

Antistreptolysin O FS*

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

Kits for use in conjunction with DiaSys CE applications.

Intended Use

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

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

1. The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
2. The reagents contain material of biological origin. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practice.
3. In very rare cases, samples of patients with gammopathy might give falsified results [4].
4. In case of product malfunction or altered appearance that could affect the performance, contact the manufacturer.
5. 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.
6. 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.
7. 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 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.

Assay Procedure

Basic settings for BioMajesty® JCA-BM6010/C

Wavelength	596 nm
Temperature	37°C
Measurement	Endpoint
Sample/Calibrator	1.0 µL
Reagent 1	100 µL
Reagent 2	20 µL
Addition reagent 2	Cycle 19 (286 s)
Absorbance 1	Cycle 23/24 (340 s/354 s)
Absorbance 2	Cycle 41/42 (586 s/600 s)
Calibration	Spline

Calculation

The concentration of ASO 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.

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

Data evaluated on BioMajesty® JCA-BM6010/C

Measuring range up to 820 IU/mL, depending on the concentration of the highest calibrator. Linearity is given within $\pm 5\%$. When values exceed this range, samples should be diluted 1 + 1 with NaCl solution (9 g/L) and the result multiplied by 2.	
Limit of detection**	4.5 IU/mL
No prozone effect up to 1500 IU/mL.	

Interference by	Interferences $\leq 10\%$ 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	$\leq 200 - 240$ 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://clinf.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>

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* Fluid Stable