

Quality Control

A colour line appearing in the control region (C) is an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique. Absence of this coloured line indicates invalid result and the test must be repeated.

Warnings and Precautions

- The kit is designed for *in-vitro* diagnostic use only
- The kit should not be used after expiration date
- Eating, drinking or smoking in the area where specimens are handled should be avoided
- Wearing of protective clothing (laboratory coat, disposable gloves, eye protection etc) is recommended when specimens are handled
- Humidity and temperature can adversely affect the test results
- Proper disposal of biohazard substances should be performed
- Only human serum or plasma should be used
- The test devices should not be reused

Limitations

1. The kit is only designed for professional use by trained laboratory personnel. It is not suitable for home use.
2. The kit only provides qualitative detection of Typhoid and Paratyphoid infections. It is not for quantitative use.
3. The kit provides a presumptive diagnosis of Typhoid and Paratyphoid infection. Confirmatory testing by blood culture must be performed for all positive tests.
4. A negative result may be obtained for samples containing very low concentrations of antibodies. Hence, a negative test result does not completely rule out the possibility of infection.



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TYPHOID & PARATYPHOID IGG/IGM ANTIBODY

Lateral flow chromatographic immunoassay for the qualitative and differential detection IgG and IgM antibodies against *Salmonella typhi* and *Salmonella paratyphi* in human serum/plasma/whole blood

Σ 25 tests



Introduction/Background

Typhoid and paratyphoid fevers are infections caused by *Salmonella typhi* and *Salmonella paratyphi* A, B and C bacteria. These bacteria spread via tainted food and water. According to data published by the World Health Organization, an estimated 17 million cases and 600,000 deaths occur due to typhoid annually. HIV patients are at an elevated risk of catching clinical infections. 1-5% of patients become chronic carriers harbouring *S. typhi* in their gall bladder.

Intended Use

The Chimera Typhoid and Paratyphoid Rapid Test is a rapid chromatographic immunoassay for the qualitative and differential detection of IgG and IgM antibodies against *S. typhi* and *S. paratyphi* in human serum or plasma. The kit is intended for professional use as a screening test. All positive samples should be confirmed by a supplemental confirmatory assay such as blood culture. The kit is not designed for home use.

Principle

The Chimera Typhoid and Paratyphoid Rapid Test is based on the principle of antigen-antibody complex formation. It is a sandwich immunoassay. Colloidal gold nanoparticles are conjugated to recombinant H and O antigens (HO Conjugates) and to rabbit IgG (control antibody), coated on the conjugate release pad. The nitrocellulose membrane strip contains two test bands (M and G bands) and a control band (C band). The M band is pre-coated with monoclonal anti-human IgM for the detection of IgM antibodies against *S. typhi* and *S. paratyphi*. Similarly, the G band is pre-coated with anti-human IgG antibodies against *S. typhi* and *S. paratyphi*. The C band is pre-coated with goat anti-rabbit IgG.

When an adequate volume of the test specimen is dispensed into the sample well of the cassette, the test specimen migrates by capillary action across the test cassette. IgM and/or IgG antibodies against *S. typhi* and/or *S. paratyphi*, if present in

the sample, bind to conjugate and form a complex. The immunocomplex moves across the nitrocellulose strip by capillary action. When the complex meets the line of the corresponding immobilized antibody, the complex is trapped forming a burgundy band which confirms a positive test result. The absence of a coloured band in the test region indicates a non-reactive test result. A red procedural control line should always develop at the 'C' region to indicate that the test has been performed properly.

Material Provided

Test device with desiccant	25 nos.
Buffer	1 no.
Kit insert	1 no.
Dropper	25 nos.

Storage and Stability

The kit should be stored at 2-30°C in a clean and dry area, away from moisture and direct sunlight. The kit should not be frozen. The test kit is stable through the expiration date printed on the sealed pouch. The test kit should not be opened before use. Use beyond the expiration date is not recommended.

Specimen Collection and Preparation

Note: Human specimens should be handled using standard biosafety procedures.

Collection by venipuncture

For all specimens: Venous blood should be collected by venipuncture into a collection tube that contains EDTA, citrate or heparin for plasma and whole blood specimens, and a collection tube without anticoagulants for serum specimens. Whole blood preparation is complete.

For plasma preparation: Plasma should be collected in a new labelled tube after centrifugation.

For serum preparation: Centrifuge the specimen after clotting, and collect the serum in a new labelled tube.

Storage: Specimens can be stored at 2-8°C for up

to 5 days (except whole blood) or tested immediately.

For longer storage specimens can be frozen at -20°C or lower. Multiple freeze-thaw cycles should be avoided. Specimens should be brought to room temperature before testing and mixed gently. Specimens should be centrifuged if they contain visible particulates before testing.

Note: Specimens exhibiting gross lipemia, gross hemolysis or turbidity should not be used in order to avoid interference with result determination.

Directions For Use

1. Allow specimens and test components to reach room temperature. The specimen must be mixed thoroughly before proceeding with the test.
2. Take the device out of the pouch and place it on a clean flat surface. Label the device properly with the patient ID.
3. Add 25-30µL (1 drop) of the specimen and 2 drops of the buffer into the centre of the sample well (S) using the provided dropper or a precise micropipette.
4. Read the result in 20 minutes. **DO NOT TAKE A READING AFTER 30 MINUTES.**

Results Determination

S. No.	IgM Line	IgG Line	Control Line	Result
1	Visible	Visible	Visible	Positive for <i>S. typhi</i> and/or <i>S. paratyphi</i> IgG and IgM antibodies
2	Visible	Not Visible	Visible	Positive for <i>S. typhi</i> and/or <i>S. paratyphi</i> IgM antibodies
3	Not visible	Visible	Visible	Positive for <i>S. typhi</i> and/or <i>S. paratyphi</i> IgG antibodies
4	Not visible	Not visible	Visible	Negative for <i>S. typhi</i> and/or <i>S. paratyphi</i> IgG and IgM antibodies
5	Visible/ Not visible	Visible/ Not visible	Not visible	Invalid

