Size : 137 x 218 mm

CE

Dengucheck™

NS 1

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

DEVICE

INTENDED USE

Dengucheck™- NS 1 is a rapid, qualitative immunochromatographic test system for the detection of Dengue NS 1 (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, retro-orbital 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).

Dengucheck™- NS 1 is a new generation rapid Immunochromatographic test for first line detection of dengue virus infection in early stage.

PRINCIPLE

Dengucheck™- NS 1 utilizes the principle of agglutination of antibodies/ antisera with respective antigen in immuno-chromatography 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 **Dengucheck™- NS 1** 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.
   2. Desiccant pouch.
   3. PIPETTE : Disposable Plastic Sample Applicator.

B. Package insert.

REF	502030010
Σ	10

STORAGE AND STABILITY

The test kit (including sealed pouches) may be stored between 4ºC to 30ºC 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.
2. For in vitro diagnostic use only. NOT FOR MEDICINAL USE. For professional use only.
3. Do not use the kit beyond expiry date and do not re-use the test device.
4. Do not intermix reagents from different lots.
5. 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.
6. Handle all specimens as if potentially infectious. Follow standard biosafety guidelines for handling and disposal of potentially infectious material.
7. If desiccant colour at the point of opening the pouch has turned from blue to pink or colourless, another test device must be run.

Colour	C	M	Y	K
Black	0	0	0	100
Green	100	20	100	10

Size : 137 x 218 mm

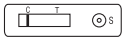
SPECIMEN COLLECTION AND PREPARATION

1. No special preparation of the patient is necessary prior to specimen collection by approved techniques. Though fresh serum/plasma is preferable, specimen may be stored at 2ºC to 8ºC for up to 24 hours, in case of delay in testing.
2. Do not use turbid, lipaemic, icteric and haemolysed serum or plasma specimen.
3. Freezing, thawing of the specimen should be avoided.
4. Specimen containing precipitates or particulate matter must be centrifuged and the clear supernatant only should be used for testing.

TEST PROCEDURE

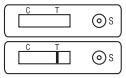
1. Open foil pouch by tearing along the "notch" and remove NS 1 antigen testing device, just prior to the testing.
2. Check the color of the desiccant pouch. It should be blue. If the desiccant has turned colorless or pink, discard that test device and use another device.
3. ***Once opened, the device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



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.

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.



Invalid Result: The test result is invalid if no 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

Dengucheck™- NS 1 was evaluated with 80 known dengue NS 1 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

1. The test detects the presence or absence of dengue NS 1 antigen in the human serum/plasma specimen. It should not be used as sole criteria for the diagnosis of dengue infection.
2. As with all diagnostic tests, a definitive clinical diagnosis 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.
4. Serological cross reactivity across the other Flavi virus group may be occurred in certain cases.
5. It is a screening test, therefore isolation of virus, antigen detection in fixed tissue, RT-PCR; etc., or any other alternative diagnostic methods can be used for confirmation.
6. Various studies have reported interference due to presence of heterophile antibodies in patient's sample. **Dengucheck™- NS 1** uses HETEROPHILIC BLOCKING REAGENT (HBR) to inhibit majority of this interference.
7. Do not interpret the test results beyond 30 minutes.

WARRANTY

This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

BIBLIOGRAPHY

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

Size : 137 x 218 mm

SYMBOL KEYS

 Temperature Limitation	 Consult Instructions for use	 Date of Manufacture	EC REP Authorised Representative in the European Community
 Manufacturer	IVD *In vitro* Diagnostic Medical Device	 This side up	
 Use by	REF Catalogue Number	 Do not reuse	PIPETTE Disposable Plastic Sample Applicator
 Contains sufficient for <n> tests	LOT Batch Number / Lot Number	DEVICE Device	

Size : 137 x 218 mm

Manufactured by:

Zephyr Biomedicals

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EC REP

CMC Medical Devices & Drugs S.L., Spain.

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