SeroMAX ASO

(Latex Slide Agglutination Method)

ORDERING INFORMATION

Ref. No.	Pack Size
AVASO-25	25 Tests
AVASO-50	50 Tests
AVASO-100	100 Tests

INTENDED USE

Kit is use for the Qualitative and Semi-Quantitative determination of Anti Streptolysin- O Antibodies in Human Serum.

PRODUCT FEATURES

1. Detects ASO as low as 200 IU/ml. (Cut off Sensitivity 200 IU/ml)
2. Uniform and Homogenous Latex Particles ensure clear Agglutination.
3. Qualitative and Semi quantitative procedures included in the same kit.
4. Positive and Negative Controls are provided for the proper validation of the kit.
5. Positive and Negative Controls provided in the kit are free from HIV & HBsAg.
6. Sample dilution is not required unlike conventional procedures.
7. Avid Agglutination ensures proper discrimination between positive and negative results.
8. Cut off sensitivity 200 IU/ml is determined in correlation with Quantitative Turbidometry.
9. Latex Reagent Sensitivity 200 IU/ml is calibrated against WHO calibrators.
10. Optimum Streptolysin-O Antigen concentration coated on to the Latex particles overcomes Immunological interferences like Prozone Effect and Hook Effect.

INTRODUCTION

(The group A Beta-Hemolytic Streptococci produces various Exotoxins such as Streptolysin-O & Streptolysin-S which can act as Antigens. The affected individuals produce specific Antibodies to Antistreptolysin-O (ASO). Detection of ASO is very useful in the diagnosis of Streptococcal Infections. The elevated ASO titres may be associated with Acute Rheumatic Fever and Glomerulonephritis. An elevated ASO titre of more than 200 IU/ml indicates an Acute Streptococcal Infection. Testing of successive serum sample after an interval of 10-12 days is diagnostically more important than a single sample.

PRINCIPLE :

The latex Reagent is coated with Streptolysin-O Antigen. The Specimen containing ASO, on mixing with Latex Reagent agglutinates, showing the positive test result. If ASO is absent there will be no agglutination, which is a negative test result

REAGENT

1. SeroMAX ASO reagent: A uniform suspension of polystyrene latex particles coated with streptolysin O. The SeroMAX ASO reagent is standardized to detect antibodies to streptolysin O in concentrations ranging from 200 IU/ml or more. The standardization of detection limit of SeroMAX ASO is traceable to the International Standard for Antistreptolysin 'O' (97/662).
2. Positive control, reactive with the SeroMAX ASO reagent.
3. Negative control, non-reactive with the SeroMAX ASO reagent.

Each batch of reagents undergoes rigorous quality control at various stages of manufacture for its specificity, sensitivity and performance.

STORAGE & STABILITY :

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

KIT CONTAINS

Name of Reagent	AVASO-25	AVASO-50	AVASO-100
Reagent 1 Latex Reagent	1.0 ml	2 x 1 ml	2 x 2 m
Reagent 2 Positive Control	0.4 ml	0.4 ml	0.4 ml
Reagent 3 Negative Control	0.4 ml	0.4 ml	0.4 ml
ACCESSORIES :			
Glass Slide (Black 4 Circles)	1 No.	1 No.	1 No.
Disposable Sample Droppers	25 Nos	50 Nos.	100 Nos.
Disposable Mixing Sticks	25 Nos	50 Nos.	100 Nos.

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. Do not read results after 2 minutes.
2. Bring all the reagents and samples to RT before use.
3. Do not freeze the Latex Reagent.
4. Do not use Hemolysed or Turbid Specimen.
5. The Latex Reagent should be shaken well before use to ensure a homogeneous suspension of latex.
6. The source material used in the manufacturing of Positive & Negative Controls is tested for HBsAg & HIV antibodies and are found to be negative. However for better safety these controls should be handled as if they are potentially dangerous.
7. While dispensing Latex Reagent, hold the Latex dropper vertically to ensure uniform drop size.

SPECIMEN :

Only Serum Is the preferred specimen. In case of a delay In testing, store the specimen at 2-8°C. Plasma or Hemolysed/ Lipaemic Serum Samples should not be used.

TEST PROCEDURE :

A. QUALITATIVE TEST :

1. Place one drop (Approximately 40-50 µl) of specimen, Positive Control and Negative Control in separate circles of the glass slide by using the Sample droppers provided.
2. Add one drop of Latex Reagent in each of these circles with the Latex dropper.
3. Mix the content of each circle separately and spread it in the entire circle with the mixing sticks provided in the kit.
4. Rock the slide gently for 2 minutes and look for any agglutination
5. Do not read results after 2 minutes.

INTERPRETATION OF RESULTS :

Agglutination with positive Control and no agglutination with Negative Control validate test results. Agglutination within 2 minutes is a positive test and indicates presence of ASO in the test specimen. No agglutination up to 2 minutes is a negative test and indicates absence of ASO in the test specimen.

Do not interpret results after 2 minutes

B. SEMI QUANTITATIVE TEST :

1. Dilute the specimen serially 1 :2, 1 :4, 1 :8, 1 :16, using normal saline.
2. Place one drop of each diluted serum sample using Sample / droppers in each circle of glass slide & proceed further as in Qualitative Test (A).

INTERPRETATION OF RESULTS :

The highest dilution which shows clear-cut agglutination within 2 minutes, indicates the ASO titre. The approximate ASO concentration can be obtained by multiplying the titre by sensitivity of the test.

ASO in IU/ml = D x S

D = Highest dilution showing clear cut agglutination.

S = Sensitivity of the test is 200 IU/ml.

PERFORMANCE CHARACTERISTICS

The performance characteristics of SeroMAX ASO were evaluated using known positive and negative serum samples. The known serum samples were validated using other commercial manufacturers latex slide test reagent having similar performance characteristics.

Specimen	SeroMAX ASO		Total
	+Ve	-Ve	
ASO + Ve samples	25	0	25
ASO - Ve samples	0	75	75
	25	75	100

Sensitivity: 100% Specificity: 100%

Repeatability and reproducibility (inter-assay and inter-lot) were evaluated on a number of ASO negative and ASO positive

serum samples. No variations were found in the outcome of different tests.

REMARKS

1. Do not read results after 2 Minutes.
2. Positive & Negative Controls are ready to use & should not be diluted while using in test procedure.
3. Improper mixing and drying of reagents may lead to erroneous results.
4. Contaminated sera and a longer reaction time after 2 minutes may lead to false positive results.
5. As with all diagnostics tests, the final diagnosis should be based on correlation of test results with other clinical symptoms and findings.
6. Non specific positive reaction may occur if plasma is used or serum is highly lipemic or hemolysed.
7. For accuracy of results, the procedure has to be followed meticulously.

WARRANTY

This product is designed to perform as described on the label and the package insert. The manufacturer disclaims any implied

warranty of use and sale for any other purpose.

REFERENCE

1. Spaun J. Bentzon M.W, Larsen S.O. et.al, International Standards for Antistreptolysin O, (1961), Bull , WHO, 24, pgs 271- 279./
2. Klein G.C., et.al. (1971), Upper Limits of Normal Antistreptolysin O and Antideoxyribonuclease B Titres, Applied Microbiology, 21, 999-1001.
3. Clinical Laboratory by Lothar Thomas , M.D., 1st edition, 1988, TH-Books, Verlagsgesellschaft mbH, Frankfurt, Germany, pgs 1202-1203.
4. Data on file: Tulip Diagnostics (P) Ltd.

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		Contains sufficient no. of test

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