



INTENDED USE:

The reagent kit is intended for the "in vitro" quantitative determination of Antistreptolysin -O in serum

CLINICAL SIGNIFICANCE:

SLO is a toxic immunogenic exoenzyme produced by *fc*-haemolytic streptococci of group A, C, and G. Measuring the A80 antibodies are useful for the diagnosis 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 A80 in human serum or plasma. Latex particles coated with Streptolysin O (SLO) are agglutinated when mixed with samples containing A80. The agglutination causes an absorbance change dependent upon the A80 contents of the patient sample that can be quantified by comparison from a calibrator of known ASO concentration.

CONTENTS:

Reagent 1: Diluent

Reagent 2: Latex Antigen

Reagent 3: A30 Calibrator.

PREPARATION OF WORKING REAGENT:

Swirl the latex vial gently before use Prepare the necessary amount as follow: 1 ml latex reagent + 9 ml Diluent.

ASO calibrator: Reconstitute With 1.0 ml of

Distilled water. Mix gently and keep at room temperature for 10 minutes before use.

STORAGE & STABILITY:

Unopened reagents are stable till the expiry date stated on the label when stored at 2°8°C away from direct su -i light.

Working Reagent: Stable for 30 days at 2 °-8 ° C.
ASO Calibrator :Stable for 1 month at 2-8°C or 3 months at 20°C. . Do not freeze; frozen latex or diluent could change the functionality of the test. 2

MATERIALS REQUIRED BUT NOT PROVIDED:

- Clean & Dry Glassware.
- Laboratory Glass Pipettes or Micropipettes & Tips.
- Bio- Chemistry Analyzer.

SAMPLES:

Fresh serum stable for 8 days at 2 -8°C or 3 months at -20° C. Samples with presence of fibrin should be centrifuged before testing. Do not use highly hemolyzed or lipemic samples.

GENARAL PARAMETERS

Reaction Type	Fix Time
Wave Length	546 nm (530-550 nm)
Cuvette Temperature	37°C
Delay Time	5 Sec.
Read Time	120Sec
Sample Volume	10 µl
Reagent Volume	1ml
Calibrator Concentration	AsMentioned on Calibrator vial
Zero Setting	Deionised Water
Light Path	1 cm

PROCEDURE

Reagent	Calibrator	Sample
Working Reagent	1ml	1ml
Calibrator	10 ul	
Sample		10 ul

Mix and read the absorbance after 5 sec. (A1) and after 120 Sec. (A2) of the sample (A1).

CALCULATION OF RESULTS:

$ASO \text{ IU/ml} = \frac{(A2 - A1) \text{ Sample}}{(A2 - A1) \text{ Calibrator}} \times \text{Calibrator Concentration}$

NORMAL VALUE:

Up to 200 IU/ml (adults) and 100IU/ ml (children <5 years of age) Each laboratory should establish its own reference range.

LINEARITY:

The reaction is linear up to 800 IU/ml.

PERFORMANCE CHARACTERISTICS:

1. Linearity Limit: Up to 800 IU/ml, under the described assay conditions.
2. Detection Limit : Values less than 20 IU/ml give non reproducible results.
3. Prozone Effect: No prozone effect was detected up to 2000IU/ml.

QUALITY CONTROL:

It is recommended that each laboratory should prepare their own quality control scheme.

LIMITATION & PRECAUTIONS:

Storage conditions mentioned on the kit must be strictly adhered. Bilirubin (20mg/dl) Haemoglobin (10 g/L), Lipemia (10 g/l and Rheumatoid factors (300 IU/ml) do not interfere. Other substances may interfere.

REFERENCES:

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