BioMajesty

Antistreptolysin O FS*

Diagnostic reagent for quantitative in vitro determination of antistreptolysin O (ASO) in serum on BioMajesty JCA-BM6010/C

Order Information

Cat. No. 1 7012 99 10 964
R1:   6 x 100 tests
R2:   6 x 100 tests

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 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 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. Reagent 2 must be carefully mixed before use. The bottles are placed directly into the reagent trays.

Specimen

Serum
Stability [1]:
2 days   at   20 – 25 °C
2 days   at   4 – 8 °C
6 months   at   –20 °C

Only freeze once. Discard contaminated specimens.

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 "First International Standard" for 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 up to 800 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**	4.5 IU/mL ASO
No prozone effect up to 1500 IU/mL ASO	
On-board stability	12 weeks
Calibration stability	12 weeks

Interferences < 10% by	
Conjugated Bilirubin up to 60 mg/dL	
Unconjugated Bilirubin up to 54 mg/dL	
Hemoglobin up to 500 mg/dL	
Lipemia (triglycerides) up to 2000 mg/dL	
For further information on interfering substances refer to Young DS [6].	

Precision			
Within run (n=20)	Sample 1	Sample 2	Sample 3
Mean [IU/mL]	44.4	93.2	229
Coefficient of variation [%]	1.92	1.50	1.72
Between run (n=20)	Sample 1	Sample 2	Sample 3
Mean [IU/mL]	91.6	197	280
Coefficient of variation [%]	2.93	2.09	1.66

Method comparison (n=80)	
Test x	DiaSys ASO FS (Hitachi 917)
Test y	DiaSys ASO FS (JCA-BM6010/C)
Slope	1.04
Intercept	−1.55 IU/mL
Coefficient of correlation	0.997

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

Reference Range [2]

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. Thomas L. Clinical Laboratory Diagnostics. Frankfurt: TH-Books Verlagsgesellschaft, 1998: p. 1201-3.
3. Bisno AL. Group A infections and acute rheumatic fever. N Engl J Med 1991; 325: 783-93.
4. 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.
5. Stevens DL. Invasive Group A streptococcus infections. Clin Infect Dis 1992; 14: 2-11.
6. 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.
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
Alte Strasse 9   65558 Holzheim   Germany

Antistreptolysin O FS

Chemistry code 10 701

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.

Analytical Conditions	
R1 volume	100
R2e volume	0
R2 volume	20
R1 diluent vol	0
R2e diluent vol	0
R2 diluent vol	0
Sample vol (S)	1
Sample vol (U)	1
Reagent 1 mix	weak
Reagent 2e mix	weak
Reagent 2 mix	weak
Reaction time	10

Endpoint Method	
Re.absorb (u)	9.999
Re.absorb (d)	-9.999

Calculation Method Setting	
M-DET.P.l	0
M-DET.P.m	41
M-DET.P.n	42
S-DET.P.p	23
S-DET.P.r	24
Check D.P.I.	0
Limit value	0.003
Variance	10
Reac.type	Inc

Sub-analy. Conditions	
Name	ASO
Digits	1
M-wave L.	596
S-wave.L	****
Analy.mthd.	EPA
Calc.mthd.	MSTD
Qualit. judge	No

Reaction Rate Method	
Cycle	2
Factor	2
E2 corre	Not do
Blank (u)	9.999
Blank (d)	-9.999
Sample (u)	9.999
Sample (d)	-9.999

Prozone	
Prozone form	No
Prozone limit	9.999
Prozone judge	Upper limit
Judge limit	9.999
M-DET.P.m	0
M-DET.P.n	0
S-DET.P.p	0
S-DET.P.r	0

Analysis Test Condition Setting (M)		
Sample Type	**Serum**	**Urine**
Reac. sample vol.	1	1
Diluent method	No dil	No dil
Undil. sample vol.	0	0
Diluent volume	0	0
Diluent position	0	0

MULTI-STD Setting								
Formula	Spline	**Axis Conv**	No conv					
Blank	Blank-any value	**Points**	6					
	FV	**Reac. smp. vol.**	**Dil. method**	**Dil. smp. vol.**	**Diluent vol.**	**Diluent pos.**	**STD H**	**STD L**
BLK	#	1	No dil	0	0	0	9.999	-9.999
1	#	1	No dil	0	0	0	9.999	-9.999
2	#	1	No dil	0	0	0	9.999	-9.999
3	#	1	No dil	0	0	0	9.999	-9.999
4	#	1	No dil	0	0	0	9.999	-9.999
5	#	1	No dil	0	0	0	9.999	-9.999

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