ImmunoScience INDIA

ImmunoTurbi

ASO

QUANTITATIVE TURBIDIMETRIC TEST FOR DETERMINATION OF ANTISTREPTOLYSIN O

For *In-Vitro* Diagnostic Use Only **Store at 2°C to 8°C**

OVERVIEW

Antistreptolysin O Latex is used for the determination of anti- streptolysin O (ASO) in human serum. ASO test method is based on an immunologic reaction between streptococcal exotoxins bound to biologically inert latex particles and streptococcal antibodies in the test sample.

ASO stands for Antistreptococcal O and it is an antibody targeted against streptolysin O, a toxic enzyme produced by group A Streptococcus bacterium. ASO and anti - DNase are the most common of several antibodies that are produced by the body's immune system in response to a strep infection with group A Streptococcus. This test measures the amount of ASO in the blood.

INTENDED USE

Quantitative determination of Antistreptolysin O in human Serum/Plasma.

This test is for in vitro diagnostic use only.

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 sample containing ASO. The agglutination causes an absorbance change, dependent upon the ASO content of the patient sample that can be quantified by comparison by comparison from calibrator of known ASO concentration.

CONTENTS OF KIT

1. Latex Diluent (R1)
2. Latex Reagent (R2)
3. ASO Calibrator (R3)
4. Pack inserts

OPTIONAL MATERIAL REQUIRED

1. Semi-automatic or Fully Automated Biochemistry Analyzer
2. PPEs (Disposable Gloves, Mask, Safety Goggles, Apron)
3. Biohazard Dust Bin.
4. Test Tubes
5. Micropipettes

PRECAUTIONS /KIT STORAGE AND STABILITY

1. Please read all the information in this package insert before performing the test.
2. Do not use after the expiration date.
3. Store in between temperature 2°C to 8°C.
4. Do not use if damaged or leaked.
5. Do not open until you are ready to start the test.
6. Keep out of the reach of children.

WARNINGS

1. Do not reuse the tested reagent.
2. Follow the instruction to get accurate results.
3. Use appropriate personal protective equipment.
4. Dispose the leftover and used reagents and samples hygienically in biohazard waste.
5. Treat samples and reagent reaction volume as potentially infectious. Avoid contact with skin.
6. For in vitro diagnostic use. Not to be taken internally.
7. Do not mix the specimen sample or interchange the different specimen.
8. Do not use the reagents of other lots in combination with the kit.
9. Discard the remaining reagent in the kit.
10. The manufacturer and distributor of this product shall not be liable for any loses, liability, claims, costs or damages whether director cons sequential rising out for related to an incorrect diagnosis.

SPECIMEN COLLECTION

1. Fresh serum or plasma shall be used.
2. Serum shall be separated from freshly collected blood in plain tube or clot activator tube.
3. Freshly collected EDTA blood can be used to separate plasma for testing.
4. The samples stored at 2-8ºC for 2 to 3 days can also be used.
5. Do not use highly haemolized or lipemic samples.

REAGENT PREPARATION

Working reagent Preparation: Mix the reagent R1 & R2 gently before use.

Mix the reagent R1 & R2 with the proportion as follows

8 ml Diluent + 2 ml Latex reagent (800µl+200µl).

Prepare the required amount of reagent only.

ASO calibrator: Ready to use value mention on vial in IU/ml.

ONE POINT CALIBRATION (LINEAR RANGE UP TO 120 IU/ML)

ASO Calibrator is ready to use.

TEST PROCEDURE

	CAL	SAMPLE
Sample	-	10 µl
Standard	10 µl	-
Reagent	1000 µl	1000 µl

1. Bring the kit component to room temperature before testing.
2. Take 400 µl of Diluent Reagent in cuvette and add 100 µl of latex reagent in it.
3. Put 5.0 µl of sample/control/calibrator in to the cuvette and mix.
4. Immediately read the absorbance of the reaction.
5. Read the absorbance of the reaction again after exactly 120 seconds.
6. Calculate concentration and interpret the results as per formula.

Wavelength	650 (600-650) nm
Cuvette	1 cm light path
Reaction Temperature	37 °c
Measurement	Against Distilled water
Reaction	2-point kinetics
Reaction Direction	Increasing
Sample / Reagent Ratio	1: 100
Linearity	800 IU/mL

INTERPRETATION OF RESULTS

1. Concentration = $\frac{\text{(A2-A1) Sample}}{\text{(A2-A1) Calibrator}}$ x Concentration of calibrator

Reference Values: - Normal: 0 to 200 IU/ml, Positive: Above 200 IU/ml

LINEARITY

The method is linear to a concentration of 800 IU/ml.

If the concentration exceeds this value, the sample should be diluted 1:3 with 0.9% saline solution and reassayed.

LIMITATIONS

1. As with all diagnostic tests, the test result must always be correlated with clinical findings.

2. The results of test are to be interpreted within the epidemiological, clinical and therapeutic context. When it seems indicated, reference correlation should be considered.

3. Any modification to the above procedure and / or uses of other reagents will invalidate the test procedure.

QUALITY CONTROL

Positive and Negative controls are recommended to monitor the performance of test procedure, as well as a comparative pattern for a better results interpretation.

REFERENCE VALUE

Reference Values: - Serum Plasma Adults: Upto 200 IU/ml, Children: Upto 100IU/ml
Each laboratory should establish its own reference range.

DISCLAIMER

The all precautions shall be taken to ensure the diagnostic ability and accuracy of this product. This product is utilized outside the control of manufacturer and distributors. The various factors including storage temperature, environmental conditions and procedure error may affect the results.

REFERENCES

1. M Fasani et al eur J Lab Med 1994; Vol 2 no 1-67.
2. Todd E W.J exp Med 1932;55:267-280

	In Vitro Diagnostic Use
	Manufacturer
	Manufacturing Date
	Expiry Date
	Lot Number
	Store at 2°C to 8°C
	Single Use
	Number of tests in the pack
	Do not use if pouch or kit damaged
	This side Up
	Read package insert before use