

1. INTENDED USE

The Biokits Dengue NS1 Rapid Test is an in-vitro diagnostic, immunochromatographic assay for the qualitative detection of Dengue virus Non-Structural Protein 1 (NS1) antigen in human whole blood, serum, or plasma. This test is intended for professional use only.

2. INTRODUCTION

Dengue is an acute mosquito-borne viral infection caused by Dengue virus serotypes 1–4 and is a major public health concern in tropical and subtropical regions. The NS1 antigen is secreted into the bloodstream during the early phase of infection and can be detected from the first day of fever. Early detection of Dengue NS1 antigen is critical for timely clinical management and prevention of disease complications. The Biokits Dengue NS1 Rapid Test provides a rapid qualitative result to assist in the early diagnosis of Dengue infection.

3. PRINCIPLE OF THE TEST

The Biokits Dengue NS1 Rapid Test is a lateral-flow immunochromatographic assay with a two-line detection system consisting of a test line (T) and a control line (C). Dengue NS1 antigen present in the specimen binds to colloidal gold-conjugated anti-Dengue NS1 antibodies and migrates along the nitrocellulose membrane by capillary action. The antigen–antibody complexes are captured by immobilized anti-Dengue NS1 antibodies at the test line region, producing a visible colored line when Dengue NS1 antigen is present. The control line is coated with polyclonal antibodies and reacts with a colored control conjugate, producing a visible line independent of the presence of Dengue NS1 antigen, thereby confirming proper sample flow, reagent integrity, and test validity.

4. KIT COMPONENTS

Each kit contains:

1. Individually pouched Dengue NS1 Test Devices with desiccant
2. Assay Diluent / Buffer vial(s)
3. Sample Dropper
4. Instructions for Use (IFU)

5. KIT STORAGE AND STABILITY

1. Store at 2–30°C. Do not freeze.
2. Protect from direct sunlight and humidity.
3. Use the device immediately after opening the foil pouch.
4. Do not use if the pouch is damaged or the seal is broken.
5. Do not mix components from different lots.
6. Use before the expiry date printed on the packaging.

6. PRECAUTIONS

1. For In-Vitro Diagnostic Use Only.
2. Do not reuse the test device.
3. Avoid testing hemolytic, lipemic, or icteric specimens.
4. Use separate droppers or pipette tips for each specimen to prevent cross-contamination.
5. Wear gloves and adhere to standard laboratory biosafety practices.
6. Do not eat, drink, or smoke in the testing area.
7. Dispose of all used materials as per biomedical waste regulations.
8. Ensure all reagents and specimens are at room temperature before testing.

7. LIMITATIONS

1. This test is qualitative and does not provide an antigen concentration.
2. A negative result does not exclude Dengue infection, particularly if the specimen is collected outside the early acute phase.
3. Cross-reactivity with other flaviviruses may occur in rare cases.
4. Clinical decisions should not be based solely on this test; results should be interpreted in conjunction with clinical findings and other laboratory tests.
5. The test is validated only for human whole blood, serum, or plasma.

8. SAFETY INFORMATION

1. Handle all specimens as potentially infectious.
2. Use appropriate PPE such as gloves, lab coat, and eye protection.
3. Clean spills thoroughly with suitable disinfectants.
4. Dispose of used test components according to biomedical waste disposal guidelines.
5. Do not pipette by mouth.

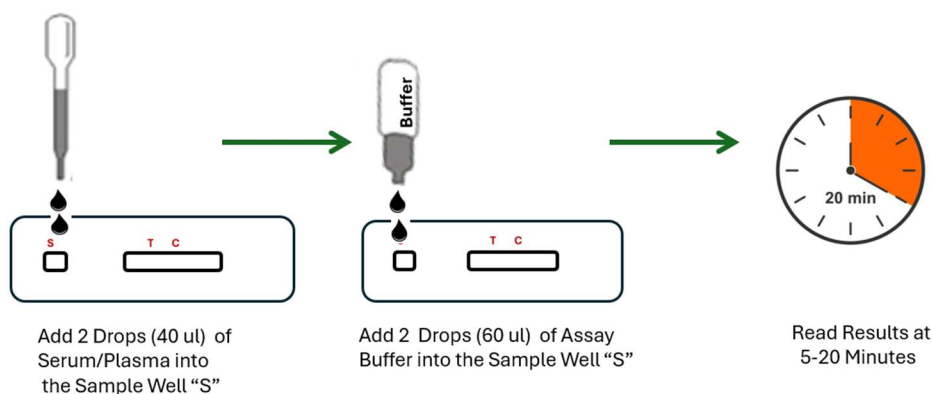
9. REFERENCES

1. World Health Organization. *Dengue: guidelines for diagnosis, treatment, prevention and control*. WHO Press, Geneva.

SPECIMEN COLLECTION AND STORAGE

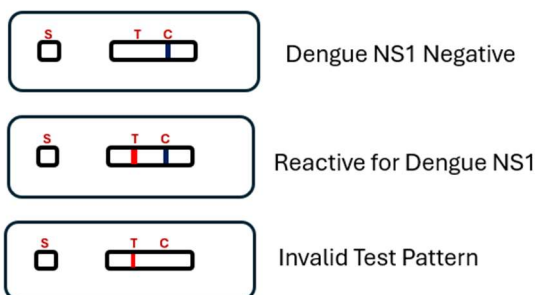
Category	Details
Accepted Specimens	<ul style="list-style-type: none"> ✓ Serum ✓ Plasma (EDTA, citrate, heparin)
Collection	<ul style="list-style-type: none"> ✓ Collect blood into a tube without anticoagulant. Allow the blood to clot completely, then centrifuge to separate the serum. ✓ Collect blood into an anticoagulant tube (EDTA, citrate, or heparin) and centrifuge to obtain plasma.
Storage	<ul style="list-style-type: none"> ✓ Test as early as possible ✓ Store at 2–8°C for up to 3 days ✓ For longer storage, freeze serum/plasma at –20°C Avoid freeze–thaw cycles

TEST PROCEDURE



Note: Do not read results after 20 min- it may give incorrect results !

RESULT INTERPRETATION



PERFORMANCE CHARACTERISTICS

- ✓ Clinical Sensitivity: 100%
- ✓ Clinical Specificity: 99.1%

M/s: ubio Biotechnology Systems Pvt Ltd. Plot No: 15A, Biotechnology Zone, KINFRA Hitech Park, Kalamaserry, Cochin, Kerala - 683503, INDIA.