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

HIV/Syphilis Antibody Combo Lateral Flow Assay Kit

Catalog No: E-HD-C061

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

The HIV/Syphilis Antibody Combo Test Kit is a lateral flow immunochromatographic assay. The test cassette consists of: 1) a burgundy colored conjugate pad containing HIV 1+2 antigens conjugated with colloidal gold (HIV 1+2 conjugates), recombinant Tp antigens conjugated with colloidal gold (Tp conjugates) and a control antibody conjugated with colloidal gold, 2) a nitrocellulose membrane strip containing two test lines (H line and S line) and a control line (C line). The H line is pre-coated with HIV 1+2 antigen, the S line is pre-coated with recombinant Tp antigens and the C line is pre-coated with a control line antibody.

When an adequate volume of test specimen is dispensed into the sample well of the cassette, it migrates by capillary action across the cassette. HIV-1 or HIV-2 antibodies, if present in the specimen, migrate through the conjugate pad where they bind to the HIV 1+2 conjugates. The immunocomplex is then captured on the membrane by the pre-coated HIV 1+2 antigens forming a burgundy colored H line, indicating a HIV 1+2 positive or reactive test result. Absence of the H line suggests an HIV-1 and HIV-2 antibody negative or nonreactive test result.

Similarly, if anti-Tp antibodies are present in the specimen, they will bind to the Tp conjugates. The immunocomplex is then captured on the membrane by the pre-coated Tp antigen forming a burgundy colored S line, indicating a Tp antibody positive test result. Absence of the S line suggests a Tp antibody negative or nonreactive result.

The test contains an internal control (C line) which should exhibit a burgundy colored line of the immunocomplex of the control antibodies regardless of color development on the test lines. 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
Dropper	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. Please do not use but not limited to the following liquids for negative control: Water, PBS.
4. The tested sample should be fresh and clear. Avoid of using samples of turbidity, polluted, high hemolysis or abnormal viscous.
5. Avoid of touching the chromatography membrane of the sample well and test well.
6. The waste of experiment should be considered as contaminant, and must be properly handled according to the local regulations.
7. The test environment should be kept at a fixed temperature to avoid testing at high temperatures.

8. Each reagent is optimized for use in the **E-HD-C061**. Do not substitute reagents from any other manufacturer into the test kit. Do not combine reagents from other **E-HD-C061** 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.

Plasma:

Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively) by venipuncture.

Separate the plasma by centrifugation.

Carefully withdraw the plasma into a new pre-labeled tube.

Serum:

Collect blood specimen into a red top collection tube (containing no anticoagulants) by venipuncture.

Allow the blood to clot.

Separate the serum by centrifugation.

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 with result interpretation.

Whole Blood:

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

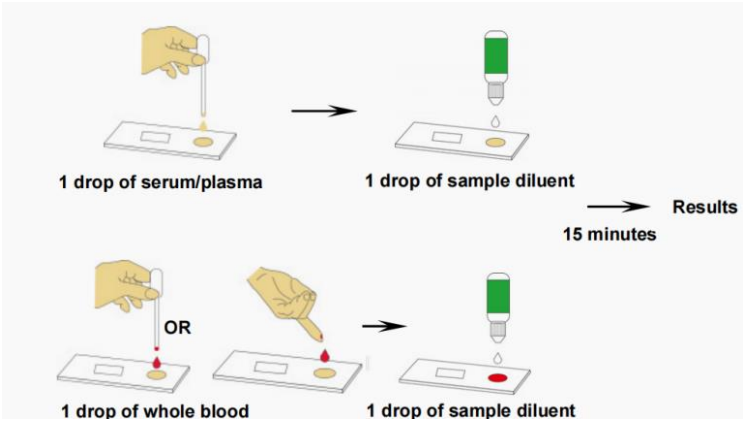
Whole blood specimens should be stored in refrigeration (2 ℃-8 ℃) if not tested immediately. The specimens must be tested within 24 hours of collection

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. Mix the specimen well prior to assay once thawed.
2. When ready to test, open the pouch at the notch and remove device. Place the test device on a clean, flat surface.
3. Be sure to label the device with specimen's ID number.

4. Fill the pipette dropper with the specimen. Holding the dropper vertically, dispense 1 drop of serum/plasma (about 35-45 μL) or apply 1 drop of whole blood (about 40- 50 μL) into the sample well. Make sure that there are no air bubbles.



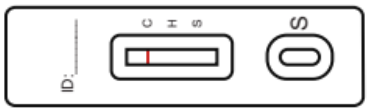
5. Then add 1 drop of sample diluent (about 35-50 μL) immediately.
6. Set up timer. Results can be read in 15 minutes. Positive results can be visible in as soon as 1 minute.

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

Judgment of result

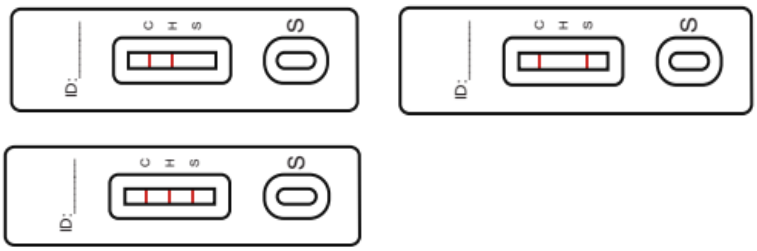
1. Negative

If only the C line is developed, the test indicates that neither anti-HIV nor anti-Tp antibodies are present in the specimen. The result is negative.



2. Positive

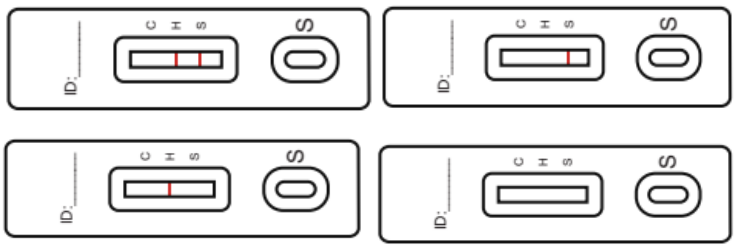
1) If both the C and the H lines are developed, the test indicates the presence of anti- HIV antibodies in the specimen. The result is positive for HIV antibodies.
2) If both the C and the S lines are developed, the test indicates the presence of anti-Tp antibodies in the specimen. The result is anti-Tp antibody positive.
3) In addition to the presence of the C line, if both the H and the S lines are developed, the result is both HIV antibody and Tp antibody positive or reactive.



Note: Samples with positive results should be confirmed with alternative testing method(s) and clinical findings before a diagnostic determination is made.

3. Invalid

If no C line is developed, the assay is invalid regardless of color development on the test lines 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 when testing for the presence of anti-HIV 1+2 and anti-Tp antibodies in serum, plasma or whole blood from individual subjects. Failure to follow the procedure may give inaccurate results.
2. The HIV/Syphilis Antibody Combo Test Kit is limited to the qualitative detection of anti-HIV and anti-Tp antibodies in human serum, plasma or whole blood. The intensity of the test line does not correlate with the antibody titer in the specimen.
3. A negative result for an individual subject indicates absence of detectable anti-HIV and/or anti-Tp antibody. However, a negative test result does not preclude the possibility of exposure to or infection with HIV and/or Tp.
4. A negative result can occur if the quantities of the anti-HIV and/or anti-Tp antibodies present in the specimen are below the detection limits of the assay or the antibodies are not present during the stage of disease in which a sample is collected.
5. If the symptoms persist while the result from HIV/Syphilis Antibody Combo Test Kit is negative or non-reactive, it is recommended to re-sample the patient a few weeks later or test with an alternative test device.
6. Some specimens containing unusually high titers of heterophile antibodies or rheumatoid factor may affect expected results.
7. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.