Dengue NS1+IgG/IgM Rapid Test Kit

Paramcare rapid Card Test for detection of NS1 Antigen + IgG/IgM antibodies to dengue virus in human Serum/Plasma/Whole blood

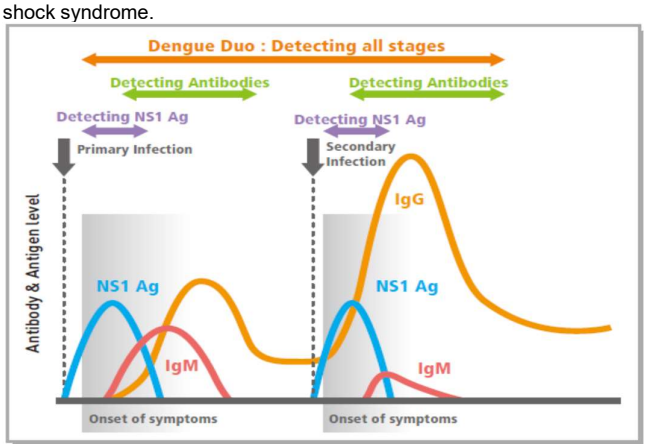
For *In-Vitro Diagnostic* Use only

ORDER INFORMATION

Pack Size	REF
1 Tests	PDBA 01
5 Tests	PDBA 05
10 Tests	PDBA 10
25 Tests	PDBA 25

CLINICAL SIGNIFICANCE

Dengue virus, a virus belonging to the Flavavirus group of viruses, is one of the most significant mosquito-borne diseases in the world in terms of morbidity and mortality. Transmitted principally by the mosquito types *Aedes aegypti* and *Aedes albopictus*, the virus is found commonly throughout the tropic and subtropic regions of the world. There are four known serotypes of dengue. Symptoms of dengue fever include high fever, headache, muscle pain and skin rash. The complications often associated with this infection are dengue hemorrhagic fever or dengue shock syndrome.



PRINCIPLE

Dengue NS1: PARAMCARE™ DENGUE NS1 RAPID TEST is a qualitative immunoassay for the detection of NS1 antigen to dengue virus in human Serum/Plasma/Whole blood. The nitrocellulose membrane is pre-coated with NS1 specific antibody at Test region and separate control to assure assay flow and test performance. The specimen is added in sample well followed by assay buffer which will react with NS1 specific monoclonal antibodies conjugated to colloidal gold. This antigen-antibody complex move upward on the membrane via capillary action and will bind with Anti-Dengue NS1 which is pre-coated on the membrane. As the reagent moves across the membrane, the Dengue NS1 antibody on the membrane will bind with antigen-antibody complex and formed pinkish purple line at the test region of the test membrane. The intensity of the lines will vary depending upon the amount of antigen present in the sample. The appearance of pinkish purple line in the test region should be considered as positive result.

Dengue IgG/IgM: PARAMCARE™ DENGUE IgG/IgM RAPID TEST is a qualitative immunoassay for the detection of Dengue antibodies in human Serum/Plasma/Whole blood. The nitrocellulose membrane is pre-coated with Anti-human IgG and Anti-human IgM at Test region and separate control to assure assay flow and test performance. The recombinant antigen for Dengue IgG & IgM conjugated with colloidal gold particles and control antibodies. When specimen is added in sample well followed by assay buffer which will react with the recombinant antigen and this antigen-antibody complex move upward on the membrane via capillary action. If the specimen contains IgG antibodies to Dengue than pinkish purple color line will appear at pre-coated Anti-human IgG test region. If the specimen contains IgM antibodies to Dengue than pinkish purple color line will appear at pre-coated Anti-human IgM test region. The intensity of the test lines will vary depending upon the amount of antibodies present in the sample. The appearance of pinkish purple line in the test region should be considered as positive result.

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Test Device of Dengue NS1 & Dengue IgG/IgM
Assay Buffer of Dengue NS1
Assay Buffer of Dengue IgG/IgM
Instruction for Use (IFU)
Disposable (Dropper) 20 µl sampling device
Desiccant

STORAGE & STABILITY

1. The kit can be stored at room temperature or refrigerated (2-30°C). The test device must remain in the sealed aluminum pouch until use. DO NOT FREEZE.
2. Do not use beyond the expiration date.
3. Do not use the test device/strip, if the pouch is damaged or seal is broken.

PRECAUTIONS

1. For professional In-vitro diagnostic use only. Do not use after expiration date.
2. Do not eat, drink or smoke in the area where the specimens or kits are handled.
3. Handle all the specimens as potentially infectious. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens and tested device/strip.
4. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
5. Read the Instruction for use carefully before performing the test.

LIMITATIONS

1. PARAMCARE™ DENGUE DUO (NS1 & IgG+IgM) RAPID TEST detects the presence of Dengue NS1 antigen & IgG/IgM antibodies to Dengue and should not be used as the sole criteria for the diagnosis of Dengue virus infection.
2. Serological cross-reactivity across the Flavivirus group is common.
3. As with all 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.
4. This is only a screening test. Therefore, isolation of virus, antigen detection in fixed tissues, RT-PCR and more specific alternative diagnosis method must be used in order to obtain a confirmation of dengue virus infection.

SPECIMEN COLLECTION & PREPARATION

1. The PARAMCARE™ DENGUE DUO (NS1 + IgG/IgM) RAPID TEST can be performed using either Serum/Plasma/Whole blood.
2. Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C.
3. USE FRESH BLOOD ONLY.
4. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
5. If specimens are to be shipped, it should be packed in compliance with federal regulations for transportation of etiologic agents.

PROCEDURE

Dengue NS1:

1. Allow test device, Assay Buffer and specimen equilibrates to room temperature (15-30°C) prior to testing.
2. Remove the test device from the aluminum foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
3. Place the test device on a clean and flat surface. Carefully dispense 1 drop (20 µl) of Serum/Plasma/whole blood in the sample well “S” using the dropper provided.

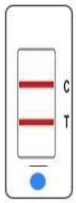
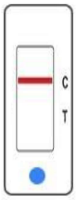
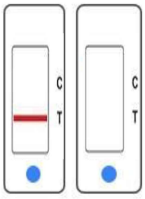
4. After that add 1 drop (appx. 40 µl) of Assay Buffer in the sample well “S”.
5. Allow reaction to occur and read the results at 15 minutes. Do not interpret the results after 20 minutes.

Dengue IgG/IgM:

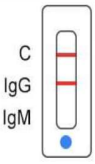
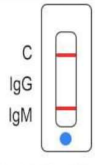
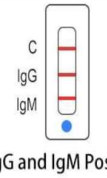
1. Allow test device, Assay Buffer and specimen equilibrates to room temperature (15-30°C) prior to testing.
2. Remove the test device from the aluminum foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
3. Place the test device on a clean and flat surface. Carefully dispense 1 drop (20 µl) of Serum/Plasma/ whole blood in the sample well “S” using the dropper provided.
4. After that add 2 drop (appx. 80 µl) of Assay Buffer in the sample well “S”.
5. Allow reaction to occur and read the results at 15 minutes. Do not interpret the results after 20 minutes.

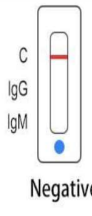
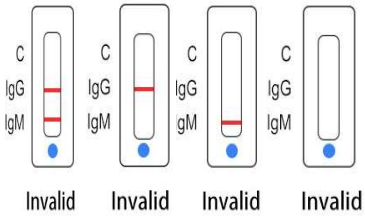
INTERPRETATION OF RESULTS

For Dengue NS1:

POSITIVE	NEGATIVE	INVALID
 **Positive**	 **Negative**	 **Invalid**
If two color lines appear, one at control region ‘C’ and other at test region ‘T’, the specimen is positive for Dengue NS1 antigen.	If only one color line appear at control region ‘C’ as the specimen is Negative for Dengue NS1 antigen.	If no color line appear, at control line 'C' within the stipulated time then result is invalid. Repeat the test using a fresh Test Device.

For Dengue IgG/IgM:

IgG POSITIVE	IgM POSITIVE	IgG+IgM POSITIVE
 IgG Positive	 IgM Positive	 IgG and IgM Positive
If two color lines appear, one at control region ‘C’ and other at test region ‘G’, the specimen is positive for Dengue IgG.	If two color lines appear, one at control region ‘C’ and other at test region ‘M’, the specimen is positive for Dengue IgM.	If three color line appear, one at control line ‘C’, one at test region ‘G’ and one at test line ‘M’, the specimen is positive for both Dengue IgG & IgM.

NEGATIVE	INVALID
 Negative	 Invalid Invalid Invalid Invalid
If only one color band appear at control line ‘C’ as the specimen is Negative for Dengue IgG & IgM infection.	If no color band appear, at control line 'C' within the stipulated time then result is invalid. Repeat the test using a fresh Test Device/Strip.

PERFORMANCE CHARACTERISTICS

The PARAMCARE™ DENGUE DUO (NS1 & IgG+IgM) RAPID TEST has been evaluated with positive and negative samples confirmed by ELISA examination.

Specimen	Positive	Negative	Sensitivity
NS1 Positive	80	00	100 %
IgG Positive	20	00	100 %
IgM Positive	20	00	100%

Specimen	Positive	Negative	Specificity
NS1 Ag Negative	02	248	99.2%
Den IgG/IgM Negative	03	247	98.8%

BIBLIOGRAPHY

1. CDC/NIH Guidelines. Biosafety in Microbiological and Biomedical Laboratories. 2nd Edition, 1988.
2. Lam, SK. Dengue haemorrhagic fever. Rev. Med. Micro. (1995), 6:39-48.
3. Siti-Strong. Diagnosis, prevention, and treatment of tropical disease, 7th ed., Philadelphia, the Ablakiston Company.
4. Sabin, AB and Schlesinger RW. Production of immunity to Dengue with virus modified by propagation in mice: Science (1945), 101:640.
5. Innis, BL, Nisalak, A., et.al. An enzyme-linked immunosorbent assay to characterize dengue infections where dengue and Japanese encephalitis co-circulate. Am. J. Trap. Med. Hygiene (1989), 40:418-427.

GLOSSARY OF SYMBOL

	Consult Instruction for Use
	Catalog Number
	Store between
	Manufacturer
	Keep away from sunlight



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