BIOLABO
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MANUFACTURER:
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LDL-CHOLESTEROL Direct Method

Reagent for quantitative determination of LDL-Cholesterol in human serum and plasma.

I	REF K1416	**R1**	2 x 15 mL	**R2**	1 x 10 mL		
I	REF K2416	**R1**	1 x 30 mL	**R2**	1 x 10 mL		
I	REF K4416	**R1**	2 x 30 mL	**R2**	1 x 20 mL		
	REF 95506	Calibrator enclosed		**R1**	1 x 2 mL	**R2**	1 x 5 mL

TECHNICAL SUPPORT AND ORDERS
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support@biolabo.fr
Latest revision: www.biolabo.fr

CE

IVD

Made In France

I: corresponds to significant modifications

I INTENDED USE

This reagent is designated for professional use in laboratory (automated method).
It allows the quantitative determination of LDL-Cholesterol in human serum and plasma.

I GENERALITIES (1) (3)

Low density lipoproteins (LDL), are synthesized in the liver by the action of various lipolytic enzymes on triglycerides rich very low density lipoproteins (VLDL). Many epidemiological and clinical studies have shown that an increased LDL-Cholesterol is associated with increased risk of atherosclerosis and coronary artery disease (CAD). Some studies showed that a reduction in LDL-Cholesterol is correlated with regression in atherosclerotic lesion.

PRINCIPLE

Direct method using selective detergents without specimen pre-treatment.
During the first phase, only non-LDL lipoproteins are solubilized by detergent 1. Such generated Cholesterol, subjected to Cholesterol oxidase (CO) and Cholesterol esterase (CE) actions, produces a colorless compound.

During the second phase, detergent 2 solubilizes LDL-Cholesterol. The chromogenic coupler allows for color formation that is proportional to the concentration of LDL-Cholesterol. The absorbance is measured at 546 nm (520-580).

REAGENTS

R1 LDL Reagent Enzymes

MES Buffer pH 6.3	Cholesterol oxidase
Ascorbic acid oxidase	Cholesterol esterase
4-amino-antipyrine	Detergent 1
Peroxidase	Preservative

EUH210: Safety data sheet available on request
EUH208: Contains CO, POD, and CE. May produce an allergic reaction.

R2 LDL Specific Detergent

MES Buffer pH 6.3	DSBmT
Detergent 2	Preservative

MES: morpholino-ethane-sulfonic acid
DSBmT: N,N-bis (4-sulphobutyl)-m-toluidine-disodium

According to 1272/2008/EC regulation, these reagents are not classified as dangerous.

SAFETY CAUTIONS

- Refer to current Material Safety Data Sheet available on request or on www.biolabo.fr
- Verify the integrity of the contents before use.
- Waste disposal: Respect legislation in force in the country.
- All specimens or reagents of biological origin should be handled as potentially infectious. Respect legislation in force in the country.

I 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.

REAGENTS PREPARATION

Ready for use.

STABILITY AND STORAGE

Stored away from light, well caped in the original vial at 2-8°C, when used and stored as described, reagents are stable:
Unopened:
- Until expiry date stated on the label.

Once opened,
- 2 separated reagents are stable for at least 3 months.

Discard any reagent if cloudy or if reagent blank at 546 nm > 0.050.

This kit should be refrigerated during transport.

SPECIMEN COLLECTION AND HANDLING (2) (4)

Specimens should be collected after 12-14 h fasting. Do not use oxalate, fluoride, citrate or heparin.

Plasma: collected on EDTA. Centrifuge and remove plasma from blood cells as soon as possible (within 3 hours).

Serum: Centrifuge and remove serum from blood cells as soon as possible (within 3 hours).

LDL-Cholesterol is stable in the specimen for:
- 1 to 3 days at 2-8°C.
- 1 month at - 20°C.

LIMITS (6) (7)

Specimens with TG > 1293 mg/dL should not be diluted. Increase the volume of reagent R1 and R2, in accordance with the ratios and take into account the dilution factor to calculate the result.

For a more comprehensive review of factors affecting this assay refer to the publication of Young D.S.

MATERIAL REQUIRED BUT NOT PROVIDED

1. Basic medical analysis laboratory equipment.
2. Biochemistry Clinical Analyzer Kenza One, Kenza 240TX/ISE or Kenza 450TX/ISE

EXPECTED VALUES (5)

Serum or plasma	mg/dL	[mmol/L]
Recommended values	< 130	[< 3.36]
Low risk	130-159	[3.36 - 4.11]
High risk	≥ 160	[≥ 4.13]

Each laboratory should establish its own normal ranges for the population that it serves.

PERFORMANCES

On Kenza 240TX,37°C, at 546 nm

Linearity Range: between 11 mg/dL (LQ) and 750 mg/dL

Detection limit: approx. 0.3 mg/dL

Precision:

Within-run N = 20	*Low level*	*Normal level*	*High Level*
Mean (mg/dL)	87	131	236
S.D. mg/dL	2.6	1.2	2.4
C.V. %	3.0	0.9	1.0

Between Run N = 20	*Low level*	*Normal level*	*High level*
Mean (mg/dL)	92	142	262
S.D. mg/dL	2.7	3.6	6.7
C.V. %	3.0	2.6	2.6

Comparison studies with commercially available reagent:

Realized on human specimens (n=99) between 34 and 221 mg/dL

y = 0.9415 x + 3.8 r = 0.9909

Analytical sensitivity: approx. 0.038 abs for 10 mg/dL

Interferences:

Turbidity	No interference up to 0.278 abs
Total bilirubin	No interference up to 369 µmol/L
Direct bilirubin	No interference up to 457 µmol/L
Ascorbic acid	No interference up to 2500 mg/dL
Glucose	No interference up to 950 mg/dL
Hemoglobin	No interference up to 317 µmol/L

Other substances may interfere (see § Limits)

On the board stability: 2 months

Calibration stability: 2 months

Make a new calibration when changing reagent batch, if quality control results are found out of the established range and after maintenance operations.

Performances and stability data on Kenza 450TX/ISE and Kenza One are available on request

CALIBRATION

- REF 95506 HDL LDL CK-MB Calibrator traceable to SRM® 1951 (Standard Reference Material®) assayed on CDC (Center for Disease Control)

The calibration frequency depends on proper instrument functions and on the preservation of the reagent.

QUALITY CONTROL

- REF 95516 HDL LDL CK-MB Control level 1
- REF 95526 HDL LDL CK-MB Control level 2
- External quality control program.

It is recommended to control in the following cases:

- At least once a run.
- At least once within 24 hours.
- When changing vial of reagent.
- After maintenance operations on the instrument.

If control is out of range, apply following actions:

1. Prepare a fresh control serum and repeat the test
2. If control is still out of range, use a new vial of fresh calibrator
3. If control is still out of range, use a new vial of reagent and reassay

If control is still out of range, please contact BIOLABO technical support or your local Agent.

PROCEDURE

Refer to validated application of the Kenza Analyzer used

CALCULATION

The analyzer provides directly final result.
Refer to the instruction of use of Kenza analyzer.

REFERENCES

(1) *TIETZ N.W. Text book of clinical chemistry, 3rd Ed. C.A. Burtis, E.R. Ashwood, W.B. Saunders (1999) p. 819-850.*

(2) *Clinical Guide to Laboratory Test, 4th Ed., N.W. TIETZ (2006) p. 684-689*

(3) *Gotto, A.M., Lipoprotein metabolism and the etiology of hyperlipidemia, Hospital Practice, 23 ; Suppl. 1, 4 (1988)*

(4) *National Institutes on Health publication No 95-3044,p.8, p.48, (1995).*

(5) *Bachorik P. S. et al., National Cholesterol Education Program Recommendations for Measurement of Low Density Lipoprotein Cholesterol ; Executive summary, Clinical Chemistry, (1995), Vol.41, n°10. P.1414-1420.*

(6) *National Committee for Clinical Laboratory Standards, National Evaluation Protocols for Interference Testing, Protocol No 7, Vol. 4,, No 8, (June. 1984).*

(7) *YOUNG D.S., Effect of Drugs on Clinical laboratory Tests, 4th Ed. (1995) p.3-379-386*

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