Rapichek
Dengue IgM & IgG (Ab)

Rapid Dengue IgM/IgG Antibody Detection Test.
Differential detection of IgM/IgG antibodies in Human Serum/Plasma

INTENDED USE

Rapid Dengue IgM/IgG test is a lateral flow chromatographic immunoassay for the simultaneous detection and differentiation of anti-dengue virus IgG & IgM in human serum/plasma. It is intended to be used by healthcare professionals to aid in the diagnosis of infection with dengue virus. Alternative test method(s) should be considered to confirm the test result obtained by this device.

PRINCIPLE

Dengue IgM/IgG test device contains three lines; "C" (Control Line),"M" (IgM test line) & "G"(IgG test line).IgM test line is coated with anti-human IgM and IgG test line is coated with anti-human IgG. When a sample is added to the device, IgM and IgG antibodies in the sample react with particles coated with dengue proteins. As this sample /particle mixture migrates along the length of the test, the anti-dengue IgM or IgG antibody particle complex is captured by relevant IgM and /or IgG test bands located in the test device causing a color band/s to form at IgM or IgG region of the test device window. The intensity of the test bands in the device will vary depending upon the amount of antibody present in the sample. The appearance of color in specific test region should be considered as positive for the particular antigen and / or antibody. A procedural control line should always develop in the test device window to indicate that the test has been performed properly. This test is intended for professional use. and must by trained person.

MATERIALS PROVIDED

Dengue IgM/IgG test kit contains following items to perform the assay.
1. Dengue IgM/IgG test device packed with desiccant.
2 Buffer Solution
3. Sample applicator or microtips.
4. Product Insert

Rapichek Dengue IgM/IgG Test Procedure

1. Allow the sample and sealed test pouch to reach room temperature (20°C to 30°C) before opening the foil pouch.

2. Open the pouch and remove the test Device and desiccant pouch.

3. Check the color of the desiccant it should be blue, if it has turned colorless or pink, discard the test and use another test. Once opened, the test must be used immediately.

4. Label the device with specimen identity.

5.Tighten the cap of the buffer solution bottle provided with the kit in clockwise direction to pierce th e dropper bottle nozzle.

6. Insert the sample applicator in the serum or plasma sample and fill the sample upto the notch of sample applicator. This will deliver Approx. 5 µl of serum or plasma sample. Add the sample in well 'S' and immediately dispense 2 to 3 drops of buffer solution in same well by holding the buffer solution bottle vertically.

7. Start the timer.

8. Read the result at 15 minutes.

9. Do not read the result after 20 minutes.

10. **INTERPRET TEST RESULTS AT THE END OF 15 MINUTES**
Caution : Do not read test results after 20 minutes, since it may give incorrect results.

For Dengue IgM/IgG Test

DENGUE IgM/IgG POSITIVE   **DENGUE IgG POSITIVE**

DENGUE IgM POSITIVE   **DENGUE IgM/IgG INVALID**

Don't consider the result if "C" line does not appear.

KIT STORAGE AND STABILITY

1. The test device should be stored at $2 - 40^0C$. DO NOT FREEZE.
2. The test device is sensitive to humidity as well as to heat.
3. Do not use the test device beyond expiration date. Expiration date of this kit is indicated on the kit cartons as well as on the individual pouches.
4. Do not use the kit if the pouch is damaged or the seal is broken.
5. Do not re-use test device.

SPECIMEN COLLECTION, STORAGE & PRECAUTION
    Plasma or Serum

I. **Plasma :** Collect the whole blood into the collection tube (Containing anticoagulants such as EDTA , Heparin or Oxalate) by venipuncture and then centrifuge blood to get plasma specimen.
II. **Serum :** Collect the whole blood into the collection tube (Not containing anticoagulants) by venipuncture, leave to settle for 30 minutes for blood coagulation and then centrifuge blood to get serum.

Note :

If the plasma or serum specimens are not tested immediately, they should be refrigerated at $2 - 8^0C$. (For storage period more than 2 weeks, freezing is recommended. The samples should be brought to room temperature $(20 - 30^0C)$ prior to use.

Plasma or serum specimen containing precipitate may yield inconsistent test results. Such specimen must be clarified prior to assaying.

LIMITATIONS OF THE TEST :

1. The test is for *In Vitro* Diagnostic Use Only.
2. This detects the presence of Dengue IgM & IgG antibodies to dengue virus in the specimen and should not be used as a sole criteria for diagnosis of dengue virus infection.
3. Serological cross-reactivity across the flavivirus group (Dengue virus, St.Louis encephalitis,Japanese encephalitis,West Nile and Yellow fever virus) is common.
4. As with diagnostic tests, all results must be correlated with other clinical findings. If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is recommended. A negative result at any time does not preclude the possibility of an early infection of dengue virus.
5. This is qualitative and only a screening test. Therefore, isolation of virus, antigen detection in fixed tissues. RT - PCR and serological tests like haemagglutination inhibition test, more specific alternative diagnosis method must in order to obtain a conformation of dengue virus infection.

PERFORMANCE CHARACTERISTICS

The **Dengue IgM/IgG Antibody** rapid detection test kit has been tested with Dengue positive and negative clinical samples confirme by ELISA. The results obtained are as follows:

Sr. No.	Sample Type	Total No. of Samples Conformed by ELISA	Test Results of Rapichek Dengue IgM / IgG Rapid Detection Test			Sensitivity (%)	Specificity (%)
			IgM Positive	IgG Positive	IgM/IgG Negative		
1	Dengue IgM Positive	86	84	0	2	97.67	-
2	Dengue IgG Positive	66	0	65	1	98.48	-
3	Dengue IgM/IgG Negative	237	0	0	237	-	100

REFERENCES

1. Clinical Evaluation of a rapid immunochromatographic test for the diagnosis of Dengue Virus Infection, Chew Theng Sang, Lim Siew Hoon, Andrea Cuzzubbo, Peter Devine. Clinical and Diagnostic Laboratory Immunology, May 1998, Vol. 5, No. 3 p. 407-409.
2. Innis BL, and Nisalak A, et al: An enzyme-linked immunosorbent assay to characterize dengue infections where denude and Japanese encephalitis co-circulate. Am. J. Trap. Med. Hygiene. 1989: 40: 418-427.Songee L. ranch and Paul N. Levett. Evaluation of four methods for detection of immunoglobulin M antibodies to dengue virus. Clin. Diagn. Lab. Immunol. Vol. 6(4) p 555-557, 1999.

DISCLAIMER

Every precaution has been taken to ensure the diagnostic ability and accuracy of this product. This product is used outside of the control of the manufacturer and the distributor and the result may accordingly be affected by environmental factors and or user error. A person who is the subject of the diagnosis should consult a doctor for further confirmation of the result.

WARNING

The Manufacturers and Distributors of this product shall not be liable for any loses, liability, claims, costs or damages whether direct or indirect or consequential arising out of or related to an incorrect diagnosis, whether positive or negative, in the use of this product.

Marketed By :

OXALIS Diagnostics Pvt. Ltd.

Mfg By.: PATHOZYME DIAGNOSTICS
Plot No. A-115, 5 Star M.I.D.C. Area, Kagal, Dist. Kolhapur 416 216 (MS) India
Customer Care No.: 0231-2305072
E-mail : contactus@pathozyme.com Website : www.pathozyme.com
An ISO 9001:2015 & 13485:2016 | CE & GMP Certified Company

| Expiry Date | IVD Invitro Dignostics Use | 2°C 40°C Storage | Mfg. Date | LOT Batch Number | See Package Insert | Keep Dry | Keep Away from Sun Light | Do not re use |