SeroMAX WIDAL

(SLIDE AGGLUTINATION Method)

ORDERING INFORMATION

Ref. No.	Pack Size	Antigen
AVWID4-20	4 x 5 ml	O, H, AH, BH
AVWID2-20	2+2 x 5 ml	O, H

INTENDED USE :

Kit is use for the Qualitative and Semi-Quantitative determination of Antibodies to Salmonella typhi and Salmonella paratyphi in Human Serum.

PRODUCT FEATURES

1) Sera from normal individuals may show agglutination upto 1 : 40 dilution.
2) Agglutination Titre greater than 1 : 80 is considered to be significant and usually suggestive of infection.
3) SeroMAX WIDAL is only a Screening Test. For confirmation of results testing with SeroMAX WIDAL– T is recommended.
4) The correlation of test results with typical Clinical Symptoms and Patient's history should be taken into account before arriving at the final diagnosis.
5) As with all diagnostic procedures, the Physician should evaluate data obtained by use of this kit in light of other clinical information.
6) For accuracy of results, the procedure has to be followed meticulously.
7) Bring all the reagents to room temperature before use.
8) Serum should not be inactivated.
9) Shake antigen vial well before use.
10) Avoid performing of the test directly under the fan.
11) In a non inoculated person the titre as high as 1 : 80 between 7th or 10th day of fever is of diagnostic value and the same titre increases gradually during subsequant period.
12) In an inculated person the question of anamnestic response should always be born in mind and 'H' titre should not be taken into account for the purpose of diagnosis unless there is a rising titre of 'H' in subsequant peroid.

INTRODUCTION

Salmonella typhi & Salmonella paratyphi are the causative agents of "Enteric Fever". In Enteric Fever once the patient is on medication it becomes difficult to isolate the organisms. In serological tests the antibodies produced as a result of infection are detected by using the killed and Inactivated bacterialantigens. The antibodies from the patient's serum react with the corresponding antigens to give clumping or agglutination. The antigens of Typhoid and Paratyphoid consist of two distinct fractions. The Stable Somatic 'O' Antigen and the Labile Flagellar 'H' Antigen. The Paratyphoid Antigens are further classified into A & B species. In Typhoid and Paratyphoid, the 'H' Antigen is Type Specific whereas the 'O' Antigen is Group Specific. SeroMAX WIDAL Antigens are stabilized smooth suspensions of killed and inactivated bacterial antigens for Qualitative and Semiquantitative Detection of S. typhi and S. paratyphi Antibodies. The different color given to each Antigen facilitates the differentiation. It also avoids the possible errors of misinterpretation. As undiluted serum is used in Slide Test, it is a Simple, Rapid and Convenient Screening Test. The slide test antigens are standardized in such a way that they can be used for either Slide or Tube Technique. In doubtful cases, it is recommended to perform the tube technique for obtaining conclusive results. A marked rise in the titre to one Serotype (above 1:80) suggests infection. Diagnostically a rising antibody titre of atleast four folds (two tube difference) is considered more significant than a single test. It is observed that individuals immunized with TAB vaccine may show a moderately high titre for all the Antigens.

PRINCIPLE :

When the coloured, smooth suspension of attenuated WIDAL antigen suspensions are incubated with the patient serum, anti-Salmonella antibodies present in the patient's serum react with the antigen suspensions to produce agglutination.

Agglutination is a positive test result, indicating presence of Salmonella antibodies in the patient's serum. No agglutination is a negative test result indicating absence of Salmonella antibodies in the patient's serum.

REAGENT

SeroMAX WIDAL contains ready to use coloured, smooth antigen suspensions of the bacilli; S. typhi 'O', S. typhi 'H', S. paratyphi 'AH' and S. paratyphi 'BH'. SeroMAX WIDAL reagents are versatile and standardized for use in a standard tube test procedure for the detection of S. typhi and S. paratyphi antibodies in the patient's serum. Each batch of reagents undergoes rigorous quality control at various stages of manufacture for its specificity and performance.

REAGENT STORAGE AND STABILITY

1. Store the reagent at 2-8^{0}C **.** DO NOT FREEZE.

2. The shelf life of the reagent is as per the expiry date mentioned on the reagent vial label.

KIT CONTAINS

Name of Reagent	Pack Size (Widal)	Pack Size (Widal "OH")
	4 x 5 ml	2+2 x 5 ml
S. Typhi 'O' Antigen	5 ml	2 x 5 ml
S. Typhi 'H' Antigen	5 ml	2 x 5 ml
S. Typhi 'AH' Antigen	5 ml	
S. Typhi 'BH' Antigen	5 ml	
Positive Control	0.3 ml	0.3 ml

ACCESSORIES :

Glass Slide (White 6 Circles)	1 No.	1 No.

REAGENT RECONSTITUTION & STABILITY

Reagent are liquid stable no need for reconstitution.

When the reagent is stored properly at 2-8°C & the contamination avoided, it is stable up to the expiry date mention on the label & kit box.

MATERIAL REQUIRED BUT NOT PROVIDED

Glass slides, Test tubes, Pasteur pipettes, Isotonic saline (0.9% NaCl Solution), Centrifuge, Timer, Mixing sticks, Sodium Hypochlorite (1%).

PRECAUTIONS:

1. Bring all the Reagents and Samples to room temperature before use.
2. Shake all the Antigens thoroughly before use.
3. Avoid using Turbid, Contaminated or Inactivated serum.

SPECIMEN:

(1). No special preparation of the patient is required prior to sample collection by approved techniques. Do not use haemolysed and turbid samples.

(2). Clean and dry glassware free from detergents must be used for sample collection.

(3). Do not heat inactivate the serum.

(4).Though freshly collected serum is preferable, store samples at 2-8°C in case of delay in testing, for upto 72 hours.

TEST PROCEDURE :

1. Rapid Screen Slide Test:-

I.) Clean the glass slide provided in the kit and wipe it to remove any dust.

ii) Place 0.05ml (50 µl) undiluted serum to be tested in each on the first four circles (1-4) of the slide. On the 5th and 6th circles place 50µl each of Positive Control and Normal Saline respectively

iii) Add one drop each of 'O', 'H', 'AH', 'BH' Antigens in the first four circles respectively over the serum sample. At the same time add a drop of any one of the antigens over Positive Control and Normal Saline

iv). Mix the contents of each circle with separate mixing sticks (Not provided in the kit) and spread it to fill the entire circle by repeated circular rocking of the slide (Anti Clock Wise)

v). Rock the slide gently for one minute and observe for agglutination.

INTERPRETATIONS OF RESULTS:

Agglutination with Positive Control and no agglutination with Normal Saline validates test results.

No agglutination upto one minute is a Negative Test, and indicates the absence of corresponding antibodies.

Agglutination within one minute is a Positive Test, and indicates presence of corresponding antibodies. Then proceed for Semi-Quantitative slide or tube technique for determination of antibody titre.

2. Semi-quantitative Slide Test:-

i. Put one drop of Normal Saline in the first circle and add 5 µl, 10 µl, 20 µl, 40 µl and 80 µl of test serum in the remaining circles respectively.

ii. To each of the above circles, add one drop of the appropriate Antigen which gives an agglutination in the Screening Slide Test.

iii. Mix the contents of each circle separately and spread it in the entire circle.

iv. Rock the slide gently for one minute and observe for agglutination.

INTERPRETATIONS OF RESULTS:

The lowest volume of Serum which shows clear agglutination indicates the cut off level of the Positive Test and the corresponding Antibody titre as per the Tube Technique is given below:

Serum Volume	Antibody Titre
80 µl	1 : 20
40 µl	1 : 40
20 µl	1 : 80
10 µl	1 : 160
5 µl	1 : 320

3. Tube Technique Using Slide Antigens:

i. Perform the assay for all four Antigens or for that which has given a positive result in the Screening Slide Test.

ii. Take a set of six test tubes (10X75mm) for each Antigen. Dilute the Serum Sample and set up the test as indicated in the table.

iii. Mix well after each addition and incubate at 37ºC for 16-20 hours.

iv. Observe for agglutination. The highest dilution of Serum which shows clear cut agglutination indicates the Antibody Titre.

Tube No.	1	2	3	4	5	6	
Dilution	Saline Control	1:20	1:40	1:80	1:160	1:320	
Normal Saline	1.0 ml	1.9 ml	1.0 ml	1.0 ml	1.0 ml	1.0 ml	
Test Serum	—	0.1 ml					
Diluted Serum	—	—	1.0 ml	1.0 ml	1.0 ml	1.0 ml	1.0 ml
Appropriate Antigen	One Drop	One Drop	One Drop	One Drop	One Drop	One Drop	Discard

REMARKS

1) Separate colour coded Antigens ensure differential diagnosis of both Salmonella typhi and Salmonella paratyphi.
2) Uniform, Homogenous and Stabilized Bacterial Antigens ensure clear Agglutination and easy interpretation between Positive and Negative results.
3) Qualitative and Semi Quantitative Slide Test and Tube Test procedures incorporated in the same kit.
4) Positive Control is provided for the proper validation of the kit.
5) Positive Control provided in the kit is free from HIV & HbsAg and is safe to use.
6) Sample dilution is not required unlike conventional procedures.
7) Avid Agglutination ensures proper discrimination between positive and negative results.
8) Optimum Bacterial Antigen concentration overcomes Immunological interferences like Prozone Effect and Hook Effect and hence accurate results.

PERFORMANCE CHARACTERISTICS

(1) The positive control antisera should produce 1+ or greater agglutination at 1: 80 in the tube test when tested with the SeroMAX WIDAL antigen suspensions.
(2) The negative control should show no agglutination with any of the SeroMAX WIDAL antigen suspensions.
(3) Generally accepted performance characteristic of this type of test is 70% specificity and sensitivity.
(4) Reproducibility of SeroMAX WIDAL antigen suspensions is 100% (+/- one double dilution).

WARRANTY

This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

REFERENCES:

1. Cruickshank, R. (1982) Medical Microbiology, 12th Edition, P. 403.
2. Felix, A. (1942) Brit. Med. J., 11, 597.

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
	Do Not Reuse	Σ	Contains sufficient no. of test

Manufactured in India by :
AVECON Healthcare Pvt. Ltd.
Transforming Research into Innovations
Plot No.: 338, Sector-2, Industrial Growth Centre, Saha (Haryana) India-133104.
E-mail : helpdesk@aveconhealthcare.com, Website : www.aveconhealthcare.com
Customer Care No. : +91 93065 12576

Ver. : 4/04-23