Test-it™ Typhoid IgM Lateral Flow Assay
Typhoid Fever – specific immunoassay for use with human serum or whole blood samples

Product Code:
IgM: TYP001

Intended use
Life Assay manufactures the Test-it™ Typhoid IgM lateral flow assay for the rapid serodiagnosis of typhoid fever. The test is aimed at the detection of disease specific IgM antibodies in human serum or whole blood samples.

Introduction
Typhoid fever is caused by the Gram-negative bacterium known as *Salmonella enterica* serotype Typhi. The clinical presentation of typhoid fever varies from a mild illness with low-grade fever, malaise, and slight dry cough to a severe clinical picture with abdominal discomfort and multiple complications. Laboratory testing is essential because signs and symptoms may resemble those of other major infectious diseases. The Test-it™ Typhoid IgM lateral flow assay provides an indirect measure for infection through the detection of pathogen specific antibodies. Specific IgM antibodies usually develop early in the diseases. The assay is a relatively simple and rapid assay that may be used as a point-of-care test in the field or at the bed-side. It does not require special training, equipment, electricity nor refrigeration. Results are obtained in 15 minutes. The assay devices and the running fluid may be stored at +4°C to +28°C.

Principle
The Test-it™ Typhoid IgM lateral flow assay is a one step immunochromatographic lateral flow assay. A lipopolysaccharide antigen (LPS) prepared from a culture of *S. enterica* serotype Typhi is immobilised in a discrete line on a porous nitrocellulose membrane located in the test zone (T). The assay utilises a dried detection reagent deposited within the device. The mobile detection reagent consists of anti-human IgM antibodies labelled with red colloidal gold particles. To perform the assay a serum or whole blood sample is placed in the sample well (S). Running fluid is added to solubilise the detection reagent and to carry the molecules from the sample and detection reagent through the porous membrane in the test zone (T). Antibodies in the clinical specimen that are specific for the pathogen attach to the LPS antigen and these antibodies will be stained by binding of the detection reagent. The presence of specific antibodies will be revealed by the appearance of a red line in the test zone (T) of the assay device. If the sample does not contain pathogen specific IgM antibodies, the sample and detection reagent will pass over the test zone and no line will appear in the test zone. With any sample a red line should always appear in the control zone (C). The control ensures that the detection reagent is still active.

Test Kit and Labelling
Each kit contains 25 individually wrapped assay devices together with 1 bottle of running fluid, sufficient for the analysis of 25 serum or whole blood samples. 25 Lancets, Alcohol swabs and pipettes are included.

Storage
Test-it™ Typhoid lateral flow kits should be stored at +4°C to +28°C, in a dry place and protected from direct exposure to sunlight for optimal performance. Individual devices may be stored up to +45°C for up to 2 months.

Expiry date
The expiry date is printed on the packaging. When stored properly tests may be used for at least two years after the date of manufacturing.

Precautions: Blood and serum samples should be handled with care as they are potentially infectious. Equipment and supplies for specimen handling should be treated accordingly. Used devices, disposables and samples should be properly decontaminated and discarded.

Specimen collection
Serum should be prepared in the same way as routinely performed for any serological assay. Freshly collected samples should be used. Serum samples stored at -20 C may be used as well. Venipuncture whole blood samples may be used provided the blood has been collected with an anticoagulant such as EDTA, heparin or citrate. Alternatively for a finger prick sample, clean the patient’s finger with the alcohol swab making sure the alcohol is dry before pricking with the lancet provided.
**Standard Assay Procedure**

1. Remove a Test-it™ Typhoid lateral flow assay device from the packaging and place on a bench top with the test window facing upwards.
2. Immediately check if desiccant is still orange in colour. If desiccant has turned green, the test has been exposed to moisture and the test must be discarded.
3. Using the plastic pipette provided, draw up serum or whole blood to the first marked line of the plastic pipette (5 µl) and spot to the oval sample port (S).
4. Immediately add 3 drops of running fluid to the oval sample port (S). *NB Pierce the tip of the buffer bottle by screwing the cap down fully*
5. You will see the reagent moving across the result window. This shows that the test is working.
6. Read results at 15 minutes. Results are stable for a further 15 minutes; thereafter false results may occur.

Note: the use of whole blood instead of serum may give some background staining in the test window. However this does not influence the reading of the test result.

**Interpretation of Test Results**

*Positive Result:* Indicated by the presence of a line at the test zone (T) and a line at the control zone (C). A positive result is consistent with acute typhoid fever.

*Negative Result:* Indicated by absence of a line at the test zone (T) and presence of a line at the control zone (C). If a negative result is obtained for a sample collected very early in the disease testing of a second sample collected a few days later may show seroconversion.

| 4+ | 3+ | 2+ | 1+ | negative | negative |

**Limitations of Use**
The sensitivity and specificity of the Test-it™ Typhoid lateral flow assay depend on various factors including stage of disease and previous antibiotic usage.

*SPECIAL NOTE:*
The intensity of the Control line (C) may vary from test to test. A weak Control line (C) does not disqualify the test and has no influence on the validity of the test result (T) whatsoever.

**Further Reading of Suggested Literature**