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 K2ASO	**R1** 1 x 40 mL	**R2** 1 x 6.5 mL	**R3** 2 x 50mL
REF K4ASO	**R1** 2 x 30 mL	**R2** 1 x 10 mL	**R3** 3 x 50mL

TECHNICAL SUPPORT AND ORDERS
Tel: (33) 03 23 25 15 50
support@biolabo.fr
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 (automated method).
This quantitative test is to detect and measure 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**	Buffer	
Phosphate buffered saline		pH	7.43
Polyethylene glycol		40	g/L
Sodium azide		0.95	g/L

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

Reagents R1, R2 are not classified as dangerous according to 1272/2008/EC regulation.

R3 **ASLO** Cleaning solution
Classification due to sodium hydroxide
Met. Corr. 1: H290 - May be corrosive to metals.
Skin Corr. 1B: H314 - Causes severe skin burns and eye damage.
P280: Wear protective gloves/protective clothing/eye protection/face protection. P301+P330+P331: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. P303+P361+P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower.
P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310: Immediately call a poison center/doctor.

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, reagent is 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, 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.

MATERIAL REQUIRED BUT NOT PROVIDED

1. Medical analysis laboratory equipment.
2. Biochemistry Clinical Analyzer KENZA One, KENZA 240TX/ISE or KENZA 450TX/ISE
3. Saline (NaCl 9 g/L)
4. REF CO4000: Cleaning solution

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

I CALIBRATION

- REF ASLO CALSET41 : Standard Set (WHO standardization)
- Use saline as zero point.
- Batch specific value are indicated in the certificate of analysis and on the label of each vial.
- Construct Standard curve as indicated in the application of KENZA analyser used

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

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/L (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

Analytical Sensitivity: 0.00141 Abs/ unit (IU/mL)

Diagnostic 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:
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

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.

I PROCEDURE

Refer to specific applications of KENZA Analyzer used.

Minimal Software revision required :

- KENZA 240TX/ISE : from 6.13
- KENZA 450TX/ISE : from 2.20
- KENZA ONE : from 2.04

Contact support@biolabo.fr for more details

CALCULATION

The analyzer provides directly result (UI/mL)
Refer to User's manual of analyzer used.

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