Chagas Ab Rapid Test(Serum)

Cat. No.:DTS204
Pkg.Size:50T

Intended use

Chagas Ab Rapid Test (Serum) is an immunochromatographic test designed to detect antibodies specific for Trypanosoma cruzi in serum. This protozoan is the causal agent for Trypanosomiasis or Chagas disease.

General Description

Trypanosoma cruzi is a species of parasitic euglenoid trypanosomes. This species causes the trypanosomiasis diseases in humans and animals in America. Transmission occurs when the reduviid bug deposits feces on the skin surface and subsequently bites; the human host then scratches the bite area, which facilitates penetration of the infected feces. Human American trypanosomiasis, or Chagas disease, has two forms, a trypomastigote found in human blood and an amastigote found in tissues. The acute form usually goes unnoticed and may present as a localized swelling at the site of entry. The chronic form may develop 10 to 20 years after infection. This form affects internal organs (e.g., the heart, the esophagus, the colon, and the peripheral nervous system). Affected people may die from heart failure.

Principle Of The Test

Chagas Ab Rapid Test (Serum) is an immunochromatographic test capable of detecting antibodies specific for various immunologically-relevant Trypanosoma cruzi antigens. The test is based on the immunological capture of microparticles that are colored and covered with a multi-antigen protein as they pass through a membrane on which the same multi-antigen protein has been immobilized.
If the sample contains antibodies against T. cruzi, they react with the RED colloid particles that are conjugated to the multi-antigen protein. The colloid particle-antibody complexes then migrate through chromatography to the reaction area. In this area, the multi-antigen protein representing T. cruzi has been deposited on a first line; the protein captures the red particle-antibody complexes, producing a RED band.
Whether the sample is negative or positive, the appearance of a BLUE band verifies that chromatography has occurred correctly and under conditions that ensure the antigen-antibody reaction.

Reagents And Materials Provided

1. 50 Reaction devices (strips)
2. 1 vial containing dilution buffer, 30 mL.

The volume of the dilution buffer provided is proportional to the number of strips included and is indicated on the label of the vial containing it.
The total volume of dilution buffer for all the strips is provided in a single vial.

Materials Required But Not Supplied

1. Graduated pipette
2. Pipette tips

Storage

Store at 8 °C – 25 °C. The expiration date is stamped on the pouch.

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Specimen Collection And Preparation

1. The test has been designed for use with sera samples.
2. Dilution of the serum in the diluent buffer may be done in a microplate wells.
3. Samples of serum to be used should be fresh or should be kept in the freezer. In this case, the sample must be completely unfrozen, taken to room temperature and homogenized before analysis.
4. If the samples are going to be kept in the refrigerator it is advisable to add azide or other kind of preservative substance in order to avoid a decrease in the antibodies titer.

Assay Procedure

1. If serum samples have been kept in the freezer, let them reach the room temperature and homogenize them.
2. Prepare a **1/15** dilution of the serum in the diluent buffer by means of the addition of 35 µL of serum into 500 µL of diluent buffer.
3. Mix well
4. Place the Strip Chagas into the previous dilution, in a vertical and stable position. When the strip is submerged in the sample, it must not go over the blue area marked with arrows.
5. Check the result at 10 minutes

Quality Control

The test is invalid if no **BLUE** line appears, whether because the test was not performed properly or the reagents have deteriorated.

Interpretation of Results

NEGATIVE:
A single **BLUE** band (control) appears in the upper part of the strip.
POSITIVE:
Two bands appear: a lower **RED** one (positive for Chagas) and an upper **BLUE** one (control).
INVALID:
No bands appear. Tests in which no **BLUE** control band appears should also be considered invalid, whether there is a red line or not. An invalid result means that the strip has been damaged (usually due to moisture/humidity) or that it has been handled incorrectly.

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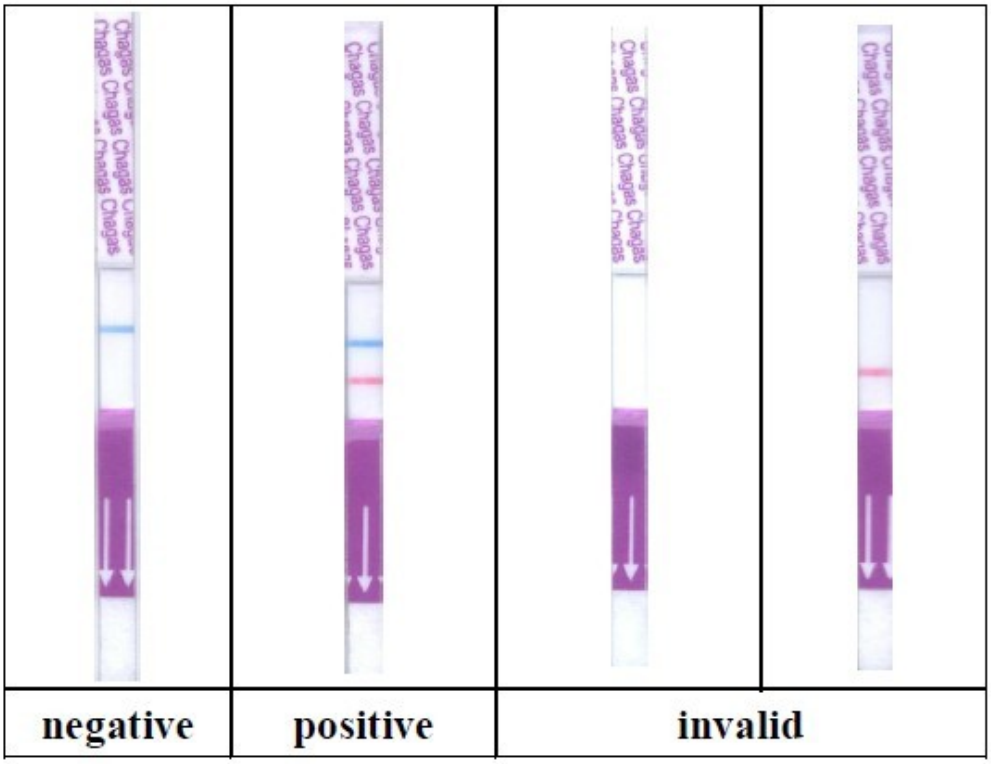

Precautions

1. Use all the reagents only for research.
2. Specimen sera samples may contain infectious agents and should be treated and discarded as potentially dangerous biological materials.
3. Do not exchange components from kits with different lot numbers.
4. Do not use kit components after the expiration dates.
5. If the package is broken, the product can still be used as long as none of the components have been damaged.
6. The used product should be discarded as indicated by current legislation.
7. Do not use the test if a colored line appears in the result area before you start to use it.

Limitations

1. Given that there is a post-infection window in which antibody concentration is too low to be detected, a negative result cannot exclude the possibility of a very recent infection by T. cruzi.
2. It is important to control reaction time. If reaction time is less than that indicated, samples containing an antibody concentration significantly higher than the sensitivity limit can be seen clearly, but those that are at the limit will not appear.
3. Some cross reaction has been observed with some African sera from samples of donors suffering from paludism. However the test has not shown cross reaction with sera from samples of donors suffering from visceral leishmaniasis or sleeping disease.

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