



**OneStep**  
**Chagas (*Trypanosoma cruzi*)**  
**Serum/WB/ Plasma**  
**RapiDip™ InstaTest**

REF 146119-25



**INTENDED USE**

The OneStep Trypanosoma RapiDip™ is for the qualitative detection of antibodies to *T. cruzi*-derived antigens in human serum or whole blood.

**SUMMARY AND EXPLANATION**

Chagas disease is caused by the flagellated protozoa *Trypanosoma cruzi* and is an endemic infection in Central and South America that affects 16 to 18 million individuals (1). Intensive eradication campaigns directed against the triatomine has dramatically diminished vector transmission of *T. cruzi*, especially in rural areas. *T. cruzi* does not exist today in many regions where infection used to be endemic. However, the transfusion of parasite-containing blood continues to be an important mode of transmission (2-4).

**TEST PRINCIPLE**

This immunochromatographic test has been designed for the qualitative detection of antibodies against the *T. cruzi* antigen. The test strip is pre-coated with a proprietary gold conjugate which binds to antibodies present in serum and whole blood. Once bound, the gold-antibody complex migrates into the test area to form a complex with immobilized *T. cruzi*-derived proteins present in the test area, forming a visible red test line if the sample contains antibodies against the *T. cruzi* antigen. The unbound gold will continue to move upward to bind forming a control line. The presence of the red

control line serves as verification for sufficient sample volume and proper flow.

**SPECIMEN COLLECTION AND PREPARATION**

1. Serum/whole blood should be tested with this test strip. For whole blood collection, K2 or K3EDTA, or heparinized blood samples should be used.
2. Remove serum from the clot of red blood cells as soon as possible to avoid hemolysis.
3. Test should be performed as soon as possible after sera/whole blood collection. Do not leave samples at room temperature for prolonged periods. Sera can be refrigerated at 2-8°C up to 3 days. Otherwise sera should be stored frozen.
4. Bring sera/whole blood to room temperature prior to testing. Frozen sera must be completely thawed prior to testing. Sera should not be repeatedly frozen and thawed.
5. If sera/whole blood are to be shipped, they should be packed in compliance with Federal Regulations covering transportation of infectious agents.

**MATERIALS AND COMPONENTS**

**Materials provided with the test kits**

1. Twenty-five (25) test strips individually pouched or 25 test strips in a vial with desiccant in the cap.
2. One (1) vial of Chase Buffer solution.

**Materials required but not provided**

1. Pipettor and tips capable of measuring 10-20 µL.
2. Test tubes or other sample reservoir wells.

**ASSAY PROCEDURE**

1. Allow the sera/whole blood to reach room temperature prior to testing.
2. Remove the test strip from the foil pouch or vial.
3. Add 10µL of human serum or 20µL whole blood to the test strip in the absorbent area beneath the arrow.

4. Separately add three or four drops (150-200µL) of the Chase Buffer solution, provided with this test kit, into a test tube or assay well (not provided).
5. Place the test strip loaded with sample into a test tube or an assay well so that the end of the strip is facing downward as indicated by the arrows on the strip.
6. Within 10-20 seconds gold migration will be visible in the test area. If no reddish-pink migration is observed, gently tap on sample tape region of the test strip until migration is initiated.
7. Read the results in 10 minutes. It is important that the background is clear before reading the test. This is especially true when samples have low titer of anti-*T. cruzi* antibody. In this case, only a weak, but unequivocal test line may appear. **Results interpreted after 15 minutes can be misleading.**

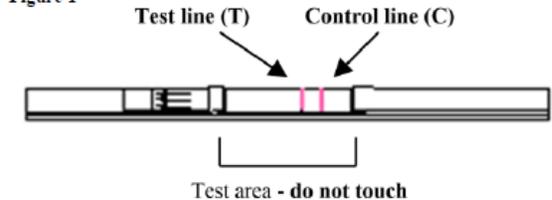
**Note:** Do not test this product with the Chase Buffer solution alone. 10µL of human serum or 20µL of whole blood must be added first.

**RESULTS**

**A Positive Result**

The test is positive when a control line and test line appear in the test area as shown in Figure 1. Even a faint test line is considered a positive result.

Figure 1



**Note:** The control line is faint blue before assay and turns red following gold migration.

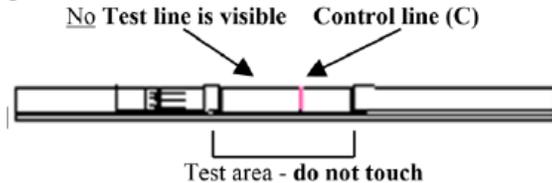
The darkness of the test line will vary depending on the concentration and affinity of specific antibodies present in *T. cruzi*-infected samples. However, neither the quantitative value nor the rate of increase in antibodies can be determined by this qualitative test.



### A Negative Result

The test is negative when only the control line appears. No test line is present as in Figure 2.

Figure 2



### An Invalid Result

A test is invalid if the control line does not appear, regardless whether a test line is observed. It is recommended to retest using a new test strip and fresh human serum or blood.

### STORAGE

The sealed pouch or vial containing the test strip(s) and the bottle containing the Chase Buffer are designed to be stored at room temperature (20°C-30°C). The test strip is designed to retain reactivity in a sealed pouch or vial for the duration of its 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. The test should be used quickly (preferably within 2-5 minutes) after removal from the pouch or vial to minimize exposure to humidity. Do not store tests exposed to sunlight (store in shade or dark places to prevent temperature increase inside the pouches/vial). All tests provided in vials must be used within 4 months of opening the vial.

### LIMITATIONS OF PROCEDURE

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

### PRECAUTION

1. Do not use after expiration date.
2. Handle all sera, whole blood and kits used as if they contain infectious agents. Observe established precautions against microbiological hazards while performing all procedures and follow the standard procedures for proper disposal of sera/whole blood and used kits.
3. Wear protective clothing, eye protection and disposable gloves while performing the assay. Wash hands thoroughly when finished.
4. Avoid all contact between hands and eyes or mucous membranes during testing.
5. Do not eat, drink or smoke in the area where the sera and kits are handled.
6. Chase Buffer contains a preservative; avoid all possible contact with skin, mouth and mucous membranes.

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