Cat: BTYP-01

BioKits Typhoid IgG-IgM Rapid Test

(Serum-Plasma-Whole Blood)

1. INTENDED USE

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

2. INTRODUCTION

Typhoid fever is a systemic bacterial infection caused by *Salmonella enterica* serovar Typhi and is transmitted primarily through contaminated food and water. Detection of anti-*S. typhi* IgM antibodies indicates recent or acute infection, while IgG antibodies indicate past exposure or later stages of infection. Differentiation of IgM and IgG antibodies assists in clinical assessment and disease staging. The Biokits Typhoid IgG/IgM Rapid Test provides a rapid qualitative result to aid in the diagnosis of typhoid fever.

3. PRINCIPLE OF THE TEST

The Biokits Typhoid 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-*Salmonella typhi* IgM and/or IgG antibodies present in the specimen bind to colloidal gold-conjugated *S. typhi* 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 class present. The control line is coated with polyclonal antibodies and reacts with a colored control conjugate, producing a visible line independent of typhoid antibodies, thereby confirming proper sample flow, reagent integrity, and test validity.

4. KIT COMPONENTS

Each kit contains:

1. Individually pouched Typhoid 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 typhoid fever, particularly in the early stage of infection.
3. IgG antibodies may persist after past infection or vaccination and should be interpreted with clinical findings.
4. Cross-reactivity with other *Salmonella* species or bacterial infections may occur.
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.

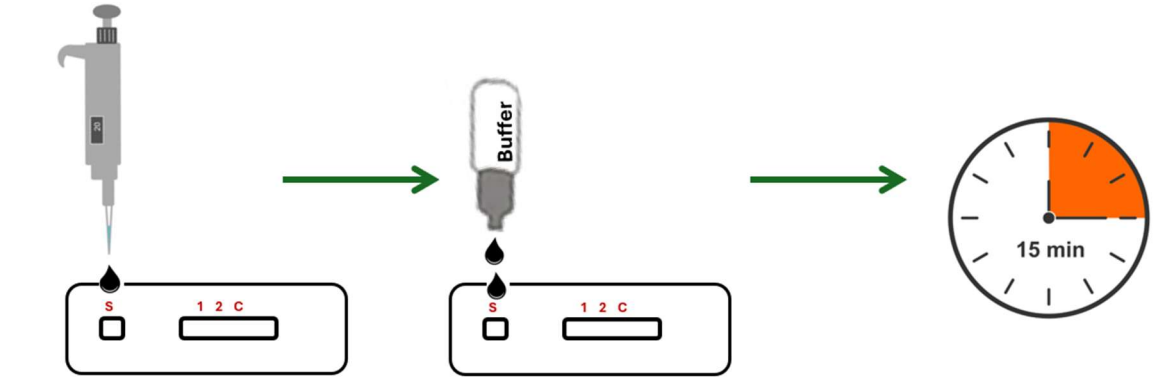
9. REFERENCES

1. World Health Organization. *Typhoid vaccines: WHO position paper.* Weekly Epidemiological Record.
2. Parry CM, et al. *Typhoid fever.* New England Journal of Medicine. 2002;347:1770–1782.

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



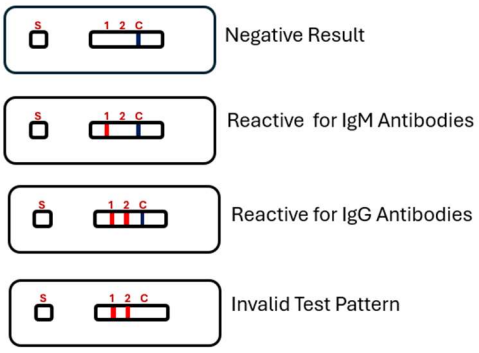
Add 10 ul of Serum/Plasma/whole blood into the Sample Well "S"

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: 96.3%
- ✓ Clinical Specificity: 98.3%

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