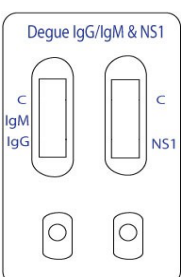
New Kombiden

One Step Dengue IgG/IgM & NS1 Test

Instructions For Use



Format: Cassette
For: Dengue IgG/IgM & NS1
Specimen: Whole Blood/Serum/Plasma
Catalog Number: A03-24-322

CE

* Please read the instructions carefully before use

INTENDED USE

One Step Dengue IgG/IgM & NS1 test is a rapid, visual, qualitative and convenient immunochromatographic in vitro assay for the differential detection of IgG/IgM antibody and NS1 antigen to dengue virus 1-4 serotypes in whole blood, serum or plasma samples. The test is intended for professional use in the diagnosis of Dengue virus infections. This assay provides only a preliminary result. Clinical expertise and professional judgment should be sought to further evaluate the result of the test.

SUMMARY AND PRINCIPLE OF THE ASSAY

Dengue diseases are potentially life-threatening diseases caused by the Dengue virus. The virus (serotypes 1–4) belongs to the group flavivirus and is transmitted in nature by day-biting Aceder mosquitoes. According to WHO, there are 50 million cases of dengue infection worldwide every year and the disease is an epidemic in over 100 countries.

The primary and secondary infections of dengue virus exhibit different clinical profiles. Primary Dengue infection, also known as Dengue Fever, is the most common type of dengue illness. It is associated with mild to high fever, headache, muscle pain, and skin rash. Secondary infection is known as Dengue Hemorrhagic Fever (DHF) or Dengue Shock Syndrome, and often results in high fever and, in many cases, hemorrhagic events and circulatory failure. The fatality rate in patients with Dengue Shock Syndrome can be as high as 44%.

Dengue NS1 antigen 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 blood sample of primary or secondary dengue infected patients. The Dengue NS1 portion of this test is an antigen-capturing immunochromatographic assay, which detects the presence of Dengue NS1 antigen in human blood samples. Monoclonal antibodies specifically against NS1 antigen are 1) conjugated with colloidal gold and deposited on the conjugate pad, and 2) immobilized on the test line of the nitrocellulose membrane. When blood sample is added the antibody conjugate is rehydrated and the NS1 antigens, if any in the samples, will interact with the colloidal gold conjugated antibodies. The antigen-antibody-gold complex will migrate towards the test window until the Test Zone (NS1) where they will be captured by immobilized antibodies, forming a visible red line (Test band), indicating a positive result. If Dengue NS1 antigen are absent in the sample, no red line will appear in the Test Zone (NS1), indicating a negative result.

Serological studies have shown that during primary infections, dengue-specific IgM antibodies are found by 5th day of infection and remain in circulation for 30-60 days, while IgG antibodies appear by the 14th day of infection and persist for life. In contrast, during secondary dengue virus infection, specific IgG and IgM levels significantly increase at 1- 2 days and the 20th day after infection, respectively. Thus, different profiles of humoral immune responses in primary and secondary dengue viral infections can be used for differential diagnosis. This is of clinical significance in predicting progression and prognosis of the disease.

The presence of high titers of IgG antibodies does not interfere with the detection of IgM antibodies in the sample. The principle of the Dengue IgG/IgM portion of this test is an antibody- capture immunochromatographic assay for the simultaneous detection and differentiation of IgG & IgM antibodies to Dengue virus in human blood samples. Dengue virus-specific antigens are conjugated to a colloidal gold and deposited on the conjugate pad. A unique combination of anti- human IgG & IgM antibodies are immobilized on the test zone of the nitrocellulose membrane, as two individual test lines (IgG line and IgM line) in the test window of the test device. The IgG line in the test window is closer to the sample well and followed by IgM line. When the sample is added the gold-antigen conjugate is rehydrated and the dengue IgG and/or IgM antibodies, if any in the sample, will interact with the gold conjugated antigen. The antigen-antibody-gold complex will migrate towards the test window until the test zone where it will be captured by the relevant anti human IgG and/or anti-human IgM, forming a visible pink line, indicating a positive result. If dengue antibodies are absent in the sample, no pink line will appear in the Test Zone, indicating a negative result.

To serve as an internal process control, a control line should always appear at the Control Zone (C) of both test windows after the test is completed. Absence of a pink control line in either Control Zone is an indication of an invalid result.

PACKAGE CONTENTS

- Pouch contents: Test Cassette, Desiccant, Sample dropper
- Diluent I (3 ml) per bottle for 20 tests.
- Diluent II (3 ml) per bottle for 20 tests.
- Test instructions.

MATERIALS REQUIRED (BUT NOT PROVIDED)

- Lancet and blood collection device.
- Gloves.
- Clock or timer.

WARNINGS AND PRECAUTIONS

- For professional *in vitro* diagnostic use only. Do not reuse.
- Do not use if the product seal or its packaging is compromised.
- Do not use after the expiration date shown on the pouch.
- Do not mix and interchange different specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection while handling potentially infectious materials or performing the assay.
- Wash hands thoroughly after finishing the tests.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Clean up spills thoroughly with appropriate disinfectants.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing procedures.
- Dispose of all specimens and used devices in a proper bio-hazard container. The handling and disposal of the hazardous materials should follow local, national or regional regulations.
- Keep out of children's reach.

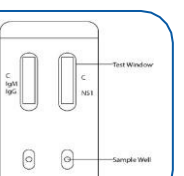
SPECIMEN PREPARATION

- Blood samples may be collected by fingerstick or venipuncture, following routine facility procedures.
- For whole blood samples, collect blood in a tube containing anticoagulant.
- For serum samples, collect blood in a tube without anticoagulant and allow it to clot.
- For plasma samples, collect blood in a tube containing anticoagulant.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
- Whole blood samples should be tested immediately after sample collection.
- The blood may be stored at 2ºC to 8ºC for up to three days if the tests cannot be performed immediately. Ensure that the blood samples should be allowed to attain room temperature prior to use.

TEST PROCEDURES

1

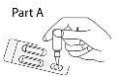
Remove the testing device from the sealed pouch by tearing at the notch and place the testing device on a leveled surface.

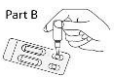


Add samples (Whole blood or Serum/Plasma)

Dengue IgG/IgM: Add samples with pipette to upper area (close to test window) of sample well of the test device according to following table. Hold the pipette vertically and gently touch the end against the pad within the sample well for transferring).

Dengue NS1: Hold the sample dropper vertically. Add the specimen without air bubbles into the Sample Well according to following table.





2

Add diluents

Immediately add 2 drops (90 µl) of diluents to the proper sample well of the testing device according to following table:

Test	Analyte	Sample well	Sample volume	Diluent type
Part A	IgG/IgM	Left	5µl	Diluent I
Part B	NS1	Right	1 drop (35 µl)	Diluent II

3

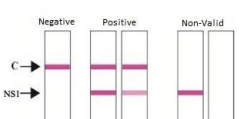
Read the results in 10-30 minutes. Read results as shown under interpretation of results.

NOTE: Strong positive specimens may produce positive result in as little as 1 minute and confirm negative results in 20-30 minutes.

DO NOT INTERPRET RESULTS AFTER 40 MINUTES

RESULT INTERPRETATIONS

NS1 Results

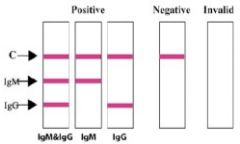


Negative
A pink colored band appears only at the control region (C), indicating a negative result for Dengue virus infection.

Positive
A clear pink control band (C) and a detectable test band (NS1) appears, indicating a positive result for Dengue virus infections.

Invalid
No visible band appears at the control region (C). Repeat with a new test device. If the test still fails, please contact the distributor with the lot number

IgG/IgM Results



Negative

A pink colored band appears only at the control region (C), indicating a negative result for Dengue infection.

Positive

Pink colored bands appear at the control region (C) and IgM and /or IgG region.

1) IgG and IgM Positive, visible bands indicating positive result for a possible a late primary or acute secondary infection.
2) IgM positive, a visible band at IgM region, indicating positive result for a possible primary dengue infection.
3) IgG positive, a visible band at IgG region, indicating a positive result for a possible secondary infection or past infection.

Invalid

No visible band appears at the control region (C). Repeat with a new test device. If the test still fails, please contact the distributor with the lot number.

QUALITY CONTROL

Although the testing device contains an internal quality control (pink colored band in the control region), good laboratory practice recommends the daily use of an outside control to ensure proper testing device performance. Quality control samples should be tested according to the standard quality control requirements established by your laboratory

STORAGE AND STABILITY

- The test device in the sealed pouch should be stored at 2-30ºC. Do not freeze the test device.
- The bottle containing the buffer should be stored at 2-30ºC.
- The test device should be kept away from direct sunlight, moisture and heat.

LIMITATION

- Humidity and temperature can adversely affect results.
- The instructions for the use of the test should be followed during testing procedures.
- There is always a possibility that false results will occur due to the presence of interfering substances in the specimen or factors beyond the control of the manufacturer, such as technical or procedural errors associated with the testing.
- Although the test demonstrates superior accuracy in detecting antibodies and antigens against the Dengue virus, a low incidence of false results can occur. Therefore, other clinically available tests are required in case of questionable results. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.