

Antistreptolysin O FS*

Order Information

Cat. No.

1 7012 99 10 964

Kit size



600 (R1: 6 x 100, R2: 6 x 100)

Intended Use

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

Summary

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 [1]. 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 [2]. Pathological ASO values always indicate the presence of a streptococcal infection whereas a negative result cannot exclude an existing or preceding GAS infection [3].

Method

Particle enhanced immunoturbidimetric test

Determination of ASO concentration by 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:	Glycine buffer	pH 8.0	100 mmol/L
	NaCl		150 mmol/L
	Latex particles coated with streptolysin O		< 1%

Storage and Stability

Reagents are stable up to the date of expiry indicated on the kit, if stored at 2 – 8°C and contamination is avoided. Do not freeze.

The open-vial stability of the reagent is 18 months until expiry date.

Warnings and Precautions

- The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
- The reagents contain material of biological origin. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practice.
- In very rare cases, samples of patients with gammopathy might give falsified results [4].
- In case of product malfunction or altered appearance that could affect the performance, contact the manufacturer.
- Any serious incident related to the product must be reported to the manufacturer and the competent authority of the Member State where the user and/or patient is located.
- Please refer to the safety data sheets (SDS) 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

Refer to local legal requirements for chemical disposal regulations as stated in the relevant SDS to determine the safe disposal.

Warning: Handle waste as potentially biohazardous material. Dispose of waste according to accepted laboratory instructions and procedures.

Reagent Preparation

Reagent 1 is ready to use. The bottle is placed directly into the reagent rotor.

The latex enhanced reagent 2 has to be mixed up by successive inversions before first use. Avoid formation of foam.

Materials Required

General laboratory equipment

Specimen

Human serum

Only use suitable tubes or collection containers for specimen collection and preparation.

When using primary tubes, follow the manufacturer's instructions.

Stability [5]:

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

Only freeze once. Discard contaminated specimens.

Calibrators and Controls

DiaSys TruCal ASO is recommended for calibration. Calibrator values have been made traceable to a commercially available standard material, traceable to the first International standard as ASL reference standard. Use TruLab Protein Level 1 and Level 2 for internal quality control. All target values of the controls are traceable to DiaSys reagent/calibrator system. Quality control must be performed after calibration. Control intervals and limits have to be adapted to the individual requirements of each laboratory. Results must be within the defined ranges. Follow the relevant legal requirements and guidelines. Each laboratory should establish corrective action in case of deviations in control recovery.

	Cat. No.	Kit size
TruCal ASO	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 820 IU/mL, depending on the concentration of the highest calibrator. Linearity is given within ± 5%.		
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	
No prozone effect up to 1500 IU/mL.		
Onboard stability	12 weeks	
Calibration stability	12 weeks	
Interference by	Interferences ≤ 10% up to	Analyte concentration [IU/mL]
Bilirubin (conjugated)	60 mg/dL	95.3
Bilirubin (unconjugated)	54 mg/dL	98.1
Hemolysis	500 mg/dL	96.2
Lipemia (triglycerides)	2000 mg/dL	102
For further information on interfering substances, refer to the literature [6,7].		

Precision			
Repeatability (n=20)	Sample 1	Sample 2	Sample 3
Mean [IU/mL]	44.4	93.2	229
CV [%]	1.92	1.50	1.72
Between day (n=20)	Sample 1	Sample 2	Sample 3
Mean [IU/mL]	91.6	197	280
CV [%]	2.93	2.09	1.66

Method comparison (n=80)	
Test x	DiaSys Antistreptolysin O FS (Hitachi 917)
Test y	DiaSys Antistreptolysin O FS (BioMajesty® 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 [8]

Adults	≤ 200 IU/mL
Children < 6 years	≤ 150 IU/mL
Children 6 – 18 years	≤ 200 – 240 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.
2. Curtis GD, Kraak WA, Mitchell RG. Comparison of latex and haemolysin tests for determination of anti-streptolysin O (ASO) antibodies. *J Clin Pathol* 1988; 41:1 331-3.
3. Stevens DL. Invasive Group A streptococcus infections. *Clin Infect Dis* 1992;14:2-11.
4. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. *ClinChemLabMed* 2007;45(9):1240-1243.
5. Guder WG, da Fonseca-Wollheim F, Heil W, et al. The Quality of Diagnostic Samples, German United Society for Clinical Chemistry and Laboratory Medicine. 3rd ed; 2010.
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. Young DS. Effects on Clinical Laboratory Tests - Drugs Disease, Herbs & Natural Products, <https://clinfx.wiley.com/aaccweb/aacc/>, accessed in March 2024. Published by AACC Press and John Wiley and Sons, Inc.
8. Thomas L. Clinical Laboratory Diagnostics [Internet]. Prof. Lothar Thomas; 2024 [cited 2024 May 22]. <https://www.clinical-laboratory-diagnostics.com>

Additions and/or changes in the document are highlighted in grey. Deletions are communicated via customer info by stating the edition no. of the package insert/instruction for use.



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* Fluid Stable

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.l.	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

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

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

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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