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

Filariasis IgG/IgM Lateral Flow Assay Kit

Catalog No: E-HD-C066

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 Filariasis IgG/IgM Rapid Test Kit is a lateral flow chromatographic immunoassay. The test cassette consists of: 1) a burgundy colored conjugate pad containing Filariasis antigens conjugated with colloidal gold (Filariasis conjugates) and rabbit IgG-gold conjugates, 2) a nitrocellulose membrane strip containing two test lines (G line and M line) and a control line (C line). The G line is pre-coated with monoclonal anti-human IgG antibody, the M line is pre-coated with monoclonal anti-human IgM antibody, and the C line 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. IgG/IgM antibodies, if present in the specimen, will bind to the Filariasis conjugates. The immunocomplex is then captured on the membrane by the pre-coated anti-human IgG/IgM antibody forming a burgundy colored G/M line, indicating a Filariasis IgG/IgM positive test result.

Absence of the test line suggests a negative result. The test contains an internal control (C line), which should exhibit a burgundy colored line of the immunocomplex of goat anti-rabbit IgG/rabbit IgG-gold conjugate regardless of color development on the T line. Otherwise, the test result is invalid and the specimen must be retested with another device.

Kit components

Item	Specification
Detection card (With Dropper)	20/40 T
Sample Diluent	1 vial
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 Do not use product out of date or in a broken aluminum foil, it is disposable and cannot be used repeatedly.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-C066**. Do not substitute reagents from any other manufacturer into the test kit. Do not combine reagents from other **E-HD-C066** 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.

Plasma

Step 1: Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively) by veinpuncture.

Step 2: Separate the plasma by centrifugation.

Step 3: Carefully withdraw the plasma into new pre-labeled tube.

Serum

Step 1: Collect blood specimen into a red top collection tube (containing no anticoagulants) by veinpuncture.

Step 2: Allow the blood to clot.

Step 3: Separate the serum by centrifugation.

Step 4: Carefully withdraw the serum into a new pre-labeled tube.

Test specimens as soon as possible after collecting. Store specimens at 2℃ to 8℃ if not tested immediately. Specimens at 2℃ to 8℃ can be stored for up to 5 days. 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.

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 (15℃-30℃) if refrigerated or frozen. Once thawed, mix the specimen well prior to assay.
2. When ready to test, open the pouch at the notch and remove the test cassette. Place the test cassette on a clean, flat surface.
3. Fill the plastic dropper with the specimen. Holding the dropper vertically, dispense 1 drop of sample (about 35-45 μL) into the sample well, making sure there are no air bubbles. Immediately add 1 drop (about 30-50 μL) of sample diluent with the bottle positioned vertically.
4. Set up the timer.

5. Observe the result after 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

IgM POSITIVE: Two lines appear.

Colored lines should be in the control line region (C) and IgM test line region. No line appears in IgG test line region.

IgG and IgM POSITIVE: Three lines appear.

Colored lines should be in the control line region(C), IgG line test region and IgM test line region. The color intensities of the lines do not have to match.

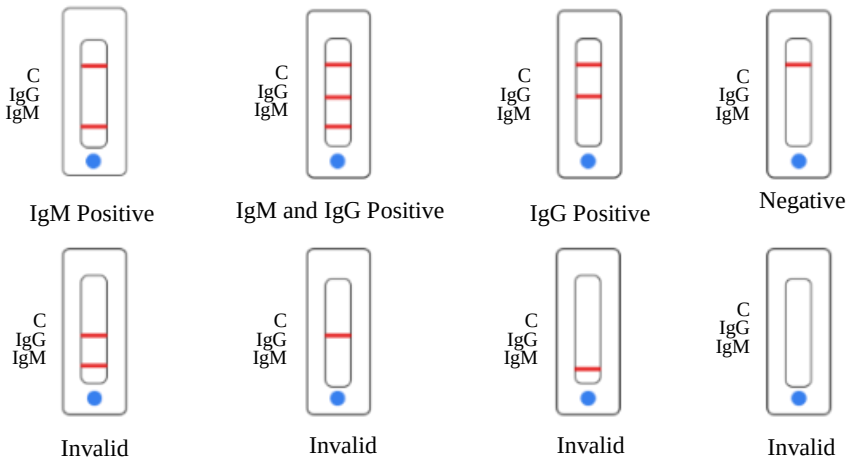
IgG POSITIVE: Two lines appear.

Colored lines should be in the control line region(C) and IgG test line region. No line appears in IgM test line region.

NEGATIVE: One colored line should be in the control line region (C). No line appears in IgG and IgM test line region(s).

INVALID: Control line fails to appear.

Insufficient buffer volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the procedure with a new cassette. If the problem persists, discontinue using the test kit and contact your local distributor.



NOTE: This figure is only used as a reference for judging results.

Limitations of this test method

1. This reagent is only used for the detection of human serum, plasma or whole blood samples. Correct results can only be obtained by careful operation in strictly accordance with the operating procedures. Any modification to the operating procedures may affect the results.
2. The test results of this reagent can only be used as an auxiliary tool for doctors or other diagnosis, and the test results should be combined with other clinical and laboratory data. If the test results are inconsistent with the clinical evaluation, further examination is required.
3. False positive results can be caused by several factors: cross-reaction of similar antibody components in blood; certain non-specific components in blood with similar epitopes capture labeled antibodies; cross contamination of samples during transportation and treatment; the consumables and equipment used during the test are contaminated.
4. False negative results may be due to the following reasons: some unknown components blocked antigen epitope to prevent it from binding to the antibody; unstable antigens gradually degrade with time and temperature and cannot be recognized by antibodies; unreasonable sample collection, transshipment and treatment resulted in too low concentration of the substance in the sample. Effective test results depend on a good sample storage environment.
5. Other factors can also cause test errors, including technical reasons, operational errors, and other sample factors.