camtech diagnostics

Dengue Virus IgG IgM Ab/NS1 Ag Combo Rapid Test

For in Vitro Diagnostic Use

REF: DGC01

Basic UDI-DI: 888130055213GH

Intended Use

Dengue Virus IgG IgM Ab/NS1 Ag Combo Rapid Test is designed for the rapid detection of dengue NS1 antigen and dengue IgG/IgM antibody in human whole blood, serum and plasma. It is used to obtain a visual, qualitative result to aid in the diagnosis of dengue infection and is intended for professional use only.

Summary

Dengue virus is transmitted to humans by the bite of an infected Aedes mosquito. When infected with dengue, individuals may exhibit the following symptoms: fever, headache, arthralgia, retro-orbital pain, rash, lymphadenopathy and leukopenia. These symptoms may take three to eight days to appear. However, these symptoms are also present in other etiologies of febrile illnesses. In the absence of clear symptoms that separate dengue infection from other febrile illnesses, Dengue Virus IgG IgM Ab/NS1 Ag Combo Rapid Test may be used to aid in the diagnosis of dengue infection.

During a dengue infection, NS1 antigen (DEN1, 2, 3, 4) would first appear in the blood, followed by IgM and IgG antibodies. NS1 antigen reaches its peak in the blood a few days after onset of symptoms and then disappears quickly, whereas the IgM antibody lasts for several months and the IgG antibodylasts for several years. In this way, the timing and level for each test item varies according to the number of days since the onset of the disease, the number of infections, etc.

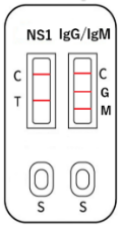
The detection of NS1 antigen indicates an active infection while the presence of IgG Ab and IgM Ab suggests if it is a primary or secondary infection.

For primary infections, the IgM Ab result will be positive.

For secondary or past dengue infections, the level of IgG antibody is high from the beginning of the infection. Therefore, the detection of positive IgG antibodies in the early stages of infection can be useful information to suggest a secondary infection.

This product is a reagent that can detect dengue virus NS1 antigen (DEN1, 2, 3, 4), anti-dengue virus IgM antibody and anti-dengue virus IgG antibody simultaneously in a short time, without the need for special equipment or techniques, and is useful as an aid in the diagnosis of dengue virus infection in a variety of clinical settings.

Principle



For IgG/IgM Test: During testing, the blood sample is added to the sample well of the cassette. If the sample contains dengue IgG/IgM antibodies, these antibodies will first bind to the red latex microsphere labeled-dengue antigen on the release pad. When these antigen-antibody conjugates flowing on the nitrocellulose membrane, they will be captured by the dengue IgG/IgM secondary antibody pre-immobilized on test line (G&M). Thus, red lines will appear at the test line (G&M)), indicating a positive result. If no dengue IgG/IgM antibodies are present in the sample, the test line (G&M) will not form red lines, indicating a negative result.

For NS1 Test: During testing, the blood sample is added to the well of the cassette and if the blood sample contains dengue NS1 antigen, these antigens will first bind to the red latex microsphere labeled- dengue NS1 monoclonal antibody-1 on the release pad. When these antigen-antibody conjugates flowing on the nitrocellulose membrane, they will be captured by the dengue NS1 monoclonal antibody-2 pre-immobilized on test line (T). Thus, a red line appears at the cassette test line (T)), indicating a positive result. If no dengue virus NS1 antigen is present in the sample, the test line (T) position will not form a red line, indicating a negative result.

To serve as a procedural control, a colored line will always appear at the control line region indicating that proper volume of specimen has been added and membrane chromatography has occurred.

Reagents and materials supplied

- Test Cassettes
- Buffer
- Disposable Pipettes
- Instructions for use

Materials required but not supplied

- Timer
- Blood collection tubes
- Lancet
- Alcohol pad or alcohol swabs

Storage and stability

Store at 4-30℃, protected from light, stable for 24 months. See product label for lot number and expiration date.

Warning and Precautions

- For in vitro diagnostic use only.
- For healthcare professionals and professionals at point of care sites.
- Do not use the test after the indicated expiration date .
- Read these Instructions for Use completely before performing the test. Failure to follow the instructions could lead to inaccurate test results.
- Do not open the sealed pouch unless ready to conduct the testing.
- Do not use hemolyzed blood specimens for testing.
- Dispose of all specimens and materials used to perform the test as bio-hazardous waste, discarded according to local regulations.
- Handle the negative and positive controls in the same manner as patient specimens.
- Do not perform the test in a room with strong air flow, i.e. an electric fan or strong air-conditioning.
- Do not use components from other test kit brands as a substitute for this kit.
- The test can only be used once.

Specimen collection and Handling

- The specimen of this test is serum, plasma or whole blood.
- Please collect the whole blood, serum or plasma specimens following regular clinical laboratory procedures.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear non-hemolyzed specimens.
- Consider any materials of human origin as infectious and handle them using standard biosafety procedures.

  --For whole blood specimens: Test immediately or store refrigerated at 2-8° C for up to 24 hours after collection. Do not freeze specimens.

--To prepare plasma: Centrifuge collected specimen and carefully withdraw plasma into new pre-labeled tube.

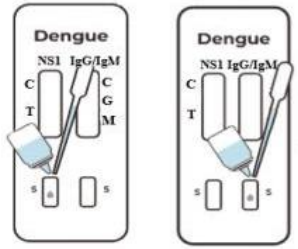
--To prepare serum: Allow blood to clot, centrifuge collected specimen and carefully withdraw serum into new pre-labeled tube.

--For plasma/serum only: Test specimens immediately after collection or store refrigerated at 2-8℃ for up to 5 days. Specimens can be frozen at -20℃ for longer storage. Avoid multiple freeze-thaw cycles.

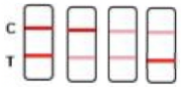
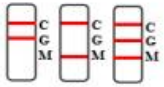
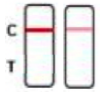
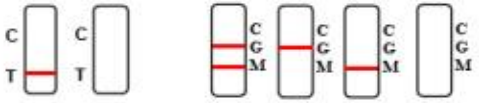
Test procedure

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.

1. Take out the test cassette from the sealed pouch and place it on a clean and level surface. Use it as soon as possible.
2. Add **1 drop (about 10μL) of blood sample** to each of the "S" well on the test cassette using the pipette provided in the kit. Then immediately add **2 drops (about 60~70μL) of buffer** to each of the "S" well after the blood sample is added. Start the timer. See illustration below.
3. Wait for the red line(s) to appear. Interpret the results at 15 minutes. The results displayed after 20 minutes are of no clinical significance.



Interpretation of results

	NS1	IgG/IgM
Positive		
Negative		
Invalid		

Positive

- NS1 positive
  Two red lines appear in the test window. One line is located in the control area(C), and the other one is located in the detection area(T). Line T may be less intense (lighter) than line C. The positive result indicates that the blood sample contains dengue NS1 antigen. This suggests an active dengue infection.
- IgG / IgM positive
- Two or three red lines appear in the test window. If three red lines appear in the test area (G), (M) and control area (C) respectively, it indicates that the blood sample contains both dengue IgG and IgM antibodies. If two red lines appear, one is located in the control area (C) and the other is located in detection area (either G or M), that means the sample contains either dengue IgM antibody or dengue IgG antibody. Positive result for IgM Ab suggests a primary dengue infection whereas a positive result for IgG Ab suggests a secondary dengue infection.

Negative

- NS1 negative
  Only one red line appears in the control area (C). The negative result indicate no dengue NS1 antigen in the specimens or the NS1 antigen level below the limit of detection.
- IgG / IgM negative
  Only one red line appears in control area (C) and no red line appear in test area (G and M). The negative result showed that there were no dengue IgM and IgG antibodies in the specimen or the IgG/IgM level below the limit of detection.

Invalid

- No red line appears in the control area(C), the test is invalid if the control line is not visible at 15 minutes. Insufficient specimen volume or incorrect testing procedure are the most likely reasons for control line failure. Check the test procedure and repeat the test with a new cassette. If the problem persists, stop using the test kit immediately and contact your local distributor.

Limitations

- The device is an in vitro diagnostic reagent for auxiliary diagnosis. The test result should not be used as the sole criteria for the diagnosis of dengue virus infection.
- This kit is used only for qualitative detection of dengue NS1 antigen and IgG/IgM antibodies in human blood samples.
- As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
- If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of dengue virus infection.

Performance

- **Limit of Detection**

The LOD for Dengue virus NS1 antigen is 21ng/mL.

- **Cross Reactivity**

No cross reactivity was observed for Syphilis, HIV, HAV, HBV, HCV, Influenza A, Influenza B, hCG, and H.pylori samples when they were tested by Dengue Virus IgG IgM Ab/NS1 Ag Combo Rapid Test.

- **Interference**

No interference reaction was observed for the following endogenous substances.

Albumin	6g/dL	Glyceride	450mg/dL
Hemoglobin	20g/dL	Rheumatoid	120 IU/mL
Bilirubin	10mg/dL		

- **Clinical Performance**

A comparison study was conducted using The Dengue Virus IgG IgM Ab/NS1 Ag Combo Rapid Test and an commercially equivalent rapid test. 149 blood samples were evaluated. The following results are tabulated from this performance study.

For NS1 antigen

		Equivalent reagents		Total
		Positive	Negative	
Dengue Kit	Positive	85	0	85
	Negative	2	62	64
Total		87	62	149
Positive percent agreement: 97.70%				
Negative percent agreement: 100.00%				
Overall percent agreement: 98.66%				

For IgM antibody

		Equivalent reagents		Total
		Positive	Negative	
Dengue Kit	Positive	44	1	45
	Negative	1	103	104
Total		45	104	149
Positive percent agreement: 97.78%				
Negative percent agreement: 99.04%				
Overall percent agreement: 98.66%				

For IgG antibody

		Equivalent reagents		Total
		Positive	Negative	
Dengue Kit	Positive	17	1	18
	Negative	0	131	131
Total		17	132	149
Positive percent agreement: 100%				
Negative percent agreement: 99.24%				
Overall percent agreement: 99.38%				

- **Hook Effect**

No hook effect at concentrations between 10.5- 525 µg/mL.

References/ Bibliography

- U.S. Food and Drug Administration. Class II Special Controls Guideline Dengue Virus Serological Reagents. Issued on: May 30, 2014
- Gan, VC et al., Diagnosing Dengue at the point-of-care: Utility of a rapid combined diagnostic kit in Singapore. PLOS ONE 9(3); e90037 (2014).

Product Owner

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Index of symbols

	Consult instructions for use		Use-by date
IVD	In vitro diagnostic medical device	LOT	Lot number
REF	Catalogue number		Manufacturer
	Contains sufficient for <n> tests		Store at 4-30℃
	Do not use if package is damaged		Do not re-use
	Keep dry		Keep away from sunlight

Instructions Manual Version and Date

Version No.: DGC01 IFU 2501
Effective Date: 10.01.2025