Code 356 Dengue NS1
25 test devices
25 disposable pipettes

CYPRESS DIAGNOSTICS

CE

Dengue NS1
Rapid Antigen Test for Dengue Fever

Intended use:
The Cypress Diagnostics Dengue NS1 test is a one step immunochromatographic test for the rapid detection of Dengue virus NS1 antigen in human serum, plasma or whole blood. This test is intended as an aid in the diagnosis of early Dengue infections.

Clinical significance:
Dengue is a viral disease. Dengue viruses, members of flaviviridae, are transmitted principally in a cycle involving humans and mosquito vectors (*Aedes aegypti* and *Aedes albopictus*). Dengue virus infection presents as two clinical syndromes: Dengue fever (DF) and dengue hemorrhagic fever (DHF) or dengue shock syndrome. DF is a self-limited febrile disease and is the most common type of dengue illness. It causes sudden fever with headache, retrobulbar pain, pain in the back and limbs (break-bone fever), lymphaderopathy, maculopapular rash and nausea. DHF is an immunopathogenic disease occurring after sequential dengue infections. DHF in its most severe form can threaten the patient's life primary through increased vascular permeability and shock. The fatality rate in patients with Dengue shock syndrome can be as high as 44%.
NS1 is a highly conserved non-structural Dengue virus protein that is present at high concentrations in the sera of dengue infected patients during the early clinical phase of the disease. NS1 can be detected in samples of primary and secondary dengue infected patients as early as 1 day after onset of symptoms up to 9 days.

This Cypress Diagnostics Dengue NS1 test provides an excellent methodology for detecting Dengue virus NS1 antigens. The Cypress Diagnostics Dengue NS1 test is a rapid immunochromato-graphic test that is simple and easy to use.

Principle of the test:
The Cypress Dengue NS1 test device has 2 pre-coated lines, "T" (NS1 Ag Test Line) and "C" (Control Line) on the surface of the device. Both lines in the result window are not visible before applying any samples. The "Control Line" is used for procedural control. A control line should always appear if the test procedure is performed properly and the test reagents of the control line are working. A pink "T" line will be visible in the result window if there are enough Dengue virus NS1 antigens in the sample. If Dengue virus NS1 antigens are not present in the sample, no colored line appears in "T" region.
When a sample is added to the sample well, Dengue virus NS1 antigens will react with colloidal gold conjugated with anti-dengue NS1 monoclonal antibody and form a complex of antibody-antigen. As this complex migrates along the length of the test device by capillary action, it will be captured by another anti-dengue NS1 monoclonal antibody immobilized in a test line across the test membrane and generate a colored line.

Kit components:
Each kit contains following items:
- 25 individually wrapped Cypress Diagnostics Dengue NS1 test devices which include one disposable pipette each
- 1 instruction leaflet

Additional materials required but not provided:
- Timer

Storage and stability:
The Cypress Diagnostics Dengue NS1 test should be stored at room temperature between 2-30°C in the original sealed pouch. The kit is stable until the date imprinted on the box label and/or pouch. Do not use expired test kits.

Warnings and precautions:
1. The Cypress Diagnostics Dengue NS1 test is FOR *IN VITRO* DIAGNOSTIC USE only. For PROFESSIONAL USE only. Use the test only in accordance with instructions supplied with the kit.
2. Treat all materials in the test as if they were infectious. Observe established precautions against microbiological hazards while performing the procedure and follow the standard procedures for proper disposal of sera and used kits.
3. Do not use test devices if the pouch is damaged or the seal is broken.
4. Do not open or remove test devices from their individually sealed pouches until immediately before their use.
5. Do not re-use test devices.

Sample collection:
The Cypress Diagnostics Dengue NS1 test is performed on serum, plasma or whole blood.
Samples with high level of hemolysis should be avoided as they can give inaccurate results.

Whole venous blood:
Collect venous blood, by the standard venipuncture procedure, into a collection tube containing anticoagulant (EDTA or heparin). Gathered blood from a syringe can cause faster hemolysis and should be avoided.

Serum: Collect the whole blood into a clean tube without anticoagulant by venipuncture. Leave to settle for 30 minutes for blood coagulation and then centrifuge the blood to obtain the serum sample from the supernatant.

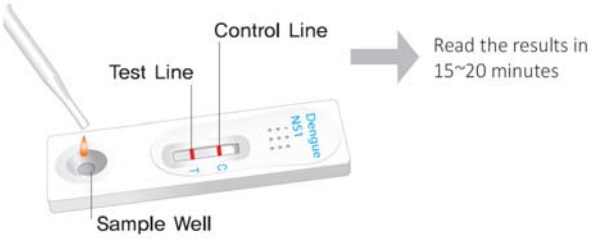
Plasma: Collect the whole blood into a clean tube containing anticoagulant (EDTA or heparin) by venipuncture and then centrifuge the blood to obtain the plasma sample from the supernatant.

Patient samples (whole venous blood, serum, plasma) perform best when tested within an hour after collection. If not to be tested within an hour, the samples should be refrigerated immediately following collection at 2-8°C and can be used up to 48 hours. For prolonged storage, serum and plasma samples may be frozen and stored at -20°C. Samples that are refrigerated or frozen should be brought to room temperature prior to use.

Headquarters - Siège social: Langdorpsesteenweg 160 • 3201 Langdorp • Belgium • www.diagnostics.be
Factory - Fabrique: Industriepark 36 • Zone B5 • 2235 Hulshout • Belgium • Tel: ++ 32 15 67 67 68 • e-mail: cypress@diagnostics.be

Test Procedure:

1. Bring all test devices, reagents and samples to room temperature for 15 minutes prior to performing the assay.
2. Use a fresh test device for every sample. The device is not reusable.
3. Just prior to use, remove the required number of Dengue NS1 test devices from their wrapper and place them on a flat surface area.
4. Label the test unit with the patient name or identification number.
5. Take 100 µl (3 drops) of whole blood or serum/plasma with the included disposable pipette or a micropipette and add into the sample well.
6. Interpret test results at 15~20 minutes.
7. Do not interpret the test results after 20 minutes, this can give false results.



Interpretation of results:

Positive

The presence of a test line (T) and a control line (C) on the test device indicates the presence of Dengue virus NS1 antigens.

Negative:

The presence of only a control line (C) on the test device indicates a negative result.

Inconclusive:

A control line should always appear in the control zone, no matter if the test line appears. If there is no distinct control line visible, the test is inconclusive. This can be due to an improper test procedure or deterioration of the test device. The test should be repeated with a new device.


Expected results:

The Dengue virus NS1 antigen is expected to be detected 1 day after onset of symptoms and persist up to 9 days in both primary and secondary dengue infections.

Quality control:

A control line should always appear in the control area. It is used as a procedural control. The control line shows that sufficient sample was added to obtain capillary flow and that the active ingredients of the main components on the strip are still functional.

Limitations of the procedure:

1. This test is designed for preliminary screening of Dengue virus NS1 antigen in human serum, plasma or whole blood. Therefore more specific alternative diagnosis methods must be used in order to obtain a confirmation of Dengue virus infection.
2. This test can provide a fast and easy way to obtain a result, but does not completely exclude the possibility of a false positive or a false negative result caused by various factors.
   As in case of 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 physician after all the clinical findings have been evaluated.
3. A negative result of the Dengue NS1 test can occur if the quantity of Dengue virus NS1 antigen present in the sample is below detection limits of the assay, or the antigens that are detected are not present during the stage of the disease in which the sample is collected.
4. Most blood samples clear within the running time of the test. However, in a few fresh samples and especially in stored samples, the background clearance may be delayed for 10-15 minutes.

Performance Characteristics

Comparison study

Cypress Dengue NS1 test showed good correlation with virus culture/ RT-PCR test:

		Virus culture/RT-PCR		
		+	-	Total
Cypress Quick test	+	93	2	95
	-	2	198	200
	Total	95	200	295

Sensitivity = 97,9% (93/95)
Specificity = 99,0% (198/200)

Reproducibility

Within-run and between-run reproducibility have been determined with 2 samples (negative and weak positive). The results were correct in 100% of the cases.

Interference

The interference of the Cypress Dengue NS1 test with known interfering samples was evaluated. In these studies, those samples didn't interfere with this test kit.

References

1. Dengue. Guidelines for diagnosis, treatment, prevention and control, WHO, Edition
2. Lam SK. Dengue haemorrhagic fever. Rev. Med. Micro.6 p 39-48, 1995
3. Alcon S. et al. Enzyme-linked immunosorbent assay specific to dengue vitus type 1 non structural protein NS1 reveals circulation of the antigen in blood during acute phase of disease in patients experiencing primary or secondary infections. J. Clin. Microbiol. 40 p 376-381, 2002
4. Halstead S.B. The pathogenesis of Dengue: challenges to molecular biology. Science 239 p 476-481, 1998
5. Halstead S.B Selective primary care: strategies for control of disease in developing world: XI, Dengue. Rev. Infect. Dis. 6 p 251-264, 1984
6. Shu P. et al. Current advances in dengue diagnosis. Clin. Diagn. Lab. Immunol. 11 (4) p 642-650, 2004

REV00/2015-02-04

Headquarters - Siège social: Langdorpsesteenweg 160 • 3201 Langdorp • Belgium • www.diagnostics.be
Factory - Fabrique: Industriepark 36 • Zone B5 • 2235 Hulshout • Belgium • Tel: ++ 32 15 67 67 68 • e-mail: cypress@diagnostics.be