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

HCV Ab Lateral Flow Assay Kit

Catalog No: E-HD-C062

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.

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Test principle

The HCV Ab Test Kit is a double antigen lateral flow chromatographic immunoassay. The test strip consists of: 1) a burgundy colored conjugate pad containing recombinant HCV fusion antigen (core, NS3, NS4 and NS5) conjugated with colloidal gold (HCV Ag conjugates) and a control antibody conjugated with colloidal gold, 2) a nitrocellulose membrane strip containing a test line (T line) and a control line (C line). The T line is precoated with recombinant HCV fusion antigen (core, NS3, NS4 and NS5), and the C line is precoated with a control line antibody.

When an adequate volume of test specimen is dispensed into the sample pad of the test strip, the specimen migrates by capillary action across the strip. Antibodies to HCV, if present in the specimen, will bind to the HCV Ag conjugates. The immunocomplex is then captured on the membrane by the pre-coated, non-conjugated HCV fusion antigen forming a burgundy colored T line, indicating a HCV Ab positive or reactive 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 control antibodies regardless of the 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
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 Do not use product out of date or in a broken aluminum foil, it is disposable and cannot be used repeatedly.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-C062**. Do not substitute reagents from any other manufacturer into the test kit. Do not combine reagents from other **E-HD-C062** 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 biosafety procedures.

1. Plasma

1) Collect blood specimen into a 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.

2. 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. Specimens can be stored at 2-8 ℃ 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.

Assay procedure

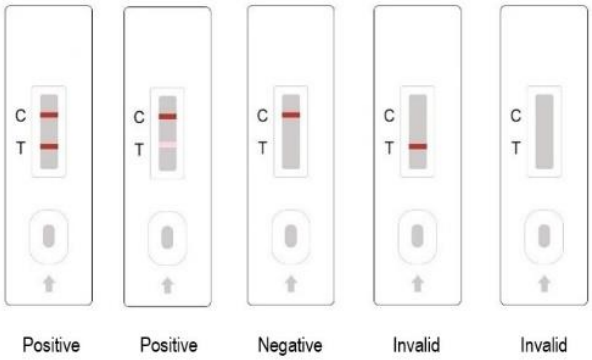
Allow all kit components and sample to reach room temperature (25℃) prior to testing.

1) Bring the specimen and test components to room temperature (15℃-30℃) if refrigerated or frozen. Once thawed, mix the specimen well prior to assay.
2) Take out the test card from the aluminum foil packaging bag, place it on a horizontal, dry plane, and use it within 1 hour after unsealing to prevent moisture of test card.
3) Collect at least 150-200 μL or 3-4 drops of serum or plasma.
4) Drip the sample collected into the sample well of the test card.
5) Set up the timer.
6) Results can be read in 15 minutes. Positive results can be visible in as short as 1 minute.

Note: Do not read the result after 20 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 antibodies to HCV in the specimen. The result is positive or reactive.
2. **Negative:** If only the C line is developed, the test indicates that no detectable antibodies to HCV are present in the specimen. The result is negative or non-reactive.
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 when testing for the presence of antibodies to HCV in serum, plasma or whole blood from individual subjects. Failure to follow the procedure may give inaccurate results.
2. The HCV Ab Test Kit is limited to the qualitative detection of antibodies to HCV in human serum, plasma or whole blood. The intensity of the test line does not have linear correlation with the antibody titer in the specimen.
3. A non-reactive result for an individual subject indicates absence of detectable antibodies to HCV. However, a non-reactive test result does not preclude the possibility of exposure to or infection with HCV.
4. A non-reactive result can occur if the quantity of the antibodies to HCV present in the specimen is below the detection limits of the assay or if 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. If the symptoms persist and the result from HCV Ab Test Kit is nonreactive, it is recommended to re-sample the patient a few days later or test with an alternative device.
7. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

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