Chagas Ab cassette CE

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For professional *in vitro* diagnostic use only			

Chagas Ab

A rapid one test for qualitative detection of IgG anti-Trypanosoma cruzi (T. cruzi) in human serum, plasma or whole blood

ONE STEP

PRINCIPLE

The LINEAR Chagas Ab 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.

REAGENT COMPOSITION

The T band is pre-coated with recombinant T. cruzi antigens, and the C band is pre-coated with anti-Protein A antibodies.

PACKAGING CONTENTS

REF 4272240 40 Chagas Ab test device
40 Plastic dropper
1 Sample diluent (5 mL)

STORAGE AND STABILITY

Store at 2-30ºC. The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. **Do not freeze the kit or expose the kit over 30°C**. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

Serum, (EDTA, citrate or heparin) or plasma unhemolyzed.
Test specimens as soon as possible after collecting. Store specimens at 2°C-8°C if not tested immediately.
Stable up to 5 days at 2-8°C or 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.
Store at 2-8°C if not tested immediately. The specimens must be tested within 24 hours of collection.
Consider any materials of human origin as infectious and handle them using standard biosafety procedures.

MATERIAL REQUIRED

- Timer
- Lancing device for whole blood test
- Pipette and tips capable of delivering 20 µL volumes with a precision better than 1.5%.

PROCEDURE

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

1. Remove the test device from the sealed pouch and use it as soon as possible.
2. Be sure to label the device with specimen's ID number.

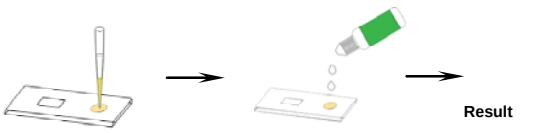
For whole blood test

- Dispense 1 drop (about 40-50 µL) of the whole blood specimen into the sample well
- Then add 1 drop (about 35 -50 µL) of Sample Diluent immediately

1 drop of blood 1 drop 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

3. Set up timer.
4. Results can be read in 15 minutes.

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

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

POSITIVE: Two distinct red lines appear. 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.

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

INVALID: Control C band 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 device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as good laboratory testing practice to confirm the test procedure and to verify proper test performance.

CLINICAL SIGNIFICANCE

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 methods2,3 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 tests4-5.
The Linear Changas Ab 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.

ANALYTICAL PERFORMANCE

Clinical Performance

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

	Linear Chagas Ab		
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 Linear Chagas Ab 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.
7. Any reactive specimen with the Linear Chagas Ab Test must be confirmed with alternative testing method(s) and clinical findings.

PRECAUTIONS

1. This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
2. Do not use the components in any other type of test kit as a substitute for the components in this kit.
3. Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
4. Users of this test should follow the US CDC Universal Precautions for prevention of transmission of HIV, HBV and other blood-borne pathogens.
5. Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
6. Dispose of all specimens and materials used to perform the test as biohazardous waste.
7. Do not perform the test in a room with strong air flow, ie. an electric fan or strong air-conditioning.

REFERENCES

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