ImmunoScience INDIA

ImmunoQuick

Dengue NS1 Ag

Rapid Dengue NS1 Antigen Test - Device

For *In-Vitro* Diagnostic Use Only **Store at 4°C to 30°C**

INTENDED USE

Rapid Dengue NS1 antigen test is an immunochromatographic assay for the qualitative detection of non-structural protein 1 (NS1) in human serum/plasma/Whole blood.

PRINCIPLE

After addition of the serum or plasma or whole blood sample to the sample well 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 delectable 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 and reagents are working properly.

CONTENTS OF KIT

1.Test
2.Desiccant
3.Plastic Dropper
4.Package Insert

OPTIONAL MATERIAL REQUIRED

1.Timer
2.Disposable gloves
3.Calibrated micropipette capable of delivering 90 µl sample accurately.

PRECAUTIONS/KIT STORAGE AND STABILITY

1.Please read all the information in this package insert before performing the test.
Pay particular attention to the position of the Control and Test lines.
2.Do not use after the expiration date printed on the foil pouch.
3.Store in the sealed pouch in a dry place in between temperature 4°C to 30°C.
Do not freeze.
4.Do not use if pouch is torn or damaged.
5.Do not open the foil pouch until you are ready to start the test.
6.Keep out of the reach of children.

WARNINGS

1.Do not reuse the test.
2.Follow the instruction to get accurate results.
3.Use appropriate personal protective equipment.
4.Dispose off hygienically in domestic waste.
5.Do not touch the membrane.
6.Treat samples and used test as potentially infectious. Avoid contact with skin.
7.For in vitro diagnostic use. Not to be taken internally.
8.Do not eat the desiccant in the package.
9.Do not mix the specimen sample or interchange the different specimen.

SPECIMEN COLLECTION

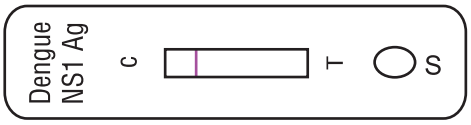
1.Testing should be performed as early as possible after collection. Do not leave serum/Plasma/whole blood at room temperature for prolonged periods.

TEST PROCEDURE

1. Allow the test and sample to reach room temperature (20°C to 30°C) before opening the foil pouch.
2. Remove the test, desiccant (Silica gel) and plastic dropper from the pouch and use the test as early as possible. Check the desiccant pouch color. It should be blue. If it has turned colorless or pink, discard the test and use another test.
3. Add two drops (i.e. approximately 90 µl) of serum or plasma or Whole blood sample in well 'S'.
4. Start the timer.
5. Read the result at 15 minutes. Do not read the result after 20 minutes.

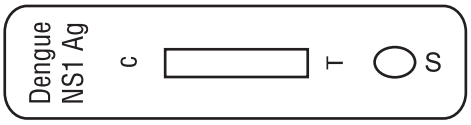
INTERPRETATION OF RESULTS

Negative : If colored line appears at the control side 'C' only.

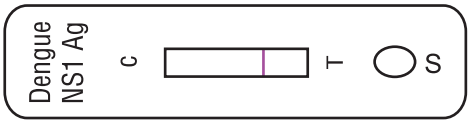


Positive : If colored lines appear at the control side 'C' and the test side 'T'.

Invalid : The test should be considered invalid if,
A) No line appears at 'C' and 'T' side.



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



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

PERFORMANCE CHARACTERISTICS

Internal Evaluation :

In an in-house study, total 315 samples were evaluated for sensitivity and specificity. We found the relative sensitivity was 100 % (i. e. 145/145) 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 NS1 Antigen positive serum samples	100	100	0	100	-
Dengue NS1 Antigen positive plasma samples	25	25	0	100	-
Dengue NS1 Antigen positive blood samples	20	20	0	100	-
Negative Human Serum samples	100	0	100	-	100
Negative Human plasma samples	50	0	50	-	100
Negative Human Blood samples	20	0	20	-	100

Cross reactivity was studied using Malaria Pf antigen positive blood samples, Malaria Pv antigen positive blood samples, no cross reactivity was observed.

External Evaluation:

In an external study, total 150 samples were evaluated for sensitivity and specificity. Relative sensitivity was 100 % (i. e. 50/50) and the relative specificity was 100 %(i. e. 100/100). Positive Predictive Value (PPV) and Negative Predictive Value (NPV) for the test was 100%.The results are summarized in the following table:

Sample	Total Number of Samples Tested	Rapid Dengue NS1 antigen Test		Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
		Positive	Negative				
Positive Samples	50	50	0	100	-	100	-
Negative Samples	100	0	100	-	100	-	100

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

The all precaution 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 Dengue Outbreak Investigation Team. Dengue fever, Hawaii, 2001-2002. Emerg Infect Dis. 2005; 11(5).
2. Alcon-LePoder S, Sivard P, Drouet MT, Talarmin A, Rice C, Flamand M. Secretion of flaviviral non-structural protein NS1: from diagnosis to pathogenesis.
3. Songee L. ranch and Paul N. Levett. Evaluation of four methods for detection of immunoglobulin M antibodies to dengue virus. Clin. Diagn. Lab. Immunol. Vol 6 (4) p 555-557, 1999.
4. Seth, J. (1991. standardization & quality assurance. In principle and practice of immunoassay, Ed. C.P. Price & D.J. Newman. Macmillan Publishers, pp.154-189.

IVD	In Vitro Diagnostic Use
	Manufacturer
	Manufacturing Date
	Expiry Date
LOT	Lot Number
30°C 4°C	Store at 4°C to 30°C
2	Single Use
Σ	Number of tests in the pack
	Do not use if pouch or kit damaged
	This side Up
i	Read package insert before use

MANUFACTURED BY

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