BIOLABO
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MANUFACTURER:
BIOLABO SAS,
Les Hautes Rives
02160, Maizy, France

Control Set

Turbidimetric Immunoassay

For quality control of quantitative determination of proteins in human serum by turbidimetric immunoassay

REF TIA CONT21 **R1** 1 x 1 mL **R2** 1 x 1 mL

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

I INTENDED USE

Titrated Control for quality control of quantitative immunochemical determination of proteins in human serum by turbidimetric immunoassay.
Designated for professional use in laboratory with manual or automated procedure with reagent's as follows:

Protein	BIOLABO Reagent
Anti-streptolysin O (ASLO)	REF ASLO050E, ASLO620E, REF K1ASO, K2ASO, K4ASO
C Reactive Protein (CRP)	REF CRP620E, REF CRP050E, REF K150E, K250E
Transferrin (TRF)	REF K1208, K2208, K4208, 92208

REAGENTS

R1	**CONT L1**	Control low	
R2	**CONT H1**	Control High	(Human Origin)

Liquid Plasma diluted in phosphate buffered saline
Contains sodium azide 0.95 g/L

SAFETY CAUTIONS (1) (2)

- 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.

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.

QUALITY CONTROL

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

MATERIAL REQUIRED BUT NOT PROVIDED

1.Reagents (§ Intended use)

REAGENTS PREPARATION

Ready for use

STABILITY AND STORAGE

Stored away from light, well cap in the original vial at 2-8°C, the control 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.

VALUES AND CONFIDENCE INTERVAL (3)

Proteins	CONT L1 LOT	CONT H1 LOT
*ASLO (IU/mL) WHO ***ASLO (IU/mL) SIEMENS		
**CRP (mg/dL)		
**TRF (mg/dL)		

*Values based on WHO standard material
**Values based on a Reference material ERM/DA740k from IFCC
***Values based on Siemens standard material

It is recommended that each laboratory validate each new batch-specific value before use.

For an optimal use, laboratories should establish their own targets and ranges. These target values must be periodically retested.

LIMITS

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) *E.R. Ashwood, W.B. Saunders (1999) p.520*

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