ASO TURBILATEX SYSTEM PACK

(LATEX TURBIDIMETRY)

B Auto 200, Unicorn 230, Unicorn 120 & Bonavera Chem 200 , Beaconic chem 200, Beaconic B200, Beaconic analyzer 120, Bonavera chem 100 (Fully Auto Biochemistry Analyzer)

Code	Product Name	Pack Size
BA208	ASO Turbilatex System Pack	1x20 + 1x5 ml

INTENDED USE

For the quantitative determination of Antistreptolysin -O activity in human serum or plasma.

PRINCIPLE

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 Streptococei 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 glomerulonephits is a renal infection that affects mainly to renal glommerulus.

REAGENT COMPOSITION

Reagent 1 Diluent	Tris buffer 20 mmol/L, pH 8.2. Preservative
Reagent 2 Latex Reagent	Latex particles coated with streptolysin O, pH 10.0 Preservative.
Reagent 3 Calibrator	Calibrator - ASO concentration is stated on the vial label.

REAGENT PREPARATION

ASO Calibrator : Redy to use

STABILITY AND STORAGE

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.

Onboard stability: Min 30 days if refrigerated (+8-+14°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.

SPECIMEN COLLECTION AND HANDLING

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 hemolyzed or lipemic samples.

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.

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.

EXPECTED 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 DATA

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/mLgive non-reproducible results.

3. Prozone effect: No prozone effect was detected up to 1000 IU/mL.

4. Sensitivity: Δ0.73mA. 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. Comparison : 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.

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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.

WARNING AND 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. MSDS will be provided on request.

WASTE MANAGMENT

Please refer to local legal requirements.

NOTE

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

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Test Name	ASO TURBILATEX
Full Name	ASO TURBILATEX
Pri Wave	546 nm
Sec Wave	-
Assay/point	FIXED TIME
Start	18
End	25
Decimal	2
Unit	IU/ML
Linearity Range Low	20
Linearity Range High	800
Sample Volume	2 µl
Reagent 1 (R1) Volume	160 µl
Reagent 2 (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
Concentration Std	Refer calibrator value sheet

BIBLIOGRAPHY

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2. Alouf Jodeph E. Pharma Ther 1980; 11: 661-717.
3. M Fasani etal. Eur J Lab Med 1994; vol2.n°1: 67.
4. Todd E W. J Exp Med 1932, 55: 267 - 280.
5. Klein, GC. Applied Microbiology 1970; 19:60-61.
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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

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