

In vitro Diagnostics

INTENDED USE

Sensit Dengue NS1 Rapid Test Kit is a qualitative immunochromatographic assay for the detection of NS1 antigen in human Serum. Sensit Dengue NS1 Rapid Test is only intended for initial screening of Dengue virus in human serum prior to the presence of IgM or IgG antibodies. Reactive samples should be confirmed by a supplemental assay such as ELISA.

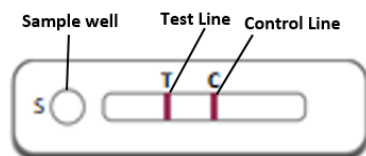
SUMMARY & TEST DESCRIPTION

Dengue viruses, transmitted by the *Aedes aegypti* and *Aedes albopictus* mosquitoes, are widely distributed throughout the tropical and subtropical areas of the world. There are four known distinct serotypes (dengue virus 1, 2, 3 and 4). In children, infection is often subclinical or causes a self-limited febrile disease. However, if the patient is infected a second time with a different serotype, a more severe disease, dengue hemorrhagic fever or dengue shock syndrome, is more likely to occur. Dengue is considered to be the most important arthropod-borne viral disease due to the human morbidity and mortality it causes. Traditionally, the serological diagnosis of an acute dengue virus infection has relied on showing a 4-fold or greater rise in anti-dengue virus antibody between paired acute and convalescent phase sera from a patient. Dengue NS1 (non-structural) protein is a multimeric secreted protein that is believed to play a role in viral replication. NS1 antigen can be detected in circulating blood during acute Dengue infection.

Sensit Dengue NS1 antigen Rapid Test is for the qualitative determination of antigen developed during Dengue infection.

TEST DESCRIPTION & PRINCIPLE

Sensit Dengue NS1 Antigen Rapid Test works on chromatographic immunoassay. Basic components of test strip includes: a) Conjugate pad, which contains Detection molecule, colloidal gold conjugated; b) a nitrocellulose membrane strip containing two lines T: Anti-Dengue NS1 monoclonal antibody and C: Goat Anti-Mouse.



Test sample that is added to the sample well, with adequate amount of buffer migrates from the sample pad along the conjugate pad where Dengue NS1 antigen present in the sample will bind to the colloidal gold conjugate to form a complex. The sample then continues to migrate across the membrane until it reaches the capture zone where the complex will bind to the immobilized Anti-Dengue NS1 monoclonal Ab (on test line) producing a visible line on the membrane. If the antibody is not present in the sample, no reaction occurs in the capture zone and no test line is formed. The sample then migrates further along the strip until it reaches the control zone, where it produces another visible line on the membrane. This control line indicates that the sample has migrated across the membrane as intended.

REAGENTS & MATERIALS PROVIDED

1. Each test pouch contains:
 - a. One test card and dropper
 - b. Desiccant
2. Instruction Leaflet

STORAGE & STABILITY

Store the test kit between 2-30°C till the expiration date indicated on the pouch / carton. DO NOT FREEZE. Ensure that the test device is brought to room temperature before opening.

PRECAUTION & WARNING

- 1) Use within 10 minutes after opening pouch.
- 2) Do not touch result window.
- 3) Use only the buffer supplied along with the kit.
- 4) Do not mix components from different kits.
- 5) Do not use with specimen containing precipitates

SAMPLE COLLECTION AND PREPARATION

Serum:

- Collect the whole blood in to a syringe (Not containing anti-coagulants). Leave the syringe preferably at an angle, to settle for 30 minutes. Once blood coagulates, collect the clotted blood in to centrifuge tube and centrifuge to get serum specimen as supernatant.

Note:

- *If the specimen is not used for testing immediately, they should be refrigerated at 2~8°C.*
- *For storage period longer than 5 days, freezing is recommended. Store at -20°C*
- *The specimen should be brought to room temperature prior to use.*

Treat the specimen as infectious and handle with standard biosafety measures.

TEST PROCEDURE

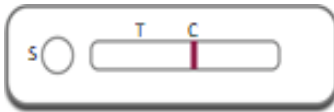
1. Take out the test card from the foil pouch and place it on a horizontal surface.
2. Add 2-3 drops of the specimen to the Sample well "S" using the dropper provided.
3. Wait for 10 minutes and interpret the result. The result is considered invalid after 15 minutes.

INTERPRETATION OF TEST RESULT

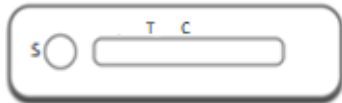
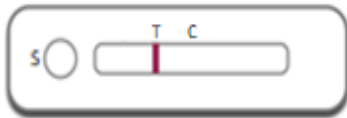
Positive: A clear pink control band (“C”) and a detectable test band (“T”) appear, indicating the presence of Dengue NS1 antigen in the sample.



Negative: A pink colored band appears only at control region (“C”) indicating the absence of Dengue NS1 antigen in the sample.



Invalid: If the control line fails to appear within the result window, the result is considered invalid. The directions may not have been followed correctly or the test may have deteriorated. It is recommended that the specimen be retested.












References

1. Chaterji S, Allen JC Jr, Chow A, Leo YS, Ooi EE. Evaluation of the NS1 rapid test and the WHO dengue classification schemes for use as bedside diagnosis of acute dengue fever in adults. *Am J Trop Med Hyg.* 2011;84(2):224-228.


DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in Dengue NS1 Antigen Rapid Test for single-step detection of Dengue NS1 antigen are the most common signs appearing on medical devices and their packaging. They are explained in more detail in the European Standards EN 980: 2008 and INTERNATIONAL Standard ISO 15223-1:2016

Key to symbols used			
	Manufacturer		Expiration/use by date
	Do not reuse		Date of manufacture
	Consult IFU [Instructions For Use]	LOT	Batch code
	Temperature limitation 2-30°C	IVD	In Vitro diagnostic medical device
	Contains sufficient for 'X' kits		Do not use if package is damaged
REF	Catalogue No		Keep dry

Please read the user manual carefully before operating to ensure proper use

Manufactured by,

 ubio Biotechnology Systems Pvt Ltd
 Plot # 15A, Biotechnology Zone
 Kalamassery, Cochin, Kerala, India 683503
 Ph.; +91-484-2970043
<http://www.ubio.in>
 e-mail: contact@ubio.co.in

UBD/QA/IFU/S001-01
 Rev. No: A1.1/13-10-2021