

TYPHIDOT Rapid IgG/IgM (Combo) Version2 (A rapid test for detection of Typhoid fever)



INTENDED USE

TYPHIDOT Rapid IgG/IgM (Combo) is an immunochromatographic assay designed for the qualitative detection and differentiation of specific IgM and IgG antibodies against specific *Salmonella typhi* OMP antigen in human serum or plasma. It is intended to be used as *in vitro* diagnostic of typhoid fever. The results obtained should not be the sole determinant for clinical decision.

SUMMARY AND EXPLANATION OF THE TEST

Typhoid fever is an infectious disease caused by a bacterium, *Salmonella typhi*. It continues to be a major health problem especially in the Asia Pacific region, the Indian subcontinent, Central Asia, Africa and South America¹. 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^{2,3}. 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 infection³. Thus all cases of fever should be tested for typhoid and a rapid laboratory tests will be required.

TYPHIDOT Rapid IgG/IgM (Combo) offers many advantages which fulfill the requirement of typhoid diagnosis. These advantages includes:

- early and specific diagnosis of typhoid fever
- fast, simple and reliable
- simple to perform and no additional sample preparation required
- no special equipment is needed
- results are easy to interpret
- minimal sample volume used

PRINCIPLE OF THE TEST

The **TYPHIDOT Rapid IgG/IgM (Combo)** is an indirect solid-phase immunochromatographic assay. The specific *S. typhi* OMP antigen is immobilized onto cellulose nitrate membrane as test lines. When the test sample is added to the sample pad, it migrates upwards. If anti-*S. typhi* IgG and IgM antibodies are present in the test sample (serum or plasma), they will react with colloidal gold-anti-human IgG or gold-anti-human IgM to form a complex. The complex will continue to move on the cellulose nitrate membrane and then captured at the test window zone by the immobilized specific *S. typhi* OMP antigen, giving a pink-purple coloured band. The control line contains rabbit anti-mouse IgG antibody which binds with the gold conjugated mouse anti-human IgG or mouse anti-human IgM antibodies. The control band serves as an indication of proper migration plus reagent control.

PERFORMANCE CHARACTERISTICS

Sensitivity and specificity for **TYPHIDOT Rapid IgG/IgM (Combo)** are 90% and 80% respectively.

REAGENTS AND MATERIALS SUPPLIED

1. **TYPHIDOT Rapid IgG/IgM (Combo)** cassette (25 pieces packed in individually sealed aluminium pouch)
2. One bottle of Chase buffer
3. One copy of instruction manual (product insert)

MATERIALS REQUIRED BUT NOT SUPPLIED

1. Sample collection and preparation device and equipment
2. Sample dispensing apparatus such as pipettes
3. Clock or timer

WARNINGS AND PRECAUTIONS

1. For professional *in vitro* diagnostic use only.
2. This product insert must be strictly followed in order to produce accurate test results.
3. Keep the test device sealed until use. Once the device pouch has been opened, the test device must be used immediately.
4. Do not use device if the sealed pouch is visibly damaged.
5. Do not use kit beyond the expiration date.
6. Handle all specimens as being potentially infectious. Dispose all materials that come in contact with the specimen as infectious waste.
7. Wipe any spills of sera or plasma promptly with 1% sodium hypochlorite solution.
8. Do not reuse test device.

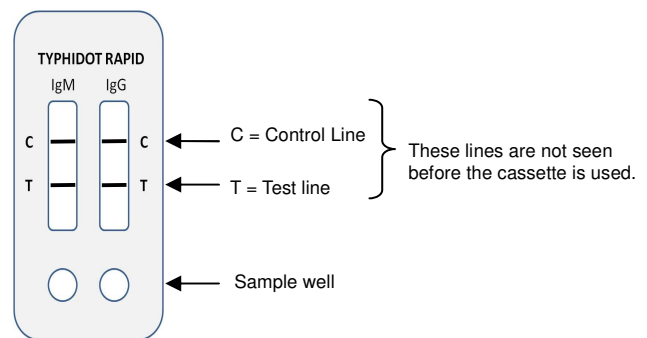
STORAGE AND STABILITY

Store at 4-30°C, do not freeze. Keep the test device sealed until used. Keep away from direct sunlight, moisture and heat.

SAMPLE COLLECTION AND PREPARATION

1. Handle all specimens as being potentially infectious. Dispose all materials that come in contact with the specimen as infectious waste.
2. Specimen should be collected aseptically by venipuncture according to the standardized methods. The use of grossly lipemic or turbid samples should be avoided. Plasma or serum is separated from the whole blood using standard procedures.
3. If serum or plasma specimens cannot be tested immediately, they should be refrigerated at 2 to 8°C. For storage periods longer than three (3) days, freeze the specimen at -20°C or below.

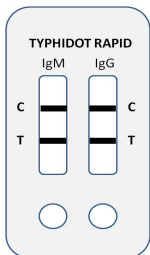
ASSAY PROCEDURE



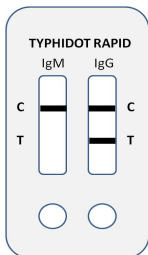
1. Bring test cassette and chase buffer to room temperature (if precipitates are noted in the chase buffer reagent, shake the bottle vigorously and allow to warm up further).
2. Gently tear open the pouch and remove the test cassette.
3. Label the test cassette with the sample name.
4. Add 45 µl serum/ plasma to each sample well; making sure that there is no air bubbles.
5. Add 1 drop of buffer to each sample well. Serum/ plasma will start wicking up the membrane. The cassette may be tapped gently on the table to facilitate the sample to flow up the membrane.
6. Read result after 20 minutes.

QUALITY CONTROL

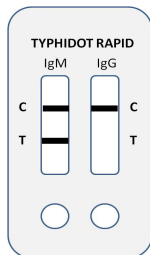
1. Positive and negative controls are not included and are optional.
2. If the control line at position C does not become visible, the test is invalid. Positive samples will have additional coloured band at position T.

INTEPRETATION OF RESULTS


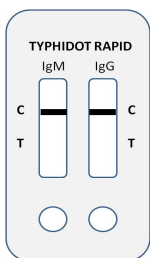
Positive for anti-S typhi IgG & IgM



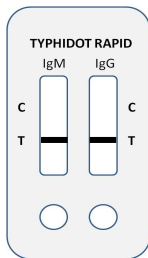
Positive for anti-S typhi IgG



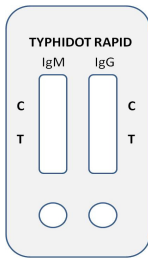
Positive for anti-S typhi IgM



Negative for anti-S typhi IgG & IgM



Invalid



1. **Positive** for *Salmonella typhi* specific antibodies:
Coloured bands appear at the Control line (C) and Test lines (T).
2. **Negative** for *Salmonella typhi* specific antibodies:
Only Control line (C) is visible.
3. **Invalid**: Control line (C) is absent. If this occurs, the assay should be repeated using a new test cassette.

LIMITATION OF THE TEST

1. This product is designed for use with human serum and plasma only.
2. The test is a qualitative assay and is not for quantitative determination of antibodies concentration levels. The intensity of the band does not have linear correlation with the antibody titer of the specimen.
3. The results obtained should only be interpreted in conjunction with other diagnostic results and clinical information.
4. Due to the limitations of the test, for cases where interpretation of result seems difficult, we strongly recommend repeating the test using **TYPHIDOT 1 hour** or **TYPHIDOT 3 hours**.

Note: TYPHIDOT 1 hour or TYPHIDOT 3 hours are Dot EIA assay designed for the qualitative detection of specific IgM and IgG antibodies against a specific outer membrane antigen of *Salmonella typhi* in human serum.

WARRANTY AND LIMITED LIABILITY

The performance characteristics stated were obtained by using the assay procedure in this insert. Failure to follow the assay procedure may derive inaccurate results. In such event, the manufacturer disclaims all warranties expressed, implied or statutory, including the implied warranty of merchantability and the fitness for use.

The manufacturer will not be liable for any damage caused by misuse, improper handling and storage, non-compliance with warnings and procedures, damage caused by events occurring after the product is released, failure to ensure the product is in proper condition before use, or any warranty given by independent distributor.

REFERENCES

1. Ivanoff B, Levine MM, Lambert PH (1994). Vaccination against typhoid fever: present status. Bull World Hlth Org 72: 957-71.
2. Ismail A, Ong KH, Zainoodin SAK (1991). Demonstration of an antigen specific for *Salmonella typhi*. Biochem Biophy Res Com 181: 301-5.
3. Levine MM, Grados O, Gilman RH, Woodward WE, Solis-Plaza R, Waldman W (1978). Diagnostic value of the Widal test in areas endemic for typhoid fever. Am J Trop Med Hyg 27: 785-800.
4. Bokkenheuser V (1964). Detection of typhoid carriers. Am J Pub Hlth 54: 477-85.

ORDER INFORMATION

Product Code	Description	Packing Size
TF-RD0202	TYPHIDOT Rapid IgG/IgM (Combo) Version2	25 tests / kit


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