Typhoid IgG/IgM Rapid Test (WB,S,P)

Labgene biotech

INTENDED USE

Labgene Typhoid IgG/IgM Rapid test kit is a lateral flow chromatographic immunoassay designed for the qualitative detection and differentiation of the IgG and IgM antibodies against Typhoid virus in human whole blood/serum/plasma samples.

ORDER INFORMATION AND MATERIALS PROVIDED

Cat No.	Test Devices	Assay Buffer	Dropper & Sillica Gel	Lancets & Alcohol Swabs
LG017-10T	10	1 X 2 mL	01 in an individual pouch	-
LG017-25T	25	1 X 3 mL		
LG017-30T	30	1 X 3 mL		
LG017-40T	40	2 X 2 mL		
LG017-50T	50	2 X 3 mL		
LG017-100T	100	4 X 3 mL		
LG017LS-10T	10	1 X 2 mL		10
LG017LS-25T	25	1 X 3 mL		25
LG017LS-30T	30	1 X 3 mL		30
LG017LS-40T	40	2 X 2 mL		40
LG017LS-50T	50	2 X 3 mL		50
LG017LS-100T	100	4 X 3 mL		100
*IFU: O1 in an individual carton box				

INTRODUCTION

Typhoid fever is an infectious disease caused by a bacterium, Salmonella typhi which are transmitted through the ingestion of tainted food and water. It continues to be a major health problem especially in the Asia Pacific region, the Indian subcontinent, Central Asia, Africa and South America. 1-5% of patients become chronic carriers harboring S. typhi in the gallbladder . Definitive clinical diagnosis of typhoid is unreliable because typhoid fever symptoms mimic other diseases with fever that are common in this part of the world. Clinical presentations vary tremendously among patients and cover a wide spectrum, hence the need for a good laboratory test. In addition, an accurate diagnosis of typhoid at an early stage is important not only for an aetiological diagnosis for the patient but also to identify individuals that might serve as a source of infection. Thus all cases of fever should be tested for typhoid and a rapid laboratory tests will be required. IgM positive or IgM /IgG both positive suggest current infection, while IgG positive suggests late stage of infection, previous infection, or latent infection.

PRINCIPLE

Labgene Typhoid IgG/IgM Rapid Test is a lateral flow chromatographic immunoassay. The test cassette consists of: 1) a burgundy colored conjugate pad containing recombinant Salmonella Flagellin antigen and a control antibody conjugated with colloidal gold, 2) a nitrocellulose membrane strip containing monoclonal anti-human IgM Antibody(test line M) and monoclonal anti-human IgG(test line G) and a control line (C line).

MATERIALS NEEDED BUT NOT PROVIDED

- Specimen collection container
- Timer
- Centrifuge
- Micropipette

PRECAUTIONS

- For professional in vitro diagnostic use only. Do not use after expiration date.
- Do not use if pouch is damaged.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves or eye protection when specimens are being tested.
- Humidity and temperature can adversely affect results.
- The used test should be discarded according to local regulations.
- Do not use expired lancet.
- Do not share used lancet.

STORAGE AND STABILITY

- Store as packaged in the sealed pouch either at room temperature or refrigerated (2°C-30°C).
- DO NOT FREEZE.
- The test device is stable through the expiration date printed on the sealed pouch.
- The test device must remain in the sealed pouch until use.

SPECIMEN COLLECTION AND PREPARATION

The Typhoid IgG/IgM Rapid Test can be performed using either serum, plasma or whole blood.

Plasma :

- Collect blood specimen into collection tube containing EDTA, Citrate or Heparin.
- Separate the plasma by centrifugation.
- Carefully withdraw the plasma into a new pre-labeled tube.

Serum :

- Collect blood specimen into a collection tube containing no anticoagulants.
- Allow the blood to clot.
- Separate the serum by centrifugation,
- Carefully withdraw the serum into a new Pre-Labeled Tube.

Test the specimens as soon as possible after collections. Store serum/ plasma at 2°C-8°C for up to three days if the tests cannot be performed immediately. The specimens should be frozen at -20°C for longer storage. Avoid multiple freeze-thaw cycles. Prior to testing, bring frozen specimens to room temperature and mix gently. Do not use haemolysed sample.

Whole Blood :

Venipuncture:

- Collect the whole blood into the collection tube (containing EDTA, citrate or heparin) by Venipuncture.
- Transfer the sample to sample well of device using sample pipette.
- Whole blood specimens should be stored in refrigeration (2°C-8°C) if not tested immediately. The whole blood must be tested within 24 hours of collection.

Collection using a lancet:

- Clean the area to be lanced with the alcohol swab.
- Squeeze the fingertip then prick the lateral side of the finger with a lancet provided .
- Wipe away the first blood drop. And immerse the open end of a micropipette and release the pressure to draw blood into it.

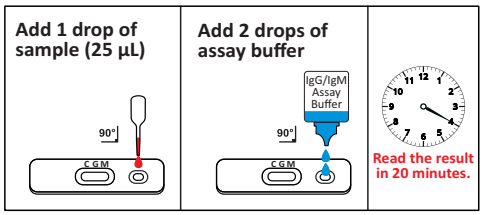
PROCEDURE

1. Allow test device, specimen, to reach room temperature (15°C- 30°C) prior to testing.
2. Place the test device on a clean and level surface.
3. **For Whole Blood/Serum/Plasma specimens:** Hold the sample dropper vertically and transfer **1 drop of sample (25 µL)** to the specimen well of the test device, and **add 2 drops of assay buffer** into the well and start the timer.
4. **Read the result at the end of 20 minutes.** Read results as shown under interpretation of Results.

Do not read the result after 25 minutes, as it can give false results.

⚠ **Strong positive specimens may produce positive result in as little as 1 minutes.**

WHOLE BLOOD/SERUM/PLASMA:



INTERPRETATION OF RESULTS

POSITIVE:

IgG and IgM positive: In addition to the band in the control area marked 'C', appearance of two pink-red coloured bands in the test region 'G' and region 'M', indicates the presence of Typhoid virus specific IgG and IgM antibodies.

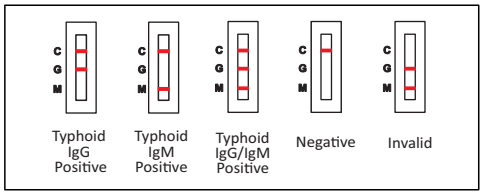
IgM positive: In addition to the control band in the control area marked 'C', appearance of a pink-red coloured band in the test region 'M', indicates the presence of Typhoid virus specific IgM antibodies.

IgG positive: In addition to the control band in the control area marked 'C', the appearance of a pink-red coloured band in the test region 'G', indicates the presence of Typhoid virus specific IgG antibodies.

NEGATIVE: Only one colored line appears in the control line region (C). No apparent colored line appears in the test line regions (G or M), indicates the absence of specific antibodies against Typhoid virus or that the amount of antibodies is below the detection limit of the test.

INVALID: No visible band appears at the control region (C). Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

RESULTS:



LIMITATIONS

- The Typhoid IgG/IgM Rapid test is for in vitro diagnostic use only.
- Humidity and temperature can adversely affect results.
- This test should be used for the detection of Typhoid IgG/IgM Rapid test in human whole blood, serum or plasma specimens only.
- As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
- Some specimens containing unusually high titers of heterophile antibodies or rheumatoid factor (RF) may affect expected results.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity studies were carried out in-house on fresh as well as frozen samples, from low risk as well as high risk groups.

Typhoid IgG Samples	Positive	Negative	Total
Positive	25	00	25
Negative	01	49	50
Total	26	49	75

Relative Sensitivity: 98.00%,
Relative Specificity: 98.00%,
Overall agreement: 100.00%

Typhoid IgM Samples	Positive	Negative	Total
Positive	10	00	10
Negative	00	50	50
Total	10	50	60

Relative Sensitivity: 100%,
Relative Specificity: 100%,
Overall agreement: 100%

REFERENCES

1. IvanoffBN, Leivne MM, and Lambert PH. Vaccination against typhoid fever: Present Status. bulletin of the world health organization 1994;72:957-71
2. Gotuzzo E, Frisancho O, Sanchez J, Leindo G, Carilla O, Black Re, Morris JG, Salmonella Typhi or Salmonella Paratyphi in an endemic typhoid area. Archives of Internal medicine 1991; 151;381-2
3. Clegg A, Passey M, Omena MK, et al. Re-evaluation of the widal agglutination test in response to the changing pattern of typhoid fever in the highlands of papua new guinea. Acta tropica 1994; 57:25563
4. Pang T. False positive Wiadal test I non-typoid Salmonella infection. Southeast Asian Journal of Tropical Medicine and Public Health 1989;20:163-4
5. Ismaill A, Hai Ok, Kader ZA, Demostration of an antigenic protein speific for salmonella, biocem niopj res commun, 1912 181(1):301-5

INDEX OF SYMBOLS

REF	Product Reference No.	ISO ISO 13485	International Organization or Standardization
	Manufacturer		Keep out of Sunlight
	Expiry date	IVD	For invitro diagnostic use only
LOT	Lot (batch) number		Read product insert before use.
2°C 30°C	Store between 2-30°c		Do not use if package is damaged
	Do not reuse		Keep Away From Moisture
	Contains sufficient for test	ART/IFU-017-02	

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