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HDL LDL CK-MB CALIBRATOR

For calibration of lipids determination (HDL-Cholesterol, LDL-Cholesterol)
For calibration during measurement of enzymes activity (CK-MB, SCHE)

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

CE

IVD

Made in France

I: corresponds to significant modifications

I INTENDED USE

For calibration of lipids determination (HDL-Cholesterol, LDL-Cholesterol)
For calibration during measurement of enzymes activity (CK-MB, SCHE).
Laboratory professional use (manual or automated method).

I GENERALITIES

To be used with BIOLABO reagents as follows:
HDL-Cholesterol (direct method)
REF 90206 , 90406,REF K1206, K2206, K4206
HDL-Cholesterol (PTA method) REF 86516, 86536
LDL-Cholesterol (direct method)
REF 90416, 90816, REF K1416, K2416, K4416
CK-MB (immuno-inhibition method)
REF 97217, 97317, REF K1207, K2207, K4207
CHOLINESTERASE (Butyrylthiocholin) REF 82526

I REAGENTS

R1 **HDL LDL CK-MB CALIBRATOR**
Freeze dried serum — Human Origin

R2 **DILUENT**
Demineralized water, preservative

I CALIBRATION VALUES AND UNCERTAINTY

BATCH XXXX

	Traceability	Calibration Values	Uncertainty
Cholinesterase (Butyrylthiocholin)	Masterlot DGKC Standardized method	IU/L	( )
CK-MB (immunoinhibition)	Masterlot IFCC standardized method	IU/L	( )
HDL-Cholesterol IS units	SRM 1951, Direct method	mmol/L	( )
Conventional units		mg/dL	( )
HDL-Cholesterol IS units	SRM 1951, PTA method	mmol/L	( )
Conventional units		mg/dL	( )
LDL-Cholesterol IS units	SRM 1951, Direct method	mmol/L	( )
Conventional units		mg/dL	( )

The calibration values were obtained using several run of determinations performed under strictly standardized conditions on different laboratories/analyzers with BIOLABO Reagents.
Each calibration value is the mean of all obtained values for each analytes.
HDL-cholesterol value (PTA method) is obtained with pre-treated calibrator. It is not necessary to multiply the obtained results by calculation factor. Refer to Reagent IFU REF 86516 and 86536.

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
   REF 95526 HDL LDL CK-MB Control Level 2

I PREPARATION

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

I 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 as described and stored in well re-cap original vial, reconstituted Calibrator is stable for :
  ✓8 hours at 15-25°C
  ✓7 days at 2-8°C

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

I 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 PERFORMANCES (3) (4)

- Assigned values are traceable to a reference method or material, using statistical techniques and metrologically controlled instrument.
- Values may vary from one lot to another, but are clearly indicated for each batch.

QUALITY CONTROL

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

PROCEDURE

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

LIMITS

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

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