

ASO

ANTISTREPTOLYSIN O

For discrete analyzers

Method: Turbidimetry

Product code: 1418-1065

Packaging: 4 x 25 mL (R1) + 4 x 5 mL (R2)

Store at 4°C

For *in vitro* use

INTENDED USE

MEDICON ASO is a set of immunoturbidimetric reagents for the quantitative determination of ASO in human serum or plasma, with BECKMAN COULTER AU400/600/600-IVD/640/2700/5400 and other discrete analyzers. For *in vitro* diagnostic use only.

CLINICAL SIGNIFICANCE

Streptococcus pyogenes is a gram-positive bacterium and is associated with many important diseases that result from the release of its toxin like: pharyngitis, sinusitis, pneumonia, septic scarlet fever and lymphangitis. It can also cause diseases by the reaction of the immune system to it such as rheumatic fever and glomerulonephritis. Streptolysin O, a haemolysin produced by streptococci, can cause an immune response and detection of antistreptolysin O (ASO) antibodies can be clinically used to confirm a recent infection. ASO antibodies can be detected 1 – 3 weeks after infection and they sustain at maximum levels for 3 – 6 weeks.

METHOD PRINCIPLE

The turbidimetric method is applied. When the sample is mixed with the appropriate buffer (R1) and latex particles coated with streptolysin (R2), anti-streptolysin antibodies react specifically with absorbed Streptolysin, leading to agglutination of latex particles. This agglutination is detected as a turbidity change at 600 nm, and it is proportional to ASO concentration in the sample.

METHOD LIMITATIONS

Refer to the book "Effects of Preanalytical Variables on Clinical Laboratory Tests" for possible interference of other pharmaceutical agents in this particular test. Interference of other agents is described in the "Clinical Guide to Laboratory Tests". The reagent is designed for *in vitro* diagnostic use only. *In vitro* diagnostic reagents can be hazardous. They should be handled according to good laboratory practices and techniques. Avoid inhalation and contact with eyes and skin.

REAGENT COMPOSITION

Reagent 1 (R1)

Tris buffer (pH 8.4): 80 mM

Polyethylene glycol: 5%

Non reactant components and preservatives.

Reagent 1 (R2)

Streptolysin O, detached from Streptococcus Pyogenes colony, bound on polystyrene particles.

Non reactant components and preservatives.

WARNINGS – PRECAUTIONS

- This reagent is designed for *in vitro* diagnostic use. *In vitro* diagnostic reagents can be hazardous. They should be handled according to good laboratory techniques. Avoid inhalation and contact with eyes and skin.
- Samples should be considered as potentially infectious. Handle according to the universal precautions and good laboratory practices.
- The reagent contains streptolysin, which is hemolyzing and may be dangerous if it enters the bloodstream. Avoid contact with the skin.
- The reagent contains sodium azide (NaN₃ < 0.1%). Avoid swallowing and contact of the reagent with skin and mucous membrane.
- Dispose all waste according to national laws.
- MSDS is available by MEDICON upon request.

PREPARATION

Reagent 1 is ready to use and can be placed on the analyzer. R2 is ready to use. Before first use, shake well to mix contents. Vials bear barcode for recognition by BECKMAN COULTER AU Series analyzers.

REAGENT DETERIORATION

The reagent should not be used:

- When it does not exhibit the specified linearity or recovery of control values lies outside the acceptable range after recalibration.
- When it appears cloudy.
- After prolonged exposure to sunlight or high temperature.

SHELF LIFE

Unopened, reagents are stable up to the stated expiry date when stored at 4°C. Once opened, they can be stored refrigerated on the instrument for 1 month.

SAMPLE

Use serum or plasma with EDTA as specimen. Sample is stable for 2 days when stored at 2 – 8°C and for 6 months when stored at –20°C.

CALIBRATION:

MEDICON ASO Calibrator (1578-1062), traceable to WHO NIBSC 1st International Standard for ASO, or BECKMAN COULTER Serum Protein Multicalibrator ODR3021 (MEDICON code: 4478-0754) can be used for calibration. Calibrate the assay every 1 month. Recalibrate following preventive maintenance or replacement of a critical part of the analyzer, when using a new reagent kit or a new reagent lot number, or when Quality Control results are out of range.

QUALITY CONTROL

MEDICON provides the following products for quality control: Immunology Control levels 1,2,3 (1578-1195-04, 1578-1196-04, 1578-1197-04) or BECKMAN COULTER ODC0014 ITA Control Serum 1, ODC0015 ITA Control Serum 2, ODC0016 ITA Control Serum 3 (MEDICON code: 4478-1190, 4478-1191, 4478-1192).

Control target values and limits should fall within acceptable intervals adjusted to the requirements of each laboratory. Target values for ASO should be verified with the corresponding working protocol. Results outside the specified values even after recalibration could be due to reagent deterioration, unsuitable storage conditions or control deterioration, instrument malfunction, or error during test procedure.

MATERIALS REQUIRED BUT NOT PROVIDED WITH THE KIT

ASO calibrator
Quality control material
Automated biochemistry analyzer
Usual laboratory equipment

REFERENCE INTERVALS

Newborns: similar to the mother

Children: ≤ 150 IU/ml

Adults: ≤ 200 IU/ml

Each laboratory should determine its own expected values as dictated by good laboratory practice.

WASTE DISPOSAL

This product contains sodium azide (NaN₃), which forms sensitive explosive compounds with copper or lead. Flush waste pipes with water after the disposal of undiluted reagent in order to avoid azide build up in the drain pipes.

SPECIFIC PERFORMANCE CHARACTERISTICS

Linearity

The assay is linear within measuring range 9 – 1000 IU/ml. When values exceed this range samples should be diluted accordingly.

Prozone Tolerance

No hook effect is observed up to 10000 IU/ml.

Sensitivity

The lowest detectable level of ASO is estimated at 8.6 IU/ml.

The lowest detection limit (LDL) is defined as the lowest concentration of analyte that is distinguishable from zero. A sample free of analyte is assayed 20 times within the assay and the LDL is calculated as the absolute mean plus three standard deviations.

Precision

Level (IU/ml)	Within run CV%	Total CV%
130	2.29	2.83
309	1.51	2.82
574	1.73	2.58

Precision is estimated on two concentration levels of analyte according to NCCLS protocol EP-5T (20 consecutive days, 2 runs per day, 2 repeats per run).

Interference

Lipemic:	insignificant up to 1000 mg/dL intralipid®
Hemoglobin:	insignificant up to 500 mg/dL
Non Conj. Bilirubin:	insignificant up to 40 mg/dL
Conj. Bilirubin:	insignificant up to 40 mg/dL
RF:	insignificant up to 3000 IU/dL

Refer to Young⁴ for further information on interfering substances.

Method Comparison











A comparison was performed between this reagent and another commercially available product. The results were as follows:

5-Point Calibration			
Y=1.008X – 6.769	R=0.997	N=96	Sample range = 5.10 – 632
1-Point Calibration			
Y=1.013X – 1.677	R=0.998	N=96	Sample range = 2.5 – 531

BIBLIOGRAPHY

1. Tietz, NW, ed. Clinical Guide to Laboratory Tests. 3rd. ed. Philadelphia: W.B. Saunders Company Ltd., 1995.
2. Burtis, CA and Ashwood, ER, ed. Tietz Textbook of Clinical Chemistry. 2nd. ed. Philadelphia: W.B. Saunders Company Ltd., 1994.
3. Jacobs, DJ, Demott, WR, Grady, HJ, Horvat, RJ, Huestis, DW and Kasten, BL, JR, eds. Laboratory Test Handbook. 4th. ed. Ohio, Hudson: Lexi-Comp Inc., 1996.
4. Young DS. Effects of Preanalytical Variables on Clinical Laboratory Tests. 2nd. ed. Washington, DC: The American Association for Clinical Chemistry Press, 1997.
5. ThomasL. Clinical Laboratory Diagnostics, Frankfurt: TH Books Verlag : 1998: 192-202

SYMBOLS

	Temperature Limits (2°C-8°C) (ISO 15223/rev. EN980/ISO 7000)-		Biohazard (ISO 15223 / rev. EN960 / ISO 7000).
	NON STERILE (ISO 15223 DAML).		Manufacturer (ISO 15223/rev. EN 980).
	Batch Code (ISO 15223 / EN980 / rev. EN980).		Content enough for (rev. EN980/ISO 7000).
	Catalogue Number (ISO 15223 / EN980 / rev. EN980).		Production Date (ISO 15223/rev. EN980/ISO 7000).
	Date of Expiry (ISO 15223 / rev. EN980).		For <i>in vitro</i> use (ISO 15223 / rev. EN980).

