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

Human HAV IgG/IgM Lateral Flow Assay Kit

Catalog No: E-HD-C097

20T/40T

Version Number:	V2.0
Replace version:	V1.0
Revision Date:	2023.02.16

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 HAV IgG/IgM Test Kit is a lateral flow chromatographic immunoassay. The test strip in the cassette device consists of: 1) a burgundy colored conjugate pad containing HAV antigens conjugated with colloidal gold (HAV conjugates) and a control antibody conjugated with colloidal gold; 2) a nitrocellulose membrane strip containing two test lines (G and M lines) and a control line (C line). The G line is pre-coated with mouse anti-human IgG for detection of anti-HAV IgG. The M line is pre-coated with mouse anti-human IgM for detection of anti-HAV IgM. The C line is pre-coated with a control antibody.

When an adequate volume of test specimen and sample diluent is dispensed into the sample well and buffer well, respectively, the specimen migrates by capillary action across the test strip. If anti-HAV IgG is present in the specimen, it will bind to the HAV conjugates. The immunocomplex is then captured on the membrane by the pre-coated mouse anti-human IgG forming a burgundy colored G line, indicating an HAV IgG positive test result. If anti-HAV IgM is present in the specimen it will bind to the HAV conjugates. The immunocomplex is then captured on the membrane by the pre-coated mouse anti- human IgM forming a burgundy colored M line, indicating an HAV IgM positive test result.

Absence of any test lines (G or M) suggests a negative 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 (G and M). If no control line (C line) develops, 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
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 may lead to inaccurate test results.
3. Do not open the sealed pouch until ready to conduct the assay.
4. Do not use expired devices or components.
5. Bring all reagents to room temperature (15-30 ℃) before use.
6. Do not use components from any other test kit as a substitute for the components in this kit.
7. Do not use hemolyzed blood for testing.
8. Wear protective clothing and disposable gloves while handling the kit reagents and specimens. Wash hands thoroughly after performing the test.
9. Users of this test should follow the US CDC Universal Precautions for prevention of transmission of HIV, HBV and other blood-borne pathogens.

10. Do not smoke, drink or eat in areas where specimens or kit reagents are being handled.
11. Dispose of all specimens and materials used to perform the test as bio- hazardous waste.
12. Handle the negative and positive controls in the same manner as patient specimens.
13. The test result should be read within 30 minutes after a specimen is applied to the sample well of the device. Reading the result after 30 minutes may give erroneous results.
14. 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

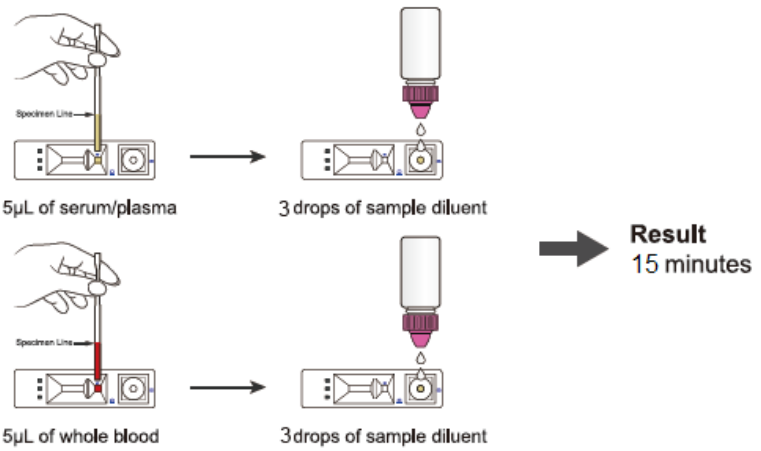
Drops of whole blood can be obtained by venipuncture. Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively). Do not use any hemolyzed blood for testing.

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.

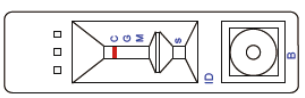
1. Bring the specimen to room temperature if refrigerated or frozen. Once thawed, mix the specimen well prior to performing the assay.
2. When ready to test, open the pouch at the notch and remove the device. Place the test device on a clean, flat surface.
3. Be sure to label the device with the specimen ID number.
4. Accurately add 5μL of plasma, serum or whole blood, dispense the entire specimen into the center of the sample well (S well), making sure that there are no air bubbles. Immediately add 3 drops (approximately 80- 100 μL) of sample diluent into the buffer well (B well) with the bottle positioned vertically
5. Set up the timer.
6. Result can be read in 15 minutes. Positive results may be visible in as soon as 1 minute. Do not read result after 30 minutes. To avoid confusion, discard the test device after interpreting the result.



Note: this figure is only used as a reference.

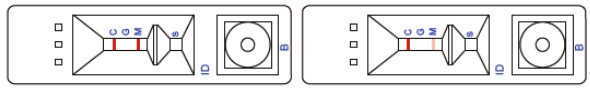
Interpretation of results

1. Negative: If only the C line develops, the test indicates that anti-HAV antibodies are not detected in the specimen. The result is negative or non-reactive.

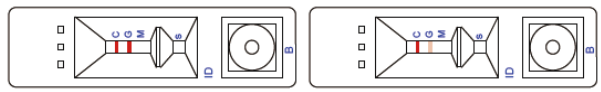


2. Positive

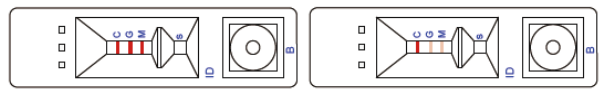
   2.1 In addition to the presence of the C line, if only the M line develops, the test indicates the presence of anti-HAV IgM. The result is HAV IgM positive or reactive.



2.2 In addition to the presence of the C line, if only the G line develops, the test result indicates the presence of anti-HAV IgG; the result is HAV IgG positive or reactive.

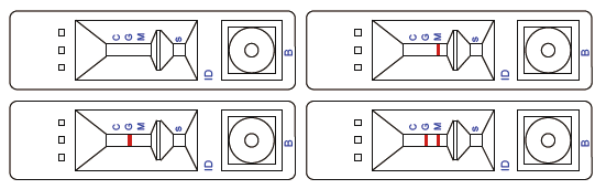


2.3 In addition to the presence of C line, if both the G and M lines develop, the test indicates the presence of anti-HAV IgG and anti-HAV IgM. The result is HAV IgG and HAV IgM positive or reactive.



Samples with positive results should be confirmed with alternative testing method(s) and clinical findings before a positive determination is made. Specimens with positive or reactive results should be confirmed with alternative testing method(s) and clinical findings before a diagnosis is made. Rheumatoid factor levels≥1,000 IU/mL may lead to unexpected positive results.

3. Invalid: If no C line is developed, the Rapid Test is invalid regardless of any burgundy color in the test bands as indicated below. Repeat the Rapid Test with a new device.



Limitations of this test method

1. The Assay Procedure and the Interpretation of Assay Result sections must be followed closely when testing for the presence of antibodies to HAV in serum, plasma or whole blood from individual subjects. Failure to follow the procedure may lead to inaccurate results.
2. The HAV IgG/IgM Test Cassette is limited to the qualitative detection of antibodies to HAV 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 negative or non-reactive test result does not preclude the possibility of exposure to or infection with HAV. A negative or non-reactive result can occur if the titer of HAV antibodies present in the specimen is below the level detectable by the assay or if HAV antibodies were not present during the stage of disease in which the sample was collected.
4. A negative result does not rule out an acute infection with HAV. Samples collected too early in the course of an infection may not have detectable levels of IgM.

5. Infection may progress rapidly. If the symptoms persist, while the result from HAV IgG/IgM Test is negative or non-reactive, it is recommended to test with an alternative test method or re-test the patient a few days later.
6. Unusually high titers of heterophile antibodies or rheumatoid factor (≥ 1,000 IU/mL) may affect expected results.
7. The test result of this reagent can only be used as auxiliary tool. The test result should be combined with other data.