



BIOLABO
 www.biolabo.fr
MANUFACTURER:
BIOLABO SAS,
 Les Hautes Rives
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ASLO Standard High

For calibration of quantitative determination
 of Antistreptolysin O (ASLO) by Turbidimetric Immunoassay

REF ASLO CALH1 R1 1 x 1 mL



Made in France

I: corresponds to significant modifications

TECHNICAL SUPPORT AND ORDERS

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Latest revision : www.biolabo.fr

INTENDED USE

Standard for the calibration of quantitative immunochemical determination of ASLO in human serum.

Suitable for manual procedure or automated instruments with BIOLABO reagents **REF** ASLO050E, **REF** ASLO620E.

REAGENTS

R1 ASLO Standard High Human origin

Liquid serum supplemented with ASLO

SAFETY CAUTIONS (1) (2)

BIOLABO reagents are designated for professional use in laboratory.

- Material Safety Data Sheet is available upon request.
- Each donor unit used to manufacture this product was tested and found non-reactive for HbsAg, antibody to Hepatitis C and antibody to HIV-1/HIV-2.
- However, no test method can offer complete assurance that infectious agents are absent. All specimens or reagents from biological origin should be handled as potentially infectious, in accordance with good laboratory practices using appropriate precautions.
- Waste disposal: Respect legislation in force in the country.

I 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

Ready for use

MATERIAL REQUIRED BUT NOT PROVIDED

1. BIOLABO Reagents (§ INTENDED USE)
2. **REF** ASLO CONT1 or **REF** ASLO CONT5: ASLO Control

QUALITY CONTROL

Verify the integrity of the vial and batch-specific value before use
 Run in accordance with the IFU of the reagent used.

STABILITY AND STORAGE

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

Unopened,

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

Once opened:

- Transfer requested quantity, well recap vials and store at 2-8°C.
- Well recapped in the original vial, at least for 6 weeks when free from contamination.

Do not freeze

PROCEDURE

Run in accordance with the IFU of the reagent used.

CALIBRATION VALUES (3)

- The Value is traceable to a reference material (WHO Standardisation)
- **Batch-specific value** is indicated on the label of the vial

LIMITATIONS

Factors which may influence results are bacterial contamination, accuracy of reconstitution volume, respect of automated instrument procedure, temperature...

REFERENCES

- (1) *Occupational Safety and Health Standards ; Bloodborne pathogens (29CFR1910.1030) Federal Register July 1, (1998) ; 6, p.267-280*
- (2) *Directive du conseil de l'Europe (90/679/CEE) J. O. de la communauté européenne n°L374 du 31.12.1990,p.1-12*
- (3) *TIETZ N.W. Textbook of clinical chemistry, 3rd Ed. C.A. Burtis, E.R. Ashwood, W.B. Saunders (1999) p.520*

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