



**BIOLABO**  
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# Control Serum

## HDL LDL CK-MB Lipids Level 1

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

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

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IVD IN VITRO DIAGNOSTIC USE

### TARGET VALUES AND RANGES <sup>(11)</sup>

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
Non-esterified Cholesterol (CHOD-PAP Method)	mmol/L	mg/dL
Phospholipids (Colorimetric Enzymatic Method)	mg/dL	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 techniques, metrologically controlled instrument. Target values are the mean of values obtained during several determinations of each analyte and range are  $\pm 2$  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.

### INTENDED 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 1

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

Vial R2

DILUENT

CK-MB and Cholinesterase activities, 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

- Basic medical analysis laboratory equipment.
- HDL LDL CK-MB Calibrator REF 95506
- 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  $\mu$ L) 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).

**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

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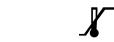
Manufacturer



Use by



In vitro diagnostic



Temperature limitation



Catalogue number



See insert



Batch number



Store away from light



sufficient for



dilute with