DIAGNOSTICA PRODUCTS

Liquid Reagents – ready to use

ASO-turbilatex (4+1)

Diagnostic reagent for the quantitative in vitro determination of ASO (Anti-Streptolysin O) in human serum by turbilatex assay.

Ref.No.	Kit Size	Content
DIA020060	50 ml	2x20 ml R1 + 1x10 ml R2
DIA020061	5 x 20 ml	4x20 ml R1 + 1x20 ml R2
DIA020062	5 x 25 ml	4x25 ml R1 + 1x25 ml R2

Additionally offered:

DIA040120	1 x 1 mL	**ASO Turbilatex Calibrator**
DIA030140	1 x 1 mL	**ASO Turbilatex Control**
DIA030160	1 x 1 mL	**Triple Turbilatex Control**

GENERAL INFORMATION

Method Immunoturbidimetric
Reaction Nonlinear, endpoint
Wavelength 540 nm (530-550)
Assay Temperature 37 °C
Sample Serum
Linearity limit Up to 800 IU/mL
Sensitivity 0.73 IU/mL
Hook Effect No risk

Automated Test Procedure
Instrument dependent – please ask for applications

REAGENT COMPOSITION

COMPONENTS	
Latex (R2)	
Latex particles coated with streptolysin O	PH 10.0
	Preservative
Diluent (R1)	
Tris buffer	20 mmol/l
	PH 8.2
	Preservative

REAGENT PREPARATION

The reagents are liquid and ready to use.

REAGENT STABILITY AND STORAGE

Conditions: Protect from light. Close immediately after use.

Stability: at 2 – 8 °C up to the expiration date
at 18 – 25 °C 1 month

Do not freeze!

SAMPLE STABILITY AND STORAGE

Stability: at 2 – 8 °C 48 hours
at – 20 °C 3 months

Freeze only once!

TEST PRINCIPLE

The ASO-turbilatex is a quantitative turbidimetric test for the measurement of ASO in human serum or plasma. Latex particles coated with streptosin 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.

REFERENCE RANGE

Normal reference: 0 – 200 IU/mL
It is recommended that each laboratory establishes its own normal range.

MANUAL TEST PROCEDURE

Samples/Controls: ready to use
Adjust the instrument to zero with distilled water.

Pipette into test tubes:	Calibrators	Samples/Controls
Diluent R1	800 µL	1000 µL
Latex R2	200 µL	200 µL
Cal./Ctrls/Samples	10 µL	10 µL
Mix and read the absorbance immediately (A1) and after 2 minutes (A2) of the sample addition.		

CALCULATION

[(A2-A1) sample / (A2-A1) calibrator] x calibrator conc =mg/L ASO

PERFORMANCE CHARACTERISTICS

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.
Detection limit: Values less than 20 IU/mL give non-reproducible results.
Prozone effect: No prozone effect was detected up to 1000 IU/mL.
Sensitivity: Δ 0,73 mA. IU/mL.
Precision: The reagent has been tested for 20 days, using three different ASO concentrations in a EP5-based study.

EP5	CV (%)		
	+/- 100 IU/mL	+/- 200 IU/mL	+/- 400 IU/mL
Total	6,4%	5,7%	5,1%
Within Run	2,4%	1,7%	1,4%
Between Run	3,6%	4,2%	4,9%
Between Day	4,7%	3,5%	0,7%

Accuracy: Results obtained using this reagent (y) were compared to those obtained using a commercial reagent (x) with similar characteristics. 60 samples of different concentrations of ASO were assayed. The correlation coefficient (r) was 0.99 and the regression equation y = 0,915x –4,844.

INTERFERING SUBSTANCES

No interference up to:

Bilirubin	20 mg/dL	Hemoglobin	10 g/L
Lipemia	10 g/L	Rheumatoid Factor	600 IU/mL

QUALITY CONTROL

All Control sera with ASO values measured by this method may be used. We recommend the Diagnostica ASO Control, Protein Control and the Triple Control.

CALIBRATION

The assay requires the use of ASO serum Calibrators. We recommend the Diagnostica ASO Calibrator High.

AUTOMATION

Applications for automated systems are available upon request.

WARNINGS AND PRECAUTIONS

1. The ASO reagents are intended for in vitro diagnostic use only.
2. Sodium azide has been reported to form lead or copper azide in laboratory plumbing which may explode on percussion.
3. Each donor unit used in the preparation of the standards and controls was found to be negative for the presence of HIV antibodies, as well as for Hepatitis B surface antigen, using a method approved by the FDA

WASTE MANAGEMENT

Please refer to local requirements.

CE IVD 2°C 8°C

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