DENGUE ANTIBODY (IgG/IgM) CARD

IMMUNOPAK

(Serum/Plasma)

Last update 10-2020

Ref. RDT-DEG.101, 10 Test
RDT-DEG.101U, 25 Test

INTENDED USE

Dengue IgG/IgM device is a chromatographic immunoassay kit for rapid and differential detection of immunoglobulin G (IgG) and immunoglobulin M (IgM) against all types of dengue viruses using human serum/plasma.

INTRODUCTION

Dengue viruses transmitted by *Aedes aegypti* and *Aedes albopictus* mosquitoes, are widely distributed throughout the tropical and sub topical areas of the world. There are four known distinct serotypes (dengue virus 1,2,3 and 4). Dengue is considered to be the most important arthropod-borne viral disease due to the human morbidity and mortality associated with it. NS1 is a highly-conserved glycoprotein that is present at high concentrations in the sera of dengue-infected patients during the early clinical phase of the disease. NS1 antigen is found from the first day and up to 9 days after onset of fever in sample of primary or secondary dengue infected patients. Usually IgM does not become detectable until 5 to 10 days after the onset of illness in cases of primary dengue infection and until 4 to 5 days after onset of illness in secondary infections. In primary infections, IgG appears on the 14th day and persist for life. Secondary infections shows that IgG rise within 1~2 days after the onset of symptoms and induces IgM response after 20 days of infection.

PRINCIPLE

Dengue IgG / IgM test device has 3 pre-coated lines, "G" (Dengue IgG Test Line), "M" (Dengue IgM Test Line) and "C" (Control Line) on the surface of the device. 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 well, the antibodies are reacted with dengue-specific antigen-gold complex moves laterally on the membrane by capillary action. The antibody-antigen gold conjugate complex are captured by the immobilized anti-human antibodies to make visible pink-purple line in the test region. To serve as a procedural control, an additional line of Goat anti-mouse IgG has been immobilized on the card. If the test is performed correctly, this will result in the formation of pink-purple line upon contact with the conjugate as a control line.

PRESENTATION

	10 Tests	25 Tests
Dengue IgG/IgM Test Cards	10 Cards	25 Cards
Assay Buffer	1 Bottle	1 Bottle

PRECAUTION

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.

STORAGE AND STABILITY

Dengue IgG/IgM test card should be stored at 2°C-40°C. The card may be stored at room temperature but not exceeding 40°C in the original sealed pouch. The shelf life or expiry of the card is printed on the pouch as well as on the carton label. The test kit should be kept away from direct sunlight, moisture and heat.

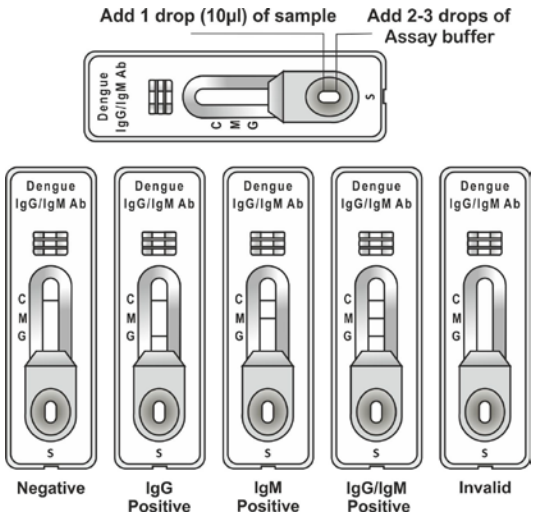
SPECIMEN COLLECTION AND STORAGE

- Serum / Plasma samples may be used with this test.
- [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.
- [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.
- If serum or plasma specimen is not tested immediately, they should be refrigerated at 2°C-8°C. For Storage period longer than 2 weeks, freezing is recommended. They should be brought to room temperature prior to use.
- Serum or plasma specimens containing a precipitate may yield inconsistent test results. Such specimens must be clarified prior to assaying.

TEST PROCEDURE

1. Take a device from the pouch and place it on a flat surface.
2. Add 1 drop (10μl) of serum / plasma into the sample well (S) directly.
3. Add 2 to 3 drops (approx. 75-90μl) of assay buffer (Diluent) into the sample well.
4. Interpret the test results in 15 to 20 minutes after dropping buffer.[Caution: Do not read the test result after 20 minutes, the reading too late can give false results]

INTERPRETATION OF RESULTS



- **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.
- **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.

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

LIMITATIONS

Dengue lgG/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

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