

EZER™ Dengue IgG/IgM Rapid Test Device

INTENDED USE

The *EZER™* Dengue IgG/IgM Rapid Test Device is a lateral flow chromatographic immunoassay for the qualitative detection of dengue IgG/IgM in human whole blood, serum or plasma. It is intended to be used as a screening test and as an aid in the diagnosis of infection with Dengue viruses. Any reactive specimen with the Dengue IgG/IgM Rapid Test Device must be confirmed with alternative testing method(s) and clinical findings.

BACKGROUND

Dengue viruses, a family of four distinct serotypes of viruses (Den 1,2,3,4), are single-strained, enveloped, positive-sense RNA viruses. The viruses are transmitted by mosquitoes of the daytime-biting *Stegomyia* family, principally *Aedes aegypti*, and *Aedes albopictus*. Today, more than 2.5 billion people living in the areas of tropical Asia, Africa, Australia, and the Americas are at risk for dengue infection. An estimated 100 million cases of dengue fever and 250,000 cases of life-threatening dengue hemorrhagic fever occur annually on a worldwide basis.

Serological detection of IgG/IgM antibody is the most common method for the diagnosis of dengue virus infection.

The Dengue IgG/IgM Rapid Test is a rapid test that utilize a combination of Dengue antigen coated colored particles for the detection of IgG and IgM Dengue antibodies in human whole blood, serum, or plasma.

PRINCIPLE

This test consists of two components, an IgG component and an IgM component. In the IgG component, anti-human IgG is coated in test line region 1 of the test. During testing, the specimen reacts with Dengue antigen-coated particles in the test strip. The mixture then migrates upward on the membrane chromatographically by capillary action and reacts with the anti-human IgG in test line region 1. If the specimen contains IgG antibodies to Dengue, a colored line will appear in test line region 1. In the IgM component, anti-ligand is coated in test line region 2 of the test. During testing, the specimen reacts with ligand anti-human IgM. Dengue IgM antibodies, if present in the specimen, reacts with the ligand anti-human IgM and the Dengue antigen-coated particles in the test strip, and this complex is captured by the anti-ligand, forming a colored line in test line region 2.

Therefore, if the specimen contains Dengue IgG antibodies, a colored line will appear in test line region 1. If the specimen contains Dengue IgM antibodies, a

colored line will appear in test line region 2. If the specimen does not contain Dengue antibodies, no colored line will appear in either of the test line regions, indicating a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

The control area (C) of the test card is coated with sheep anti-rabbit IgG. Regardless of the presence of IgM/IgG antibodies in the sample, rabbit antibody-colloidal gold complex combine to it and forms a purplish red band. Otherwise, the test results are invalid and must be repeated with another test card.

CONTENTS

Dengue IgG/IgM test device	20 Tests
Sample buffer	1 Tube
Plastic dropper	20 Pcs.
Package Insert	1 Pc.

STORAGE CONDITIONS

Store the *EZER™* Dengue IgG/IgM Rapid Test Device Kit at room temperature or refrigerated (2-30°C). All reagents are stable until the expiration dates printed on the kit box or the label inside.

SAMPLE COLLECTION AND PREPARATION

1. Whole Blood

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

2. Plasma

- (1) Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively in Vacutainer®) by venipuncture.
- (2) Separate the plasma by centrifugation.
- (3) Carefully withdraw the plasma into new pre-labeled tube.

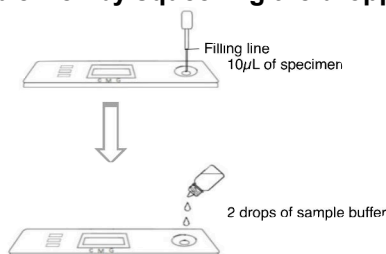
3. Serum

- (1) Collect blood specimen into a red top collection tube (containing no anticoagulants in Vacutainer®) 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.

PROCEDURE

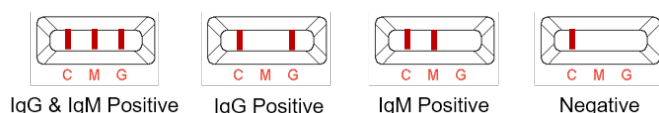
Allow the **EZER™ Dengue IgG/IgM Rapid Test Device Kit** and collected samples to equilibrate to room temperature (15–30°C) prior to testing. Refer to testing procedures printed inside the kit.

1. Bring the specimen and test components to room temperature if refrigerated or frozen. Mix the specimen well prior to assay once thawed.
 2. 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. For whole blood, plasma and serum samples:
Fill the plastic dropper with the specimen. Holding the dropper vertically, then add 10µL of specimen and 2 drops of buffer into the sample well, making sure that there are no air bubbles.
- ❖ For specimen collection with provided dropper, draw specimen to fill entire length of the narrow tip for 10 µL volume. Release specimen in the sample well by squeezing the dropper.



5. Read the results after 10 minutes, if more than 20 minutes. Please retest with another test card.

INTERPRETATION OF RESULTS



IgG Positive:

The colored line in the control line region (C) appears and a colored line appears in test line region 1 (G). The result is positive for Dengue virus specific-IgG and is probably indicative of secondary Dengue infection.

IgM Positive:

The colored line in the control line region (C) appears and a colored line appears in test line region 2 (M). The result is positive for Dengue virus specific-IgM antibodies and is indicative of primary Dengue infection.

IgG & IgM Positive:

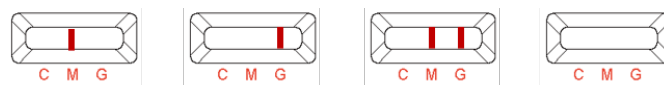
The colored line in the control line region (C) appears and two colored lines should appear in test line regions 1 and 2 (G and M). The color intensities of the lines do not have to match. The result is positive for IgG & IgM antibodies and is indicative of secondary Dengue infection.

※**NOTE:** The intensity of the color in the test line region(s) (G and/or M) will vary depending on the concentration of Dengue antibodies

in the specimen. Therefore, any shade of color in the test line region(s) (G and/or M) should be considered positive.

Negative Result:

The colored line in the control line region (C) appears. No line appears in test line regions 1 or 2 (G or M).



Invalid

Invalid:

Control band 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 test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

PRECAUTIONS FOR ASSESSMENT

- For *in vitro* diagnostic use only.
- Do not use after the expiration date.
- Ensure foil pouch containing test device is not damaged before opening for use.
- Perform the test at room temperature (15 to 30°C).
- Wear gloves when handling the samples, avoid touching the reagent membrane and sample well
- Test specimens as soon as possible after collecting. Store specimens at 2°C to 8°C if not tested immediately.
- Store specimens at 2°C to 8°C up to 5 days. The specimens should be frozen at -20°C 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.
- All samples and used accessories should be treated as infectious and discarded according to local regulations.

PERFORMANCE CHARACTERISTICS

The specimens obtained from a population of symptomatic and asymptomatic individuals. Results were compared by a leading commercial Dengue ELISA test.

Dengue IgG/IgM Rapid Test vs. ELISA

Dengue Infection	Result	IgM	IgG
Primary Infection	Positive	67	0
	Negative	2	69
	Total	69	69
	Sensitivity	97.1%	0%
Secondary Infection	Positive	43	47
	Negative	4	0
	Total	47	47
	Sensitivity	91.5%	>99.0%

Non-Dengue Infection	Positive	0	0
	Negative	384	384
	Total	384	384
	Specificity	>99.0%	>99.0%

For the primary and secondary infection, the overall sensitivity is 97.4%, the overall specificity is 100% and the overall accuracy is 99.4%.

LIMITATIONS OF THE PROCEDURE

- The rapid test kit for dengue antibodies is limited to qualitative detection of Dengue IgM/IgG antibodies in human whole blood, serum or plasma. There is no linear relationship between the strength of the detection band and the concentration of antibodies in the sample.
- A negative test result does not preclude the possibility of exposure to or infection with dengue viruses.
- A negative result can occur if the quantity of dengue Ab/Ag present in the specimen is below the detection limits of the assay, or the dengue Ab that are detected are not present during the stage of disease in which a sample is collected.
- Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.

The results obtained with this test should be interpreted in conjunction with other diagnostic procedures and clinical findings.

REFERENCES

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Index of Symbols			
	Attention, see instructions for use		Tests per kit
	For in vitro diagnostic use only		Use by
	Store between 2–30°C		Lot Number
	Authorized Representative		Do not reuse
	Catalog #		

EC REP Lotus NL B.V.
Koningin Julianaplein 10, le Verd, 2595AA,
The Hague, Netherlands.

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