TurbiMAX ASO

(Turbilatex / Immunoturbidometric)

ORDERING INFORMATION

Ref.No.	Pack Size	Presentation
AVASOT- 50	50 ml	Two Liquid Reagents with Calibrator
AVASOT- 100	2 x 50 ml	

INTENDED USE:

TurbiMAX ASO is an in-vitro diagnostic kit for the Quantitative determination of anti-streptolysin O (ASO) in human Serum.

PRODUCT FEATURES :

1. Quantitative Immunoturbidometric Assay.
2. Two liquid stable reagents (Turbilatex and Diluent).
3. Linearity : 800 IU/mL.
4. Calibrator provided (Liquid Stable).
5. No Prozone effect was detected upon 3000 IU/mL
6. Can be automated to semi and fully auto analyzers.

CLINICAL SIGNIFICANCE

SLO is a toxic immunogenic exoenzyme produced by β-heamolitic Streptococci of groups A, C and G. Measuring the ASO antibodies are useful for the diagnostic of rheumatoid fever, acute glomerulonephritis and streptococcal infections. Rheumatic fever is an inflammatory disease affecting connective tissue from several parts of human body as skin, heart, joints etc… and acute glomerulonephritis is a renal infection that affects mainly to renal glommerulus.

PRINCIPLE

The ASO-Turbilatex is a quantitative turbidimetric test for the measurement of ASO in human serum or plasma. Latex particles coated with streptolysin O (SLO) are agglutinated when mixed with samples containing ASO. The agglutination causes an absorbance change, dependent upon the ASO contents of the patient sample that can be quantified by comparison from a calibrator of known ASO concentration.

STORAGE AND STABILITY

All the components of the kit are stable until the expiration date on the labels when stored at 2-8ºC and the contaminations is prevented during their use. Do not freeze the latex and diluent.

KIT COMPONENTS

1. Diluent Reagent R1
2. Turbi Latex Reagent R2
3. ASO Calibrators : Concentration as stated on the label

COMPOSITION

Diluent (R1)	Tris buffer 20 mmol/L, pH 8.2. Sodium azide 0.95 g/L.
Latex (R2)	Latex particles coated with streptolysin O, pH 10.0. Sodium azide 0.95 g/L.
ASO-CAL	Liquid Stable Calibrator.

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

Laboratory Instrumentation, Spectrophotometer UV/VIS with thermostatic cuvette holder or clinical chemistry analyzer: semi auto, calibrated micropipettes, glass or high quality polystyrene cuvettes, test tube/rack, heating bath controls, saline.

REAGENT DETERIORATION

Discard reagent if blank reagent absorbance exceeds 1.3 at 546 nm against Distilled water.

WARNING & PRECAUTIONS

- Reagent may contain some non reactive and preservative components. It is recommended to handle carefully, avoiding contact with skin and ingestion.
- Specimen should be considered infectious and handled appropriately.
- Contamination by soap or glycerol will affect this assay.
- Perform the test according to the general " Good Laboratory Practice" GLP

SPECIMEN COLLECTION & STORAGE

Fresh serum. Stable 7 days at 2-8ºC or 3 months at –20ºC.
Samples with presence of fibrin should be centrifuged before testing.
Do not use highly hemolized or lipemic samples.

SYSTEM PARAMETERS :

Reaction Type	:	Fixed Time / Initial Rate / Two Point Kinetic
Reaction Direction	:	Increasing
Sample Volume	:	10 µl
Working Reagent Volume	:	1000 µl
Wave Length	:	546 nm (530-550 nm)
Calibrator Conc.	:	**Printed on the vial**
Flow Cell Temp.	:	37^0C
Linearity	:	800
Zero setting with	:	Distilled Water
Units	:	IU/mL
Delay	:	10 sec.
Interval	:	120 sec

TEST PROCEDURE

Pipette into test tubes labeled Calibrator (C) and Test (T).

Reagent	(C)	(T)
Buffer Reagent R1	800 µl	800 µl
ASO Calibrator	10 µl	-
Sample	-	10 µl
Latex Reagent R2	200 µl	200 µl

Mix well and read absorbances of Calibrator (C) and Test (T) against distilled water at 546 nm (530-550 nm) as follows:

Initial absorbance A1 -exactly after 10 sec.
Final absorbance A2 - exactly 120 sec. after A1
Determine ΔA for Calibrator (C) and Test (T)

CALCULATIONS :

$$\text{ASO Conc.: (IU/mL)} = \frac{(A2\text{-}A1)\ \text{Sample}}{(A2\text{-}A1)\ \text{Calibrator}} \times \text{Calibrator Concentration (Printed on the vial)}$$

EXPECTED VALUES

Normal values up to 200 IU/ml (adults) and up to 150 IU/ml (children < 5 years old) Each laboratory should establish its own reference range.

QUALITY CONTROL & CALIBRATION

Control sera are recommended to monitor the performance of manual and automated assay procedures. Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

Calibration

Use ASO calibrator, which is ready to use. The calibration in the automated analyzer is stable for 2 week which a new curve must be generated. Re-calibrate when control result are out of specified tolerances, when using different lot of reagent and when the instrument is adjusted.

PERFORMANCE CHARACTERESTICS:

1. Linearity
Linearity : 800 IU/mL

2. Sensitivity/ Limit of Detection (LOD)
The lower limit of detection is 10 IU/mL

3.Interferences:
Hemoglobin (10 g/l), bilirubin (20 mg/dl) and lipemia (10 g/l) do not interfere.

4. Precision: The reagent has been tested for 20 days, using three levels of serum in a EP5-based study (NCCLS).

Intra-Assay

N=10	Mean (IU/mL)	SD (IU/mL)	CV%
Control serum 1	135	1.5	1.11
Control serum 2	236	1.2	0.51
Control serum 3	372	1.95	0.52

Inter-Assay

N=10	Mean (IU/mL)	SD (IU/mL)	CV%
Control serum 1	135.5	1.61	1.19
Control serum 2	237.2	1.32	0.56
Control serum 3	373.6	2.2	0.58

5. Method Comparison:
Results obtained using this reagent (y) were compared to those obtained using a commercial reagent (x) with similar characteristics. 86 samples ranging from 1 to 180 IU/mL of ASO were assayed. The correlation coefficient (r) was 0.95 and the regression equation y = 0.797x -1.075.

The results of the performance characteristics depend on the analyzer used.

LIMITATIONS (calibration curve): 10-800 IU/ml, under the described assay conditions. Samples with higher concentrations should be diluted 1/5 in saline (10 parts serum sample + 40 parts normal saline ex: 10µl serum sample+40 µl saline) and retested again and the results should be multiplied by 5. The linearity limit and measurement range depends on the sample to reagent/ratio, as well as the analyzer used. It will be higher by decreasing the sample volume, although the sensitivity of the test will be proportionally decreased.

WASTE DISPOSAL

Reagents must be disposed off in accordance with local regulations.

REFERENCE

1. Haffejee I, Quarterly Journal of Medicine 1992, New series 84; 305: 641 – 658.
2. Alouf Jodeph E. Pharma Ther 1980; 11: 661-717.
3. M Fasani et al. Eur J Lab Med 1994; vol2.nº1: 67.
4. Todd E W. J Exp Med 1932; 55: 267 - 280.
5. Klein, GC. Applied Microbiology 1970; 19:60-61.
6. Klein GC. Applied Microbiology 1971; 21: 999-1001.
7. Young DS. Effects of drugs on clinical laboratory test, 4th ed. AACC Press, 1995.

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
	Contains sufficient no. of test		

Ver. : 05/01-26

Manufactured in India by :
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