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Trypanosome Cruzi (Chagas) Antibody Test

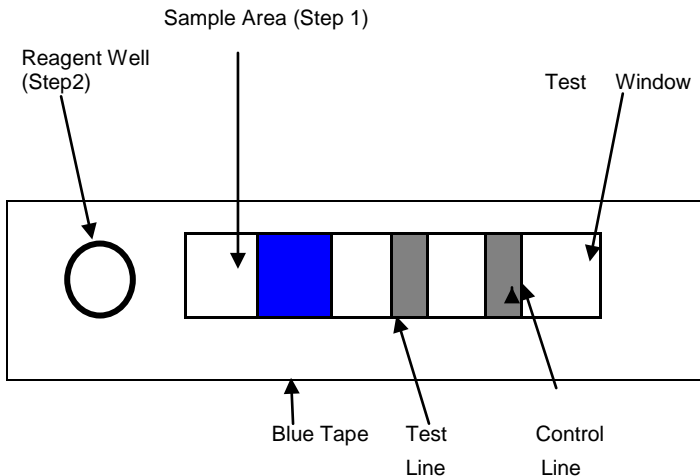
A rapid Immunoblot Assay for IgG Antibodies to Trypanosoma cruzi in Human Serum/Plasma

SUMMARY OF TEST PROCEDURE

Step	Description	Time
1	Apply 10 µl sample in the sample area of the device with supplied pipette*	
2	Apply 3 drops of conjugate to the reagent well*	
3	Read result	10 minutes after conjugate application

* Refer to Illustration 1 and the package insert for details.

Illus. 1: Test Device



INTENDED USE:

The Lateral Blot *Trypanosoma cruzi* (T.cruzi) Antibody Test (The Test) is an immunoblot assay intended for qualitative detection of antibodies to *Trypanosoma cruzi* in serum or plasma.

INTRODUCTION

T. cruzi is the etiologic agent for American Trypanosomiasis, also known as Chagas' disease. A zoonosis, Chagas' disease occurs throughout the American continent, including Central and South America, Texas and California. Patients can present with either an acute or a chronic disease. A large number of patients with positive serology can remain asymptomatic. Humans contract *T. cruzi* infection through insect-bite wounds, exposed mucus membranes, blood transfusion, placental transfer, organ transplant and accidental ingestion of parasitized reduviid bugs.

Acute systemic signs occur around the second and third week of infection and are characterized by high fever, hepatosplenomegaly, myalgia, erythematous rash, acute myocarditis, lymphadenopathy and subcutaneous edema of face, legs and feet.

Chronic Chagas' disease is diagnosed more commonly than the acute phase. Symptoms of the chronic phase are related to the damage sustained during the acute phase of the disease. Chronic Chagas' disease may develop years or decades after undetected infection or after diagnosis of the acute disease. The most frequent clinical sign of chronic Chagas' disease is cardiomyopathy manifested by cardiomegaly and conduction changes. Some patients are more likely to have megaesophagus or megacolon. Congenital transmission can occur in both the acute and chronic phase of the disease. Infants or seropositive mothers should be monitored for up to a year after birth to rule out infection.

A definitive diagnosis of the disease depends on the presence of trypomastigotes in the blood, amastigote states in tissues, or positive serologic tests. Trypomastigotes may be easily detected in the blood in the acute phase of the disease; however, in the chronic phase of the disease, this is rare or absent, except during febrile episodes.

Healthcare personnel working with specimen from patients suspected of having Chagas' disease should follow the bloodborne pathogen guidelines. Trypomastigotes are highly infectious.

The Test is a rapid visual assay based on principles of immunoblot and Immuno-chromatography to qualitatively

detect the presence of IgG antibodies to T.cruzi in human serum or plasma specimen.

Due to the nature of the test, it is important to fully evaluate the test within the target population before use for diagnostic or blood product screening purposes.

PRINCIPLES OF THE TEST

The Test utilizes an assay platform technology based on integrated principles of immunoblot and immuno-chromatography. The device of the Test has T. cruzi antigens immobilized on the membrane within the test zone. Specimen applied in the membrane migrates by capillary action through the test zone. The IgG antibodies to T. cruzi present in the specimen are captured by the immobilized antigens in the test zone and subsequently visualized in the form of a magenta test line by the gold-Protein A conjugate applied to the test device. The absence of the test line indicates a negative test. In the control zone, the conjugate-binding reagent is immobilized on the membrane. A magenta control line in the control zone appears in every valid test indicating that the Test is properly performed and reagents are functional as specified.

MATERIAL PROVIDED

1. Test Device
2. Conjugate Reagent
3. 10 µl Pipette (optional)

MATERIAL REQUIRED BUT NOT PROVIDED

1. Micropipette for 10 µl (if 10 µl pipette not supplied)
2. Timer

STORAGE AND STABILITY

Store the test device at 2-30°C. Store the conjugate reagent at 2-8°C. **DO NOT FREEZE.** Do not use beyond the expiration date.

PRECAUTIONS

1. Do not use the test device and reagent beyond the expiration date.
2. Treat all specimens as infectious. Practice universal precautions and wear protection throughout the procedure. Properly dispose of specimens and other testing materials according to standard procedures.
3. Bring testing materials, including specimen, to room temperature before testing.

SPECIMEN COLLECTION AND PREPARATION

1. The Test can be performed on either serum or plasma. It is recommended that fresh specimens be used if possible. Specimens may be stored at 2-8°C for up to 3 days before testing. For long term storage, specimens should be kept below 20°C.

2. Separation of serum or plasma from blood should be performed as soon as possible to avoid hemolysis. Only clear, non-hemolyzed specimens can be used.

3. 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.

PROCEDURE (see illustration 1)

Allow the test device, reagent, specimen and controls to equilibrate to room temperature (15-30°C) before testing. Place the test device on a clean and level surface.

1. Transfer 10 µl of sample into the membrane in the sample area at the bottom of the rectangle test window **RIGHT BELOW THE BLUE TAPE.***

- Directions for using the 10 µl pipette supplied with the test:

- a) Squeeze the upper part of the pipette and then release to draw sample. Make sure the liquid level is right at the black mark.
- b) To apply sample, touch the membrane in the device's sample area lightly with the tip of the pipette and then squeeze the pipette so that all the liquid gets applied onto the membrane.

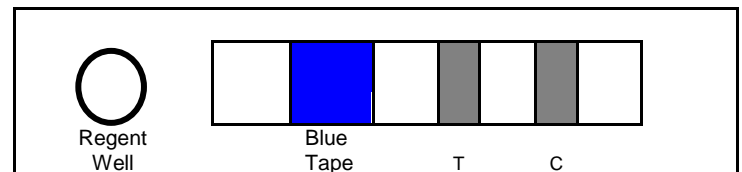
2. Hold the conjugate dropper bottle vertically and transfer 3 full drops (100-120 µl) of conjugate into the reagent well. Incubate the test device at room temperature for 10 minutes before reading the results.

3. Read the results at 10-20 minutes after the conjugate application. Do not attempt to interpret the results after 20 minutes.

RESULT INTERPRETATION (refer to illustration 1 above)

Positive: Both test and control lines appear.

(Note – Low titers of antibody might result in a faint test line appearing in the test zone after a prolonged time.)



7. Optimal assay performance requires strict adherence to the assay procedures described in this insert sheet. Deviations may lead to aberrant results.

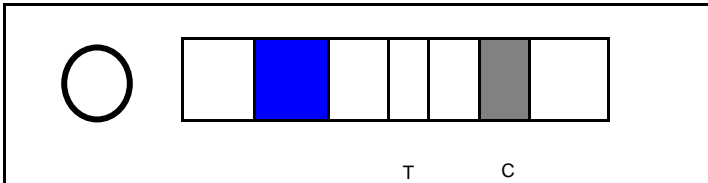
PERFORMANCE CHARACTERISTICS

The Test showed concordance with other commercial tests when tested with performance panel and clinical specimens.

REFERENCE

1. WHO Expert Committee. 1991. Control of Chagas' disease. W.H.O. Tech. Rep. Ser.
2. Navin, T.R., Roberto, R.R., Juranek, D.D., Limpakarnjanarat, K., Mortenson, E.W., Clover, J.R., Yescott, R.E., Taclindo, C., Stuerer, F., and Allain, D. 1985. Human and Sylvatic Trypanosoma cruzi infection in California. Am.J.Public Health 75:366-369
3. Theis, J.H. 1990. Latin American immigrants-blood donation and Trypanosoma cruzi transmission. Am. Heart J. 120:1483-1484
4. Brucker, D.A. and Labarca, J.A. 1999. Leishmania and Trypanosoma. Manual of Clinical Microbiology. Ed. Murray, P.R., Baron, E.J., Tenover, F.C., and Tenover, R.H. 1368-1370

Negative: Only control line appears.



Invalid: Control line fails to appear. The test should be repeated on a new device.

QUALITY CONTROL

The control line in the control zone is a built-in procedural control in the Test. The control line appearing as specified indicates that the test is properly performed and reagents are functional.

LIMITATIONS:

1. The Test (Serum/Plasma) is for in vitro use only.
2. The Test is a qualitative test.
3. The Test may cross-react with Leishmania spp. and Trypanosoma rangeli.
4. The Test is an aid to clinical diagnosis of Chagas' disease. As with all diagnostic tests, however, results from the Test should not be used as the only basis for a definite diagnosis. The results should be interpreted together with all other clinical laboratory findings by a physician before a definite diagnosis can be reached.
5. Positive results should be confirmed by independent confirmatory tests.
6. In cases where the test result is negative while clinical symptoms persist, further consultation with a physician and additional tests of other methods should be followed.

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FM77504 - Quality Award
FDA Registration No.: 1048532