



ASO

IMMUNOTURBIDIMETRY

Intended use:

Immunoturbidimetric assay for the in vitro quantitative determination of antistreptolysin-O in human serum and plasma on automated clinical chemistry analyzers.

Summary:

Immunological testing for specific antibodies to streptococcus metabolic products yields important information about previous streptococcus infections. Antibodies are produced against the pathogen and its metabolic products. One example is the anti- body to streptolysin O, an enzyme produced by Lancefield group A B-haemolytic streptococci. Determination of antistreptolysin O is performed when toxic and sensitising associated illnesses occur, such as rheumatic fever (major symptoms: carditis, polyarthritis, chorea minor, subcutaneous nodules, erythema annulare) and poststreptococcal acute glomerulonephritis. Various methods are available for assaying antistreptolysin O, such latex agglutination and hemolysis inhibition. These ASO assay is based on the principle of immunological agglutination test principle using latex particles as reaction enhance.

Test principle:

Immunoturbidimetric assay

- Sample and addition of R1 (buffer)
 - Addition of R2 (streptolysin O latex/buffer) and start of reaction
- Streptolysin O coated on latex reacts with antibodies in the sample to form an antibody/antigen complex. Following agglutination this is measured turbidimetrically.

Reagent concentration:

R1: TRIS buffer* pH 8.2	170 mmol/l
R2: Borate buffer pH 8.2	10 mmol/l
Latex particles coated with streptolysin O	1.7 g/l

*TRIS= Tris (hydroxymethyl)-aminomethane

Preparation and stability:

R1: Ready for use.
R2: Ready for use.
On board stability: R1: 28 days
R2: 28 days (If R2 mix weekly)

Specimen:

Collect serum using standard sampling tubes
Heparinized and EDTA-Plasma Stability:
2 days at +20°C to +25°C
2 days at +4°C to +8°C
6 months at - 20°C

Centrifuge samples containing precipitate before performing the assay.

Limitations - interference:

Criterion: Recovery within ±10% of initial value.
Icterus: No significant interference up to an index I of 26 (approximate conjugated and unconjugated bilirubin concentration: 26 mg/dl).
Hemolysis: No significant interference up to an index H of 1000 (approximate haemoglobin concentration: 1000 mg/dl).
Lipemia (Intralipid): No significant interference up to an index L of 1000 (approximate triglycerides concentration: 2000 mg/dl). There is poor correlation between turbidity and triglycerides concentration. Rheumatoid factors < 180 IU/l do not interfere. A high-dose hook-effect may occur at antistreptolysin O concentrations above 4000 IU/ml

Expected values:

Adults: Up to 200 IU/ml
Children: Up to 150 IU/ml
Each laboratory should investigate the transferability of the expected values to its own patient population and if necessary determine its own reference range. For diagnostic purposes the ASO results should always be assayed in conjunction with the patient's medical history, clinical examinations and other findings.

Measuring/reportable range:

15-800 IU/ml
At higher concentrations, dilute the sample with 0.9% NaCl (e.g. 1 + 1). Multiply the result by the appropriate factor (e.g. 2).

Testing procedure:

Applications for automated systems are available on request.
Materials provided
• Working solutions as described above *Additional materials required*
• Calibrators and controls as indicated below
• 0.9% NaCl

Manual procedure:		
Wavelength:	530 nm	
Temperature:	+37°C	
Cuvette:	1 cm	
Zero adjustment:	against reagent blank	
	Blank	Sample/ Calibrator
Sample/Calibrator	-- --	5 µl
R1	400	400 µl
Mix, incubate. 1 min. Then add.		
R2	100 µl	100 µl
Mix, read absorbance A1 after 9 sec. incubate 2 min. and read absorbance A2.		
Calculation:		
$A = [(A_2 - A_1) \text{ sample or Calibrator}] - [(A_2 - A_1) \text{ blank}]$		
The concentration of ASO in patient serum has to be calculated from A using linear method For zero value is recommended to use saline solution (0.9%)		

Imprecision:

Reproducibility was determined using human samples and controls in an internal protocol (n = 21). The following results were obtained:

Sample	Within run		
	Mean IU/ml	SD IU/ml	CV %
Human serum	126	1.6	1.3
Protein Control 1	150	1.7	1.1
Protein Control 2	258	2.6	1.0

Sample	Between day		
	Mean IU/ml	SD IU/ml	CV %
Human serum	147	5,0	3,4
Protein Control 1	180	4,6	2,5
Protein Control 2	310	6,6	2,1

Method comparison:

A comparison of the BIOANALYTIC ASO (y) with a commercial obtainable assay (x) gave the following result (IU/ml). $y = 1.07 x + 2.01$; $r = 0.992$

Quality Control:

RHEUMATOID CONTROL LEVEL 1 5 x 1 ml #B10846
RHEUMATOID CONTROL LEVEL 2 5 x 1 ml #B10849

The control intervals and limits must be adapted to the individual laboratory and country-specific requirements. Values obtained should fall within established limits. Each laboratory should establish corrective measures to be taken if values fall outside the limits.

Calibration:

Standardization: This ASO method was calibrated against an international standard defined for ASO.

S1: BIOANALYTIC ASO CAL. SET 5 x 1 ml # B11890



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Calibration stability

It is suggested to use Calibrator products produced by Bioanalytic. It is suggested to use supplementary calibrator (pure water or 0.9% NaCl) to conduct 2-point calibration. The calibration curve is formed automatically. When lot number is changed or QC is invalid, calibration shall be conducted again. Recalibrate the assay every 30 days under ideal conditions, or when the following occur:
Change in reagent lot or significant shift in control values;
Major preventative maintenance was performed on the analyser or a critical part was replaced(Halogen Lamp)

Literature:

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4. Borque L, Rus A, Dubios H et al. Automated Determination of Streptolysin O Antibodies by a Turbidimetric Latex Immunoassay Method. Journal of Clinical Immunoassay 1992;15:182-186
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6. Guder WG, Narayanan S, Wisser H, Zawta B. List of Analytes Preanalytical Variables. Brochure in: Samples: From the Patient to the Laboratory. Darmstadt: GIT-Verlag, 1996
7. Yoshimoto M, Hosoi S, Fuyisawa S et al. High levels of antibodies of streptococcal cell membrane antigens specifically bound to monoclonal antibodies in acute poststreptococcal glomerulonephritis. J Clin Microbiol 1987;25:680
8. Peter G, Smith AL. Group A streptococcal infections of the skin and pharynx. N Engl J Med 1977;297:311
9. Ricci A, Berti B, Moauro C et al. New haemolytic method for determination of antistreptolysin O in whole blood. J Clin Microbiol 1978;8:263
10. Tadzynski LA, Ryan ME. Diagnosis of rheumatic fever. A guide to criteria and manifestations. Postgrad Med 1986;79:295

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SYMBOLS

- IVD** for in vitro diagnostic use only
- LOT** lot of manufacturing
- REF** code number
-  storage at temperature interval
-  expiration date (year/month)
-  warning, read enclosed documents
-  Read the directions

Order information (Cat. No):

CC340	CR340	B22030	B27030	B30030	B32032	B35031	B80031
CC341	BASO500	B24030	B27031	B30031	B33030	B36030	B80032
OL340	BASO250	B24031	B27032	B30032	B33031	B36031	B80033
OL341	BASO125	B24032	B27033	B30033	B33032	B36032	
KL340	B21030	B25030	B28030	B31030	B33033	B37030	
KL341	B21031	B25031	B28031	B31031	B34030	B37031	
AB340	B21032	B25032	B28032	B32030	B34031	B37032	
AB341	B21033	B25033	B28033	B32031	B35030	B80030	

Manufacturer

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