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Medsource Ozone Biomedicals Pvt. Ltd.

OZOTEX - WIDAL

(Stained Salmonella Antigens for Widal Slide agglutination Test)

INTENDED USE: For the Qualitative and Semi-Quantitative determination of Antibodies to Salmonella typhi and Salmonella paratyphi in Human Serum.

PRODUCT FEATURES:

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.

CLINICAL IMPORTANCE:

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 Bacterial Antigens. 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.

OZOTEX - 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 Stereotype (above 1:80) suggests infection. Diagnostically a rising antibody titre of at least 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 :

The Antibodies present in the Serum Sample react with the corresponding Bacterial antigens to give an Agglutination.

CONTENTS:

Reagent 1	S. typhi 'O' Antigen	5 ml
Reagent 2	S. typhi 'H' Antigen	5 ml
Reagent 3	S. paratyphi 'AH' Antigen	5 ml
Reagent 4	S. paratyphi 'BH' Antigen	5 ml
Reagent 5	Positive Control	1 vial

Accessories :

1. Glass Slide

STORAGE AND STABILITY:

All the reagents are stable at 2-8°C till the expiry date mentioned on the labels.

SPECIMEN:

Fresh Serum is the preferred Specimen.

In case of a delay in testing, store at 2-8°C.

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.

PROCEDURE:

Rapid Screen Slide Test :

i. On a Slide with six circles, place 0.05ml (50 μl) of Test Serum in each of the first two circles and 0.05ml (50 μl) each of Positive Control and Normal Saline in each of the last two circles respectively.

ii. Add one drop each of 'O', 'H', 'AH', 'BH' Antigens in the first four

circles respectively and one drop of any one Antigen in the last two circles.

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:

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-Quantilative slide or tube technique for determination of antibody titre.

Semi-quantitative Slide Test :

i. Put one drop of Normal Saline in the first circle and 5 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

Tube Technique Using Slide Antigen:

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 37°C 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	1.0ml	1.9ml	**1.0ml**	1.0ml	1.0ml	1.0ml
Test Serum	--	0.1ml				
Diluted Serum	--	--	1.0ml	1.0ml	1.0ml	1.0ml
Appropriate Antigen	One Drop	One Drop	One Drop	One Drop	One Drop	One Drop

1.0ml discard

NOTE:

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) OZOTEX-WIDAL is only a Screening Test.

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.

REFERENCES:

1. Cruickshank, R. (1982) Medical Microbiology, 12th Edition, P. 403.

2. Felix, A. (1942) Brit. Med. J., 11, 597.

Symbol	Explanation	Symbol	Explanation
	Manufactured by	IVD	In vitro diagnostic medical device
LOT	Lot No.		See instruction for use
	Manufacturing Date	2°C 8°C	Temperature Limitation
	Expiry Date	REF	Catalogue Number

IFU/WDL/121 R-00
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Manufactured by:

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