

ANTISTREPTOLYSIN (O)

Cat. No.	Pack name	Packaging (Content)
BLT20001	ASO	5 x 25 ml ASO Buffer 1 x 10 ml ASO Latex 1 x 1 ml ASO Calibrator
BLT20002	ASO	2 x 25 ml ASO Buffer 1 x 5 ml ASO Latex 1 x 1 ml ASO Calibrator



INTENDED USE

Diagnostic reagent for *in vitro* quantitative determination of Antistreptolysin (O) (ASO) in human serum by turbidimetric immunoassay.

DIAGNOSTIC IMPLICATIONS

The group A β -haemolytic streptococci produces various toxins that can act as antigens, one of these exotoxins is streptolysin O. The affected organism produces specific antibodies against streptolysin O. The concentration of ASO in the patient's serum will enable to establish the degree of infection due to β -haemolytic streptococci.

METHOD

Measurement of antigen-antibody reaction by the end-point method.

REAGENTS PROVIDED

Buffer

Phosphate buffered saline (pH 7.43)
Polyethylene glycol (40 g/l)
Sodium azide (0.09 %)

Latex

Glycine Buffer (pH 8.2)
ASO sensitized Latex (0.17 %)
Sodium azide (0.09 %)

Calibrator

Pooled human serum, diluted with high levels of ASO with phosphate buffered saline containing 1g% bovine serum albumin and 0.09 % sodium azide as preservative.
Concentration : see bottle label

PREPARATION AND STABILITY OF REAGENTS

Reagent Preparation

Liquid reagents, ready for use.

Stability and Storage

The reagents are stable until expiry date when kept at 2-8°C. Stability in the instrument is at least 4 weeks if contamination is avoided. Do not freeze.

REAGENTS REQUIRED BUT NOT SUPPLIED

Saline (9 g/l NaCl)

SAMPLE COLLECTION

Use fresh serum. If the test can not be carried out on the same day, the serum may be stored at 2-8°C for 48 hours. If stored for a longer period, the sample should be frozen.

AUTOMATION

Application procedures on clinical chemistry analyzers are available upon request.

Manual Procedure

Sample/Control: Ready for use

Calibrator: ready for use. Use saline 9 g/l as zero point.

Test: Mix 12 μ l samples, calibrator and control(s) with 900 μ l buffer. Read optical density (OD1) of samples, calibrator and control(s) at 600 nm. Add 120 μ l ASO Latex. Mix and incubate for 5 minutes at room temperature. Read optical density (OD2) of samples, calibrator and control(s) at 600 nm.

Calculate Δ OD's, and calculate the results by the formula:

$$[\text{sample}] = [\text{calibrator}] \times \frac{\Delta \text{OD}_{\text{sample}} - \Delta \text{OD}_{\text{zero}}}{\Delta \text{OD}_{\text{calibrator}} - \Delta \text{OD}_{\text{zero}}}$$

REFERENCE VALUES

Normal values: 0 - 200 IU/ml (WHO)

This range is given for orientation only. Each Laboratory should establish its own reference values.

PERFORMANCES

The performance characteristics for the Antistreptolysin (O) reagents were measured on a clinical chemistry analyzer (Cobas Mira).

Measuring Range:	0 – 400 IU/ml
Detection Limit:	12.5 IU/ml
Hook Effect:	No
Sensitivity:	0.00077 ABS units/concentration unit
Precision:	
[%CV]	

	Low	Medium	High
Intra-Run	2.9	-	3.6
Inter-Run	-	6.32	-

Accuracy:
[IU/ml])

Control	Assigned	Measured
Biorad 1	62 (49-74)	65
Biorad 2	173 (138-208)	171

Specificity: Monospecific

Interferences: No interference with hemolysed, icteric nor lipemic sera. Rheumatoid Factor has no effect.

Limitations: None

Comparison with Turbidimetry : $y = 0.9981x - 8.1154$
 $r = 0.9972$

PRECAUTIONS AND WARNINGS

1. *In vitro* diagnostic use only.
2. Sodium azide has been reported to form lead or copper azide in laboratory plumbing which may explode on percussion. Flush drains with water thoroughly after disposing of fluids containing sodium azide.
3. Polyethylene glycol is non biohazardous.
4. Each donor unit used in the preparation of the calibrators and controls was found to be negative for the presence of HIV1 and HIV2 antibodies, as well as for the hepatitis B surface antigen and anti-hepatitis C antibodies, using a method approved by the FDA.









Also available Calibrators and Controls


Cat. No.	Product name	Pack name	Content
BLT20003	ASO CALIBRATOR	ASO CAL	1 x 1 ml
BLT20004	ASO CONTROL	ASO CON	1 x 1 ml
BLT20034	MULTICONTROL LEVEL 1	MULTICON L1	1 x 1 ml
BLT20035	MULTICONTROL LEVEL 2	MULTICON L2	1 x 1 ml

REFERENCES

1. Dillon, H. C. jr., Reeves M. A., Am. J. Med., 56, 333-346 (1974)
2. Klein, G. C., Baker, C. N., Jones, W. L., 21, 999-1001 (1971)

USED SYMBOLS

 LOT	Lot Number	 IVD	In vitro Diagnostics	 i	See Instruction for Use
 REF	Catalogue Number		Manufacturer	 CONT	Content
	Expiry Date		Storage Temperature		

 Erba Lachema s.r.o., Karásek 2219/1d, 621 00 Brno, CZ
e-mail: diagnostics@erbamannheim.com, www.erbamannheim.com

QUALITY SYSTEM CERTIFIED
ISO 9001 ISO 13485