Dengue IgG/IgM Ab Card (Serum/Plasma)

IMMUNOPAK
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EXPLANATION OF THE TEST

Dengue IgG/IgM device is a chromatographic immunoassay kit for rapid and differential detection kit of immunoglobulin G (IgG) and immunoglobulin M (IgM) against all types of dengue viruses using human serum / plasma. Dengue-specific antigen complexed with gold conjugate is placed in the conjugate pad and anti-human IgG and anti-human IgM are immobilized on the membrane. When dengue antibody-positive specimen is loaded into sample injection point, the antibodies are captured the immobilized anti-human antibodies. And then, the antibodies are reacted with dengue-specific antigen-gold complex to make visible band in the test line.

PROPERTIES

Dengue IgG/IgM device can detect dengue-specific antibodies so that the kit is suitable for the diagnosis of 4 types of dengue infections.

MATERIALS PROVIDED

Dengue IgG/IgM device kit contains the following Items:

1. Dengue IgG/IgM Device ….....10/25 Test
2. Capillary Dropper (10µl) .....10/25 pcs
3. Assay Buffer (Diluent) .....1 vial
4. Product Insert ……..…….....1

PRECAUTIONS

1. The device is sensitive to humidity as well as to heat. So, it's very important to take off the device from the sealed pouch when it use.
2. Do not use the kit after the expiration date
3. For in vitro diagnostic use only.
4. Wear protective gloves while handling samples and wash hands thoroughly after the test.
5. Dispose all the samples and kits properly after test, in accordance with GLP.
6. Do not pipette reagent or blood by mouth.

SPECIMEN COLLECTION, STORAGE & PRECAUTION

1. Specimen Collection and Storage

1) Serum / Plasma samples may be used with this test.

2 Serum or Plasma

1) [Serum] Collect the whole blood into the collection tube (NOT containing anticoagulants such as heparin, EDTA and sodium citrate) by venipuncture, leave to settle for 30 minutes for blood coagulation and then centrifuge blood to get serum specimen or supernatant.
2) [Plasma] Collect the whole blood into the collection tube (containing anticoagulant such as heparin, EDTA and sodium citrate) by venipuncture and then centrifuge blood to get plasma specimen.
3) If serum or plasma specimen is not tested immediately, they should be refrigerated at 2-8^{0}C For Storage period longer than 2 weeks, freezing Is recommended. They should be brought to room temperature prior to use.
4) Serum or plasma specimens containing a precipitate may yield inconsistent test results.
   Such specimens must be clarified prior to assaying.

2. Precaution

1) Anticoagulants such as heparin, EDTA, citrate do not affect the test result.
2) Use separately disposable capillary dropper or pipette tips for each sample in order to avoid cross-contamination of either samples which could cause erroneous results.

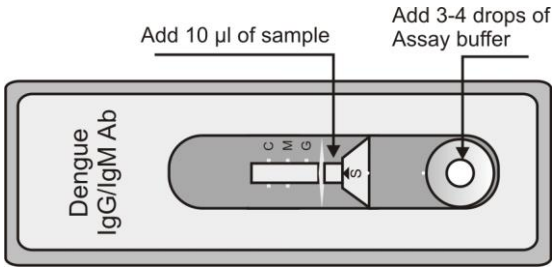
TEST PROCEDURE

1. Take a device from the pouch and place it on a flat surface.
2. Add 10µl of serum / plasma into the square shape of sample well (S) directly.
   Apply serum / plasma to the "S" area as mentioned in below figure.
3. Add 3-4 drops (approx. 90-120µl) of assay buffer (Diluent) into the round shape of assay buffer well.
4. Interpret the test results in 15-20 minutes after dropping buffer.
   [Caution: Do not read the test result after 20 minutes, the reading too late can give false results]

Important Note:

It is essential during addition of sample to sample window "s" that the tip of the sample dropper touches onto the membrane of the device for 1 to 2 seconds to ensure that the complete sample is transferred on the membrane. This is to avoid sticking of very small volume (10 µl) sample on the side of sample well. This can be seen by observing the flow of the sample in device window. If the sample does not flow, again press the dropper tip gently onto the membrane so that flow can happen. Even if, still the sample does not flow, it could be that it contains particulate matter or is turbid, if so, rerun the test, after centrifuging at 10,000 rpm, for 10 minutes or more (in case clear sample is not obtained after centrifugation).

It is essential, that first the sample flow on the membrane and then only the assay buffer should be added in the buffer well for accurate results.



STORAGE & EXPIRATION

1. Dengue IgG/IgM kit should be stored between 4 to 30 ^{0}C.
2. Expiration date of this kit is 24 months after its manufacture date.

INTERPRETATION OF THE RESULTS

1. Negative
The control line is only visible on the test device. No dengue-Specific IgG and IgM antibodies were detected. Retest in 3-5 days if dengue Infection is suspected.

2. IgM Positive
The control line (C) and IgM line (IgM) are visible on the test device. This is positive for IgM antibodies to dengue virus. This is indicative of a primary dengue infection.

3. IgG Positive
The control line (C) and IgG line (IgG) are visible on the test device. This is positive for IgG antibodies. This is indicative of a secondary or previous dengue infection.

4. IgG and IgM Positive
The control line (C), IgM (IgM) and IgG (IgG) are visible on the test device. This is positive for both IgM and IgG antibodies. This is indicative of a late primary or early secondary dengue infection.

5. Invalid
The control line fails to appear. Insufficient specimen volume or incorrect procedural techniques may be reason for control line failure. Repeat the test using a new test device.

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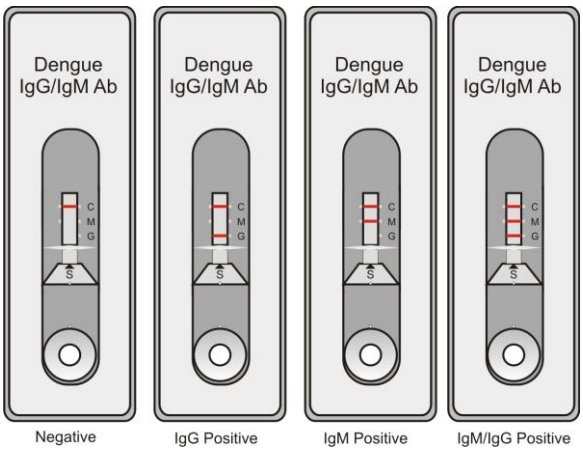

LIMITATIONS OF THE TEST

Dengue IgG/IgM Device is designed for primary screening test of dengue infection. This kit can provide fast and easy way to get a result, but do not completely exclude the possibility of false positive and false negative result caused by various factors. Therefore, please refer to the result of this kit and please make a final decision with clinical manifestation with other test results and doctor's view collectively.

REFERENCES

1. Halstead, S.B.(1981), The pathogenesis of Dengue, Amer. J. Epidemiol 114:632.
2. Henchal, E.A. and Putnuk, R.J., The Dengue viruses, Clin. Microl. Rev., Oct.376 – 396, 1990.
3. Advances in Dengue Diagnosis, Maria G. Guzman, Gustavo Kouri, Clinical and Diagnostic Laboratory Immunology, Nov 1996, Vol..3, No. 6, p. 621-627.
4. Clinical Evaluation of a rapid Immunochromafographic 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.
5. Dengue and Dengue Hemorrhagic Fever, Duane J. Gulber, Clinical Microbiology Reviews, July 1998, Vol.11, No.3 p.480-496.

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3/7, B.I.D.C., Gorwa, Vadodara 390 016 (INDIA)
Web: www.reckondiagnostics.com
Phone: +91·265·2281631
Email: mail@reckondiagnostics.com

RECKON DIAGNOSTICS P. LTD.