

ELISURE

Chagas Rapid Test (Whole Blood/Serum/Plasma)

For professional use

IVD

REF

SIC-RDT-CHG-202072

A rapid test for the qualitative detection of IgG anti-Trypanosoma cruzi (T. cruzi) in human whole blood, serum or plasma specimen.
For professional in vitro diagnostic use only.

INTENDED USE

The Chagas Rapid Test is a lateral flow chromatographic immunoassay for the qualitative detection of IgG anti-Trypanosoma cruzi (T. cruzi) in human serum, plasma or whole blood. It is intended to be used as a screening test and as an aid in the diagnosis of infection with T. cruzi. Any reactive specimen with the Chagas Rapid Test must be confirmed with alternative testing method (s) and clinical findings.

SUMMARY

Chagas disease is an insect-borne, zoonotic infection by the protozoan T. cruzi, which causes a systemic infection of humans with acute manifestations and long term sequelae. It is estimated that 16-18 million individuals are infected worldwide, and roughly 50,000 people die each year from chronic Chagas disease (World Health Organization).¹

Buffy coat examination and xenodiagnosis used to be the most commonly methods^{2,3} in the diagnosis of acute T. cruzi infection. However, both methods are either time consuming or lack of sensitivity. Recently, serological test becomes the mainstay in the diagnosis of Chagas's disease. In particularly, recombinant antigen based tests eliminate false-positive reactions which are commonly seen in the native antigen tests.^{4,5}

The Chagas Rapid Test is an instant antibody test which detects IgG antibodies the T. cruzi within 15 minutes without any instrument requirements. By utilizing T. cruzi specific recombinant antigen, the test is highly sensitive and specific.

PRINCIPLES

The Chagas Rapid Test (Whole Blood/Serum/Plasma) is a qualitative, membrane based immunoassay for the detection of IgG anti-Trypanosoma cruzi (T. cruzi) in whole blood, serum or plasma. The membrane is pre-coated with recombinant mouse anti-human IgG on the test line region of the cassette. During testing, the whole blood, serum or plasma specimen reacts with recombinant Chagas antigen conjugated colloid gold. The mixture migrates upward on the membrane chromatographically by capillary action to react with mouse anti-human IgG on the membrane and generate a colored line. Presence of this colored line indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear at the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

MATERIALS

Materials provided

- Test cassettes
- Droppers
- Buffer
- Package insert
- Specimen collection containers
- Materials required but not provided
- Centrifuge
- Timer
- Lancets (for fingerstick whole blood only)
- Heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)

WARNINGS AND PRECAUTIONS

- For professional in vitro diagnostic use only. Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Humidity and temperature can adversely affect results.

STORAGE AND STABILITY

The kit can be stored at room temperature or refrigerated (2-30°C). The test cassette is stable through the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

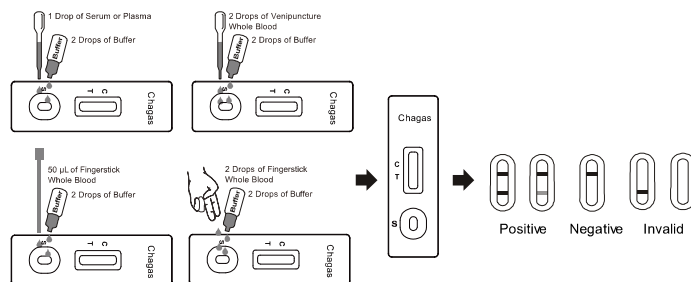
SPECIMEN COLLECTION AND PREPARATION

- The Chagas Rapid Test (Whole Blood/Serum/Plasma) can be performed using whole blood (from venipuncture or fingerstick), serum or plasma.
- To collect Fingerstick Whole Blood specimens:
 - Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
 - Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
 - Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
 - Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
 - Add the Fingerstick Whole Blood specimen to the test by using a capillary tube:
 - Touch the end of the capillary tube to the blood until filled to approximately 50 µL. Avoid air bubbles.
 - Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood to the specimen area of the test cassette.
 - Add the Fingerstick Whole Blood specimen to the test by using hanging drops:
 - Position the patient's finger so that the drop of blood is just above the specimen area of the test cassette.
 - Allow 2 hanging drops of fingerstick whole blood to fall into the center of the specimen area on the test cassette, or move the patient's finger so that the hanging drop touches the center of the specimen area. Avoid touching the finger directly to the specimen area.
- Separate the serum or plasma from blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed specimens can be used.
- Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
- If specimens are to be shipped, they should be packed in compliance with federal regulations for transportation of etiologic agents.

DIRECTIONS FOR USE

Allow test cassette, specimen, buffer and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the cassette on a clean and level surface.
For **Serum or Plasma** specimen: Hold the dropper vertically and **transfer 1 drop of serum or plasma** (approximately 25 µL) to the specimen area, then **add 2 drops of buffer** (approximately 80 µL), and start the timer, see illustration below.
For **Venipuncture Whole Blood** specimen: Hold the dropper vertically and **transfer 2 drops of whole blood** (approximately 50 µL) to the specimen area, then **add 2 drops of buffer** (approximately 80 µL), and start the timer. See illustration below.
For **Fingerstick Whole Blood** specimen:
 - To use a capillary tube: Fill the capillary tube and **transfer approximately 50 µL of fingerstick whole blood specimen** to the specimen area of test cassette, then **add 2 drops of buffer** (approximately 80 µL) and start the timer. See illustration below.
 - To use hanging drops: Allow **2 hanging drops of fingerstick whole blood specimen** (approximately 50 µL) to fall into the specimen area of test cassette, then **add 2 drops of buffer** (approximately 80 µL) and start the timer. See illustration below.
3. Wait for the colored line(s) to appear. **The test result should be read at 15 minutes.** Do not interpret the result after 20 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

POSITIVE: Two colored lines appear. One colored line should be in the control region (C) and another colored line should be in the test region (T).

NOTE: The intensity of the colored in the test line region (T) will vary depending on the concentration of Chagas antibodies present in the specimen. Therefore, any shade of red in the test region should be considered positive.

NEGATIVE: One colored line appears in the control region (C). No line appears in the test region.

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is an internal procedural control. It confirms sufficient specimen volume and correct procedural technique.

Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

1. The Assay Procedure and the Assay Result Interpretation must be followed closely when testing the presence of anti-T. cruzi antibody in serum, plasma or whole blood from individual subjects. Failure to follow the procedure may give inaccurate results.
2. The Chagas Rapid Test is limited to the qualitative detection of anti-T. cruzi antibody in human serum, plasma or whole blood. The intensity of the test band does not have linear correlation with the antibody titer in the specimen.
3. A negative result for an individual subject indicates absence of detectable anti-T. cruzi antibody. However, a negative test result does not preclude the possibility of exposure to or infection with T. cruzi.
4. A negative result can occur if the quantity of the anti-T. cruzi antibody present in the specimen is below the detection limits of the assay, or the antibodies that are detected are not present during the stage of disease in which a sample is collected.
5. Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.
6. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

A total of 264 samples from susceptible subjects were tested by the Chagas Rapid Test and by a commercial Chagas ELISA kit. Comparison for all subjects is shown in the following table.

Method	ELISA		Total Results
	Results	Positive	Negative
Chagas Rapid Test (Whole Blood/Serum/Plasma)	Positive	13	4
	Negative	1	246
Total Results		14	250

Relative Sensitivity: 92.9% (95%CI*: 66.1%-99.8%)

Relative Specificity: 98.4% (95%CI*: 96.0%-99.6%)

Accuracy: 98.1% (95%CI*: 95.6%-99.4%)

*Confidence Intervals

Limitation of Detection

The minimum detection level is 1:8 for Chagas antibody positive specimen.

Precision Intra-Assay

Within-run precision has been determined by using 10 replicates of 4 specimens: a negative, a low positive, a medium positive and a high positive. The negative, low positive, medium positive and high positive values were correctly identified > 99% of the time.

Inter-Assay

Between-run precision has been determined by 10 independent assays on the same 4 specimens: a negative, a low positive, a medium positive and a high positive. Three different lots of the The Chagas Rapid Test (Whole Blood/Serum/Plasma) have been tested using negative, low positive medium positive and high positive specimens. The specimens were correctly identified >99% of the time.

Cross-reactivity

The Chagas Rapid Test (Whole Blood/Serum/Plasma) has been tested by HAMA, RF, HBsAg, HBsAb, HBeAg, HBeAb, HBcAb, Syphilis, HIV, *H. Pylori*, MONO, CMV, Rubella and TOXO positive specimens. The results showed no cross-reactivity.

Interfering Substances

The following potentially interfering substances were added to Chagas negative and positive specimens.

Acetaminophen: 20 mg/dL	Caffeine: 20 mg/dL
Acetylsalicylic Acid: 20 mg/dL	Gentisic Acid: 20 mg/dL
Ascorbic Acid: 2 g/dL	Albumin: 2 g/dL
Creatin: 200 mg/dL	Hemoglobin: 1,000 mg/dL
Bilirubin: 1 g/dL	Oxalic Acid: 60 mg/dL

None of the substances at the concentration tested interfered in the assay.

BIBLIOGRAPHY

1. World Health Organization. Control of Chagas disease: report of a WHO expert committee. 1991
2. Frasch ACC, Reyes MB, Sanchez DO. Diagnosis of Chagas disease: present and future. In: Chagas' disease and the nervous system. Washington, DC: pan American Health Organization. 1994: 47-53
3. Frasch AC, Reyes MB. Diagnosis of Chagas disease using recombinant DNA technology. Parasitol Today. 1990,6(4):137-9
4. Lorca M, Gonzalez A, Reyes V, Veloso C, Vergara U, Frasch C. [The diagnosis of chronic Chagas disease using recombinant antigens of Trypanosoma cruzi] Rev Med Chil. 1993 121(4):363-8.
5. da Silveira JF, Umezawa ES, Luquetti AO. Chagas disease: recombinant Trypanosoma cruzi antigens for serological diagnosis. Trends Parasitol. 2001, 17(6):286-91.

INDEX OF SYMBOLS

	Consult instructions for use		Contains sufficient for <n> tests
	In vitro diagnostic medical device		Use-by date
	Temperature limit		Batch code
	Do not use if package is damaged		Manufacturer
	Catalogue number		Do not re-use



Sicuro Bioengineering Ltd
Address: 19 East West Road,
Port Harcourt - Nigeria
Email: info@sicurobio.com
Website: www.sicurobio.com

Number: M150576002B
Revision date: 2026-07-20