BIOLABO
www.biolabo.fr
MANUFACTURER:
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Control Serum

HDL LDL CK-MB Lipids Level 1

For quality control of enzymes activity (CK-MB and Cholinesterase) and lipids (HDL, LDL, Cholesterol and Triglycerides)

REF 95516 **R1** 2 x 2 mL **R2** 1 x 5 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

TARGET VALUES AND RANGES

LOT xxxxxx	**(IS) Units**	**Conventional units**
HDL-Cholesterol (Direct method)	mmol/L	mg/dL
HDL-Cholesterol- (PTA method) (*)	mmol/L	mg/dL
LDL-Cholesterol (Direct method)	mmol/L	mg/dL
CK-MB (immuno-inhibition) at 37°C	IU/L	IU/L
SCH: Cholinesterase (butyryl thiocholine) at 37°C	IU/L	IU/L
Cholesterol (CHOD-PAP Method)	mmol/L	mg/dL
Triglycerides (GPO Method)	mmol/L	mg/dL

(*) PTA method: Treat control as a specimen (refer to § CALCUL of the insert of the reagent used: REF 86516 or REF 86536).
Values are batch specific. It is recommended that each laboratory validate each new batch-specific values before use.

I INTENDED USE

Control serum Level 1 for use during determination of lipids (HDL-Cholesterol, LDL-Cholesterol, Cholesterol, Triglycerides) and enzymes activity (CK-MB, SCH). Laboratory professional use (manual or automated method).

I GENERALITIES

Human control titrated with BIOLABO reagents as follows :
HDL-Cholesterol (direct method) REF 90206, REF 90406, REF K1206, K2206, K4206
HDL-Cholesterol (PTA method) REF 86516, REF 86536
LDL-Cholesterol (direct method) REF 90416, REF 90816 REF K1416, K2416, K4416
CK-MB (immuno-inhibition method) REF 97217, REF 97317, REF K1207, K2207, K4207
CHOLINESTERASE (Butyrylthiocholin) REF 82526
CHOLESTEROL (CHOD-PAP Method), REF 80106, REF 87356, REF LP80106, REF K1106, K2106
TRIGLYCERIDES (GPO Method) REF 80019, REF 87319, REF LP80519, REF LP80619 REF K1519, K2519

QUALITY CONTROL

Verify the integrity of the vial and batch-specific values before use.

I REAGENTS

R1 CONTROL LEVEL 1

Freeze dried serum — Human Origin

R2 DILUENT

Demineralized water, preservative

I PERFORMANCES (3) (4)

- Assigned values are traceable to a reference method or material, using statistical techniques and metrologically controlled instrument.
- Target values and ranges were obtained using several run of determinations performed under strictly standardized conditions on different laboratories/analyzers with BIOLABO Reagents.
- Each assigned value is the mean of all obtained values for each analytes.

LIMITS

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

MATERIAL REQUIRED BUT NOT PROVIDED

1. Basic medical analysis laboratory equipment.
2. REF 95506 HDL LDL CK-MB Calibrator
3. REF 95015 Multicalibrator or standard enclosed in the kit
4. REF 95526 HDL LDL CK-MB Lipids Control Level 2

SAFETY CAUTIONS (1) (2)

- Refer to current Safety Data Sheet available on request or on www.biolabo.fr
- Each human donation was tested with approved tests and found negative for HBsAg, anti-HCV and anti-HIV I and II.
- 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.

I PREPARATION

- Open the vial R1 carefully and add slowly exactly 2 mL of diluent (R2) at room temperature.
  Recap and wait for 5 to 10 minutes at room temperature. Gently agitate before use (to avoid foam).

I STABILITY AND STORAGE

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

Unopened:
- Until expiry date stated on the label.

Once opened:
- R1 must be reconstituted immediately,
- R2 is stable until expiry date stated on the label.

Once reconstituted, values are usually stable for:
- ✓ 8 hours at 15-25°C
- ✓ 7 days at 2-8°C
- ✓ 4 weeks at – 20°C (**freeze once only**)

Discard any control if cloudy or contaminated.
Don't use reconstituted Control after expiry date stated on the label.

PROCEDURE

- Run in accordance with the IFU of the reagent used.

REFERENCES

(1) *Council Directive (2000/54EC). Official Journal of the European Communities No. L262 from Oct. 17th, 2000.*
(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) *A. VASSAULT et Al., Ann. Biol. clin., 1986, 44, 686-745*
(4) *BIOLABO Quality Standard operating procedures*

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