BIOLABO REAGENTS
www.biolabo.fr

MANUFACTURER:
BIOLABO SA,
02160, Maizy, France

TECHNICAL SUPPORT AND ORDERS
Tel : (33) 03 23 25 15 50
Fax : (33) 03 23 256 256

HDL / LDL / CK-MB Calibrator

For calibration of HDL-Cholesterol determination (direct method and PTA method)
For calibration of LDL-Cholesterol determination (direct method)
For calibration of CK-MB activity determination (immuno-inhibition method)

REF 95506 **R1** 2 x 2 mL **R2** 1 x 5 mL

CE

IVD **IN VITRO DIAGNOSTIC USE**

INTENTED USE

BIOLABO HDL / LDL / CK-MB calibrator is a preparation of lyophilised human serum containing different forms of lipoproteins, including high density lipoproteins (HDL), low density lipoproteins (LDL) and CK-MB.

The HDL / LDL Cholesterol values are traceable to SRM® 1951b (Standard Reference Material®) which values were determinated at CDC (Center for Disease Control) and are around the medical decision level. CK-MB activity was determined under standardized conditions, using BIOLABO reagents and masterlot calibrator, and metrologically controlled instrument. To be used with:

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-inhibiton method)
REF 97217 (10 x 3 mL), REF 97317 (8 x 20 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 CALIBRATOR**

Lyophilised serum (human origin) : 2 x 2 mL

Vial R2 **DILUENT**

HDL-Cholesterol, LDL-Cholesterol and CK-MB values are indicated in the "Calibration values" table (batch specific values).

MATERIAL REQUIRED BUT NOT PROVIDED

1. Basic medical analysis laboratory equipment.
2. HDL / LDL /CK-MB control sera (human origin)
   REF 95516 HDL / LDL / CK-MB Control, level 1 (2 x 2 mL)
   REF 95526 HDL / LDL / CK-MB Control, level 2 (2 x 2 mL)

PREPARATION

- Open vial R1 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 Calibrator as a specimen before use (supernatant)

Do not shake (to prevent foam formation).

STABILITY AND STORAGE

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

- Unopened, this calibrator is stable until expiry date stated on the label.
- Without contamination, used and stored as described in the insert, reconstituted Calibrator 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 Calibrator if cloudy or contaminated.
Don't use reconstituted Calibrator 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.

CALIBRATION VALUES AND UNCERTAINTY

BATCH	Calibration Values	Uncertainty
CK-MB (immunoinhibition)	IU/L	( )
HDL-Cholesterol (Direct method) IS units	mmol/L	( )
Conventional units	mg/dL	( )
HDL-Cholesterol (PTA method) IS units	mmol/L	( )
Conventional units	mg/dL	( )
LDL-Cholesterol (Direct method) IS units	mmol/L	( )
Conventional units	mg/dL	( )

Calibration values were determinated in several independent laboratories or in our laboratory using :

- BIOLABO procedure and International Standards for HDL and LDL cholesterol (SRM® 1951b : Standard Reference Material®) which values were determinated at CDC (Center for Disease Control) and a BIOLABO masterlot calibrator for the determination of CK-MB activity.
- Recommended and validated statistical technics.
- Metrologically controlled instrument.

Assigned value is the median of values obtained for each analyte.

The assigned value with PTA method is traceable to SRM® 1951b and is obtained with pre-treated calibrator. It is not necessary to multiply the obtained results by calculation factor. Refer to package insert REF 86516 and 86536.

Values in brackets indicate the enlarged uncertainty taking into account all the sources of error which may influence the result

REFERENCES

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(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).*
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(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)*

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