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

Human Treponema Pallidum Antibody Lateral Flow Assay Kit

Catalog No: E-HD-C096

20T/40T

Version Number:	V1.2.1
Replace version:	V1.2
Revision Date:	2022.10.21

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

The test cassette consists of: 1) a burgundy colored conjugate pad containing recombinant Tp antigens conjugated with colloid gold (Tp conjugates) and rabbit IgG-gold conjugates, 2) a nitrocellulose membrane strip containing a test band (T band) and a control band (C band). The T band is pre-coated with non-conjugated recombinant Tp antigens, and the C band is pre-coated with goat anti-rabbit IgG antibody. When an adequate volume of test specimen is dispensed into the sample well of the cassette, the specimen migrates by capillary action across the cassette. Anti-Tp antibody, if present in the specimen will bind to the Tp conjugates. The immunocomplex is then captured on the membrane by the pre-coated Tp antigen, forming a burgundy colored T band, indicating a Tp antibody positive test result. Absence of the T band suggests a negative result. The test contains an internal control (C band) which should exhibit a burgundy colored band of the immunocomplex of goat anti-rabbit IgG/rabbit IgG-gold conjugate regardless of color development on the T band. Otherwise, the test result is invalid and the specimen must be retested with another device.

Kit components

Item	Specification
Detection Card	20T/40T
Sample Diluent	1 bottle
Dropper	20/40 pieces
Manual	1 copy

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

Notes

1. It is a disposable reagent. Do not reuse it. Please use it within the validity date.
2. This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
3. Do not open the sealed pouch, unless ready to conduct the assay.
4. Do not use expired devices.
5. Bring all reagents to room temperature (15-30 ℃) before use.
6. Do not use the components of any other type of test kit as a substitute for the components in this kit.
7. Do not use hemolyzed blood specimen for testing.
8. Wear protective clothing and disposable gloves while handling the kit reagents and specimens. Wash hands thoroughly after performing the test.
9. Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
10. Dispose of all specimens and materials used to perform the test as bio-hazardous waste.
11. The testing results should be read 15 minutes after a specimen is applied to the sample well of the device. Any results interpreted outside of the 20 minute window should be considered invalid and must be repeated.

12. Do not perform the test in a room with strong air flow, i.e. an electric fan or strong air-conditioning.
13. If you have any questions or suggestions during use, please contact the manufacturer.

Storage and expiry date

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

Expiry date: expiration date is on the packing box.

Requirements of sample

Consider any materials of human origin as infectious and handle them using standard biosafety procedures.

For plasma samples

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

For serum samples

1) Collect blood specimen into a red top collection tube (containing no anticoagulants) by venipuncture.
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. If not tested immediately, store specimens at 2-8℃ for up to 5 days. For longer storage, specimens should be kept frozen at -20℃. 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.

For whole blood samples

Drops of whole blood can be obtained by venipuncture. Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively). Do not use any hemolyzed blood for testing.

Whole blood specimens should be stored at 2-8℃ if not tested immediately. The specimens must be tested within 24 hours of collection.

Assay procedure

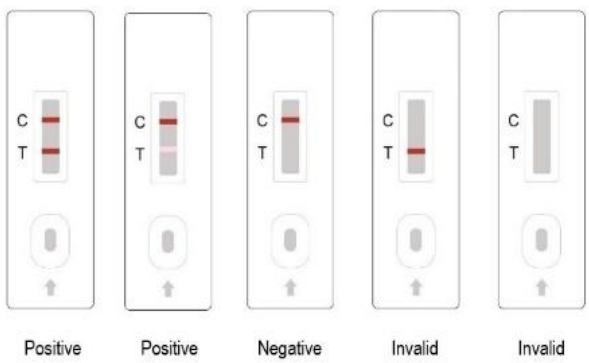
Please read the operation manual completely and bring the test reagent to room temperature (15℃-30℃) before testing. If the reagent is stored in the refrigerator, please take it out and equilibrate it to the room temperature in advance. The test should be performed at room temperature.

1. Bring the specimen and test components to room temperature if refrigerated or frozen. Once thawed, mix the specimen 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 ID number.
4. Add 1 drop (about 30μL-45μL) of the specimen into the specimen well, making sure there are no air bubbles. Immediately add 1 drop (about 35-50 μL) of sample diluent to the sample well with the bottle positioned vertically.
5. Read the test result within 15 minutes. Positive results could be visible in as soon as 1 minute. Do not read the result after 20 minutes. To avoid confusion, discard the test device after interpreting the result.

Interpretation of results

1. Positive: in addition to one purplish red line in the control line (C) region, an apparent colored line will also appear in the test line (T) region.
2. Negative: only one purplish red line appears in the control line (C) region. No line appears in the test line (T) region.
3. Invalid: no line appears in the control line (C) region. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test cassette.



Note: this figure is only used as a reference.

Limitations of this test method

1. The Test Procedure and the Interpretation of Results must be followed closely when testing the presence of anti-Tp antibody in serum, plasma or whole blood from individual subjects. Failure to follow the procedure may give inaccurate results.
2. The Treponema Pallidum Antibody Test Kit is limited to the qualitative detection of anti-Tp antibody in human serum or 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-Tp antibody. However, a negative test result does not preclude the possibility of exposure to or infection with Tp.

4. A negative result can occur if the quantity of the anti-Tp 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 titer of heterophile antibodies or rheumatoid factor may affect expected results.
6. The test result of this reagent can only be used as auxiliary tool. The test result should be combined with other data.