

174-020 Chagas 20 tests
20 test strips
1 vial buffer solution



CHAGAS QUICK TEST

A Rapid Immunochromatographic Assay for Detecting Antibodies to *Trypanosoma cruzi* in Human Serum or Whole Blood

Intended Use

This test is used for the diagnosis of infection due to *Trypanosoma cruzi*. The test employs a multi-epitope recombinant antigen.

Summary and explanation

Trypanosoma cruzi is an organism which is indicated as an etiological agent of Chagas' disease, a major public health concern in Latin America.

The disease was first described in 1909 by Carlos Chagas. In Latin America, an estimated 65 million persons inhabit endemic areas where there is risk of infection. Approximately fifteen to 20 million inhabitants of rural and urban areas are thought to be infected with *Trypanosoma cruzi*. It's leading manifestation is chronic myocarditis with high morbidity and mortality.

Trypanosoma cruzi, a protozoan of the Kinetoplastida family, is parasitic to both insects and a wide variety of mammals. Blood-sucking reduviids serves as the principle transmission vector by passage of *Trypanosoma cruzi* infected feces into bite wounds or mucosal surfaces. In endemic countries where not all blood samples are controlled and detection methods are not available, transfusion of infected blood is another important means of transmission. Alternatively, infection can occur through organ transplantation, ingestion of contaminated food and congenitally.

Several strategies exist for the diagnosis of Chagas' disease. Direct detection of the parasite in the blood by microscopy, hemoculture, xenodiagnosis, or PCR is highly specific and confirms the existence of an infection. However, these procedures are technically and operationally demanding. In addition, as a consequence of the pathology of the disease, direct detection is not very sensitive during the indeterminate and chronic phases of Chagas' disease. Other tests currently used include measurement of antibodies against crude lysate, complement fixation, indirect hemagglutination, and fluorescent antibody (IFA). All are lacking specificity and/or sensitivity. Serologic tests that detect antibodies specific for antigens expressed by the different developmental stages of the parasite are well suited for a fast and easy diagnosis of the disease.

The Cypress' Chagas quick test is a rapid immunochromatographic test and is simple and easy to perform with a high degree of sensitivity and specificity.

Principle

The Cypress' quick test is a rapid immunochromatographic screening test for the detection of antibodies to *Trypanosoma cruzi*. It can be used with human serum or whole blood. The method employs a multi-epitope recombinant antigen, composed of a total of nine different epitopes.

If the sample contains any antibodies to *Trypanosoma cruzi*, the antibodies will bind to the specific antibody binding protein-gold conjugate. Then, as this complex flow laterally

through the membrane, it will bind to the immobilized T. cruzi derived proteins present on the solid phase in the test zone producing a red band. In the absence of *Trypanosoma cruzi* antibodies there is no line in the positive reaction zone. The liquid continues to migrate along the membrane and produces a red band in the control zone demonstrating that the reagents are functioning properly.

Storage and stability

Store the sealed pouches, containing the dipsticks, and the buffer solution at 20°C-28°C for the duration of their shelf-life. Exposure to temperatures over 30°C can impact the performance of the test and should be minimized. The strips should not be frozen and must be protected from exposure to humidity and sunlight. The test should be used quickly (preferable within 2-5 minutes) after removal from the pouch. The kit is stable until the date printed on the box label and/or pouch.

Precautions

- This test is designed for In Vitro Diagnostic Use only.
- Do not pipet any material by mouth. Do not smoke, eat or drink in areas where samples or kit reagents are handled.
- Use suitable protective clothing (gloves, lab coat, safety glasses) when handling the kit or samples and performing the assay.
- Avoid all contact between hands and eyes or mucous membranes during testing.
- Treat all materials in the test as if they were infectious. Observe established precautions against microbiological hazards while performing the procedure and follow the standard procedures for proper disposal of sera and used kits.
- The buffer solution contains a preservative. Avoid all contact with skin, mouth or mucous membranes.
- Do not use kit beyond the expiration date which appears on the package label.

Sample collection

The Chagas quick test should be performed on serum or whole blood. Remove the serum from the clot of red cells as soon as possible to avoid hemolysis. For whole blood collection K₂EDTA, K₃EDTA or heparinized blood samples should be used.

Patient samples should be tested as soon as possible after collection. Do not leave the samples at room temperature for prolonged periods. Sera can be refrigerated immediately at 2° to 8°C following collection for up to 3 days. If testing within 3 days is not possible, the sera should be frozen (minus 20°C or colder). Bring sera to room temperature prior to testing. Frozen sera must be completely thawed prior to testing. Sera should not be repeatedly frozen and thawed. If samples are to be shipped, they should be packed in compliance with regulations covering the transportation of etiologic agents.

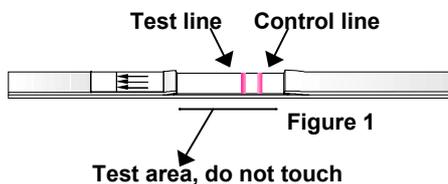
Test procedure

- If the test sample is refrigerated, allow it to come to room temperature.
- Remove the desired number of test units from its pouch.
- Add 10 µl of human serum or 20 µl of whole blood to the test strip in the absorbent area beneath the arrow.
- Add three or four drops (150-200 µl) of the buffer solution provided with this test kit into a test tube or assay well.
- Place the test strip loaded with the sample into the test tube or assay well so that the end of the strip is facing downward as indicated by the arrows on the strip.
- Within 10-20 seconds gold migration will be visible on the membrane region of the dipstick. If no migration is observed, gently tap on the sample tape region of the dipstick until the gold conjugate migration is free flowing.
- Read the results in 10 minutes. It is significant that the background is clear before reading the test. This is especially true when sera have low titer of anti-*T.cruzi* antibody. In this case, only a weak, but unequivocal band may appear in the test region. Results interpreted after 15 minutes can be misleading.

Note: Do not test this product with the buffer solution alone. 10 µl of human serum or 20 µl of whole blood must be added first.

Interpretation of results

POSITIVE In addition to the control line, a distinguishable red test line also appears in the test region as shown in Figure 1. Even a very faint test line should be considered positive. As a guide for interpretation, the red color of in the test region will vary depending on the concentration of anti-*T.cruzi* antibodies present. The test line for "weakly positive" sera samples may show a weak positive but distinct red line. ("Weakly positive" samples are those with low affinity antibodies.)



NEGATIVE Only one red control line appears. No visible test line.

INCONCLUSIVE If there is no distinct control line visible the test is inconclusive. It is recommended, in this case, to repeat the test with a new device.

NOTE:

- The control line is faint blue before assay and turns red following gold migration.
- Note: The red color in the test region will vary depending on the concentration of specific antibodies present in *T.cruzi* infected hosts. However, neither the quantitative value nor the rate of increase in antibodies can be determined by this qualitative test.

Limitations

- For positive samples, the test will only indicate the presence of antibodies against the recombinant antigen and should not be used as the sole criterion to diagnose *Trypanosoma cruzi* infection. It is recommended that a more specific reference test will be performed, and clinical evaluation of the patient's situation should be performed before a final diagnosis is made.
- A negative result at any time does not preclude the possibility of infection with *Trypanosoma cruzi*. Additional follow-up testing is required if clinical symptoms persist.

- Do not use serum or whole blood samples containing any glycerol or other viscous materials. This will compromise the sensitivity of the assay dramatically.
- Do not use highly hemolyzed or aged samples. Highly hemolyzed samples will interfere with test performance.

Performance Characteristics

Performance of Cypress Diagnostics' Chagas Quick test has been correlated with a number of archive sera.

The results of a study in Chile are included:

		ELISA / IFA		
		+	-	Total
Cypress Chagas Quick test	+	51	0	51
	-	0	40	40
Total		51	40	91

Sensitivity: 100% Specificity: 100%

All positive samples were confirmed positive by ELISA and IFA. The negative samples included 10 sera from patients with toxoplasmosis.

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