezawa ES, Luquetti AO, Levitus G, et al: Serodiagnosis of chronic and acute Chagas' disease with Trypanosoma cruzi recombinant proteins: results of a collaborative study in six Latin American countries. J Clin Microbiol 2004;42:449-452)

PDF Report
No

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

Analytic Time
Same day/1 day

Maximum Laboratory Time
8 days

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 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
86753-T. cruzi IgG, ELISA, S
86753-T. cruzi IgG, LFA, S (if appropriate)

LOINC® Information

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<th>Test ID</th>
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<th>Order LOINC Value</th>
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<tbody>
<tr>
<td>CHAG</td>
<td>T. cruzi IgG, ELISA, S</td>
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