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

Human DENV IgG/IgM Lateral Flow Assay Kit

Catalog No: E-HD-C088

20T/40T

Version Number:	V1.2
Replace version:	V1.1
Revision Date:	2024.07.11

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

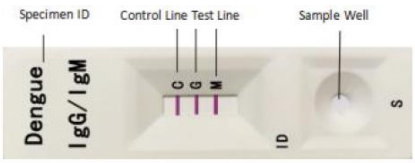
Email: techsupport@elabscience.com

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 DENV IgG/IgM Test Kit is a lateral flow chromatographic immunoassay. The test strip in the cassette consists of: 1) a burgundy colored conjugate pad containing dengue recombinant envelope antigens conjugated with colloidal gold (dengue Ag 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 antibodies for the detection of IgG anti-dengue virus, the M line is pre-coated with antibodies for the detection of IgM anti-dengue virus, and the C line is precoated with a control line antibody.



When an adequate volume of test specimen is dispensed into the sample well of the test cassette, the specimen migrates by capillary action along the cassette. IgG anti-dengue virus, if present in the specimen, will bind to the dengue Ag conjugates. The immunocomplex is then captured by the pre-coated anti-human IgG, forming a burgundy colored G line, indicating an IgG anti-dengue virus positive test result and suggesting a secondary or past infection with dengue virus.

IgM anti-dengue virus, if present in the specimen, will bind to the dengue Ag conjugates. The immunocomplex is then captured by the pre-coated anti-human IgM, forming a burgundy colored M line, indicating an IgM anti-dengue virus positive test result and suggesting either an acute primary or secondary dengue infection. An IgM and IgG positive result indicates a late primary or early secondary acute infection.

Absence of any G, M or T lines suggests a negative result. Each test contains an internal control (C line) which should exhibit a burgundy colored line of the control antibodies regardless of color development on any of 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	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 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 clinical 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. The testing results should be read 20-25 minutes after a specimen is applied to the sample well of the device. Any results interpreted outside of the 20-25 minutes window should be considered invalid and must be repeated.
13. Do not perform the test in a room with strong air flow, i.e. an electric fan or strong air-conditioning.

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.

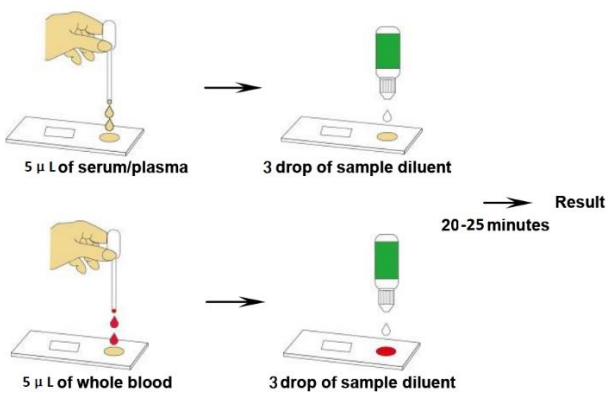
For whole blood samples

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

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 specimen's ID number.
4. Accurately add 5 μL serum, plasma or whole blood specimen into the sample well, for better precision, transfer the specimen by a pipette capable of delivering 5μL of volume, making sure that there are no air bubbles. Immediately add 3 drops (about 90-120 μL) of Sample Diluent into the sample well with the bottle positioned vertically.

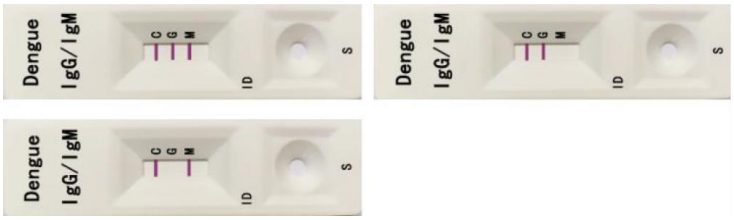


5. Set up the timer.
6. Read the result at 20-25 minutes. Positive results may be visible in as short as 1 minute. Negative results must be confirmed at the end of the 25 minutes only. **Any results interpreted outside of the 20-25 minute window should be considered invalid and must be repeated. Discard used devices after interpreting the result following local laws governing the disposal of devices.**

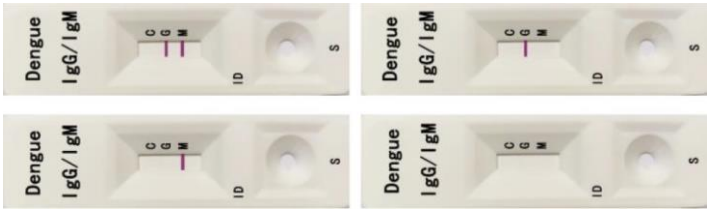
Interpretation of results

1. Negative: If only the C line is present, the absence of any burgundy color in both test lines (G and M) indicates that no anti-dengue virus antibodies are detected. The result is negative or non-reactive.

2. Positive: In addition to the presence of C line, if only the G line develops, the result is IgG anti-dengue virus positive or reactive; if only the M line develops, the result is IgM anti-dengue virus positive or reactive; if both test lines (G and M) develops, the result is IgG anti-dengue virus and IgM anti-dengue virus positive or reactive.



3. Invalid: If no C line develops, the assay is invalid regardless of color development on the T line as indicated below. Repeat the assay with a new device.



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 antibodies to dengue virus in serum, plasma and whole blood from individual subjects. Failure to follow the procedure may lead to inaccurate results.
2. The DENV IgG/IgM Test Kit is limited to the qualitative detection of IgG and IgM anti–dengue virus in human serum, plasma and whole blood. The intensity of the test band does not have linear correlation with the antibody titer in the specimen.
3. Information about the dengue virus serotype(s) present in a specimen cannot be provided from this test.
4. The DENV IgG/IgM Test Kit cannot differentiate primary or secondary infection.
5. Serological cross-reactivity with other flaviviruses is common (e.g., Japanese encephalitis, West Nile virus, yellow fever, etc.). Therefore, it is possible that patients who were exposed to these viruses may show some level of reactivity with this test.
6. A negative or non-reactive result for an individual subject indicates absence of detectable dengue virus antibodies. However, a negative or non-reactive test result does not preclude the possibility of exposure to or infection with dengue virus.

7. A negative or non-reactive result can occur if the quantity of antibodies to dengue virus present in the specimen is below the limits of detection, or if the antibodies that are detected are not present during the stage of disease in which a sample is collected.
8. Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.
9. Infection may progress rapidly. If the symptoms persist, while the result from DENV IgG/IgM Test Kit is negative or non-reactive, it is recommended to test with an alternative test method.
10. The test result of this reagent can only be used as auxiliary tool. The test result should be combined with other data.