BIOLABO
www.biolabo.fr
MANUFACTURER:
BIOLABO SAS,
Les Hautes Rives
02160, Maizy, France

Control Serum
HDL LDL CK-MB Lipids Level 2

For quality control of CK-MB activity, HDL / LDL-Cholesterol, Cholinesterase and lipids

REF 95526 **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 (11)

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
Cholinesterase (butyrylthiocholine) 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 and refer to § CALCUL of the insert of the reagent used (i.e. REF 86516 or REF 86536).
Target values and range are obtained by using: BIOLABO reagents and calibrators traceable to a reference method or material, Recommended and validated statistical technics, metrologically controlled instrument. Target values are the mean of values obtained during several determinations of each analyte and range are ±2 or 3 standard deviations.
It is recommended that each laboratory validate each new batch-specific values before use. For an optimal use, laboratories should establish their own targets and ranges. These target values have to be periodically retested.

I INTENDED USE

Assayed multicomponent sera designated for professional use in laboratory (manual or automated procedure) , 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 (Butyrylthiocholine)
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

REAGENTS COMPOSITION

R1 **HDL LDL CK-MB LIPIDS** **CONTROL LEVEL 2**

Lyophilized serum — Human Origin

R2 **DILUENT**

CK-MB and Cholinesterase activities, HDL-Cholesterol, LDL-Cholesterol, Triglycerides, Cholesterol values are indicated in the batch specific table.

MATERIAL REQUIRED BUT NOT PROVIDED

1. Basic medical analysis laboratory equipment.
2. HDL LDL CK-MB Calibrator REF 95506
3. Multicalibrator REF 95015 or standard enclosed in the kit
4. HDL LDL CK-MB Lipids Control Level 1 REF 95516

SAFETY CAUTIONS

- 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.

REAGENT PREPARATION

- Open the vial carefully, avoiding any loss of lyophilised material.
- Reconstitute with exactly 2 mL (2000 µL) of vial R2.
- Close the vial and allow standing for 20 minutes at room temperature.
- Dissolve completely the contents by swirling gently before use.
- PTA method: Treat control as a specimen before use (supernatant).

WARNING: Do not shake. Store away from light.

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, 15 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.

REFERENCES

(1) Gotto, A.M., Lipoprotein metabolism and the etiology of hyperlipidemia, Hospital Practice, 23;Suppl. 1, p.4-p.13 (1988).
(2) Crouse, J.R. and al., Studies of low density lipoprotein molecular weight in human beings with coronary artery disease, J. Lipid Res., 26;p.566-p.574 (1985).
(3) Badimon, J. J., Badimon, L., Fuester, V., Regression of Atherosclerotic Lesions by High Density Lipoprotein Plasma Fraction in the Cholesterol-Fed Rabbit, Journal of Clinical Investigation, 85: p.1234-p.1241 (1990).
(4) Castelli, W.P. and al., LDL Cholesterol and other lipids in coronary heart disease, Circulation, 55; p.767 (1977).
(5) Barr, D.P., Russ E. M., Eder, H.A., Protein-lipid relationships in human plasma, Am. J. Med., 11; p.480-p.493 (1951).
(6) Gordon, T. and al., High density lipoprotein as a protective factor against coronary heart disease, Am. J, Med., 62; p.707-p.714 (1977).
(7) Williams, P., Robinson, D., Baily, A., High density lipoprotein and coronary risk factor, Lancet, 1; p.72-p.75, (1979).
(8) Kannel, W.B., Castelli, W.P., Gordon, T., Cholesterol in the prediction of atherosclerotic disease; New perspectives based on the Framingham study, Am. J. Med., 90: p.85-p.91, (1979).
(9) National Institutes of Health publication No. 93-3095, September, (1993).
(10) Tietz, N. W., Clinical Guide to Laboratory Tests, W. B. Saunders Co., Philadelphia, p. 256-257, (1986)
(11) SMQ BIOLABO : « évaluation et titrage des sérums de contrôles et calibrateurs »

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