BIOLABO
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MANUFACTURER:
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ASLO Turbidimetric Immunoassay

Reagent for quantitative determination
of Antistreptolysin O (ASLO) in human serum.

REF ASLO050E	**R1** 1 x 50 mL	**R2** 1 x 7 mL
REF ASLO620E	**R1** 6 x 20 mL	**R2** 1 x 15 mL

TECHNICAL SUPPORT AND ORDERS
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Latest revision: www.biolabo.fr

CE

IVD

Made in France

I: corresponds to significant modifications

INTENDED USE

This reagent is designated for professional use in laboratory (manual or automated method).
It allows the quantitative determination of Antistreptolysin O antibodies in human serum for screening streptococcal infection.

GENERALITIES (1) (2)

Streptolysin O, one of the various exotoxins produced by the group A β-haemolytic streptococci, can act as antigen.
In patients suspected of having acute poststreptococcal glomerulonephritis, evidence of recent infection may be found in increased titers of antibodies to streptococcal extracellular products (antistreptolysin O, antihyaluronidase, antideoxyribonuclease B).

PRINCIPLE (1)

Turbidimetric Immunoassay (TIA): Antistreptolysin O found in infected patient's sera, leads to an agglutination of ASLO sensitized latex particles. The photometric measurement of this agglutination is realised by end-point method at 600 (580 – 620) nm.

REAGENTS

R1	**ASLO TIA**	Buffer
Phosphate buffered saline		pH 7.43
Polyethylene glycol		40 g/L
Sodium azide		0.95 g/L

R2	**ASLO TIA**	Strepto-Latex
Glycin Buffer		pH 7.43
ASLO sensitized Latex		0.17 %
Sodium azide		0.95 g/L

According to 1272/2008 regulation, these reagents are not classified as dangerous.

SAFETY CAUTIONS

- Refer to current Material Safety Data Sheet available on request or on www.biolabo.fr
- Verify the integrity of the contents before use.
- Waste disposal: Respect legislation in force in the country.
- All specimens or reagents of biological origin should be handled as potentially infectious. Respect legislation in force in the country.

Any serious incident that has occurred in connection with the device is notified to the manufacturer and the competent authority of the Member State in which the user and/or patient is based.

REAGENTS PREPARATION

Liquid Reagents, ready for use.

STABILITY AND STORAGE

Stored away from light, well cap in the original vial at 2-8°C, reagents are stable when stored and used as described in the insert:

Unopened,
- Until the expiry date stated on the label of the Kit.

Once opened:
- When free from contamination, 2 separated reagents are stable for :
  - 3 months at 2-8° C
  - 24 h at room temperature

SPECIMEN COLLECTION AND HANDLING (4)

Use fresh serum.

If the test cannot 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.

LIMITS (4)

Serum β-lipoprotein in liver disease and growth products of some bacteria may neutralize the haemolytic properties of Streptolysin O, causing false-positive titres.

I MATERIAL REQUIRED BUT NOT PROVIDED

1. Medical analysis laboratory equipment.
2. Spectrophotometer or Biochemistry Clinical Analyzer
3. Saline (NaCl 9 g/L)
4. REF CO4000: Solution for cleaning measuring system of analysers

Manufacturer	Expiry date	In vitro diagnostic	Storage temperature	Dematerialized water	Biological risk
Product Reference	See Insert	Batch number	Store away from light	Sufficient for	Dilute with

QUALITY CONTROL

- REF ASLO CONT1: ASLO Control
- REF TIA CONT21: Control Set
- External quality control program.

It is recommended to control in the following cases:

- At least once a run.
- At least once within 24 hours.
- When changing vial of reagent.
- After maintenance operations on the instrument.

If control is out of range, apply following actions:

1. Prepare a fresh control serum and repeat the test.
2. If control is still out of range, use a new vial of calibrator or a fresh calibrator and repeat the test.
3. If control is still out of range, repeat the tests with a new vial of reagent.

If control is still out of range, please contact BIOLABO technical support or your local Agent.

REFERENCE INTERVALS (1) (3)

WHO Values: 0-200 IU/mL

These values may vary with many factors (age, season and region).

Each laboratory should establish its own normal ranges for the population that it serves.

PERFORMANCES

On a clinical chemistry analyser (XL-600)

Linearity range: between 12,5 IU/mL (LOQ) and 400 IU/mL.

Above 400 IU/mL, dilute the specimen with saline solution and re-assay considering the dilution factor to calculate the result. Linearity limit depends on specimen/reagent ratio.

Precision:

Within-run N = 10	*Low level*	*Normal level*	*High level*
Mean IU/mL	26	103	351
S.D. IU/mL	2.1	3.8	4.3
C.V. %	8.1	3.7	1.2

Accuracy:

Between run N = 9	*Low level*	*Normal level*	*High level*
Mean IU/mL	54.6	135	322
S.D. IU/mL	1.8	6.1	5.3
C.V. %	3.3	4.5	1.7

Sensitivity:0.00141 Abs/ unit (IU/mL)

Specificity: Monospecific

Hook effect: None

Comparison study with Nephelometry:

y = 0,7631x + 22.6 r = 0.9834

Interferences:

No interference with hemolysed, icteric or lipemic sera.
Rheumatoid Factor has no effect.
Other substances may interfere (see § Limitations)

On-board stability:
2 separate reagents are stable 30 days

Calibration Frequency:
Make a new calibration when changing reagent batch, if quality control results are found out of the established range and after maintenance operations

CALIBRATION

- REF ASLO CALSET41 ASLO Standard Set
- Use saline as zero point.

Calibration values are based on WHO Standardisation.

The calibration frequency depends on proper instrument functions and on the preservation of the reagent.

PROCEDURE

Let stand reagents, standards, control and specimens at room temperature.
Before use, mix reagent R2 by gentle swirling.

Manual Procedure:

Realise standard curve (§ Calibration)

Set up the instrument to read micro-volumes.	Blank	Standard	Assay
Buffer (R1)	900 µL	900 µL	900 µL
Standard		12 µL	
Saline	12 µL		
Specimen			12 µL
Mix well. Record absorbance A1 at 600 nm.			
Add	Blank	Standard	Assay
Strepto-Latex (R2)	120 µL	120 µL	120 µL
Mix and let stand for 5 minutes at room temperature. Record absorbance A2 at 600 nm.			

1- With Manual Procedure on Spectrophotometer, performances and stability data should be validated by user

2- Applications proposal are available on request for other analyzers

CALCULATION

Manual Procedure:

$$\text{Result (IU/mL)} = \frac{\text{(A2 – A1) Assay – (A2-A1) Blank}}{\text{(A2 – A1) Standard- (A2-A1) Blank}} \times \text{Standard concentration}$$

Automatic Biochemistry analyser:

The analyser provides directly result.
For more details about calibration and calculation of results, refer to User's manual and specific application.

REFERENCES

(1) TIETZ N.W. Textbook of clinical chemistry, 3rd Ed. C.A. Burtis, E.R. Ashwood, W.B. Saunders (1999) p.215, p.1224-1225.

(2) Dillon, H. C. jr., Reeves M. A., J. Med., 56, p.333-346 (1974).

(3) Klein, G. C., Backer, C. N., Jones, W. L. 21, p.999-1001 (1971)

(4) Clinical Guide to Laboratory Test, 3rd Ed., N.W. TIETZ (1995) p. 919