GENESIS

Instructions For Use

ASOT Turbilatex (4+1) (Turbidimetric Method)

Cat no.	size
6101 101	50 Test
6101 102	100 Test
6101 103	200 Test

INTENDED USE

ASOT Turbi Latex Reagent is intended for the in vitro Quantitative diagnostic determination of Antistreptolysin-O in human serum.

PRINCIPLE OF THE METHOD

The ASO Turbilatex is a quantitative turbidmetric 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.

CLINICAL SIGNIFICANCE

SLO is a toxic immunogenic exoenzyme produced by β-hemolytic 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.

REAGENTS

Reagent (R1)	Tris buffer 20 mmol/L, pH 8.2. Sodium azide 0.95 g/L.
Reagent (R2)	**Latex particles coated with streptolysin O, pH 10.0. Sodium azide 0.95 g/L.**
Calibrator	Calibrator. Human serum. ASO concentration is stated on the vial label.

PRECAUTIONS AND WARNINGS

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

CALIBRATION

Use ASO Calibrator.
The sensitivity of the assay and the target value of the calibrator have been standardized against the ASO International Calibrator (WHO).
Recalibrate when control results are out of specified tolerances, when using different lot of reagent and when the instrument is adjusted.

PREPARATION

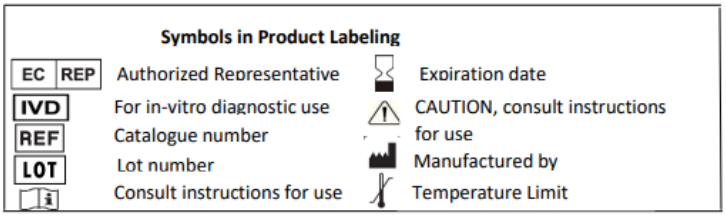
Working reagent: Swirl the latex vial gently before use. Prepare the necessary amount as follow:

1 part of Latex Reagent + 4 part of Diluent
ex: 100 µL Latex reagent + 400 µL diluent

ASO Calibrator: Reconstitute with 1.0 mL of distilled water. Mix gently and incubate at room temperature for 10 minutes before use.

STORAGE AND STABILITY

All the components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8ºC and contaminations prevented during their use. Do not use reagents over the expiration date.
Reagent deterioration: Presence of particles and turbidity.
Working reagent: Stable for 30 days at 2-8ºC.
Reconstituted Calibrator: Stable for 1 month at 2-8ºC or 3 months at –20ºC.
Do not freeze; frozen Latex or Diluent could change the functionality of the test.



ADDITIONAL EQUIPMENT

- Thermostatic bath at 37ºC.
- Spectrophotometer or photometer thermostat able at 37ºC with a 540 nm filter.

SAMPLES

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

PROCEDURE

1. Bring the working reagent and the photometer (cuvette holder) to 37ºC.
2. Assay conditions:
   Mode: fixed time
   Wavelength: 540nm(530-550)
   Temperature: 37ºC
   Cuvette light path: 1 cm
   Delay time: 5 sec
   Measuring time: 120 sec
3. Adjust the instrument to zero with distilled water.
4. Pipette into a cuvette:

R1(µL)	400
R2(µL)	100
Calibrator or sample (µL)	5

5. Mix and read the absorbance (A1) after **5 sec** ,and after **2 minutes** read the absorbance (A2).

CALCULATIONS

$$\frac{(A2\text{-}A1)\ \text{sample}}{(A2\text{-}A1)\ \text{calibrator}} \times \text{Calibrator concentration} = \text{IU/mL ASO}$$

QUALITY CONTROL

Control sera are recommended to monitor the performance of manual and automated assay procedures. It should be used the controls ASO/CRP/RF Level (Low) and Level (High).
Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

REFERENCE VALUES

Normal values up to 200 IU/mL (adults) and 100 IU/mL (children < 5 years old).
Each laboratory should establish its own reference range.

PERFORMANCE CHARACTERISTICS

1. **Linearity limit:** Up to 850 IU/mL, under the described assay conditions. Samples with higher concentrations, should be diluted **1/3** in physiological saline and retested again. The linearity limit depends on the sample/reagent ratio, as well 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. **Prozone effect:** No prozone effect was detected up to **3000** IU/mL.
4. **Sensitivity:** 0.73 mA. IU/mL.
5. **Precision:**

	Intra-assay (n=10)			Inter-assay (n=10)		
Mean (IU/mL)	135	236	372	135	236	372
SD	3.4	5.4	5.9	7.9	13.2	17.7
CV	2.5	2.3	1.6	5.9	5.5	4.8

6. **Accuracy:** Results obtained using this reagent (y) were compared to those obtained using a commercial reagent (x) with similar characteristics. 80 samples ranging from 20 to 800 IU/mL of ASO were assayed. The correlation coefficient (r) was 0.98 and the regression equation

y = (1.305x –7.65).

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

INTERFERENCES

Bilirrubin (20 mg/dL), hemoglobin (10 g/L), lipemia (10 g/L) and rheumatoid factors (600 IU/mL), do not interfere. Other substances may interfere.

NOTES

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

BIBLIOGRAPHY

Haffejee I, Quarterly Journal of Medicine 1992, New series 84; 305: 641 – 658

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