ASO TURBILATEX SYSTEM PACK

Unicorn 480, Bonavera Chem 480 & Bonavera Chem 400

(Fully Auto Biochemistry Analyzer)

Code	Product Name	Pack Size
UNI08	ASO Turbilatex System Pack	1 X 40+1 X 10 ml

BEACON

Quantitative determination of anti-streptolysin O (ASO)

IVD

Store 2–8°C.

PRINCIPLE OF THE METHOD

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 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-heamolitic 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

Diluent (R1)	Tris buffer 20 mmol/L, pH 8.2. Preservative.
Latex Reagent (R2)	Latex particles coated with streptolysin O, pH 10.0 Preservative.
Calibrator	Calibrator ASO concentration is stated on the vial label.

PRECAUTIONS

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.

CALIBRATION

Use ASO Calibrator Provided with kit.
The sensitivity of the assay and the target value of the calibrator have been standardized against the ASO International Standard from NIBSC 97/662.

PREPARATION

ASO Calibrator: Redy to use

STORAGE AND STABILITY

All the components of the kit are stable until the expiration date on the label when stored tightly closed at 2–8°C and contaminations prevented during their use. Do not use reagents over the expiration date.

On board stability: Min 30 days if refrigerated (2-10°C) and not contaminated.

Reagent deterioration: Presence of particles and turbidity.
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.

ADDITIONAL EQUIPMENT

- Thermostatic bath at 37°C.
- Spectrophotometer or photometer thermostatable at 37°C with a 540 nm filter.

SAMPLES

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 hemolized or lipemic samples.

QUALITY CONTROL

Control sera are recommended to monitor the performance of manual and automated assay procedures.
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)[6].
Each laboratory should establish its own reference range.

PERFORMANCE CHARACTERISTICS

1. **Linearity limit:** 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 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 1000 IU/mL.
4. **Sensitivity:** Δ 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 similer characteristics. 80 samples ranging from 20 to 800 IU/mL of ASO were assayed. The correclation coefficient (r) was 0.98 and the regression equation y = 1.305x –7.65.

The results of the perfomance 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[7].

NOTES

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

Parameter for Unicorn 480, Bonavera Chem 480 &

Bonavera chem 400 (Fully Auto Biochemistry Analyzer)

TEST NAME	ASO TURBILATEX
FULL NAME	ASO TURBILATEX
PRI WAVE	546 nm
SEC WAVE	-
ASSAY/POINT	FIXED TIME
START	10
END	23
DECIMAL	2
UNIT	IU/ML
LINEARITY RANGE LOW	20
LINEARITY RANGE HIGH	800
SAMPLE VOLUME	2 µ l
REAGENT 1 (R1) VOLUME	160 µl
REAGENT 1 (R2) VOLUME	40 µl
SUBSATRATE DEPLETED	-
LINEARITY	800 IU/ML
OUT OF LINEARITY RANGE	-
CALIBRATION TYPE	2 Point linear
POINTS	2
BLANK TYPE	Reagent
CONCENTRATION BLANK	0.00
CONCENTARTION STD	Refer calibrator value sheet.
SAMPLE VOLUME	2 µ l

BIBLIOGRAPHY

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3. M Fasani et al. Eur J Lab Med 1994; vol2.nº1: 67.
4. Todd E W. J Exp Med 1932; 55: 267 - 280.
5. Klein, GC. Applied Microbiology 1970; 19:60-61.
6. Klein GC. Applied Microbiology 1971; 21: 999-1001.
7. Young DS. Effects of drugs on clinical laboratory test, 4th ed. AACC Press, 1995.

IVD

SYMBOLS USED ON LABELS

REF Catalogue Number

Manufacturer

See Instruction for Use

LOT Lot Number

CONT Content

Storage Temperature

Expiry Date

IVD In Vitro Diagnostics