EnCore Biomedicals

EnSure RAPID DENGUE NS1 ANTIGEN TEST

Rapid Diagnostics Test for Dengue NS1 — Store at 2°C to 30°C

INTENDED USE

Rapid Dengue NS1 Antigen test is a lateral flow chromatographic immunoassay for the qualitative detection of Dengue NS1 antigen in human blood/serum/plasma. It is intended to be used by healthcare professionals to aid in the diagnosis of infection with dengue virus. Alternative test method(s) should be considered to confirm the test result obtained by this device.

SUMMARY

The dengue NS1 test stands for Dengue non-structural protein 1. It is used to diagnose dengue fever early. The test detects the presence of dengue NS1 antigen in the blood. It allows rapid detection on the first day of fever, before antibodies appear some 5 or more days later. Common symptoms include high fever,body ache,mild skin rash,pain behind the eyes,loss of apetite, vomiting and nausea.

PRINCIPLE OF THE ASSAY

After addition of the serum or plasma or whole blood sample on the sample port of the device containing a test strip, the sample moves on to the gold conjugate pad containing colloidal gold particles conjugated with Dengue NS1 antigen specific antibodies and rabbit IgG. If the sample contains detectable levels of the Dengue NS1 antigens it reacts with the gold conjugated Dengue NS1 antibodies to form a complex. This complex along with unbound gold particles move on nitrocellulose membrane. The complex reacts with Dengue NS1 antibodies coated on nitrocellulose membrane at test side to form a colored band (Test Line). The unbound complex, unbound gold conjugate particles and the rabbit IgG conjugated colloidal gold particles move further to the goat anti-rabbit IgG coated control area to form a colored band (Control line). The appearance of test line and control line in respective area indicates the positive result. Appearance of only control line indicates a negative result. The control line acts as a procedural control. Control line should always appear if the test is performed as per the procedure.

PACKAGE CONTAINS

1. Each pouch contents: Test Cassettes, Sample dropper, Desiccant.
2. 1 Instruction for use per box
3. 1 Assay buffer bottle per box

MATERIALS REQUIRED BUT NOT PROVIDED

1. Timer
2. Disposable gloves
3. Calibrated micropipette capable of delivering 25 µl sample accurately.

WARNINGS AND PRECAUTIONS

1. Please read the instruction carefully before performing the test.
2. For In Vitro Diagnostic use only.
3. Do not reuse the test.
4. Do not use the test after the expiration date.
5. Do not use cassette if cassette pouch is torn or damaged.
6. Use appropriate Personal Protective Equipments. Avoid direct skin contact.
7. Immediately carry out the test after removing the test device from the pouch.
8. Do not eat the Silica Gel Pouch provided in the package.
9. Do not mix or interchange the specimen sample.
10. Handle all specimen as if potentially infectious. Follow Standard Biosafety Guidelines during handling and disposal of materials to avoid the risk of infections.
11. The manufacturer and the distributor of this product shall not be liable for any loses, liability, claims, costs or damages whether direct or consequential arising out of or related to an incorrect diagnosis, whether positive or negative, in the use of this product.

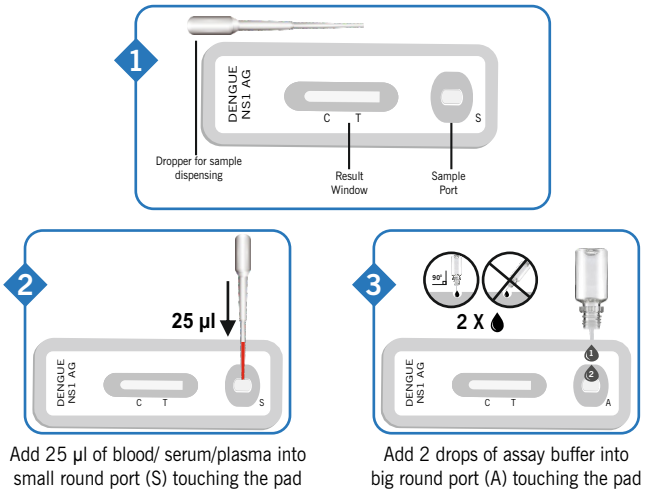
SPECIMEN COLLECTION

1. No special preparation of the patient is necessary prior to specimen collection by approved techniques.
2. **BLOOD SPECIMEN:** For Whole Blood, collect blood into suitable anti-coagulant tube (EDTA, Heparin or Oxalate) and used the freshly collected blood.
3. **PLASMA SPECIMEN:** Collect blood into suitable anti-coagulant tube (EDTA, Heparin or Oxalate) and centrifuged the tube to obtain plasma specimen.
4. **SERUM SPECIMEN:** Collect the venous whole blood in the commercially available plain tube, not containing any anti-coagulant as mention above and leave to settle about 30 minutes for blood coagulation and then centrifuge to obtain serum specimen.
5. Repeated freezing and thawing of specimen should be avoided.
6. Do not use haemolyzed, clotted, contaminated, viscous/turbid specimen.
7. Refrigerated specimen must be brought to room temperature before testing.
   Testing should be performed as early as possible after collection. Do not leave Serum/Plasma/Whole blood at room temperature for prolonged period.

TEST PROCEDURE

1. Allow the test and the sample to reach room temperature (2°C to 30°C) before opening the foil pouch.
2. Remove the Cassette, Silica Gel pouch and plastic dropper from the pouch. Check the Silica Gel pouch color, It should be blue. If it has turned colorless or pink, discard the test and use another test. Once open the device must be used immediately.
3. Label the device with specimen identity.
4. Add one drop (25 µl) of serum or plasma or blood sample in port 'S'.
5. Immediately add 2 drops (Approx. 60-70 µl) assay buffer.
6. Start the timer.
7. Read the result at 15 minutes. Do not read the result after 20 minutes.

TEST PROCEDURE



Add 25 µl of blood/ serum/plasma into small round port (S) touching the pad

Add 2 drops of assay buffer into big round port (A) touching the pad

Do not interpret the test results beyond 20 minutes

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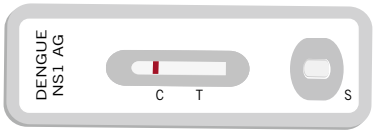
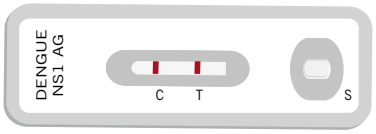
INTERPRETATION OF RESULTS

NEGATIVE : colored line appears at the control region 'C' only.

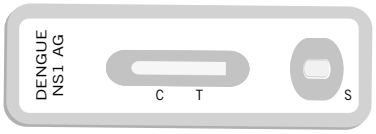


POSITIVE: A distinct colored lines appear at control region 'C' and test regions "T".

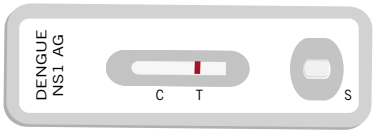


INVALID: The test should be considered invalid if,

A) No line appears at 'C' and 'T' regions.



B) No line appears at 'C' side and appear only at 'T' region.



NOTE: The intensity of the color at the test line re (T) will vary depending upon the concentration of dengue virus NS1 antigen in specimen.

PERFORMANCE CHARACTERISTICS: -

Internal Evaluation:

In an in-house study, total 297 samples were evaluated for sensitivity and specificity. We found the relative sensitivity was 100 % (i. e. 127/127) and the relative specificity was 100 % (i. e. 170/170). The results are summarized in the following table:

Sample	Total Number of samples tested	Rapid Dengue NS1 Antigen Test		Sensitivity (%)	Specificity (%)
		Positive	Negative		
Dengue NS1Antigen Positive serum	89	89	0	100	-
Dengue NS1Antigen Positive plasma	19	19	0	100	-
Dengue NS1Antigen positive blood	19	19	0	100	-
Negative Human Serum	90	0	90	-	100
Negative Human Plasma	40	0	40	-	100
Negative Human Blood	40	0	40	-	100

Cross reactivity was studied using Influenza A, Influenza B, Respiratory syncytial virus, Mycobacterium tuberculosis, Adenovirus, HBsAg, HCV, Streptococcus pyrogens, Pneumocystis Jirovecii (PJP), Syphilis TP, no cross reactivity was observed.

LIMITATIONS

This test provides presumptive diagnosis of Dengue. A confirmed Dengue diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated

DISCLAIMER

All precautions shall be taken to ensure the diagnostic ability and accuracy of this product. This product is utilized outside the control of manufacturer and distributors. The various factors including storage temperature, environmental conditions and procedure error may affect the results. This test provides presumptive diagnosis of dengue infection. A confirmed dengue infection diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

REFERENCES

1. Pang L, Kitsutani P, Vorndam V, Nakata M, Ayers T,Elm J, Tom T, Reiter P, Rigau-Perez JG, Hayes JM, Mills K, Napier M, Clark GG, Gubler DJ; Hawaii
2. Dengue Outbreak Investigation Team. Dengue fever, Hawaii, 2001-2002. Emerg Infect Dis. 2005; 11(5)
3. Alcon-LePoder S, Sivard P, Drouet MT, Talarmin A, Rice C, Flamand M. Secretion of flaviviral non-structural protein NS1: from diagnosis to pathogenesis.
4. Songee L. ranch and Paul N. Levett. Evaluation of four methods for detection of immunoglobulin M antibodies to dengue virus. Clin.Diagn. Lab. Immunol. Vol6 (4) p 555-557, 1999.
5. Seth, J. (1991. standardization & quality assurance. In principle and practice of immunoassay, Ed. C.P. Price & D.J. Newman. Macmillan Publishers, pp.154-189.

SYMBOL KEY

IVD	In Vitro Diagnostic Use	30°C 2°C	Temperature limitation
	Manufacturer		Single Use only
	Manufacturing Date	Σ	Number of tests in the pack
	Expiry Date		Do not use if pouch or kit damaged
LOT	Lot Number		Read package insert before use

Manufacturer By

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