

Antistreptolysin-O (ASO-Turbidimetric)

Diagnostic reagent for the quantitative in vitro determination of anti-streptolysin O (ASO) in serum on photometric systems.

Reagent

Reagent 1: Buffer Solution

Reagent 2: Latex Solution

Calibrator Lyophilized Calibrator (Value on Label)

Principle

Endpoint 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.

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

Storage Instruction and Reagent Stability

The reagents and Calibrator is stable until the expiration date on the label when stored tightly closed at 2°-8°C. If found Particles and Turbidity means Reagent deterioration.

Do not freeze; frozen Latex or Diluent could change the functionality of the test.

Components and Concentration

Reagent contained: Tris buffer 20 mmol/L, Latex particles coated with anti-human IgG against ASO and Preservative.

Calibrator: Lyophilized Serum -ASO value on label

Waste Management

Please refer to local legal requirements.

Reagent Preparation

Reagent 1 and 2 ready to use.

ASO Calibrator: Reconstitute with 1.0 mL of distilled water. Mix gently and incubate 20 minutes at room temperature before use. Reconstituted Calibrator Stable for 3 months at -20°C.

Materials required but not provided

NaCl solution 9 g/L

General laboratory equipment

Specimen

Serum, heparin, plasma or EDTA plasma separate at the latest 1h after blood collection from cellular contents.

7 days at 2°-8°C

60 days at -20°C

Only freeze once! Discard contaminated specimens.

Assay Procedure

Wavelength 546 nm

Temperature 37°C

Light path 10 mm

	Sample/ Calibrator
Reagent 1	800 µl
Reagent 2	200 µl
Sample /Calibrator	10 µl
Mix and read the absorbance immediately (A1) and after 2 minutes (A2) of the sample addition.	

CALCULATIONS

$$\text{ASO (IU/mL)} = \frac{(\text{A2-A1}) \text{ sample}}{(\text{A2-A1}) \text{ calibrator}} \times \text{Calibrator concentration}$$

Quality Controls

For internal quality control any normal and abnormal controls should be assayed with each batch of samples.

Each laboratory should establish corrective action in case of deviations in control recovery.

Warnings and Precautions

1. Keep out of reach of children. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
2. Take off immediately all contaminated clothing.
3. The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow. Avoid contact with skin and mucous membranes.
4. For professional use only!

Performance Characteristics

Measuring Range

The test has been developed determine ASO activities within a measuring range from 20 - 800 IU/mL. If such value is exceeded the sample should be diluted 1 + 4 with NaCl solution (9 g/L) and results multiplied by 5.

Linearity/Limit of Maximum Detection

The higher limit of detection is 800 IU/mL.

Sensitivity/Limit of Detection

The lower limit of detection is 20 IU/mL.

Interferences

No interference was observed by, Bilirubin up to 20 mg/dL and Triglycerides up to 1000 mg/dL.

Precision

Intra-assay n = 20	Sample 1	Sample 2	Sample 3
Mean(IU/mL)	127.16	265.39	418.93
SD(IU/mL)	1.37	2.44	3.00
CV(%)	1.08	0.92	0.72

Inter-assay n = 20	Sample 1	Sample 2	Sample 3
Mean(IU/mL)	136.74	275.96	440.37
SD(IU/mL)	1.48	2.52	2.80
CV(%)	1.08	0.91	0.64

Method Comparison

A comparison of Precision Biomed ASO (y) with a commercially available test (x) using 15 samples gave following results:

$$y = 1.008x - 1.562, R^2 = 0.998$$

Reference Range

Adults ≤ 200 IU/mL

Children ≤ 150 IU/mL

Each laboratory should check if reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

Quick Reference

Parameter	ASO
Mode	Fixed time
Reaction slope	Increasing
Wavelength	546 nm
Path length	10 mm
Temperature	37°C
Reagent 1 volume	800 µL
Reagent 2 volume	200 µL
Sample volume	10 µL
Delay	5 Sec
Rate	120 sec
No. of readings	2 Nos.
Normal range	Adults - < 200 IU/mL
	Children < 150 IU/mL
Linearity	800 IU/mL
Sensitivity	20 IU/mL

Pack Size

Cat No.	Configuration	Pack
ASOT0050	Reagent R1 - 1 x 40mL Reagent R2 - 1 x 10mL Calibrator – 1 x 1mL	50mL

Literature

1. Curtis GD, Kraak WA, Mitchell RG. Comparison of latex and haemolysin tests for determination of antistreptolysin O (ASO) antibodies. J ClinPathol 1988; 41:1331-3.
2. Stevens DL. Invasive Group A streptococcus infections. Clin Infect Dis 1992; 14:2-11.
3. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001. p. 16-7.
4. 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.
5. Thomas L. Clinical Laboratory Diagnostics. Frankfurt: TH-Books Verlagsgesellschaft, 1998:1201-3.

Version : ASOT/00

 In Vitro Diagnostic Use
  See Pack Insert For Procedure
  Single Use only
  CE

 Temperature Limit
  Manufacturer's Address
  Manufacturing Date
  Expiry Date
  LOT Lot Number



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