TEST-IT TYPHOID TEST KIT

Typhoid IgM lateral flow assay for serodiagnosis of typhoid fever in humans.

Regulatory Approvals: ISO 9001, ISO 13485

PRODUCT DESCRIPTION

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.

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.

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.

https://www.viaglobalhealth.com/product/test-it-typhoid-kit/
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

• measures IgM
• uses whole blood or serum
• 95.7% agreement with Rose Bengal
• >92.9% sensitive for 7-9 days fever
• 100% sensitive for >9 days fever
• >98% specific
• better performance than Widal
• ideal for field use
• on-the-spot results in 15 minutes
• no equipment or training required

Typhoid Test Kit Instructions
Typhoid Test Kit Product Brochure


We are a company based in Cape Town, South Africa, where our state-of-the-art manufacturing facility produces a wide range of world-class diagnostics for government and NGO procurement and also for private use. http://www.lifeassay.com/1 Kit1-4 weeks 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. What sample do these tests require? 

The tests can be performed using whole blood or serum. 

What sample preparation is recommended? 

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.

How long will the shipment take?
Depending on the size and availability of the order, anywhere from 1-4 weeks. Please contact the manufacturer to confirm.

**When does the product expire?**

The product expires two years after the date of manufacture. Product replacements on faulty/non-performing product as per Life Assay’s quality control check procedures on retainer samples.