BIOLABO
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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
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CE

IVD IN VITRO DIAGNOSTIC USE

PRINCIPE ET UTILISATION

TARGET VALUES AND RANGES (11)

LOT XXXX	(IS) Units	Conventional units
HDL-Cholesterol (Direct method)		
HDL-Cholesterol- (PTA method) (*)		
LDL-Cholesterol (Direct method)		
CK-MB (immuno-inhibition) à 37°C		
Cholinesterase (Butyrylthiocholine) à 37°C		
Cholesterol (CHOD-PAP Method)		
Non-esterified Cholesterol (CHOD-PAP Method)		
Phospholipids (Colorimetric Enzymatic Method)		
Triglycerides (GPO Method)		

(*) 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 value before use. For an optimal use, laboratories should establish their own targets and ranges. These target values have to be periodically retested.

INTENTED USE

This Control Serum is intended to monitor the reproducibility and accuracy of methods and analysis performed with BIOLABO kits for the following analysis :
BIOLABO HDL-Cholesterol (direct method)
REF 90206 (200-250 Tests), REF 90406 (400-500 Tests),
REF 90426 (2000-2500 Tests).
BIOLABO HDL-Cholesterol (PTA method)
REF 86516 (1 x 125 mL), REF 86536 (1 x 30 mL),
BIOLABO LDL-Cholesterol (direct method)
REF 90416 (100-125 tests), REF 90816 (200-250 Tests).
BIOLABO CK-MB (immuno-inhibition method)
REF 97217 (10 x 3 mL), REF 97317 (8 x 20 mL)
BIOLABO CHOLINESTERASE (Butyrylthiocholine)
REF 82526 (5 x 10 mL)
BIOLABO CHOLESTEROL (CHOD-PAP Method),
REF 80106 (2 x 100 mL), REF 87356 (10 x 100 mL), REF 87656 (6 x 500 mL)
BIOLABO PHOSPHOLIPIDS (Colorimetric Enzymatic Method),
REF 99105 (10 x 50 mL), REF 99110 (10 x 100 mL)
BIOLABO Non-esterified CHOLESTEROL (CHOD-PAP Method),
REF 88656 (2 x 100 mL), REF 99656 (6 x 500 mL)
BIOLABO TRIGLYCERIDES (GPO Method),
REF 80019 (2 x 50 mL), REF 87319 (10 x 100 mL)
Suitable for manual procedure or automated instruments.
In case of use with another reagent, refer to corresponding instructions.

REAGENTS COMPOSITION

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

Lyophilised serum (human origin) : 2 x 2 mL.

Vial R2 **DILUENT**

CK-MB and Cholinesterase activity, HDL-Cholesterol, LDL-Cholesterol, Triglycerides, Cholesterol, Phospholipids and Non-esterified Cholesterol concentrations are indicated in the batch specific values 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

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 to stand 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).

Do not shake (to prevent foam formation).

STABILITY AND STORAGE

Store at 2-8°C, well recapped in the original vial and away from light.

- Unopened, lyophilised Control is stable until expiry date stated on the label.
- Without contamination, used and stored as described in the insert, reconstituted Control is 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.

SAFETY CAUTIONS

BIOLABO reagents are designated for professional, in vitro diagnostic use.

- **Caution : Human origin**. Each component of this product has been tested with FDA-approved methods and found nonreactive for the presence of HBsAg, HCV and antibodies to HIV1/2. Because no known test method can offer complete assurance that infectious agents are absent, this material should be handled as potentially infectious.
- Use adequate protections (overall, gloves, glasses).
- Do not pipette by mouth.
- In case of contact with skin or eyes, thoroughly wash affected areas with plenty of water and seek medical advice.
- Reagent contains sodium azide (concentration < 0.1%) which may react with copper and lead plumbing. Flush with plenty of water when disposing.
- Material Safety Data Sheet is available upon request.
- Waste disposal: Respect legislation in force in the country.

All specimens should be handled as potentially infectious, in accordance with good laboratory practices using appropriate precautions. Respect legislation in force in the country.

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 | Use by | IVD In vitro diagnostic | Temperature limitation | REF Catalogue number | See insert | LOT Batch number | Store away from light | Σ sufficient for | → dilute with