MAYO CLINIC LABORATORIES

Test Definition: CHAGS

Trypanosoma cruzi Total Antibody, Enzyme-Linked Immunosorbent Assay, Serum

Overview

Useful For

Diagnosis of chronic *Trypanosoma cruzi* infection (Chagas disease)

Method Name

Enzyme-Linked Immunosorbent Assay (ELISA)

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: 0.7 mL
Collection Instructions: Centrifuge and aliquot serum into a plastic vial.

Forms

If not ordering electronically, complete, print, and send Infectious Disease Serology Test Request (T916) with the specimen.

Specimen Minimum Volume

0.6 mL

Reject Due To

Gross hemolysis	Reject
Gross lipemia	Reject

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container

Serum	Frozen	14 days	

Clinical & Interpretive

Clinical Information

Chagas disease (American trypanosomiasis) is an acute and chronic infection caused by the protozoan hemoflagellate *Trypanosoma cruzi*. *T 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, food ingestion, and vertically from mother to fetus. 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 or buffy coat or by molecular detection. Parasitemia decreases and is undetectable within approximately 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 of 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, 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

Negative:

No antibodies to *Trypanosoma cruzi* (Chagas disease) detected. Antibodies to *T cruzi* may be absent during acute infection, therefore a negative result cannot be used to rule out recent infection. Repeat testing in 3 to 4 weeks is recommended if clinically indicated.

Indeterminate:

Repeat testing in 2 to 3 weeks if clinically indicated.

Reactive:

Antibodies to *T cruzi* detected. Result is not diagnostic. Supplemental testing by a second, different *T cruzi* serologic assay is recommended.

Cautions

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

Diagnosis of chronic Chagas disease requires both clinical evaluation (including exposure history) and laboratory testing. 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 be decreased in significantly immunosuppressed patients.

Clinical Reference

1. Bern C, Montgomery SP, Herwaldt BL, et al: Evaluation and treatment of Chagas disease in the United States: A Systematic Review. JAMA. 2007 Nov 14;298(18):2171-2181
2. Bern C, Messenger LA, Whitman JD, Maguire JH: Chagas disease in the United States: a public health approach. Clin Microbiol Rev. 2019 Nov 27;33(1):e00023-19. doi: 10.1128/CMR.00023-19

Performance

Method Description

The Wiener Chagatest ELISA recombinante v.3.0 test kit is a qualitative technique for the detection of anti-*Trypanosoma cruzi* antibodies. The sample is diluted in the support in which the recombinant antigen (1, 2, 13, 30, 36, and SAPA) is immobilized (3rd generation method). These antigens are obtained by DNA recombinant techniques starting from specific proteins from the epimastigote and trypomastigote stages of the *T cruzi* corresponding to highly conserved zones among different strains. The technology used allows us to ensure an antigenic mixture of known and permanent composition batch to batch, giving reproducible, specific, and highly sensitive results. If the sample contains specific antibodies, these will form a complex with the antigens and will remain bound to the support. The unbound fraction is eliminated by washing, after which antihuman immunoglobulin antibodies conjugated to peroxidase are added. If a reaction is produced in the first step of the process, the conjugate is bound. After a new wash, the enzymatic substrate is added. If bound conjugate is present, a light-blue color is developed. The reaction is stopped by adding sulfuric acid, and the color changes to yellow.(Package insert: Chagatest ELISA recombinante v.3.0. Wiener Laboratorios S.A.I.C.; 801146000/00)

PDF Report

No

Day(s) Performed

Monday

Report Available

Same day/1 to 8 days

Specimen Retention Time

14 days

Performing Laboratory Location

Rochester

Fees & 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 account representative. 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

86753

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
CHAGS	T. cruzi Total Ab, EIA, S	57320-4

Result ID	Test Result Name	Result LOINC® Value
CHAGS	T. cruzi Total Ab, EIA, S	57320-4