respons®910

Antistreptolysin O FS*

Diagnostic reagent for quantitative in vitro determination of antistreptolysin O (ASO) in serum on DiaSys respons®910

Order Information

Cat. No. 1 7012 99 10 921
4 twin containers for 100 tests each

Method

Particle enhanced immunoturbidimetric test

Principle

Determination of ASO concentration 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 cases, 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 patient's 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 reagents must be carefully mixed before use. The bottles are placed directly into the reagent rotor.

Specimen

Serum

Stability [1]:

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 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
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 from 38 IU/mL 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 rerun function).	
Limit of detection**	12 IU/mL ASO
No prozone effect up to 1500 IU/mL ASO	
On-board stability	6 weeks
Calibration stability	2 weeks

Interfering substance	**Interferences < 10%**	**ASO [IU/mL]**
Ascorbate	up to 30 mg/dL	148
Hemoglobin	up to 400 mg/dL	168
	up to 500 mg/dL	327
Bilirubin, conjugated	up to 40 mg/dL	155
	up to 40 mg/dL	310
Bilirubin, unconjugated	up to 40 mg/dL	153
	up to 40 mg/dL	308
Lipemia (triglycerides)	up to 1800 mg/dL	152
	up to 2000 mg/dL	313
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]	150	239	365
Coefficient of variation [%]	3.01	2.47	2.74
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [IU/mL]	130	260	366
Coefficient of variation [%]	3.23	2.85	3.07

Method comparison (n=101)	
Test x	DiaSys Antistreptolysin O FS (Hitachi 911, 917)
Test y	DiaSys ASO FS (respons®910)
Slope	0.998
Intercept	1.21 IU/mL
Coefficient of correlation	0.998

** according to NCCLS document EP17-A, vol. 24, no. 34

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

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

Manufacturer

IVD CE

DiaSys Diagnostic Systems GmbH
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respons®910

Antistreptolysin O FS

Application for serum samples

This application was set up and evaluated by DiaSys. It is based on the standard equipment at that time and does not apply to any equipment modifications undertaken by unqualified personnel.

Identification	
This method is usable for analysis:	Yes
Twin reaction:	No
Name:	ASO
Shortcut:	
Reagent barcode reference:	701
Host reference:	701

Technic	
Type:	Fixed Time Kinetic
First reagent:[µL]	160
Blank reagent	Yes
Sensitive to light	
Second reagent:[µL]	32
Blank reagent	No
Sensitive to light	
Main wavelength:[nm]	600
Secondary wavelength:[nm]	
Polychromatic factor:	
1 st reading time [min:sec]	5:36
Last reading time [min:sec]	9:12
Reaction way:	Increasing
Linear Kinetics Substrate depletion: Absorbance limit	
Linearity: Maximum deviation [%]	
Fixed Time Kinetics Substrate depletion: Absorbance limit	
Endpoint Stability: Largest remaining slope	
Prozone Limit [%]	

Reagents	
Decimals	
Units	

Sample	
Diluent	DIL A (NaCl)
Hemolysis:	
Agent [µL]	0 (no hemolysis)
Cleaner	
Sample [µL]	0
Technical limits	
Concentration technical limits-Lower	38.0000
Concentration technical limits-Upper	700.0000
SERUM	
Normal volume [µL]	2.0
Normal dilution (factor)	1
Below normal volume [µL]	
Below normal dilution (factor)	
Above normal volume [µL]	2.0
Above normal dilution (factor)	6
URINE	
Normal volume [µL]	2.0
Normal dilution (factor)	1
Below normal volume [µL]	
Below normal dilution (factor)	
Above normal volume [µL]	2.0
Above normal dilution (factor)	6
PLASMA	
Normal volume [µL]	2.0
Normal dilution (factor)	1
Below normal volume [µL]	
Below normal dilution (factor)	
Above normal volume [µL]	2.0
Above normal dilution (factor)	6
CSF	
Normal volume [µL]	2.0
Normal dilution (factor)	1
Below normal volume[µL]	
Below normal dilution (factor)	
Above normal volume [µL]	2.0
Above normal dilution (factor)	6
Whole blood	
Normal volume [µL]	2.0
Normal dilution (factor)	1
Below normal volume[µL]	
Below normal dilution (factor)	
Above normal volume [µL]	2.0
Above normal dilution (factor)	6

Results	
Decimals	1
Units	IU/mL
Correlation factor-Offset	0.0000
Correlation factor-Slope	1.0000

Range	
Gender	All
Age	
SERUM	>= <=200
URINE	
PLASMA	
CSF	
Whole blood	
Gender	
Age	
SERUM	
URINE	
PLASMA	
CSF	
Whole blood	

Contaminants
Please refer to r910 Carryover Pair Table

Calibrators details	
Calibrator list	**Concentration**
Cal. 1/Blank	0
Cal. 2	*
Cal. 3	*
Cal. 4	*
Cal. 5	*
Cal. 6	*
	Max delta abs.
Cal. 1	0.0100
Cal. 2	0.0100
Cal. 3	0.0100
Cal. 4	0.0100
Cal. 5	0.0200
Cal. 6	0.035
Drift limit [%]	2.00

Calculations	
Model	Cubic Spline
Degree	

* Enter calibrator value