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Dengue NS 1 Ag Rapid Test Kit (Serum/Plasma/Whole Blood)

QBL/DNS1/RPT_060

The Dengue NS1 Ag Rapid Test Kit is a rapid chromatographic immunoassay for the qualitative detection of Dengue NS1 Antigen in human Serum/Plasma/ Whole Blood specimens.

For *In-Vitro Diagnostic* Use only

ORDER INFORMATION

Pack Size	REF
01 Test	PDGA 01
05 Tests	PDGA 05
10 Tests	PDGA 10
25 Tests	PDGA 25
50 Tests	PDGA 50

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.

Dengue NS1 Antigen Test provides an excellent methodology for specifically detecting Dengue NS1 antigen within up to 1 day of infection.

PRINCIPLE

THE PARAMCARE DENGUE NS1 Ag 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.

KIT COMPONENTS

1. Test Device
2. Assay Buffer
3. Instruction for Use (IFU)
4. Disposable Dropper

MATERIALS REQUIRED BUT NOT PROVIDED

• Specimen Collection Containers • Timer

PRECAUTIONS

1. For professional *in vitro* diagnostic use only. Do not use after the expiration date.
2. Wear protective gloves while handling specimens wash thoroughly afterwards.
3. The device is sensitive to humidity as well as heat. Therefore, take out the device from seal pouch before test.
4. Do not mix reagents from different lot.
5. Dispose all the samples and kits properly as per the instruction after test in accordance in GLP.
6. Follow the testing procedure exactly as mention in the insert.

STORAGE AND STABILITY

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

SPECIMEN COLLECTION & PREPARATION

1. Allow the test, specimen and/or controls to reach room temperature (15-30°C) prior to testing.
2. **For Serum/Plasma specimen**: Place the cassette on a clean and level surface. For Serum or Plasma specimen: Hold the dropper vertically and transfer 1 drops of serum or plasma (approximately 25µL) to the specimen well and add 1 drop assay buffer, and start the timer
3. **For Venipuncture Whole Blood**: Hold the dropper vertically and transfer 1 drops of whole blood (approximately 25 µL) to the specimen well, then add 1 drop of buffer (approximately 40 µL), and start the timer

DIRECTIONS FOR USE

Allow the test device, specimen and/or buffer to equilibrate at room temperature (15-30°C) before testing.

- Allow test device, Assay Buffer and specimen equilibrates to room temperature (15-30°C) prior to testing.
- 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.
- Place the test device on a clean and flat surface. Carefully dispense Serum/Plasma/Whole Blood in the sample well "S" using the dropper provided.
- After that add Assay Buffer in the sample well "S".
- Allow reaction to occur and read the results at 15 minutes. Do not interpret the results after 20 minutes.

INTERPRETATION OF RESULTS

Positive Result	
Negative Result	

1) Positive

One colored band appears in control line zone (C). One colored band is found in test line zone. This result indicates the specimen is positive for Dengue NS1 Antigen.

2) Negative

One colored band appears in control line zone (C). No colored band is found in test line zone. This result indicates the specimen is Negative for Dengue NS1 Antigen.

3) Invalid

The control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the likely reasons for control line failure. Repeat the test using a new test device.

Quality Control

Internal procedural controls are included in the test individually. A colored line appearing in control line region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

Limitations of the Test

1. The Paramcare Dengue Ns1 Ag Rapid Test is for professional in vitro diagnostic use, and should be only used for the qualitative detection of Dengue NS1 Ag.
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.

Performance characteristics

Diagnostic Performance

Commercial Dengue NS1 Ag Rapid Test Results	Dengue NS1 Ag Rapid Test		Total
	Positive	Negative	
Positive	40	0	40
Negative	1	99	100
Total	41	99	140

Relative sensitivity: 98%, Relative Specificity: 100%, Overall agreement: 98.57%

BIBLIOGRAPHY

1. Baselt RC. Disposition of Toxic Drugs and Chemicals in Man. 2nd ed. Davis: Biomedical Publications; 1982.
2. 2. Hawks RL, Chiang CN, eds. Urine Testing for Drugs of Abuse. Rockville: Department of Health and Human Services, National Institute on Drug Abuse; 1986.
3. 3. Substance Abuse and Mental Health Services Administration. Mandatory Guidelines for Federal Workplace Drug Testing Programs. 53

GLOSSARY OF SYMBOL

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

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