# Chagas IgG Antibody Rapid Test (Serum/Plasma/Whole Blood)

Cat no. CHAG 411

## INTENDED USE

The Chagas Ab Combo 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 Ab Combo Rapid Test must be confirmed with alternative testing method(s) and clinical findings.

## SUMMARY AND EXPLANATION OF THE TEST

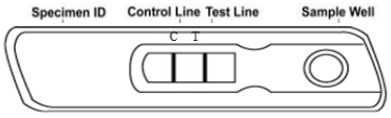
Chagas disease is an insect-borne, zoonotic infection by the protozoan *T. cruzi*, which causes a systemic infection of humans with acute manifestations and long term sequelae. It is estimated that 16-18 million individuals are infected worldwide, and roughly 50,000 people die each year from chronic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

## TEST PRINCIPLE

The Chagas Ab Combo Rapid Test is a lateral flow chromatographic immunoassay based on the principle of indirect immunoassay. The test cassette consists of: 1) a burgundy colored conjugate pad containing Protein A conjugated with colloid gold (Protein A conjugates), 2) a nitrocellulose membrane strip containing a test band (T band) and a control band (C band). The T band is pre-coated with recombinant *T. cruzi* antigens, and the C band is pre-coated with anti-Protein A antibodies.




When an adequate volume of test specimen is dispensed into the sample well of the test cassette, the specimen migrates by capillary action across the cassette. The IgG antibodies to *T. cruzi* if present in the specimen will bind to the Protein A conjugates. The immunocomplex is then captured on the membrane by the pre-coated *T. cruzi* antigens, forming a burgundy colored T band, indicating a Chagas Ab positive test result.

Absence of the T band suggests a negative result. The test contains an internal control (C band) which should exhibit a burgundy colored band of the immunocomplex of anti-protein A antibody-Protein A gold conjugates regardless of color development on the T band. Otherwise, the test result is invalid and the specimen must be retested with another device.

## REAGENTS AND MATERIALS PROVIDED

1. Each sealed in a foil pouch with three items inside:
   a. One cassette device.
   b. One plastic dropper.
   c. One desiccant.
2. Sample diluent (1 bottle, 5 mL)
3. One package insert (instruction for use).

## MATERIALS REQUIRED BUT NOT PROVIDED

1. Clock or Timer

## WARNINGS AND PRECAUTIONS

**For *in Vitro* Diagnostic Use**

1. This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
2. Do not open the sealed pouch, unless ready to conduct the assay.
3. Do not use expired devices.
4. Bring all reagents to room temperature (15°C -30°C) before use.
5. Do not use the components in any other type of test kit as a substitute for the components in this kit.
6. Do not use hemolized blood specimen for testing.
7. Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
8. Users of this test should follow the US CDC Universal Precautions for prevention of transmission of HIV, HBV and other blood-borne pathogens.
9. Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
10. Dispose of all specimens and materials used to perform the test as biohazardous waste.
11. The testing results should be read within 15 minutes after a specimen is applied to the sample well or sample pad of the device. Reading result after 15 minutes may give erroneous results.
12. Do not perform the test in a room with strong air flow, ie. an electric fan or strong air-conditioning.

## REAGENT PREPARATION AND STORAGE INSTRUCTIONS

All reagents are ready to use as supplied. Store unused test devices unopened at 2°C-30°C. If stored at 2°C-8°C, ensure that the test device is brought to room temperature before opening. The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit over 30°C.

## SPECIMEN COLLECTION AND HANDLING

Consider any materials of human origin as infectious and handle them using standard biosafety procedures.

**Plasma**

1. Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively in Vacutainer® ) by veinpuncture.
2. Separate the plasma by centrifugation.
3. Carefully withdraw the plasma into new pre-labeled tube.

**Serum**

1. Collect blood specimen into a red top collection tube (containing no anticoagulants in Vacutainer®) by veinpuncture.
2. Allow the blood to clot.
3. Separate the serum by centrifugation.
4. Carefully withdraw the serum into a new pre-labeled tube.

Test specimens as soon as possible after collecting. Store specimens at 2°C-8°C if not tested immediately.

Store specimens at 2°C-8°C up to 5 days. The specimens should be frozen at -20°C for longer storage.

Avoid multiple freeze-thaw cycles. Prior to testing, bring frozen specimens to room temperature slowly and mix gently. Specimens containing visible particulate matter should be clarified by centrifugation before testing. Do not use samples demonstrating gross lipemia, gross hemolysis or turbidity in order to avoid interference on result interpretation.

**Blood**

Drops of whole blood can be obtained by either finger tip puncture or veinpuncture. Do not use any hemolized blood for testing.

Whole blood specimens should be stored in refrigeration (2°C-8°C) if not tested immediately. The specimens must be tested within 24 hours of collection.

## ASSAY PROCEDURE

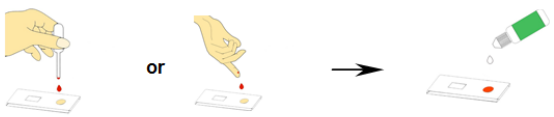
Step 1: Bring the specimen and test components to room temperature if refrigerated or frozen. Mix the specimen well prior to assay once thawed.

Step 2: When ready to test, open the pouch at the notch and remove device. Place the test device on a clean, flat surface.

Step 3: Be sure to label the device with specimen's ID number.

Step 4: **For whole blood test**

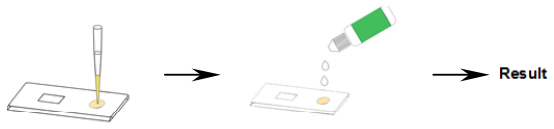
- Dispense 1 drop (about 40-50 µL) of the whole blood specimen into the sample well
- Then add 2 drops (about 70 -100 µL) of Sample Diluent immediately




**1 drop of blood** **2 drops of sample diluent**

**For serum or plasma test**

- Dispense 20 µL of the specimen into the sample well
- Then add 2 drops (about 70-100 µL) of Sample Diluent immediately




**20 µL of serum/plasma** **2 drops of sample diluent 15 minutes**

Step 5: Set up timer.

Step 6: Results can be read in 15 minutes. Positive results can be visible in as short as 1 minute.

***Don't read result after 15 minutes. To avoid confusion, discard the test device after interpreting the result.***

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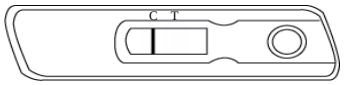
## INTERPRETATION OF ASSAY RESULT

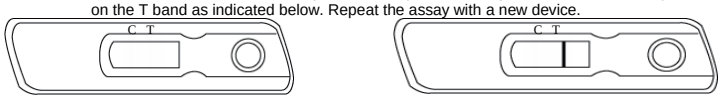
1. **NEGATIVE RESULT**: If only the C band is developed, the test indicates that no detectable anti -*T. cruzi* antibody present in the specimen. The result is negative.




2. **POSITIVE RESULT**: If both C and T bands are developed, the test indicates for the presence of anti -*T. cruzi* antibody in the specimen. The result is positive.


*Samples with positive results should be confirmed with alternative testing method(s) and clinical findings before a positive determination is made*.

3. **INVALID:** If no C band is developed, the assay is invalid regardless of color development on the T band as indicated below. Repeat the assay with a new device.




## PERFORMANCE CHARACTERISTICS

**Clinical Performance**

A total of 214 samples from susceptible subjects were tested by the Chagas Ab Combo Rapid Test and by a commercial IgG EIA test. Comparison for all subjects is showed in the following table:

| | Chagas Ab Combo Rapid Test | | |
|---|---|---|---|
| **IgG EIA** | **Positive** | **Negative** | **Total** |
| **Positive** | 13 | 1 | 14 |
| **Negative** | 0 | 200 | 200 |
| **Total** | 13 | 201 | 214 |

Relative Sensitivity: 92.9% , Relative Specificity: 100%, Overall Agreement: 99.5%

## LIMITATIONS OF TEST

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 Ab Combo 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.

## REFERENCES


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.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