Dengue NS1 Antigen Rapid Test Cassette/Strip (WB/S/P)

English

For professional and in vitro diagnostic use only.

[INTENDED USE]

The Dengue NS1 Antigen Rapid Test Cassette/Strip is a lateral flow chromatographic immunoassay for the qualitative detection of antigens to Dengue viruses in human Whole Blood/Serum/Plasma. It provides an aid in the diagnosis of infection with Dengue viruses.

[SUMMARY]

Dengue is a flavivirus, transmitted by Aedes aegypti and Aedes albopictus mosquitoes. It is widely distributed throughout the tropical and subtropical areas of the world, and causes up to 100 million infections annually. Classic Dengue infection is characterized by a sudden onset of fever, intense headache, myalgia, arthralgia and rash. The Dengue NS1 Antigen Rapid Test Cassette/Strip detect antigens to Dengue viruses infection in human Whole Blood/Serum/Plasma. It is a noninvasive method and does not use radioactive isotopes. The test is easy to perform and requires no specialized equipment. Visual interpretation provides an accurate qualitative result. It is a useful on-site aid in the diagnosis of Dengue viruses infection. Diagnosis of Dengue viruses infection by antigen immunoassay can reduce the number of patients requiring endoscopy.

[PRINCIPLE]

The Dengue NS1 Antigen Rapid Test Cassette/Strip is an immunoassay based on the principle of the double antibody-sandwich technique. During testing, anti-Dengue antibody is immobilized in the test line region of the device. After a Whole Blood/Serum/Plasma specimen is placed in the specimen well, it reacts with anti-Dengue antibody coated particles that have been applied to the specimen pad. This mixture migrates chromatographically along the length of the test strip and interacts with the immobilized anti-Dengue antibody. If the specimen contains dengue virus antigen, a colored line will appear in the test line region indicating a positive result. If the specimen does not contain dengue virus antigen, a colored line will not appear in this region 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 wicking has occurred.

[WARNINGS AND PRECAUSIONS]

- For in vitro diagnostic use only.
- For healthcare professionals and professionals at point of care sites.
- Do not use after the expiration date.
- Please read all the information in this leaflet before performing the test.
- The test cassette/strip should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test cassette/strip should be discarded according to federal, state and local regulations.

[COMPOSITION]

The test contains a membrane strip coated with anti-Dengue antibody on the test line, goat anti rabbit antibody on the control line, and a dye pad which contains colloidal gold coupled with anti-Dengue antibody.
The quantity of tests was printed on the labeling.

Materials Provided

•Test cassette/strip •Package insert
•Buffer

Materials Required But Not Provided

•Specimen collection container •Timer

[STORAGE AND STABILITY]

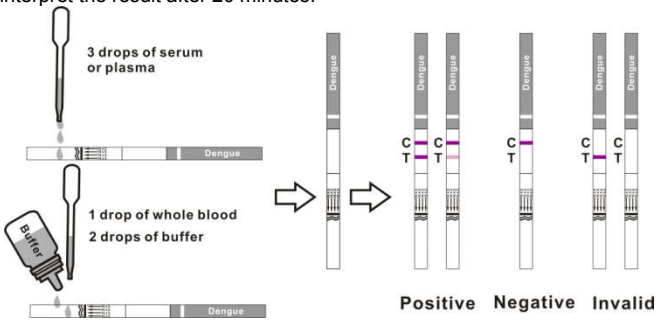
- Store as packaged in the sealed pouch at temperature (4-30℃ or 40-86 ℉). The kit is stable within the expiration date printed on the labeling.
- Once open the pouch, the test should be used within one hour. Prolonged exposure to hot and humid environment will cause product deterioration.
- The LOT and the expiration date were printed on the labeling.

[SPECIMEN]

- The test can be used to test Whole Blood/Serum/Plasma specimens.
- Collect blood specimen (containing EDTA, citrate or heparin) by vein puncture following standard laboratory procedures.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear non-hemolyzed specimens.
- Store specimens at 2-8℃ (36-46℉) if not tested immediately. Store specimens at 2-8℃ up to 7 days. The specimens should be frozen at -20℃ (-4℉) for longer storage. Do not freeze whole blood specimens.
- Avoid multiple freeze-thaw cycles. 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.
- Do not use samples demonstrating gross lipemia, gross hemolysis or turbidity in order to avoid interference on result interpretation.

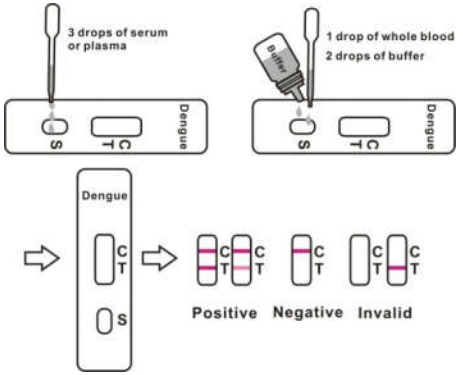
[TEST PROCEDURE]

Allow the test device and specimens to equilibrate to temperature (15-30℃or 59-86℉) prior to testing.
[For Strip]
1. Remove the test strip from the sealed pouch and use it as soon as possible.
2. Place the test strip on a clean and level surface.
3. For serum or plasma specimen: Hold the dropper vertically and transfer 3 drops of serum or plasma (approximately 100µl) to the specimen pad of the test strip, then start the timer. See illustration below.
4. For whole blood specimens: Hold the dropper vertically and transfer 1 drop of whole blood(approximately 35µl) to the specimen pad of the test strip, then add 2 drops of buffer (approximately 70µl) and start the timer. See illustration below.
5. Wait for the colored line(s) to appear. Read results at 15 minutes. Do not interpret the result after 20 minutes.



(The picture is for reference only, please refer to the material object.)

[For Cassette]
1. Remove the test cassette from the sealed pouch and use it as soon as possible.
2. Place the test cassette on a clean and level surface.
3. For serum or plasma specimen: Hold the dropper vertically and transfer 3 drops of serum or plasma (approximately 100µl) to the specimen well (S) of the test cassette, then start the timer. See illustration below.
4. For whole blood specimens: Hold the dropper vertically and transfer 1 drop of whole blood(approximately 35µl) to the specimen well(S) of the test cassette, then add 2 drops of buffer (approximately 70µl) and start the timer. See illustration below.
5. Wait for the colored line(s) to appear. Read results at 15 minutes. Do not interpret the result after 20 minutes.



(The picture is for reference only, please refer to the material object.)

[INTERPRETATION OF RESULTS]

Positive:*Two lines appear. One colored line should be in the control region (C), and another apparent colored line adjacent should be in the test region (T). This positive result indicates the presence of antigens to Dengue.

Negative: One colored line appears in the control region (C). No line appears in the test region (T). This negative result indicates the absence of antigens to Dengue.

Invalid: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test using a new test cassette/strip. If the problem persists, discontinue using the lot immediately and contact your local distributor.

[QUALITY CONTROL]

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

[LIMITATIONS]

- The Dengue NS1 Antigen Rapid Test Cassette/Strip is limited to provide a qualitative detection. The intensity of the test line does not necessarily correlate to the concentration of the antigen in the blood.
- The results obtained from this test are intended to be an aid in diagnosis only. Each physician must interpret the results in conjunction with the patient's history, physical findings, and other diagnostic procedures.
- A negative test result indicates that antigens to Dengue are either not present or at levels undetectable by the test.

[PERFORMANCE CHARACTERISTICS]

Accuracy

A side-by-side comparison was conducted using the Dengue NS1 Antigen Rapid Test and commercially available Dengue rapid tests. 1030 clinical specimens from three Professional Point of Care sites were evaluated with the Dengue NS1 Antigen Rapid Test and the commercial kit. The specimens were checked with a commercially available ELISA to confirm the presence of Dengue antigen in the specimens. The following results are tabulated from these clinical studies:

Agreement with Commercial Dengue Rapid Test

		Commercial Dengue Rapid Test		Total
		Positive	Negative	
CLUNGENE®	Positive	342	1	343
	Negative	2	707	709
Total		344	708	1052

The agreement between these two devices is 99.42% for positive specimens, and 98.86% for negative specimens. This study demonstrated that the Dengue NS1 Antigen Rapid Test is substantially equivalent to the commercial device.

Agreement with ELISA

		ELISA		Total
		Positive	Negative	
CLUNGENE®	Positive	342	1	343
	Negative	2	707	709
Total		344	708	1052

A statistical comparison was made between the results yielding a clinical sensitivity of 99.42%, a clinical specificity of 98.86% and an accuracy of 99.71%.

Cross-Reactivity and Interference

1. Other common causative agents of infectious diseases were evaluated for cross reactivity with the test. Some positive specimens of other common infectious diseases were spiked into the Dengue NS1 positive and negative specimens and tested separately. No cross reactivity was observed with specimens from patients infected with HIV, HAV, HBsAg, HCV, HTLV, CMV and TP.
2. Potentially cross-reactive endogenous substances including common serum components, such as lipids, hemoglobin, bilirubin, were spiked at high concentrations into the Dengue NS1 positive and negative specimens and tested, separately. No cross reactivity or interference was observed to the device.

Analytes	Conc.	Specimens	
		Positive	Negative
Albumin	20mg/ml	+	-
Bilirubin	10μg/ml	+	-
Hemoglobin	15mg/ml	+	-
Glucose	20mg/ml	+	-
Uric Acid	200μg/ml	+	-
Lipids	20mg/ml	+	-

3. Some other common biological analytes were spiked into the Dengue positive and negative specimens and tested separately. No significant interference was observed at the levels listed in the table below.

Analytes	Conc. (μg/ml)	Specimens	
		Positive	Negative
Acetaminophen	200	+	-
Acetoacetic Acid	200	+	-
Acetylsalicylic Acid	200	+	-
Benzoylecgonine	100	+	-
Caffeine	200	+	-
EDTA	800	+	-
Ethanol	1.0%	+	-
Gentisic Acid	200	+	-
β - Hydroxybutyrate	20,000	+	-
Methanol	10.0%	+	-
Phenothiazine	200	+	-
Phenylpropanolamine	200	+	-
Salicylic Acid	200	+	-

Reproducibility

Reproducibility studies were performed for Dengue NS1 Antigen Rapid Test at three physician office laboratories (POL). Sixty (60) clinical serum specimens, 20 negative, 20 borderline positive and 20 positive, were used in this study. Each specimen was run in triplicate for three days at each POL. The intra-assay agreements were 100% at two sites, and 99.4% at one site. The inter-site agreement was 99.8%.

[Bibliography]

1. Halstead SB, Selective primary health care: strategies for control of disease in the developing world: XI, Dengue. Rev. Infect. Dis. 1984; 6:251-264.
2. Halstead SB, Pathogenesis of dengue: challenges to molecular biology. Science 1988; 239:476-481.

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Index of Symbol

Do not reuse	For in vitro diagnostic use only
Store between 4-30℃	Consult instructions for use
Caution	Lot number
Use by	Contains sufficient for <n> tests
Keep away from sunlight	Keep dry
Manufacturer	Do not use if package is damaged

EC REP Authorized representative in the European Community

Cost per Test: Php 180.00

Version No.: 3.0
Effective Date: Jul. 30, 2018

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