SBio Dengue NS1 Test

Rapid test for the detection of Dengue NS-1 antigen in human serum/ plasma

Temperature Limitation	Contains sufficient for <n> tests</n>	PIPETTE Disposable Plastic Sample Applicator	EC REP Authorised Re in the Europea	presentative
Use by	Consult Instructions for use	DEVICE Device		NaN, R22 523-46-61 Harmful if swallowed. Do not breathe vapour.
Date of Manufacture	REF Catalogue Number	Do not reuse	Do not use if a is damaged	Aackage If swallowed, seek medical advice immediately and show this container or label. Avoid release to the environment. Refer to special instructions.
LOT Batch Number/ Lot Number	In vitro Diagnostic Medical Device	This side up	Dengue NS1 Rapid test for of Dengue NS1 human serum	the detection Tantigen in plasma

INTENDED USE

SBio Dengue NS1 Test is a rapid, qualitative immunochromatographic test system for the detection of Dengue NS1 (Dengue Non-Structural Protein-1) antigen in human serum or plasma. The test can be used as a screening test in early phase of Dengue viral infection in conjunction with other criteria. For professional use only.

SUMMARY

Dengue virus (serotypes 1-4) belongs to the family of Flaviviridae, which is widely distributed in the epidemic and endemic areas throughout tropical and subtropical regions of the world. Dengue virus infection is considered significant in terms of morbidity, mortality and economic cost associated with it an estimated 100 million cases of dengue fever occurring throughout the world yearly. Dengue virus is transmitted in nature principally by the Aedes aegypti and Aedes albopictus mosquitoes. The mosquito vector is highly domesticated and an urban species. Dengue presents typically as a fever of sudden onset with headache, retroorbital pain, pain in the back and limbs (break-bone fever), lymphadenopathy and maculopapular rash. Dengue virus infection is characterized by elevation in dengue virus specific NS 1 antigen level in patient's blood stream from 1-6 days after onset of symptoms (Early phase).

SBio Dengue NS1 Test is a new generation rapid Immunochromatographic test for first line detection of dengue virus infection in early stage.

PRINCIPLE

SBio Dengue NS1 Test utilizes the principle of agglutination of antibodies/ antisera with respective antigen in immunochromatography format along with use of nano gold particles as agglutination revealing agent. As the test sample flows through the membrane assembly of the device, the highly specific Agglutinating sera for dengue NS 1 - colloidal gold conjugate complexes with dengue NS 1 antigen present in the sample and travels on the membrane due to capillary action. The complex moves further on the membrane to the test region (T) where it is immobilized by another specific Agglutinating sera for dengue NS 1 coated on the membrane leading to the formation of a pink-purple band. Absence of this colored band in the test region indicates a negative test result for dengue NS 1 antigen. A built-in control band in the control area marked 'C' appears when the test has been performed correctly. regardless of the presence or absence of the dengue NS 1 antigen in the specimen. It serves to validate the test performance.

REAGENT AND MATERIAL SUPPLIED

- A. Each SBio Dengue NS1 Test pouch contains :
 - 1. DEVICE : Membrane pre-dispensed with Agglutinating

sera for dengue NS 1- colloidal gold conjugate, Agglutinating sera for dengue NS 1 and Agglutinating sera for mouse globulin coated at the respective regions.

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2. Desiccant pouch.

3. PIPETTE : Disposable Plastic Sample Applicator.

B. Package insert.

STORAGE AND STABILITY

The test kit (including sealed pouches) may be stored between 4°C to 30°C till the duration of the shelf life as indicated on the pouch/ carton. DO NOT FREEZE.

NOTE

- 1. Read the instructions carefully before performing the test.
- For in vitro diagnostic use only. NOT FOR MEDICINAL USE. For professional use only.
- Do not use the kit beyond expiry date and do not re-use the test device.
- 4. Do not intermix reagents from different lots.
- Contact with the contents of desiccant pouch containing, among other substances, cobalt chloride (CAS# 7646-79-9) should be kept to a minimum. Inhalation / swallowing may cause harm.
- Handle all specimens as if potentially infectious. Follow standard biosafety guidelines for handling and disposal of potentially infectious material.
- If desiccant colour at the point of opening the pouch has turned from blue to pink or colourless, another test device must be run. invalidate the test procedure.
- The specimen dispensing dropper provided in the kit is to be used for NS-1 antigen testing only.
- 6. Do not interchange the buffer or the devices of different lots.
- Handle all specimens as if potentially infectious. Follow standard bio-safety guidelines for handling and disposal of potentially infective material.

SPECIMEN COLLECTION AND PREPARATION

- Fresh serum/plasma may be used for the test, if specimens cannot be tested immediately they may be stored at 2-8 °C for up to 24 hours and then used provided they are not contaminated.
- The use of turbid, lipaemic, icteric and haemolysed serum or plasma specimen should be avoided as it may lead to erroneous results.
- 3. Repeated freezing, thawing of the specimen should be avoided.
- Specimen containing precipitates or particulate matter may yield erroneous results. Such specimens must therefore be centrifuged and the clear supernatant should only be used for

testing.

TEST PROCEDURE

- Open foil pouch by tearing along the "notch" and remove NS 1 antigen testing device, just prior to the testing.
- Check the color of the desiccant pouch. It should be blue. If the 2 desiccant has turned colorless or pink, discard that test device and use another device.
- Once opened, the device must be used immediately. 3
- Label the device with specimen identity and place it on a flat 4 horizontal surface and perform the test.
- Holding the sample applicator vertically, carefully dispense 5 exactly 3 drops (75 µl) of the serum/plasma specimen into the specimen port (S). Alternatively, using a 75 μI precision micropipette, carefully dispense exactly 75 µl of the serum/ plasma specimen into the specimen port (S).
- 6 Immediately start the stopwatch and read the result at the end of 15 minutes

INTERPRETATION OF RESULTS



Negative Result: Only one pink / purple colored band appears at the Control Region (C). This indicates absence of dengue NS 1 antigen in the specimen.

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Positive Result: Two pink / purple colored bands appear at the Control Region (C) and Test Region (T). This indicates that the specimen contains detectable level of Dengue NS 1 antigen.



bands appear on the device. The test should also be considered invalid if only the test band appears and no control band appears. Verify the test procedure and repeat the test with a new device.

PERFORMANCE CHARACTERISTICS

SBio Dengue NS1 Test was evaluated with 80 known dengue NS1 positive samples and 60 known dengue negative samples in comparison with a commercially available Dengue NS 1 test. 100% correlation in results has been found...

LIMITATION OF THE TEST

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- (The test detects the presence or absence of dengue NS 1 1 antigen in the human serum/plasma specimen. It should not be used as sole criteria for the diagnosis of dengue infection.
- As with all diagnostic tests, a definitive clinical diagnosis 2. should not be based on the results of a single test but should rather be made by a clinician after all clinical and diagnostic findings have been evaluated.

- 3. NS 1 antigen is an in-vitro diagnostic marker for dengue detection in early phase only. Negative result does not always rule out the chances of infection of Dengue. Patient should be tested after 3-4 days with other markers in case of clinically non-correlated result.
- Serological cross reactivity across the other Flavi virus group 4. may be occurred in certain cases.
- It is a screening test, therefore isolation of virus, antigen detection in fixed tissue, RT-PCR; etc., or any other 5 alternative diagnostic methods can be used for confirmation.
- 6. Various studies have reported interference due to presence of heterophile antibodies in patient's sample. SBio Dengue NS1 Test uses HETEROPHILIC BLOCKING REAGENT (HBR) to inhibit majority of this interference.
- 7. Do not interpret the test results beyond 30 minutes.

BIBLIOGRAPHY

- (Maria G. Guzman, Gustavo Kouri, Clinical and Diagnostic Laboratory Immunology, Advances in Dengue Diagnosis, Nov 1996, Vol. 3, No.6, p. 621-627.
- Chew Thang Sang, Lim Siew Hoon, Andrea Cuzzubbo, Peter 2. Devine, Clinical Evaluation of a rapid immunochromatographic test for the diagnosis of Dengue Virus Infection, May 1998, p 407-409.
- Dengue: Guideline for diagnosis, treatment, prevention and control. New edition. (WHO-TDR), Geneva: World Health Organization 2009.
- Hematological observations as diagnostic markers in dengue 4. hemorrhagic fever – a reappraisal, Sunil Gombe, K.N. Agarwal, P. Gupta, Piyush Gupta and D.K. Dewan, Indian Pediatrics 2001:38: 477-481.





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EC REP

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