LordsMed Typhoid IgG/IgM Ab Rapid Test

(Wholeblood/Serum/Plasma)

Catalog No.	Pack Size	Specimen Type
TABLMR01	25 Test Device	WholeBlood/Serum/Plasma
TABLMR02	50 Test Device	WholeBlood/Serum/Plasma
TABLMR03	25 Test Device	Serum/Plasma
TABLMR04	50 Test Device	Serum/Plasma

INTENDED USE

LordsMed Typhoid IgG/IgM Rapid Test is an immunochromatographic assay for the qualitative detection of S. Typhi specific IgG/IgM antibodies in human serum/plasma or wholeblood. It is intended for professional use.

PRINCIPLE

After addition of the sample and the assay buffer to the sample well of the device containing a test strip, the sample moves on the conjugate pad containing colloidal gold particles conjugated with recombinant S .Typhi specific antigens. If the sample contains detectable levels of the S. Typhi specific IgM and IgG antibodies, it reacts with the gold conjugated recombinant S.typhi specific antigens to form a complex. This complex moves further and S. Typhi specific IgM antibodies conjugate complex reacts with anti-human IgM test line and the S. Typhi specific IgG antibodies react with the anti-human IgG antibodies test line on the nitrocellulose membrane area to form colored bands. The unbound complex and the colloidal gold particles move further to the control area to form colored band (Control line). The appearance of the test line and the control line in respective area indicates the positive result. Appearance of only control line indicates a negative result. The control line acts as a procedural control. Control line should always appear if the test is performed as per the procedure and reagents are working properly.

STORAGE AND STABILITY

1. Store as packaged in the sealed pouch at room temperature or refrigerated (2-30℃). The test device is stable through to the expiration date printed on the sealed pouch.
2. The test must remain in the sealed pouch until used.

MATERIALS PROVIDED

1.Test device
2. Assay Buffer
3. Plastic dropper
4. Package insert
5. Desiccant

MATERIAL REQUIRED BUT NOT PROVIDED

1. Timer

PRECAUTION

1. For professional in vitro diagnostic use only. Do not use after the expiration date.
2. Do not eat, drink or smoke in the area where the specimens and kits are handled.
3. Handle all specimens as if they contain infectious agents
4. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of specimens.
5. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.

SPECIMEN COLLECTION AND PREPARATION

1.The test can be used for the human serum, plasma, and whole blood specimen.
2.A serum / plasma / whole blood specimen must be collected in a clean and dry container. EDTA, sodium citrate, sodium oxalate, heparin can be used as the, anticoagulants. Detect immediately after collecting blood. If blood coagulation occurs serum sample is to use. Use the fresh whole blood samples.
3. Samples may be stored at 2-8℃ for 1 week prior to assay, and at -20 ℃ for 2 years. Frozen refrigerated samples should be recovered to room temperature before detection and thoroughly mixed. Repeat freeze and thaw for no more than 3 times. Samples exhibiting visible precipitates, stink or muddy should not be used. Instead, it should be centrifuged, filtered, or allowed to settle to obtain a clear sample for testing

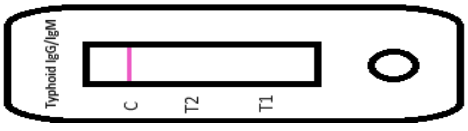
TEST PROCEDURE

For LordsMed Typhoid IgG/IgM Ab Rapid Test

1.Remove the test device from the sealed pouch and use it as soon as possible.
2. Place the test device on a clean and level surface. Be sure to label the device with specimen's ID number.
3. Prior to testing open buffer bottle correctly by breaking seal of the cap and pierce the nozzle by tightly screwing the cap of the bottle.
4. **(a) For Serum/Plasma :** Add 10 µl of serum/plasma in sample well and add 2 drops (Approx. 60µl) of assay buffer in sample well.
4. **(b) For Wholeblood : :** Add 20 µl of wholeblood in sample well and add 2 drops (Approx. 60µl) of assay buffer in sample well.
5. Start the timer.
6. Read results at 15 minutes. Do not read the result after 20 minutes.

INTERPRETATION OF RESULTS

Negative: Only one colored line appears at the control region 'C' and no band in front of T1 or T2, indicates that no anti-S.typhi or paratyphi antibody is detected in the specimen. The result is negative.

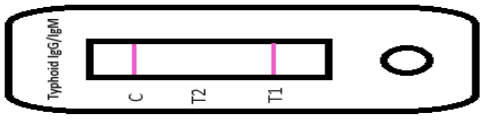


Positive:

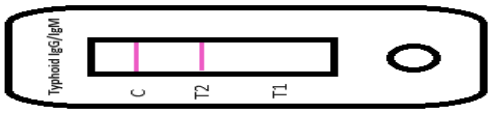
A)A distinct colored line appears at the control region 'C', and at the test region 'T1' indicates for the presence of anti-S.typhi or paratyphi IgM in the specimen. The result is positive.

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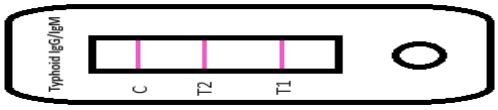
(Wholeblood/Serum/Plasma)



B) A distinct colored line appears at the control region 'C' and at the test region 'T2' indicates for the presence of anti-S.typhi or paratyphi IgG in the specimen. The result is positive.

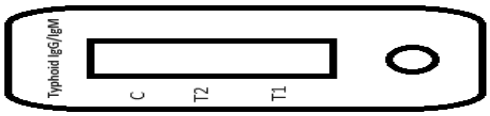


C) A distinct colored line appears at the control region 'C' and the both the test region T1 &T2 indicates for the presence of anti-S.typhi or paratyphi IgM and IgG in the specimen. The result is positive.

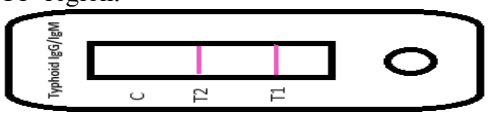


Invalid: the test should be considered invalid if,

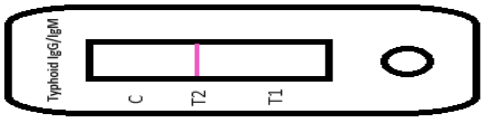
A) No line appears at **'**C' region , 'T2' and 'T1' region



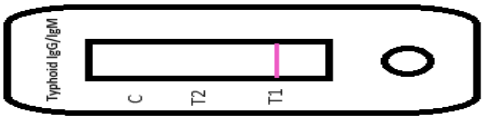
B) No line appears at 'C' region and line appear at 'T2' and 'T1' region.



C) No line appears at 'C' and at 'T1' region and line appear at 'T2' region.



D) No line appears at 'C' and at 'T2' region and line appear at 'T1' region.



PERFORMANCE CHARACTERISTICS

The results demonstrated 98.21% sensitivity and 100% specificity with an overall accuracy of 98.67%

SENSITIVITY & SPECIFICITY

	Positive sample	Negative sample	Rate
Positive sample	55	01(IgM)	98.21% (Sensitivity)
		01(IgG)	
Negative sample	00	19	100% (Specificity)
Total	55	20	98.67% (Accuracy)

LIMITATION

1. The assay procedure and the test result interpretation must be followed closely when testing the presence of antibodies to S. Typhi or paratyphi in serum/plasma or wholeblood.
2. False positive results may occur in high titer of rheumatoid arthritis antibodies may show cross reactivity.
3. False negative result may occur in following condition in early infections and some secondary infections, detectable levels of IgM antibodies may be low. Some patient may not produce detectable levels of antibody within the first seven to ten days after infection. Where symptoms persist, patient should re-tested 3-5 days after the first testing date.

BIBLIOGRAPHY

1. Ivan off BN, Levine MM, 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, Liendo G, Carillo C, Black RE, Morris JG. Association between the acquired immunodeficiency syndrome and infection with Salmonella typhi in an endemic typhoid area. Archives of Internal Medicine 1991; 151: 381-2.

REF	Catalog No		Attention Caution
LOT	Batch No.		Instruction for use
	Manufacturing Date	IVD	*In-vitro* Diagnostics
	Expiry Date		Storage temperature
	Manufacturer	Σ	No. of Tests

IFU/TAB/02 Rev.:01 Dated:15/07/2024

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