

Core Chagas (T. Cruzi)

Cat N° CHA-240024

Two Step Assay for the Detection of IgG Antibodies to Chagas Disease in
Serum, Plasma or Whole Blood
For *In Vitro* Diagnostic Use

Description

Chagas disease is caused by the protozoan parasite *Trypanosoma cruzi* and it is widespread in Latin/South America. Transmission of *T. cruzi* can occur through contact with feces of blood sucking reduviid bugs (Triatominae), by the transplacental route, or through transfusion of blood products of people unaware of being infected. There are three stages of infection with Chagas disease. The acute stage, generally seen in children, is usually asymptomatic. Most acute cases resolve over 2-3 months into an asymptomatic chronic period. In the Indeterminate stage, seropositivity is the only indication of the existence of the disease. Severe chronic disease may lead to death, usually due to heart failure. Antibody based tests are the most useful assays for routine screening of Chagas disease and may include IHA and Elisa. New serological tests such as the Core Chagas rapid test are among the simplest and fastest means of identifying Chagas antibodies.

Principle of the Test

The Core Chagas test kit is a rapid membrane based screening test to detect the presence of antibodies to Chagas virus. This test is the newer generation lateral flow immunochromatographic type assay. These are among the simplest and easiest to use POC (point of care) assays.

The test can be used either with serum, plasma or whole blood. The test employs the use of an antibody binding protein conjugated to a colloidal gold particle and a unique conation of Chagas antigens immobilized on the membrane.

Once the sample is added to the test cassette along with the diluent, the mixture passes through the antibody binding/gold complex, which then binds the immunoglobulins in the sample. As this complex passes over the immobilized antigens on the membrane, if any antibodies to Chagas are present the antigens capture them in turn. This produces a pink/purple band in the B zone of the test card. The remaining complex continues to migrate to a control area in the test card and produces a pink/purple band in the C area. This control band indicates that the test has been performed properly.

Kit Components

Each test kit contains:

1. Core Chagas test packs – 25
2. Diluent in dropper vial
3. Directions for Use

Needed but not provided:

1. Measuring pipet capable of delivering 5ul's and 10ul's

Stability and Storage Conditions

The Core Chagas test kit is stable at any room temperature between 8-30°C when in the unopened pouches.

DO NOT FREEZE the kit or expose to temperature extremes.

Stability of the kit is 24 months from the date of manufacture – dating is indicated on the Pouch and kit label.

General Precautions

- The test is for In Vitro Diagnostic Use only.
- Appropriate infection control and handling procedures should be followed – do not smoke, eat or drink in the area where the test is to be performed. Use suitable clothing and gloves when handling samples and when performing the test.
- Do not pipet any samples or reagents by mouth.
- All materials should be considered as potentially infectious. To disinfect, either autoclave materials at 121.5°C for 1 hour or treat with Sodium hypochlorite (1 percent solution).
- Do not use test beyond the expiration date indicated.

Sample Collection

The Core Chagas test can be run on serum or whole blood.

The test works best on fresh samples. If testing cannot be done immediately, they should be stored at 2-8°C after collection for up to 3 days. If testing cannot be done within 3 days, serum can be stored frozen at -20°C or colder. Whole blood samples cannot be frozen and it is recommended that finger prick blood be used not samples collected in EDTA. Shipment of samples should comply with local regulations for transport of etiologic agents.

Test Procedure

1. Remove as many test cards from the pouches as needed. Lay on a clean flat surface.
2. For WHOLE BLOOD - add 10 uls of sample to the (A) well of the test card using a measuring pipet.
For SERUM or PLASMA – add 5 uls of sample to the (A) well of the test card using a measuring pipet.
3. Follow sample addition with **6 (six) drops** of the diluent provided in the dropper bottle by holding the bottle vertically over the (A) well. Add diluent slowly drop wise.
4. **Results are then read in as little as 5 minutes for strong positives or up to 20 minutes for weaker positives and to make sure negatives are confirmed.**

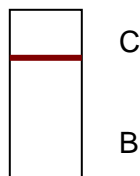
Do Not Read Results After 25 Minutes

NOTE: If the dye has not cleared the membrane or blood is still present after 10-15 minutes, one more drop of diluent may be added to the (A) well.

Reading the Test Results

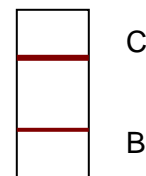
Negative

Only one pink/purple band
Appears in the C (Control)
area of the test card.



Positive

Two pink/purple bands appear.
One in the B (Test) area and
one in the C (Control) area of
the test card.



PLEASE NOTE: When reading this test, any visible **colored line** in the B (Test) area of the card within the prescribed time limit of the test indicates a POSITIVE result.

Indeterminate

If only one band appears in the B well – Test area, or no band appears at all in the C well – Control area. It is then recommended that a fresh device be used and the test repeated carefully following the directions in this insert.

Quality Control

A known positive and negative control should be run to insure proper performance. All controls should be handled in the same manner as patient samples.

Limitations of the Test

The instructions for use and reading of the test instructions must be followed carefully for the test to perform properly.

The Core Chagas test is designed to detect antibodies against Chagas virus in serum or whole blood. Testing of any other body fluids has not been validated and may not yield appropriate results.

For samples that test positive by the Core Chagas test, more specific confirmatory testing should be done. A clinical evaluation of the patient's situation and history should also be made before a final diagnosis is established. The use of a rapid test alone is not sufficient to diagnose Chagas infection even if antibodies are present. Also, a negative result does not preclude the possibility of infection with Chagas virus.

Performance Characteristics

As there are no true standards established for determining the absence or presence of Chagas antibodies in serum or whole blood samples it is recommended that the performance of the kit be compared to established serum panels or reference materials. The CORE CHAGAS Chagas kit is tested against characterized serum samples and has shown to be highly sensitive and specific for Chagas antibodies.

In samples assayed using **3 different test methods** (Chagas Elisa test, IHA and IFI) the Core Chagas rapid test yielded the following performance characteristics;

Specificity of > 98.5 percent

Sensitivity of > 98.8 percent

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