

Antistreptolysin O FS*

Diagnostic reagent for quantitative in vitro determination of antistreptolysin O (ASO) in serum on DiaSys respons[®]920

Order Information

Cat. No. 1 7012 99 10 921

4 twin containers for 100 determinations each

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

- The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
- To avoid carryover interference, please take care of efficient washing especially after use of interfering reagents. Please refer to the DiaSys respons[®]920 Carryover Pair Table. Carryover pairs and automated washing steps with the recommended cleaning solution can be specified in the system software. Please refer to the user manual.
- In very rare cases, samples of patients with gammopathy might give falsified results [7].
- 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 patient's medical history, clinical examinations and other findings.
- For professional use only!

Waste Management

Please refer to local legal requirements.

Reagent Preparation

The reagents are ready to use. The reagents must be carefully mixed before use. The bottles are placed directly into the reagent rotor.

Specimen

Serum

2 days	at	20 – 25°C
2 days	at	4 – 8°C
6 months	at	-20°C

Discard contaminated specimens. Freeze only once.

Calibrators and Controls

For calibration, 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 ASO reference standard. For internal quality control a DiaSys TruLab Protein control should be assayed. Each laboratory should establish corrective actions in case of deviations in control recovery.

	Cat. No.	Kit size
TruCal ASO (5 levels)	1 7010 99 10 059	5 x 1 mL
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

Performance Characteristics

Measuring range up to 700 IU/mL ASO, at least up to the concentration of the highest calibrator (in case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use the rerun function).	
Limit of detection**	3 IU/mL ASO
No prozone effect up to 1500 IU/mL ASO	
On-board stability	4 weeks
Calibration stability	4 weeks

Interferences < 10% by
Ascorbate up to 30 mg/dL
Bilirubin up to 60 mg/dL
Hemoglobin up to 400 mg/dL
Lipemia (triglycerides) up to 1600 mg/dL
For further information on interfering substances refer to Young DS [2].

Precision			
Within run (n=20)	Sample 1	Sample 2	Sample 3
Mean [IU/mL]	159	265	465
Coefficient of variation [%]	3.17	2.23	2.87
Between run (n=20)	Sample 1	Sample 2	Sample 3
Mean [IU/mL]	160	265	483
Coefficient of variation [%]	2.71	2.14	2.90

Method comparison (n=125)	
Test x	DiaSys ASO FS (Hitachi 917)
Test y	DiaSys ASO FS (respons [®] 920)
Slope	1.00
Intercept	8.50 IU/mL
Coefficient of correlation	0.996

** lowest measurable concentration which can be distinguished from zero mean + 3 SD (n=20) of an analyte free specimen

Reference Range [3]

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

- Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001; p. 16-7.
- 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.
- Thomas L. Clinical Laboratory Diagnostics. Frankfurt: TH-Books Verlagsgesellschaft, 1998; p. 1201-3.
- Bisno AL. Group A infections and acute rheumatic fever. N Engl J Med 1991; 325: 783-93.
- Curtis GD, Kraak WA, Mitchell RG. Comparison of latex and haemolysin tests for determination of anti-streptolysin O (ASO) antibodies. J Clin Pathol 1988; 41: 1331-3.
- Stevens DL. Invasive Group A streptococcus infections. Clin Infect Dis 1992; 14: 2 – 11.
- Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed 2007;45(9):1240-1243.

Manufacturer



DiaSys Diagnostic Systems GmbH
Alte Strasse 9 65558 Holzheim Germany

Antistreptolysin O FS

Application for serum

Test Details		Test Volumes		Reference Ranges	
Test	: ASO			Auto Rerun	<input type="checkbox"/>
Report Name	: Antistreptolysin O			Online Calibration	<input type="checkbox"/>
Unit	: IU/mL	Decimal Places	: 1	Cuvette Wash	<input type="checkbox"/>
Wavelength-Primary	: 578	Secondary	: 0	Total Reagents	: 2
Assay Type	: 2-Point	Curve Type	: Cubic Spline	Reagent R1	: ASO R1
M1 Start	: 19	M1 End	: 19	Reagent R2	: ASO R2
M2 Start	: 33	M2 End	: 33	Consumables/Calibrators:	
Sample Replicates	: 1	Standard Replicates	: 3	Blank /Level 0	: 0
Control Replicates	: 1	Control Interval	: 0	Calibrator 1	: **
Reaction Direction	: Increasing	React. Abs. Limit	: *	Calibrator 2	: **
Prozone Limit %	: 97	Prozone Check	: Lower	Calibrator 3	: **
Linearity Limit %	: 0	Delta Abs./Min.	: 0.0000	Calibrator 4	: **
Technical Minimum	: *	Technical Maximum	: *	Calibrator 5	: **
Y = aX + b	a = 1.0000	b = 0.0000		Calibrator 6	: **

*Technical limits are automatically defined by the software via the upper and lower calibrator level.

** Enter calibrator value.

Test Details		Test Volumes		Reference Ranges	
Test	: ASO				
Sample Type	: Serum				
Sample Volumes				Sample Types	
Normal	: 2.00 μ L	Dilution Ratio	: 1 X	<input checked="" type="checkbox"/> Serum <input type="checkbox"/> Urine <input type="checkbox"/> CSF <input type="checkbox"/> Plasma <input type="checkbox"/> Whole Blood <input type="checkbox"/> Other	
Increase	: 6.00 μ L	Dilution Ratio	: 1 X		
Decrease	: 2.00 μ L	Dilution Ratio	: 2 X		
Standard Volume	: 2.00 μ L				
Reagent Volumes and Stirrer Speed					
RGT-1 Volume	: 160 μ L	R1 Stirrer Speed	: High		
RGT-2 Volume	: 32 μ L	R2 Stirrer Speed	: High		

Test Details		Test Volumes		Reference Ranges	
Test	: ASO				
Sample Type	: Serum				
Reference Range	: DEFAULT				
Category	: Male				
Reference Range				Sample Types	
	Lower Limit (IU/mL)	Upper Limit (IU/mL)		<input checked="" type="checkbox"/> Serum <input type="checkbox"/> Urine <input type="checkbox"/> CSF <input type="checkbox"/> Plasma <input type="checkbox"/> Whole Blood <input type="checkbox"/> Other	
Normal	: 0.00	: 200.00			
Panic	: 0.00	: 0.00			