MAYO CLINIC LABORATORIES

# Test Definition: CRUZI

Trypanosoma cruzi (Chagas) Antibody Panel, Serum

## Overview

### Useful For

Diagnosis of chronic *Trypanosoma cruzi* infection (Chagas disease) using two different methods

### Profile Information

| Test Id | Reporting Name | Available Separately | Always Performed |
|---|---|---|---|
| CHAGS | T. cruzi Total Ab, EIA, S | No | Yes |
| CHAGL | T. cruzi IgG, LFA, S | No | Yes |
| CHAGI | T. cruzi Interpretation | No | Yes |

### Highlights

Diagnostic testing for chronic Chagas disease requires serologic assessment using two assays based on different antigens and/or methods. Specimens with discordant results by these two assays should be evaluated at a public health laboratory or the CDC for resolution.

### Method Name

CHAGS: Enzyme-Linked Immunosorbent Assay (ELISA)
CHAGL: Lateral Flow Assay (LFA)

### NY State Available

Yes

## Specimen

### Specimen Type

Serum

### Specimen Required

**Supplies:** Sarstedt Aliquot Tube 5 mL (T914)
**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 1 of the following forms with the specimen:

-Kidney Transplant Test Request
-Infectious Disease Serology Test Request (T916)

### Specimen Minimum Volume
0.5 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 caused by the protozoan hemoflagellate *Trypanosoma cruzi* and can lead to acute and chronic clinical manifestations of disease. *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 stage of disease is frequently undiagnosed and often resolves spontaneously. Diagnosis of acute *T cruzi* infection is typically 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 expert guidelines and the Centers of Disease Control and Prevention, serologic confirmation of chronic *T cruzi* infection requires positivity on 2 tests utilizing two different methodologies and/or two 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

| CHAGS result | CHAGL result | Interpretive comment |
|---|---|---|
| Positive | Positive | Antibodies to Trypanosoma cruzi (Chagas disease) detected by two separate methods, suggesting current or past infection. Results should be interpreted alongside clinical presentation and exposure history. |
| Positive | Negative | Antibodies to Trypanosoma cruzi (Chagas disease) detected by one of two assays. Discordant results can be resolved through submission of a new sample for testing or through additional testing at a public health laboratory. |
| Positive | Invalid | Submission of a new sample is recommended to resolve discordant results. |
| Indeterminate | Positive | Antibodies to Trypanosoma cruzi (Chagas disease) detected by one of two assays. Discordant results can be resolved through submission of a new sample for testing or through additional testing at a public health laboratory. |
| Indeterminate | Negative | Submission of a new sample is recommended to resolve discordant results. |
| Indeterminate | Invalid | Submission of a new sample is recommended to resolve discordant results. |
| Negative | Positive | Antibodies to Trypanosoma cruzi (Chagas disease) detected by one of two assays. Discordant results can be resolved through submission of a new sample for testing or through additional testing at a public health laboratory. |
| Negative | Negative | No antibodies to Trypanosoma cruzi (Chagas disease) detected. False negative results may occur in patients tested within 4 weeks of infection. |
| Negative | Invalid | Submission of a new sample is recommended to resolve discordant results. |

## 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 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;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;33(1):e00023-19. doi:10.1128/CMR.00023-19
3. Forsyth CJ, Manne-Goehler J, Bern C, et al. Recommendations for screening and diagnosis of Chagas disease in the United States. J Infect Dis. 2022;225(9):1601-1610. doi:10.1093/infdis/jiab513

## Performance

### Method Description

*Trypanosoma cruzi* Total Antibody:
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)

*Trypanosoma cruzi* IgG:
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 sample and a proprietary blend of a stable liquid conjugate labeled with protein A are 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; 01/05/2018)

### PDF Report

No

### Day(s) Performed

Monday

### Report Available

Same day/1 to 8 days

### Specimen Retention Time

2 weeks

### Performing Laboratory Location

Mayo Clinic Laboratories - Rochester Superior Drive

# Test Definition: CRUZI

Trypanosoma cruzi (Chagas) Antibody Panel, Serum

## 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 x2

### LOINC® Information

| Test ID | Test Order Name | Order LOINC® Value |
|---|---|---|
| CRUZI | T. cruzi (Chagas) Ab Panel, S | 23785-9 |

| Result ID | Test Result Name | Result LOINC® Value |
|---|---|---|
| CHAGS | T. cruzi Total Ab, EIA, S | 57320-4 |
| CHAGL | T. cruzi IgG, LFA, S | 87994-0 |
| CHAGI | T. cruzi Interpretation | 59464-8 |