

Antistreptolysin O (ASO)









Order Information

Cat. No. OMR1035 Kit Configuration Reagent 1: 1 X 40 mL Reagent 2: 1 X 10 mL Calibrator: 1 X 1 mL

Summarv

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.

Method

Turbidimetric method

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.

Reagent Storage Instruction and Stability

The reagent 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. All the components of the kit are stable until the expiration date on the label when stored tightly.

Reagent 1: Buffer **Solution Reagent 2: Latex Solution**

Calibrator: Lyophilized serum - Separate pack

Composition

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)

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!

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. 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.

2° -8°C 7 days at 60 days at -20°C

Only freeze once! Discard contaminated specimens.

Assay Procedure

Wavelength 540 nm (530-550)

Temperature 37°C Light path 10 mm

	Sample/ Calibrator	
Reagent 1	800 µl	
Reagent 2	200 μΙ	
Sample /Calibrator	10 µl	
Mix and read the absorbance immediately (A1) and		
- (1 0		

after 2

minutes (A2) of the sample addition.

CALCULATIONS

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.

Performance Characteristics Measuring Range

The test has been developed determine ASO activities within a measuring range from 20 - 1000 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.

Interferences

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

Sensitivity/Limit of Detection

The lower limit of detection is 20 IU/mL.

Linearity

The higher limit of detection is 1000 IU/mL.

Precision

Intra-	Mean	SD	CV
assay n =	(IU/mL	(IU/mL	(%
20)))
Sample 1	271.65	1.11	0.41
Sample 2	148.36	0.29	0.20

Inter-	Mean	SD	CV
assay n =	(IU/mL	(IU/mL	(%
20)))
Sample 1	106.57	1.28	1.21
Sample 2	291.63	1.13	0.39

Method Comparison

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

y = 1.004x - 0.0052, $R^2 = 0.999$

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.

Literature

- 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.
- Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001. p. 16-7.
- 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.

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