ASO (ANTI-STREPTOLYSIN O) (TURBI LATEX) TEST

(Turbi Latex Method)

SAWIN BIOMEDICALS PVT LTD

INTENDED USE

This reagent is used for the quantitative determination of anti-streptolysin O (ASO) in human Serum.

CLINICAL SIGNIFICANCE

Streptolysin "O" is a toxic immunogenic exoenzyme produced by haemolytic Streptococci of groups A, C and G. Measuring the ASO antibodies are useful for the diagnosis of rheumatoid fever, acute glomerulonephritis and streptococcal infection. 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 glomerulus.

PRINCIPLE

The reagent consists of a suspension of latex particles of homogeneous size sensitized with anti-ASO, capable of aggregation in the presence of ASO. This aggregation process produces an increase in the size of the latex particles which in turn produces an increase in the Absorbance of the system.

REAGENTS / KIT CONTENTS :

Reagent Name	Storage Temperature
R1-ASO Buffer	2-8°C.
R2-ASO Latex	2-8°C.
ASO Calibrator	2-8°C.

REAGENT PREPARATION, STORAGE AND STABILITY

The reagents are ready to use and usable up to the expiration date when stored at 2-8°C. The reagents are stable for 10 days on board the analyser at 2-8°C. Protect from light and avoid contamination. Assay can be performed with use of separate R1-ASO Buffer and R2-ASO Latex or with use of working reagent.

Bring reagents to RT before use; when unused, store at 2-8°C.

Working reagent Preparation: for working reagent preparation mix gently **4 parts** of **R1-ASO Buffer** with **1 part** of **R2-ASO Latex** without foaming. This working reagent is stable for 7 days when stored at 2-8°C.

SPECIMEN SAMPLES

Fresh Serum or stored at 2-8°C for no longer than 48 hrs. It is necessary to freeze the sample when the assay is to be carried out after that period of time. Discard contaminated or haemolysed sera.

EXPECTED RANGE :

Up to 200 IU/ml

These values are for orientation purpose; each laboratory should establish its own reference range.

LINEARITY :

This method is linear up to 800 IU/ml.

SYSTEM PARAMETERS:

Method	Fixed Time (2-Point)
Reaction Slope	Increasing
Wavelength	546 nm
Zero Setting	Distilled Water
Temperature Setting	37° C
Delay Time	10 secs
Read Time	120 secs
Sample Volume	05 µl
Reagent Volume	500 µl (R1 400 µl +R2 100µl)
Standard Concentration	Refer Standard vial
Units	IU/ml
Linearity	800 IU/ml

PLOTTING OF MULTIPOINT CURVE

The ASO (Anti-Streptolysin O) (Turbi Latex) Test is based on Non-Linear reactions, hence it is strongly recommended to run Multi-standard mode to plot the Multi-point curve to have better accuracy and precise result.

Serial dilution sequence					
Reagent	1st	2nd	3rd	4th	5th
ASO Calibrator	100 µl	50 µl from 1st tube	50 µl from 2nd tube	50 µl from 3rd tube	50 µl from 4th tube
Normal saline	0	50 µl	50 µl	50 µl	50 µl
Ratio of Dilution	Neat	1/2	1/4	1/8	1/16

ASSAY PROCEDURE

Take in to a clean glass tubes :

Reagent	Calibartor(C)	Test (T)
R1-ASO Buffer	400 µl	400 µl
R2-ASO Latex	100 µl	100 µl
Bring upto the temperature of determination. Then add		
ASO Calibrator	05 µl	---
Sample	---	05 µl
Mix well, after about 10 sec. (37°C) read absorbance A1 of Calibrator (C) and Test (T) against distilled water or air at 546 nm. After exactly 120 sec. (for all temperature) read absorbance A2 of Calibrator (C) and Test (T). Calculate ΔA/min. (A2-A1) for the Calibrator (C) and Test (T).		

CALCULATION

$$\text{ASO Conc.: (IU/ml)} = \frac{\Delta\text{ A Test}}{\Delta\text{ A Calibrator}} \text{ X Calibrator Concentration}$$

NOTE

Professional Use In-Vitro Diagnostic Test Kits.

Each laboratory should establish its own normal range due to variations in inter - laboratory assay conditions.

To ensure adequate quality control, each run should include a normal and abnormal assayed control. If commercial controls are not available it is recommended that known value samples to be aliquot, frozen and used as controls.

WARNING AND PRECAUTIONS

This *in vitro* diagnostic reagents to perform testing are handled by entitled and professionally educated person only. In vitro diagnostic reagents can be hazardous. Avoid inhalation and contact with eyes and skin. Handle according to universal precautions and good laboratory practices.

Use separate micro pipette tips for reagent, standard & specimen to avoid contamination.

WASTE MANAGEMENT

Please refer to local legal requirements.

BIBLIOGRAPHY:

1) Manual of clinical lab. Inmuno., ED by Rose, N.R., Friedman, H., Fahey, J.L.,3a ed. 336-339.
2) Wannamaker, L.W., Ayoub, E.M.(1960). Circulation, 21, 614.
3) Klein, G.C., Baker, C.N., Jones, W.C. (1971). Appl. Microbiol. V21 (6), 999-1001.
4) Winkles, J., Lunec, J., Deverill, I. (1987). Clin. Chem. 33 (5), 685 - 689. 5)Winkles, J.W., Lunec, J., Gray, L. (1989). Clin. Chem.35 (2), 303 – 307.
7) young DS. Effects of drugs on clinical laboratory tests, 5th ed.

PRODUCT CODE	PACK SIZE
10009	50 ml

SYMBOLS USED ON LABELING IN BOX, BOTTLE LABEL

Symbol	Meaning	Symbol Location
	Manufacturer	R1, R2 & Calibrator Bottle Labels, Primary Box Label
	5.1.3 Date of Manufacture	R1, R2 & Calibrator Bottle Labels, Primary Box Label
	5.1.4 Use by Date	R1, R2 & Calibrator Bottle Labels, Primary Box Label
LOT	5.1.5 Batch Code	R1, R2 & Calibrator Bottle Labels, Primary Box Label
REF	5.1.6 Catalogue Number	Primary Box Label
	5.3.1 Fragile, Handle with care	Secondary Box
	5.3.2 Keep away from Sunlight	Primary & Secondary Box
	5.3.4 Keep Dry	Secondary Box
	5.4.3 Consult Instructions for use or consult electronic Instructions for use	Primary Box
	5.4.4 Caution	Primary Box
IVD	5.5.1 In Vitro Diagnostic Medical Device	Primary Box

Mfg. Lic. No.: MFG/IVD/2024/000109

Manufactured by : **M/s. SAWIN BIOMEDICALS PVT. LTD.**

Plot No: M82/2,Medical Devices Park, Sultanpur, Ameenpur Mandal, Sangareddy Dist - 502 319, Hyderabad, Telangana, INDIA..

✆ : +91 8455 - 240822 / +91 7816 075705, E-mail : info@sawinbio.com / www.sawinbio.com.

***** AN ISO 13485 CERTIFIED COMPANY *****

Rev.A