DENGUE NS1 RAPID TEST

INTENDED USE

Nuvision Dengue NS1 Test is a rapid immunochromatographic assay for the qualitative detection of dengue NS1 antigen in human Whole Blood/Serum/Plasma samples. It is intended for professional use as a tool in the diagnosis and controlling the treatment of various dengue infections.

SUMMARY

Dengue viruses, transmitted by the mosquito, *Aedes aegypti* and *Aedes albopiaus* 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 NS1 antigen is a highly-conserved glycoprotein that is present at high concentrations in the sera of dengue-infected patients during the early clinical phase of the disease. NS1 antigen is found from the first day and up to 9 days after onset of fever in serum/plasma sample of primary or secondary dengue infected patients.

PRINCIPLE OF THE ASSAY

Nuvision Dengue NS1 device is a chromatographic immunoassay kit for rapid detection of dengue NS1 antigen in human Whole Blood/serum/plasma samples. Monoclonal antibodies specifically against NS1 antigen are conjugated with colloidal gold and deposited on the conjugate pad, and immobilized on the test line of the nitrocellulose membrane. When Whole Blood/serum/plasma sample is added the antibody conjugate is rehydrated and the NS1 antigens, if any in the samples, will interact with the colloidal gold conjugated antibodies. The antigen-antibody-gold complex will migrate towards the test window until the Test Zone (T) where they will be captured by immobilized antibodies, forming a visible red line (Test band), indicating a positive result. If Dengue NS1 antigen are absent in the sample, no red line will appear in the Test Zone (T), indicating a negative result. To serve as an internal process control, a control line should always appear at Control Zone (C) after the test is completed. Absence of a colored control line in the Control Zone is an indication of an invalid result.

The detection limit of Nuvision Dengue NS1 Antigen Test is approximately 1 ng/ml for recombinant NS1 antigen.

PACKAGE CONTENTS

- **25 Test kits (pouches) per box**
- **Pouch contents: Test Cassette, Desiccant.**
- **Sample Dropper (25 Nos.)**
- **Buffer Solution (1 vial, 2 mL/vial)**
- **1 Test instruction per box**

MATERIALS REQUIRED (BUT NOT PROVIDED)

- **Clean, specimen collection container.**
- **Clock or timer.**

WARNINGS AND PRECAUTIONS

- **For professional *in vitro* diagnostic use only.**
- **Do not reuse.**
- **Do not use if the product seal or the packaging is compromised.**
- **Do not use after the expiration date shown on the pouch.**
- **Do not mix and interchange different specimens.**
- **Wear protective clothing such as laboratory coats, disposable gloves and eye protection while handling potentially infectious materials and performing the assay.**
- **Wash hands thoroughly after finishing the test.**
- **Do not eat, drink or smoke in the area where the specimens or kits are handled.**
- **Clean up spills thoroughly with appropriate disinfectants.**
- **Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing procedures.**
- **Dispose of all specimens and used devices in a proper bio-hazard container. The handling and disposal of the hazardous materials should follow local, national or regional regulations.**
- **Keep out of children's reach.**

SPECIMEN PREPARATION

- **For serum samples, collect blood in a tube without anticoagulant and allow it to clot.**
- **For plasma samples, collect blood in a tube containing anticoagulant.**
- **Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.**
- **Whole blood: whole blood should be collected over heparin, citrate, or EDTA. Mix the blood by inversion and use it to the test. If fingertip blood is used to the test, prick the finger and collect the blood by a capillary tube. And then, load the blood onto the sample well (S) of the test device.**
- **Load the blood onto the sample well (S) of the test device.**
- **Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods.**
- **The blood may be stored at 2°C to 8°C for up to three days if the tests cannot be performed immediately. Ensure that the blood samples are allowed to attain room temperature prior to use. Note: Hemolytic samples should not be used!**

PROCEDURE

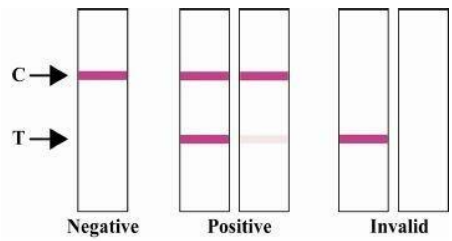
- **Bring the kit components to room temperature before testing.**
- **Open the pouch and remove the Test. Once opened, the test must be used immediately.**
- **Label the test card with patient's identity.**
- **<u>For Serum/Plasma samples</u>: Hold the sample dropper vertically and add two full drops <u>(70-80 µL)</u> of serum/plasma into the sample well that is marked with "S" on the testing device. No buffer required for serum/plasma samples.**
- **<u>For Whole Blood samples</u>: Hold the sample dropper vertically and add One full drop <u>(40-50µL) whole blood.</u>**
- **After about 25 seconds add 2 drops (~90 µL) of buffer solution in the sample well.**
- **Read the results at the end of 20 minutes. A strong positive sample may show result earlier.**

Note:

1. Some positive samples may show positive results before 10 minutes.

2. DO NOT READ RESULTS AFTER 30 MINUTES. To avoid confusion, discard the test device after interpreting the results.

INTERPRETATION OF RESULTS



Negative

A pink colored band appears only at the control region (C), No band appears in Test region.

Positive

A clear pink control band (C) and a detectable test band (T) appears, indicating a positive result for Dengue virus infections.

Invalid

No visible band appears at the control region (C). Repeat with a new test device. If the test still fails, please contact the distributor with the lot number.

STORAGE AND STABILITY

- **Test device in the sealed pouch should be stored at 2°-30°C. Do not freeze the test device.**
- **If stored at 2°-8°C, ensure that the device is brought to room temperature before opening.**
- **The test device should be kept away from direct sunlight, moisture and heat.**
- **Do not expose the kit over 30°C.**

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity studies were carried out in-house on fresh as well as frozen samples, from low risk as well as high risk groups.

Dengue NS1 Samples	Positive	Negative	Total
Positive	40	02	42
Negative	01	114	115
Total	41	116	157

Relative Sensitivity: 95.23%, Relative Specificity: 99.13%, Overall agreement: 97.18%

LIMITATIONS

- **This product is an *in vitro* diagnostic test designed for professional use only.**
- **Humidity and temperature can adversely affect results.**
- **The instructions for the use of the test should be followed during testing procedures.**
- **There is always a possibility that false results will occur due to the presence of interfering substances in the specimen or factors beyond the control of the manufacturer, such as technical or procedural errors associated with the testing.**
- **Although the test demonstrates superior accuracy in detecting Dengue NS1 antigen, a low incidence of false results can occur.**
- **Therefore, other clinically available tests are required in case of questionable results. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.**

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