ASO – TURBILATEX

IMMUNOPAK

(Latex Turbidimetric Test)

Last update 09-2020

Ref. IM-AST.081, 1x50 ml

INTENDED USE

Quantitative determination of anti-streptolysin 0 (ASO) IVD

DIAGNOSTIC SIGNIFICANCE

SLO is a toxic immunogenic exoenzyme produced by 3-hemolytic Streptococci of groups A, C and G. Measuring the ASO antibodies are useful for the diagnostic of streptococcal infections, acute glomerulonephritis and rheumatoid fever. 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 0 (SLO) are agglutinated when mixed with samples containing ASO & the agglutination causes an absorbance change, dependent upon the ASO contents of the patient's sample that can be quantified by comparison from a calibrator of known ASO concentration.

PRESENTATION

All the reagents to be stored at 2-8°C	No. of Bottles / Vials
• R1 Diluent	1x50 ml
• R2 Latex	1x45 ml
• ASO Calibrator	1x5 ml
	1

* Value may vary from lot to lot.

PRECAUTION

Components from human origin have been tested and found to be negative for the presence of HBsAg, HCV, and antibody to HIV (1/2). However handle cautiously as potentially infectious.

PREPARATION OF WORKING REAGENT

Mix 0.9 ml of Diluent (R1) with 0.1 ml of latex (R2).

PREPARATION OF WORKING CALIBRATOR

Reconstitute with 1.0 ml of distilled water. Mix gently and incubate at room temperature for 10 minutes before use.

REAGENT STORAGE AND STABILITY

All reagents are stable at 2-8°C till the expiry date mentioned on the label. Do not freeze; frozen Latex or Diluent could change the functionality of the test.

Reagent deterioration: Presence of particles and turbidity in diluent.

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.

SPECIMEN COLLECTION

Fresh serum : Stable 7 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 hemolysed or Lipemic samples.

REACTION PARAMETERS

• Type of Reaction	:	Two Point / Fix Time
• Wavelength	:	540 nm (530-550)
• Flow cell temperature	:	37°C
• Delay Time	:	5 Sec.
• Read Time	:	120 Sec.
• Sample/Calibrator Volume	:	10µl
• Reagent Volume	:	1 ml
• Zero setting with	:	Distilled Water
• Light Path	:	1 cm
• Calibrator concentration	:	319 IU/ml

TEST PROCEDURE

Pipette In Test Tube	TEST
Working Reagent (ml)	1.0
Calibrator or sample (µl)	10

Mix and read the absorbance immediately (A1) and after 2 minutes (A2) of the sample addition.

TEST RESULTS

$$\text{ASO IU/ml} = \frac{(A_2\text{-}A_1)\ \text{sample}}{(A_2\text{-}A_1)\ \text{calibrator}} \text{X Calibrator concentration}$$

QUALITY CONTROL

Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

LIMITATIONS FOR INTERFERENCES

Bilirubin (<20 mg/dL), Hemoglobin (<10 g/L), Lipemia (<10 g/L) and rheumatoid factors (600 IU/mL) do not interfere. Other substances may interfere.

NORMAL VALUE

Adults: Up to 200 IU/ml

Children (<5 years): Up to 100 IU/ml

Each laboratory should establish its own reference range.

PERFORMANCE CHARACTERISTICS

1. Linearity: Up to 800 IU/mL, under the described assay conditions. Samples with higher concentrations, should be diluted 1/3 in NaCl 9 g/L and retested again. The linearity limit depends on the sample / 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.
2. Detection limit: Values less than 20 IU/mL give non-reproducible results.
3. Sensitivity : Δ 0.73 mA / IU/ml

NOTE

Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

REFERENCES

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

Regd. Office.3/7, B.I.D.C., Gorwa, Vadodara 390 016 (INDIA)
Web: www.reckondiagnostics.com Ph: +91·265·2281631
Email: mail@reckondiagnostics.com
An ISO 13485:2016 Certified Company

RECKON DIAGNOSTICS P. LTD.
THE TEST OF CONFIDENCE - SINCE 1989