Antistreptolysin O FS*

Diagnostic reagent for quantitative in vitro determination of antistreptolysin O (ASO) in serum on photometric systems

Order Information

Cat. No.	Kit size					
1 7012 99 10 021	R1	5 x	25 mL	+ R2	1 x	25 mL
1 7012 99 10 930	R1	4 x	20 mL	+ R2	2 x	8 mL
1 7012 99 10 935	R1	2 x	20 mL	+ R2	1 x	8 mL
1 7010 99 10 059		5 x	1 mL	TruCal ASO: Calibrator set with 5 different levels		

Summary [1-3]

Antistreptolysins (ASL) are specific antibodies to extracellular products of Streptococcus pyogenes (Group A streptococcus: GAS), among which antistreptolysin O (ASO) is the one most used for clinical laboratory evaluation. Antistreptolysin O determination provides useful information for diagnosis and monitoring of human streptococcal infections such as in tonsillitis, otitis, erysipela, scarlet fever as well as connected diseases like rheumatic fever or glomerulonephritis. Antibodies against streptolysin O can be detected 1 – 3 weeks after infection with maximum levels reached at 3 – 6 weeks. Pathological ASO values always indicate the presence of a streptococcal infection whereas a negative result cannot exclude an existing or preceding GAS infection.

Method

Particle enhanced immunoturbidimetric test

Principle

Determination of the concentration of ASO via photometric measurement of the antigen-antibody-reaction of latex particles coated with streptolysin O and antibodies to streptolysin O present in the sample.

Reagents

Components and Concentrations

R1:	Phosphate buffer	pH 7.0	100 mmol/L
	NaCl		150 mmol/L
R2:	Latex particles coated with streptolysin O		
	Glycine buffer	pH 8.0	100 mmol/L
	NaCl		150 mmol/L

Storage Instructions and Reagent Stability

The reagents are stable up to the end of the indicated month of expiry, if stored at 2 – 8 °C and contamination is avoided. Do not freeze the reagents!

Warnings and Precautions

1. The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
2. In very rare cased, samples of patients with gammopathy might give falsified results [7].
3. Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents. For diagnostic purposes, the results should always be assessed with the patients' medical history, clinical examinations and other findings.
4. For professional use only!

Waste Management

Please refer to local legal requirements.

Reagent Preparation

The reagents are ready to use. The latex reagent (R2) must be carefully mixed before use.

Materials required but not provided

NaCl solution 9 g/L
General laboratory equipment

Specimen

Serum

Stability[4]:	2 days	at	20 – 25 °C
	2 days	at	4 – 8 °C
	6 months	at	–20 °C

Only freeze once!

Discard contaminated specimens!

Assay Procedure for Analyzers

Application sheets for automated systems are available on request.

Wavelength	500 – 600 nm
Optical path	1 cm
Temperature	37 °C
Measurement	Against reagent blank

	Blank	Sample or calibrator
Sample or calibrator	-	3 µL
Dist. water	3 µL	-
Reagent 1	250 µL	250 µL
Mix, incubate for 3 - 5 min., then add:		
Reagent 2	50 µL	50 µL
Mix, and read absorbance (A1). Incubate for a further 5 min. and read absorbance again (A2).		

ΔA= (A2 – A1) sample or calibrator

Calculation

The concentration of antistreptolysin O in unknown samples is derived from a calibration curve using an appropriate mathematical model such as spline. The calibration curve is obtained with five calibrators at different levels and NaCl solution (9 g/L) for determination of the zero value.
Stability of calibration: 4 weeks.

Calibrators and Controls

For the calibration of automated photometric systems the DiaSys TruCal ASO calibrator set is recommended. The assigned values of TruCal ASO have been made traceable to a commercially available standard material, traceable to the First International Standard as ASL reference standard. For internal quality control a DiaSys TruLab Protein control should be assayed. Each laboratory should establish corrective action in case of deviations in control recovery.

	Cat. No.	Kit size
TruLab Protein Level 1	5 9500 99 10 046	3 x 1 mL
TruLab Protein Level 2	5 9510 99 10 046	3 x 1 mL

* fluid stable

Performance Characteristics

Measuring Range

The test is developed to determine ASO concentrations within a measuring range from 7 – 800 IU/mL, at least up to the concentration of the highest calibrator. When values exceed this range the samples should be diluted 1 + 1 with NaCl solution (9 g/L) and the result multiplied by 2.

Prozone Limit

No prozone effect was observed up to an ASO concentration of 1500 IU/mL.

Specificity/Interferences

Due to its antibodies, DiaSys Antistreptolysin O FS is a specific immunoassay for Antistreptolysin O. No interference was observed by ascorbic acid up to 30 mg/dL, bilirubin up to 40 mg/dL, hemoglobin up to 500 mg/dL and lipemia up to 2000 mg/dL triglycerides. For further information on interfering substances refer to Young DS [5].

Sensitivity/Limit of Detection

The lower limit of detection is 7 IU/mL.

Precision (n = 20)

Intra-assay precision	Mean [IU/mL]	SD [IU/mL]	CV [%]
Sample 1	168	3.43	2.04
Sample 2	284	5.90	2.08
Sample 3	479	11.1	2.32

Inter-assay precision (daily calibration)	Mean [IU/mL]	SD [IU/mL]	CV [%]
Sample 1	170	5.06	2.98
Sample 2	267	8.21	3.08
Sample 3	481	12.8	2.65

Inter-assay precision (single calibration)	Mean [IU/mL]	SD [IU/mL]	CV [%]
Sample 1	165	5.84	3.54
Sample 2	275	8.82	3.20
Sample 3	472	15.8	3.34

Method Comparison

A comparison of DiaSys Antistreptolysin O FS (y) with a commercially available test (x) using 77 samples gave the following result: y = 0.89 x +1.80 IU/mL; r= 0.987

Reference Range [6]

Adults ≤ 200 IU/mL
Children ≤ 150 IU/mL

Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

Literature

1. Bisno AL. Group A infections and acute rheumatic fever. N Engl J Med 1991;325:783-93.
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3. Stevens DL. Invasive Group A streptococcus infections. Clin Infect Dis 1992;14:2-11.
4. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001. p. 16-7.
5. Young DS. Effects of Drugs on Clinical Laboratory Tests. 5th ed. Volume 1 and 2. Washington, DC: The American Association for Clinical Chemistry Press 2000.
6. Thomas L. Clinical Laboratory Diagnostics. Frankfurt: TH-Books Verlagsgesellschaft, 1998:1201-3.
7. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed 2007;45(9):1240-1243.

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