TYPHOID (IgG/IgM)

METHOD – LATERAL FLOW IMMUNOASSAY
PRODUCT CODE – RC06

ANAMOL
THE ORIGINAL MAKERS

INSTRUCTIONS FOR USE

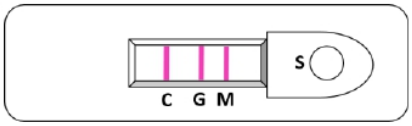
INTENDED USE: Test for qualitative detection and differentiation of IgG/IgM antibodies of *S. typhi* and *S. paratyphi.*

SUMMARY AND EXPLANATION OF TEST

Typhoid fever is a life threatening illness caused by the bacterium typhus, and was observed by Eberth (1880) in the mesenteric nodes and spleen of fatal cases of typhoid fever. It is common in developing countries where it affects about 12.5 million persons annually. The infection is acquired typically by ingestion. On reaching the gut, the bacilli attach themselves to the epithelial cells of the intestinal villi and penetrate the lamina and submucosa. They are then phagocytosed there by polymorphs and mesenteric lymph nodes, where they multiply and, via the thoracic duct, enter the blood stream. A transient bacteremia follows, during which the bacilli are seeded in the liver, gall bladder, spleen, bone marrow, lymph nodes, and kidneys, where further multiplication takes place. Towards the end of the incubation period, there occurs a massive bacteremia from these sites, heralding the onset of the clinical symptoms. The diagnosis of typhoid consists of isolation of the bacilli and the demonstration of antibodies. The isolation of the bacilli is very time consuming and antibody detection is not very specific. Other tests include the widal test that takes only 10-30 minutes and requires only a small amount of serum or plasma to perform.

TEST PRINCIPLE

The *S. typhi* IgG/IgM Test Device (Serum/Plasma) is a qualitative test for the detection of IgG and IgM antibodies to *S. typhi* in human serum or plasma. The test provides a differential detection of anti-*S. typhi*-IgG and anti-*S. typhi* -IgM antibodies and can be used for the presumptive distinction between a current, latent and/or carrier *S. typhi* infection. Serum or plasma samples may be used with this test.



First a specimen is dispensed into the sample well of the test device. If IgG or IgM antibodies to *S. typhi* are present in the specimen they will bind to the colloidal gold-antigen conjugate and travel up the membrane chromatographically. The antibody-Antigen-colloidal gold complex will then bind to the immobilized anti-Human IgG and/or anti-Human IgM coated on the membrane. This will cause pale to dark coloured lines to form at the IgG or IgM test region and can be seen in the results window. The intensity of the lines will vary depending upon the amount of antibody present in the sample. The appearance of a coloured line in a specific test region should be considered as positive for that particular antibody (IgG and/or IgM). To serve as a procedural control, a coloured line will always appear in the control line region indicating that proper volume of specimen has been added and proper membrane wicking has occurred.

MATERIALS PROVIDED

1. One cassette device.
2. One plastic dropper.
3. One desiccant.
4. Sample diluent.
5. One package insert or instructions for use.

MATERIALS REQUIRED BUT NOT PROVIDED IN THE KIT

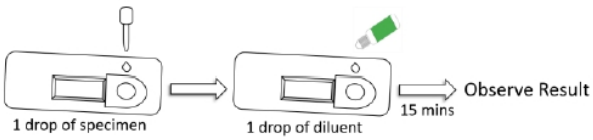
1. Positive Control.
2. Negative Control.
3. General laboratory wares such as pipettes, tips, gloves, tubes, etc.

SPECIMEN COLLECTION, STORAGE AND PRESERVATION

Use fresh Serum or Plasma for the test. If testing is not performed within 3 days of collection of specimen, the specimen should be refrigerated immediately at 2-8 °C.

ASSAY PROCEDURE

1. Bring the specimen and kit components to room temperature.
2. Open the pouch (by using a cuter or scissor) from one end and remove test device. Place the device on clean, dry and flat surface.
3. Label the specimen with proper ID.
4. Dispense 1-2 drops (40 µl) of specimen into the sample well (S). Then add 1 drop (40 µl) of Sample Diluent immediately.
5. Read the result after 15 minutes. The device can be discarded after interpreting the result.



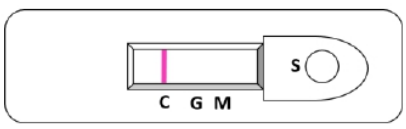
QUALITY CONTROL

Run positive and Negative sample under the following circumstances to monitor test performance:

1. A new operator uses the kit, prior to performing testing of specimens.
2. A new test kit is used.
3. A new shipment of kits is used.
4. The temperature used during storage of kit falls outside of 2-30 ^{0}C.
5. The temperature of the test falls outside 15-30 ^{0}C.

INTERPRETATION OF TEST RESULT

1. NEGATIVE OR NON-REACTIVE RESULT



If only C band is present, the absence of any burgundy colour in both the bands (M and G) indicates that no anti-*S. typhi* or *paratyphi* antibody is detected in the specimen. The result is negative or non-reactive.

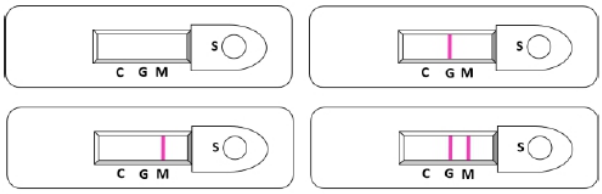
2. POSITIVE OR REACTIVE RESULT

In addition to the presence of C band, if only M band is developed, the test indicates for the presence of anti-*S. typhi* or *paratyphi* IgM in the specimen. The result is IgM positive or reactive.

In addition to the presence of C band, if only G band is developed, the test indicates for the presence of anti-*S. typhi* or *paratyphi* IgG in the specimen. The result is IgG positive or reactive.

In addition to the presence of C band, if both M and G bands are developed, the test indicates for the presence of anti-*S. typhi* or *paratyphi* IgG and IgM in the specimen. The result is both IgG and IgM positive or reactive.

3. INVALID TEST



If no C band is developed, the assay is invalid regardless of any burgundy colour in the test bands as indicated in the figure. Repeat the assay in a new device.

LIMITATIONS OF TEST

1. This test is for *in-vitro* diagnostic use only.
2. This is a qualitative test only. The intensity of test band does not have linear correlation to antibody titre in the specimen.
3. The negative test result indicates absence of detectable antibodies. However, it does not preclude the possibility of exposure to *S. typhi* or *paratyphi.*
4. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

PERFORMANCE CHANACTERISTICS

1. **Clinical performance for IgM Test:** A total of 334 samples from susceptible subjects were tested by Typhoid IgG/IgM Rapid Test and a commercial *S. typhi* IgM EIA:

	Typhoid IgG/IgM Rapid Test		
IgM EIA	Positive	Negative	Total
Positive	31	3	34
Negative	2	298	300
Total	33	301	334
Relative Sensitivity		**91%**	
Relative Specificity		**99.30%**	
Overall Agreement		**98.50%**	

2. **Clinical performance for IgG Test:** A total of 314 samples from susceptible subjects were tested by Typhoid IgG/IgM Rapid Test and a commercial *S. typhi* IgG EIA:

	Typhoid IgG/IgM Rapid Test		
IgG EIA	Positive	Negative	Total
Positive	13	1	14
Negative	2	298	300
Total	15	299	314
Relative Sensitivity		**92.9%**	
Relative Specificity		**99.30%**	
Overall Agreement		**99%**	

3. **Performance comparison with Blood Culture:**
9 *S. paratyphi* and 11 *S. typhi* specimens confirmed with blood culture were tested with the Typhoid IgG/IgM Rapid Test. The test correctly identified 9 out of 9 *S. paratyphi* and 10 out of 11 *S. typhi* specimens. The agreement was 95%.

BIBLIOGRAPHY

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2. Hatta M *et al.* Simple dipstick assay for the detection of *S. typhi*-specific IgM antibodies and the evolution of the immune response in patients with typhoid fever. Am. J. Trop. Med. Hyg., 66(4), 2002, pp. 416–421.
3. Bhutta ZA *et al.* Rapid Serologic Diagnosis of Paediatric Typhoid Fever In An Endemic Area: A Prospective Comparative Evaluation Of Two Dot-Enzyme Immunoassays And The Widal Test. Am. J. Trop. Med. Hyg. 61(4), 1999, pp. 654–657
4. Gopalkrishna V., Sekhar W. Y., Soo E. H., Vinsent R. A. & Devi S., Singapore Med J. 2002 Vol. 43(7) 354-358.

SYMBOLS: Read Instruction for use | IVD In Vitro Diagnostic Use Only | Manufactured by | Expiry Date | Storage Temperature

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Palghar – 401 404. India.
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ISO 9001 : 2015
ISO 13485 : 2003
GMP
CE