AVECON
Transforming Research into Innovations

One Step Rapid Test for Typhoid Antibody

MaxLINE Typhoid Ab Rapid Test

Serum/Plasma Test Protocol

ORDERING INFORMATION

Ref. No.	Pack Size
AVTYPABSP-10	10 Tests
AVTYPABSP-20	20 Tests
AVTYPABSP-25	25 Tests
AVTYPABSP-30	30 Tests
AVTYPABSP-50	50 Tests

NOTE : 10T, 20T, 25T, 30T Pack Sizes are not available for domestic trade.

INTENDED USE :

The MaxLINE Typhoid Ab Rapid Test Cassette is a rapid chromatographic immunoassay for the simultaneous detection and differentiation of IgG and IgM types of antibodies against Salmonella typhi (S. typhi) in human serum or plasma. It is intended to be used as a screening test as an aid in the diagnosis of infection with S. typhi. Any reactive specimen with the Typhoid rapid test cassette needs to be confirmed with alternative testing method.

PRODUCT FEATURES :

1. Lateral Flow Immuno Chromatography Assay.
2. Double Antigen Sandwich Principle.
3. Detects Typhoid Antibody to S. typhi.
4. Sensitivity: 98% for IgG and 98.5% for IgM
5. Specificity: 99.3% for IgG and 99.3% for IgM

INTRODUCTION

Typhoid fever is caused by S. typhi, a Gram-negative bacterium. World-wide an estimated 17 million cases and 600,000 associated deaths occur annually[1]. Patients who are infected with HIV are at significantly increased risk of clinical infection with S. typhi[2]. Evidence of h. pylori infection also presents an increase risk of acquiring typhoid fever. 1-5% of patients become chronic carrier harboring S. typhi in the gallbladder.

The clinical diagnosis of typhoid fever depends on the isolation of S. typhi from blood, bone marrow or a specific anatomic lesion in the facilities that cannot afford to perform this complicated and time consuming procedure, Widal Test (also referred as Weil-Felix Test) is used to facilitate the diagnosis. However, many limitations lead to difficulties in the interpretation of the Widal test [3, 4].

In contrast, the MaxLINE Typhoid Ab Rapid Test Cassette is a simple and rapid laboratory test. The test simultaneously detects and differentiates the IgG and the IgM antibodies to S. typhi specific antigen[5] in serum or plasma thus aid in the determination of current or previous exposure the S. typhi.

PRINCIPLE

The MaxLINE Typhoid Ab Rapid Test Cassette is a qualitative, membrane based immunoassay for the detection of antibodies (IgG and IgM) to Salmonella typhi (S. typhi) in human serum or plasma. The diagnostic test cassette consists of two components: an IgG component and an IgM component. The IgG line region is pre-coated with reagents for the detection of anti-S. typhi (IgG). The IgM line region is pre-coated with monoclonal anti-human IgM for detection of anti-S. typhi (IgM).

During testing, specimen dispensed into the sample well of the test cassette binds with Typhoid conjugates impregnated in the reagent area, if the specimen contains anti-Typhoid antibodies. The immunocomplex thus formed migrates by capillary action. If the present antibodies in specimen are of IgG types, the immunocomplex is then captured by the pre-coated reagents on the membrane, forming a colored IgG line, indicating a S. typhi IgG positive test result. If the present antibodies in the specimen are of IgM type, the immunocomplex would be captured on the membrane by the pre-coated anti-human IgM antibody, forming a colored IgM line, indicating a S. typhi IgM positive test result.

Absence of any T lines (IgM and IgG) indicates a negative result. A colored control line (C) should always appear in case of a positive or a negative result. Its absence indicates invalid test results.

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (4-30°C). 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. DO NOT FREEZE. Do not use beyond the expiration date.

KIT CONTAINS

Ref. No.	Pack Size	Test Device	Buffer	Product Insert
AVTYPABSP-10	10 Tests	10Nos.	1 No.	1 No.
AVTYPABSP-20	20Tests	20 Nos.	1 No.	1 No.
AVTYPABSP-25	25 Tests	25 Nos.	1 No.	1 No.
AVTYPABSP-30	30 Tests	30 Nos.	2 Nos.	1 No.
AVTYPABSP-50	50 Tests	50 Nos.	3 Nos.	1 No.

MATERIALS

1. Materials Provided

Each kit contains :

a) Assay Buffer
b) Individually packed test strip
c) Sample Dropper
d) Product insert

2. Materials Required But Not Provided

- Specimen collection containers
- Centrifuge (for serum/ plasma separation only)
- Stop Watch

PRECAUTION

1. For in vitro diagnostic use only. Do not use after the expiration date.
2. Do not smoke, drink, or eat in areas where specimens or kits reagents are handled.
3. Dispose of all specimens and materials used to perform the test as biohazardous waste.
4. This package insert must be read completely before performing the test.
5. Bring all reagents to room temperature (15°C-30°C) before use.
6. Do not interchange the assay buffer and test cassettes of different lots.
7. Do not use hemolized blood specimen for testing.

SPECIMEN COLLECTION AND PREPARATION

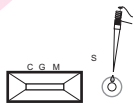
1. The MaxLINE Typhoid Ab Rapid Test Cassette can be performed using whole blood, serum or plasma.
2. Separate the serum or plasma from blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed specimens can be used.
3. Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 3 days. For long-term storage, specimens should be kept below -20°C.
4. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
5. If specimens are to be shipped, they should be packed in compliance with local regulations.

TEST PROCEDURE

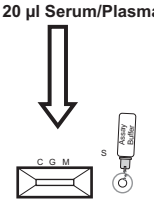
1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it within one hour. Best results will be obtained if the assay is performed within one hour.
2. Place the test cassette on a clean and level surface.
3. Hold the dropper vertically and transfer 1 drop (20µL) of serum/plasma/whole blood to the specimen well (S) of test Cassette.
4. Add 1 drop of assay buffer (approximately 35µL) and start the timer. Avoid trapping air bubbles in the specimen well.
5. Wait for the colored line(s) to appear. The result should be read at 10-20 minutes. Do not interpret results after 20 minutes.
6. See the illustration below.

INTERPRETATION OF RESULT

Use Only serum/plasma



1 Drop or 20 µl Serum/Plasma



Add 1 Drop of Assay Buffer

* Special Instruction *
25 µl Serum/Plasma and 1 drop Assay Buffer

10 - 20 mins

Negative: One bands appears in Window "C" Region

Typhoid IgM Positive : Two bands appears in Window "C" and "M" Region

Typhoid IgG POSITIVE : Two bands appears in Window "C" and "G" Region

Typhoid IgM & IgG POSITIVE: Three bands appears in Window "C", "G" and "M" Region

INVALID: No bands appears in Window Region. The Result is considered invalid

INVALID: The result should also be considered invalid if only test band (G & M) appears and no control band appears in window region.

INTERPRETATION OF RESULTS

(Please refer to the illustration above)

POSITIVE:* Two or three lines appear. One colored line should always appear in the control line region (C) and another one or two apparent colored line(s) should be in the test line region(s) (G and M).

IgM Positive: Along with line in Control region "C", a line appears in "M" region. It indicates a positive Test result for antibodies to S. typhi (Isotype IgM)

IgG Positive: Along with line in Control region "C", a line appears in "G" region. It indicates a positive Test result for antibodies to S. typhi (Isotype IgG)

***NOTE:** The intensity of the color in the test line regions (G and M) may vary depending on the concentration of Typhoid antibodies present in the specimen. Therefore, any shade of color in the test line region (G and M) should be considered positive.

NEGATIVE: One colored line appears in the control line region "C". No line appears in the test line regions (G and M).

INVALID: Control line fails to appear. 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. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is an internal positive procedural control. It confirms sufficient specimen volume.

EXPECTED VALUES

The MaxLINE Typhoid Ab Rapid Test Cassette (Serum/Plasma) has been compared with a leading commercial Typhoid ELISA test. The correlation between these two systems is over 97%.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

A clinical evaluation was conducted comparing the results obtained using the Typhoid Rapid Test Cassette to Typhoid IgG/IgM ELISA Testing. The study included 200 IgG specimens and 200 IgM specimen, and about the IgG specimen both assays identified 4 negative and 196 positive results, about the IgM specimen both assays identified 3 negative and 197 positive results.

IgG Results

Method		*S. typhi* EIA (IgG)		Total Results
Typhoid Rapid Test Cassette for IgG	Results	Positive	Negative	
	Positive	196	4	200
	Negative	7	993	1000
Total Results		203	997	1200

Relative Sensitivity: 98% Relative Specificity: 99.3% Overall agreement : 99.1%

IgM Results

Method		*S. typhi* EIA (IgM)		Total Results
Typhoid Rapid Test Cassette for IgM	Results	Positive	Negative	
	Positive	197	3	200
	Negative	7	993	1000
Total Results		203	997	1200

Relative Sensitivity: 98.5% Relative Specificity: 99.3% Overall agreement : 99.2%

Precision

Intra-Assay

Within-run precision has been determined by using 10 replicates of three specimens: a negative, a low positive, and a high positive. The negative, low positive, and high positive values were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 10 independent assays on the same three specimens: a negative, a low positive, and a high positive. Three different lots of the Typhoid Rapid Test cassette (Serum/Plasma) have been tested over a 3-day period using negative, low positive, and high positive specimens. The specimens were correctly identified >99% of the time.

INTERFERING SUBSTANCES

The following potentially interfering substances were added to Syphilis negative and positive specimens.

Acetaminophen:	20 mg/dL	Caffeine:	20 mg/dL
Acetylsalicylic Acid:	20 mg/dL	Gentisic Acid:	20 mg/dL
Ascorbic Acid:	2g/dL	Albumin:	2 g/dL
Creatin:	200 mg/dL	Hemoglobin:	1.1 mg/dL
Bilirubin:	1g/dL	Oxalic Acid:	600mg/dL

None of the substances at the concentration tested interfered in the assay.

LIMITATIONS

1. The assay procedure and the test result interpretation must be followed closely when performing the assay. Failure to follow the procedure may give inaccurate results.
2. The Typhoid Rapid Test Cassette is for qualitative detection of antibodies to S. typhi in human serum or plasma. The intensity of the test band has not linear correlation with the antibody titer in the specimen.
3. A negative result only indicates absence of anti-S. typhi antibodies above detectable levels. A negative test result does not preclude the possibility of exposure to S. typhi as a negative result can occur if the quantity of anti-S typhi antibodies present in the specimen is below the detection limit of the assay, or the antibodies that are detected are not present during the stage of disease in which a sample is collected.
4. Specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.
5. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

DISCLAIMER:

The manufacturer has take every precaution to ensure the diagnostic ability and accuracy of this product, the product is used outside of the control of the Manufacturer and Distributor and the result may accordingly be affected by user error and/or environmental factors. A person who is the subject of the diagnosis should consult a clinician for further confirmation of the result.

WARNING:

The Manufacturer and Distributors of this product shall not be liable for any losses, liability, claims, costs or damages whether direct or indirect or consequential arising out of or related to an incorrect diagnosis, whether positive or negative, in the use of this product.

REFERENCE

1. Ivanoff BN, 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, Liendo G, Carillo C, Black RE, Morris JG. Salmonella typhi or Salmonella paratyphi in an endemic typhoid area. Archives of Internal Medicine 1991;151:381-2

Symbols Used on Pack

REF	Catalogue Number		Warning/Caution
LOT	Batch No.	IVD	In vitro diagnostic device
	Manufacturing Date		Storage Limit
	Expiry Date		Consult instruction for use
	Manufacturer		Keep away from sunlight
	Keep Dry		Do not use if package is damaged
2	Do Not Reuse	Σ	Contains sufficient no. of test

MAKE IN INDIA

ISO 13485 Certified Company

GMP 5^th^Schedule MDR 2017

Manufactured in India by :

AVECON™ Healthcare Pvt. Ltd.

Transforming Research into Innovations

Plot No.: 338, Sector-2, Industrial Growth Centre, Saha, Ambala, Haryana (INDIA)-133104

E-mail : helpdesk@aveconhealthcare.com, Website : www.aveconhealthcare.com

Customer Care No. : +91 93065 12576, CIN No.: U24230HR2006PTC118875

Ver. : 05/02-26