（**FOR RESEARCH USE ONLY. DO NOT USE IT IN CLINICAL DIAGNOSIS !**）

Chagas Antibody Lateral Flow Assay Kit

Catalog No: E-HD-C065

20T/40T

This manual must be read attentively and completely before using this product.

If you have any problems, please contact our Technical Service Center for help.

Toll-free: 1-888-852-8623 Tel: 1-832-243-6086 Fax: 1-832-243-6017

Email: techsupport@elabscience.com

Website: www.vetassay-elab.com

Please kindly provide us the lot number (on the outside of the box) of the kit for more efficient service.

Test principle

Chagas Antibody Test Kit is a lateral flow chromatographic immunoassay based on the principle of indirect immunoassay. The test cassette consists of: 1) a burgundy colored conjugate pad containing Protein A conjugated with colloidal gold (Protein A conjugates), 2) a nitrocellulose membrane strip containing a test line (T line) and a control line (C line). The T line is pre-coated with recombinant T. cruzi antigens, and the C line is pre-coated with anti-Protein A antibodies.

When an adequate volume of test specimen is dispensed into the sample well of the test cassette, the specimen migrates by capillary action across the cassette. The IgG antibodies to T. cruzi, if present in the specimen, will bind to the Protein A conjugates. The immunocomplex is then captured on the membrane by the pre-coated T. cruzi antigens forming a burgundy colored T line, indicating a Chagas Ab positive test result.

Absence of the T line suggests a negative result. The test contains an internal control (C line) which should exhibit a burgundy colored line of the immunocomplex of anti-Protein A antibody-Protein A-gold conjugates regardless of color development on the T line. If the C line does not develop, the test result is invalid and the specimen must be retested with another device.

Kit components

Item	Specification
Detection card	20/40 T
Sample Diluent	1 vial
Plastic droppers	20/40
Manual	1 copy

Note: All reagent bottle caps must be tightened to prevent evaporation and microbial pollution.

Notes

1. Please read the manual carefully before use, changes of operation may result in unreliable results.
2. Do not use product out of date or in a broken aluminum foil, it is disposable and cannot be used repeatedly.
3. The detection card should be brought to room temperature before opening after take it out from the refrigerator. The opening detection card should be used as soon as possible.
4. Please do not use but not limited to the following liquids for negative control: Water, PBS.
5. The tested sample should be fresh and clear. Avoid of using samples of turbidity, polluted, high hemolysis or abnormal viscous.
6. Avoid of touching the chromatography membrane of the sample well and test well.
7. The waste of experiment should be considered as contaminant, and must be properly handled according to the local regulations.
8. The test environment should be kept at a fixed temperature to avoid testing at high temperatures.
9. Each reagent is optimized for use in the **E-HD-C065**. Do not substitute reagents from any other manufacturer into the test kit. Do not combine reagents from other **E-HD-C065** with different lot numbers.

Storage and expiry date

Storage: Store at 4-30℃. With cool and dry environment, avoid freeze.

Expiry date: expiration date is on the packing box.

Sample preparation

Consider any materials of human origin as infectious and handle them using standard bio-safety procedures.

1) Serum

1) Collect blood specimen into a red top collection tube (containing no anticoagulants) by veinpuncture.
2) Allow the blood to clot.
3) Separate the serum by centrifugation.
4) Carefully withdraw the serum into a new pre-labeled tube.

Test specimens as soon as possible after collecting. Store specimens at 2 ℃ - 8 ℃ if not tested immediately for up to 5 days. The specimens should be frozen at -20 ℃ for longer storage.

Avoid multiple freeze-thaw cycles. Prior to testing, bring frozen specimens to room temperature slowly and mix gently. Specimens containing visible particulate matter should be clarified by centrifugation before testing.

Do not use samples demonstrating gross lipemia, gross hemolysis or turbidity in order to avoid interference on result interpretation.

2) Plasma

1) Collect blood specimen into lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively) by veinpuncture.
2) Separate the plasma by centrifugation.
3) Carefully withdraw the plasma into new pre-labeled tube.

3) Whole Blood

Drops of whole blood can be obtained by either fingertip puncture or veinpuncture. Do not use hemolized blood for testing.

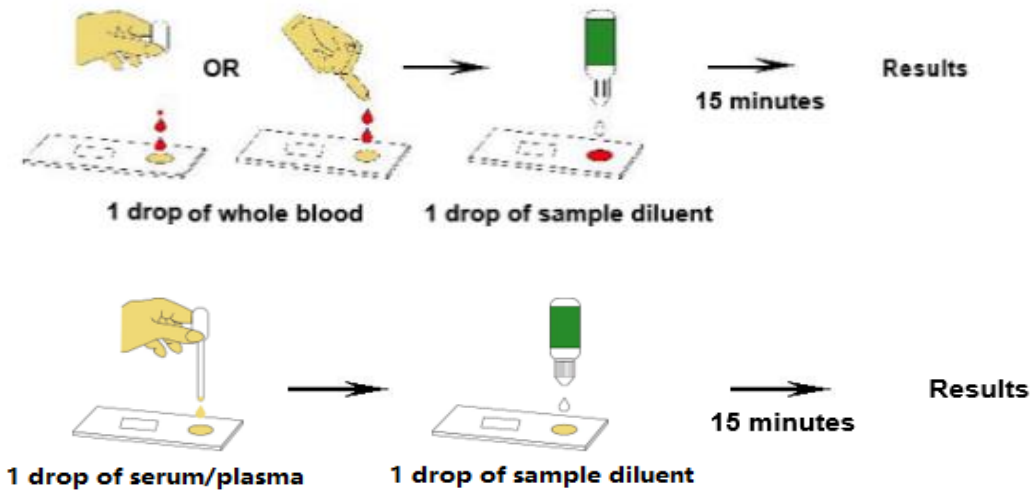
Whole blood specimens should be stored in refrigeration (2 ℃ - 8 ℃) if not tested immediately.

The specimens must be tested within 24 hours of collection.

Assay procedure

Allow all kit components and sample to reach room temperature (25℃) prior to testing.

1. Bring the specimen and test components to room temperature if refrigerated or frozen. Once the specimen is thawed, mix well prior to performing the assay.
2. When ready to test, open the pouch at the notch and remove the device. Place the test device on a clean, flat surface.
3. Be sure to label the device with the specimen's ID number.
4. For whole blood test: Dispense 1 drop (about 45-50 μL) of whole blood specimen into the sample well. Then add 1 drop (about 35-50μL) of sample diluent immediately. For serum or plasma test: Dispense 1 drop (about30-45 μL) of the specimen into the sample well. Then add 1 drop (about 40-50 μL) of sample diluent immediately.

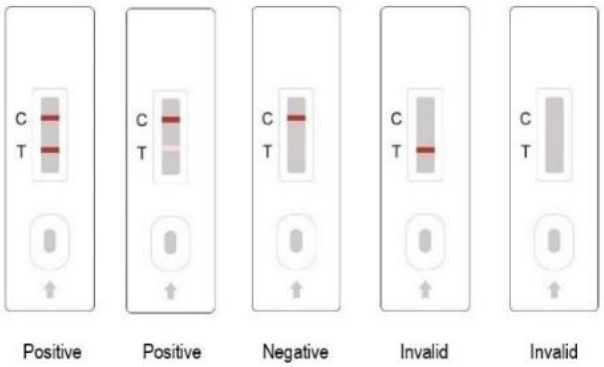


5. Set up the timer.
6. Results can be read within 15 minutes.

Do not read the result after 15 minutes. To avoid confusion, discard the test device after interpreting the result.

Judgment of result

1. **Positive:** If both the C and the T lines are developed, the test indicates the presence of anti-T. cruzi antibodies in the specimen. The result is positive.
2. **Negative:** If only the C line is developed, the test indicates no detectable anti-T. cruzi antibodies are present in the specimen. The result is negative.
3. **Invalid:** If no C line is developed, the assay is invalid regardless of color development on the T line as indicated below. Repeat the assay with a new device.



Limitations of this test method

1. The Test Procedure and the Interpretation of Results sections must be followed closely for the presence of anti-T. cruzi antibody in serum, plasma or whole blood from individual subjects. Failure to follow the procedure may give inaccurate results.
2. The Chagas Antibody Test Kit is limited to qualitative detection of anti-T. cruzi antibody in human serum, plasma or whole blood. The intensity of the test line does not have a linear correlation with the antibody titer in the specimen.
3. A negative result for an individual subject indicates absence of detectable anti-T. cruzi antibodies. However, a negative test result does not preclude the possibility of exposure to or infection with T. cruzi.
4. A negative result can occur if the quantity of the anti-T. cruzi antibody present in the specimen is below the detection limits of the assay or the antibodies that are detected are not present during the stage of disease in which a sample is collected.
5. Some specimens containing unusually high titers of heterophile antibodies or rheumatoid factor may affect expected results.
6. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings