Cat: BDEN-01

BioKits Dengue IgG-IgM Rapid Test

(Serum-Plasma-Whole Blood)

1. INTENDED USE

The Biokits Dengue IgG/IgM Rapid Test is an in-vitro diagnostic, immunochromatographic assay for the qualitative detection and differentiation of IgG and IgM antibodies to Dengue virus in human whole blood, serum, or plasma. This test is intended for professional use only.

2. INTRODUCTION

Dengue is a mosquito-borne viral infection caused by Dengue virus serotypes 1–4 and is endemic in many tropical and subtropical regions. Detection of anti-Dengue IgM antibodies indicates recent or acute infection, while anti-Dengue IgG antibodies indicate past exposure or secondary infection. Differentiation of IgM and IgG antibodies assists in clinical assessment and disease staging. The Biokits Dengue IgG/IgM Rapid Test provides a rapid qualitative result to aid in the diagnosis of Dengue infection.

3. PRINCIPLE OF THE TEST

The Biokits Dengue IgG/IgM Rapid Test is a lateral-flow immunochromatographic assay with a three-line detection system consisting of an IgM test line (M), an IgG test line (G), and a control line (C). Anti-Dengue IgM and/or IgG antibodies present in the specimen bind to colloidal gold-conjugated Dengue antigens and migrate along the nitrocellulose membrane by capillary action. The immune complexes are captured by immobilized anti-human IgM antibodies at the M line and anti-human IgG antibodies at the G line, producing visible colored lines corresponding to the antibody type present. The control line is coated with polyclonal antibodies and reacts with a colored control conjugate, producing a visible line independent of Dengue antibodies, thereby confirming proper sample flow, reagent integrity, and test validity.

4. KIT COMPONENTS

Each kit contains:

1. Individually pouched Dengue IgG/IgM Test Devices with desiccant
2. Assay Diluent / Buffer vial(s)
3. 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 antibody titers.
2. A negative result does not exclude Dengue infection, particularly in the early phase before antibody development.
3. Cross-reactivity with other flaviviruses may occur.
4. IgG antibodies may persist long after infection and should be interpreted in conjunction with clinical findings and patient history.
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.

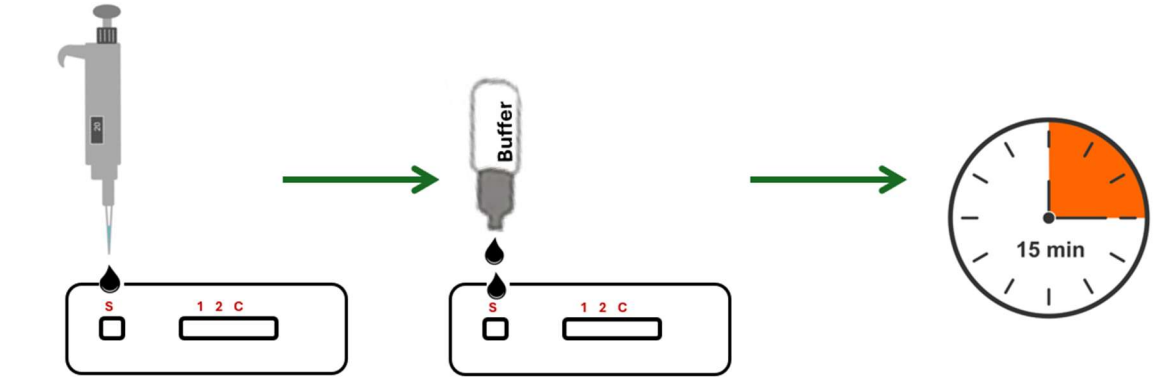
9. REFERENCES

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

SPECIMEN COLLECTION AND STORAGE

Category	Details
Accepted Specimens	✓ Whole blood (finger prick or venous) ✓ Serum ✓ Plasma (EDTA, citrate, heparin)
Collection	✓ Finger prick or venous blood using standard procedures ✓ For serum: allow to clot, then centrifuge For plasma: centrifuge anticoagulated blood
Storage	✓ 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



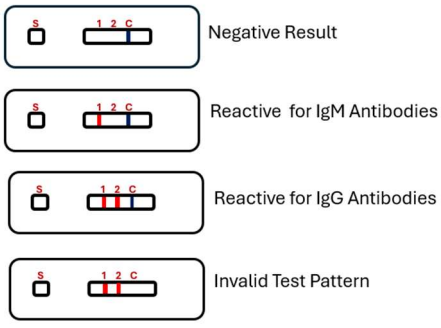
Add 10 ul of Serum/Plasma/whole blood into the Sample Well "S"

Add 2 Drops (60 ul) of Assay Buffer into the Sample Well "S"

Read Results at 5-15 Minutes

Note: Do not read results after 15 min- it may give incorrect results !

RESULT INTERPRETATION



PERFORMANCE CHARACTERISTICS

- ✓ Clinical Sensitivity: 99.3%
- ✓ Clinical Specificity: 98.7

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

Symbols Used: Instructions to use | Do Not reuse | Storage temperature | Away from direct sunlight | Store dry | No of tests | IVD | For *In-Vitro* diagnostic use | REF | Product code | Manufactured site | Manufactured date | Use before | LOT | Lot number