

Dengue NS1 Rapid test (Strip)

Cat. No.:DTS349

Pkg.Size:

Intended use

The Dengue NS1 Rapid test(Strip) is an immunochromatographic strip assay for the qualitative detection of non-structural protein 1(NS1) in human serum, and serves as an aid in the diagnosis of early Dengue infections.This test will aid in the rapid diagnosis of Dengue virus in human serum even prior to the presence of IgM or IgG antibodies. This test is intended for research use only.

Principle Of The Test

The Dengue NS1 Rapid test(Strip) is a qualitative,membrane based immunoassay for the detection of NS1 antigen in human serum.The rapid test membrane is precoated with a NS1 specific antibody on the test line region and utilizes a separate control to assure assay flow and performance.During testing,the test sample is added directly to the sample region and the test is placed into a well containing 3 drops of buffer. The buffer and serum mix and interact with NS1-specific monoclonal antibodies conjugated to gold nanoparticles.The solution migrates upward on the membrane (via capillary action)to react with the anti-NS1 antibody on the membrane. If NS1 antigen is present,a red line will appear at the test line.The red line at the control region should always appear if the assay is performed correctly.The presence of this red line verifies that proper flow has occurred and catastrophic failure of the conjugate has not occurred.The entire procedure takes approximately 30 minutes.

Reagents And Materials Provided

- 1.Twenty-five Dengue NS1 Rapid Test dipsticks,individually pouched or 25 test strips in a vial with desiccant in the cap.Store at room temperature in vial.
- 2.One vial of Chase Buffer Type A,6ml.Store at room temperature.

Materials Required But Not Supplied

- 1.Pipettor and tips capable of measuring 5-50 μ l of solution.
- 2.Test tube or other sample reservoir well.

Specimen Collection And Preparation

- 1.Human serum must be used with this assay. Reagents have not been optimized, or tested with whole blood or plasma so they cannot be tested directly.
- 2.Remove serum from the clot of red cells as soon as possible to avoid hemolysis.
- 3.Testing should be performed as soon as possible after collection. Do not leave sera at room temperature for prolonged periods.
- 4.Serum should be used and the usual precautions for venipuncture should be observed. The samples may be stored at 2-8°C for up to 7 days or frozen at -20°C or lower for up to 30 days.To maintain long-term longevity of the serum, store at -70°C. Avoid repeated freezing and thawing of samples.
- 5.Frozen samples should be thawed to room temperature and mixed thoroughly by gentle swirling or inversion prior to use. Always quick spin before use.
- 6.If sera are to be shipped, they should be packed in compliance with Federal Regulations covering transportation of infectious agents.
- 7.Do not use sera if any indication of growth is observed.

Assay Procedure

Before beginning, remove the Dengue NS1 Rapid test (Strip) from the foil pouch or vial and assure that all test serum samples are allowed to reach room temperature.

Ensure that no physical damage (e.g., scratched membrane, torn pads, etc.) is apparent on the rapid test. SECURE an individual reservoir well in a microtube holder. Equivalently, a well from a 96-well ELISA plate or small test tube may be used to run the assay. Never reuse reservoir wells. Always run the rapid test with a fresh well.

1. Add THREE drops (approximately 120 µl) of Chase Buffer Type A to the well.
2. Carefully add 50µl of test sample to the Sample Pad.
3. Immediately place the rapid test in the well. Ensure that the 'Sample' side of the rapid test is facing downward into the well. If a red color is not seen moving up the membrane within 20 seconds, gently touch the arrows above the sample pad to permit flow of the conjugate and sample up the membrane.
4. Read the rapid test after 30 minutes. Do NOT interpret results after 45 minutes, as this may lead to erroneous results.

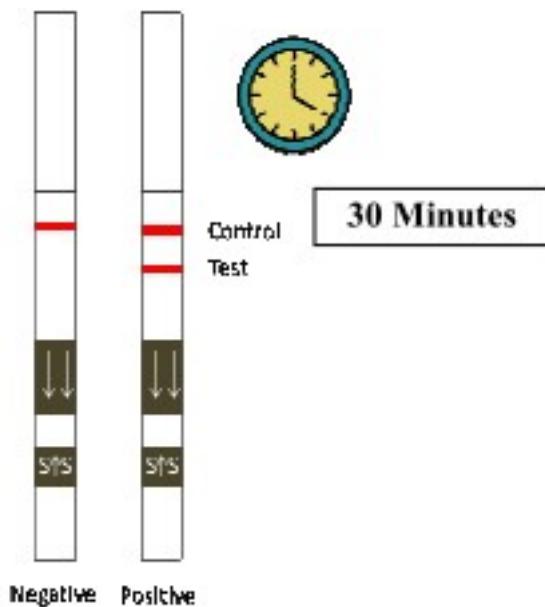
Interpretation of Results

1. Positive: The test is positive for NS1 antigen when the control line (C) and the test line (T) appear in the test area. A faint line is considered a positive result. As a guide for interpretation, the red color in the test region will vary depending on the concentration of the NS1 antigen present. The test line for 'weakly positive' sera samples may show a weak positive but distinctly red line. The presence of a weak red test line should be considered a positive result.

2. Negative: The test is negative when only the control line appears. If no test line is present IN 30 MINUTES, it is an Invalid Result.

3. Invalid: No lines appear at the control line areas. The test is also invalid if no control line appears, but a test line is seen. It is recommended to retest using a new Dengue NS1 rapid test and fresh serum.

Note: The red color in the test region will vary depending on the concentration of antibodies present. However, neither the quantitative value nor the rate of increase in antibodies can be determined by this qualitative test.



Sensitivity

1.6ng/ml

Precautions

The sealed pouch or vial containing the test strip is designed to be stored at room temperature (22°C-30°C) for the duration of its shelf life. The bottle containing the Chase Buffer is designed to be stored at room temperature for the duration of its shelf life. Exposure to temperatures over 30°C can impact the performance of the test and should be minimized. The strips should not be frozen. The test should be used within 15 minutes after removal from the pouch or vial to prevent exposure to humidity (5 minutes in high humidity areas).