BIOLABO
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HDL-CHOLESTEROL Direct Method

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

I REF K1206	**R1**	2 x 15 mL	**R2**	1 x 10 mL
I REF K2206	**R1**	1 x 30 mL	**R2**	1 x 10 mL
I REF K4206	**R1**	2 x 30 mL	**R2**	1 x 20 mL
I 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 HDL-Cholesterol in human serum and plasma.

I GENERALITIES (1) (3)

The principal role of high density lipoproteins (HDL) in lipid metabolism is the uptake and transport of cholesterol from peripherical tissues to the liver through a process known as reverse cholesterol transport. Low HDL cholesterol levels are strongly associated with an increased risk of coronary heart disease and coronary artery disease. Hence, the determination of serum HDL-Cholesterol is a useful tool in identifying high-risk patients. Increased Total Cholesterol/HDL-Cholesterol ratio is significant of an increased risk of atherosclerosis.

PRINCIPLE

Accelerator selective detergent methodology.
Direct method, without specimen pre-treatment.
During the first phase, LDL, VLDL particles and Chylomicrons generate free Cholesterol, which through an enzymatic reaction, produce Hydrogen peroxide. The generated peroxide is consumed by a peroxidase reaction with DSBmT yielding a colorless product.

During the second phase, specific detergent solubilizes HDL-Cholesterol. In conjunction with CO and CE action, POD + 4-AAP develop a colored reaction which is proportional to HDL-Cholesterol concentration. The absorbance is measured at 600 nm.

LDL = Low density lipoproteins
VLDL = Very low density lipoproteins
CO = Cholesterol Oxidase
HDL = High density lipoproteins
POD = Peroxidase
CE = Cholesterol Esterase
4-AAP = 4-Aminoantipyrine
AAO = Ascorbate Oxidase
DSBmT = N,N-bis (4-sulphobutyl)-m-toluidine-disodium

REAGENTS COMPOSITION

R1 HDL Accelerator

Good's Buffer		
CO	< 1000	UI/L
POD	< 1300	ppg UI/L
DSBmT	< 1	mmol/L
AAO	< 3000	UI/L
Accelerator	< 1	mmol/L
Preservative	< 0.06	%

R2 HDL Selective Detergent

Good's Buffer		
CE	< 1500	UI/L
4-AAP	< 1	mmol/L
Detergent	< 2	%
Stabilizer	< 0.15	%
Preservative	< 0.06	%

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

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, and used 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 at 2-8°C, 24 h at room temperature.

Discard any reagent if cloudy or if reagent blank at 620 nm > 0.050.

This kit should be refrigerated during transport.

SPECIMEN COLLECTION AND HANDLING (4)

Specimens should be collected after 12 h–14 h fasting.

Plasma: collected on EDTA or lithium/sodium heparinate.
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).

HDL-Cholesterol in specimen is stable for:

- 1 to 3 days at 2-8°C
- 1 month at - 20°C.

LIMITS (5)

This reagent may interfere with the magnesium determination

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 (6)

Serum or plasma	mg/dL	[mmol/L]
Low level (Risk factor)	< 40	< 1.0
High level (Protective factor)	≥ 60	≥ 1.5

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

PERFORMANCES

On Kenza 240TX, 37°C, 620 nm

Linearity Range: between 9 mg/dL (LQ) and 189 mg/dL

Detection limit: approx. 0.3 mg/dL

Precision:

Within-run N = 20	*Low level*	*Normal level*	*High Level*
Mean (mg/dL)	36	52	103
S.D. mg/dL	0.8	1.1	1.7
C.V. %	2.1	2.1	1.6

Between Run N = 20	*Low level*	*Normal level*	*High level*
Mean (mg/dL)	32	48	100
S.D. mg/dL	1	1.5	2
C.V. %	3.2	3.1	2.0

Comparison studies with commercially available reagent:
Realised on human specimens (n=94) between 14 and 96 mg/dL

y = 1.0438 x + 1,77 r = 0.9908

Analytical sensitivity: approx. 0.012 abs for 10 mg/dL

Interferences:

Turbidity	No interference up to 0.171 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: 24 hours

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) *Badimon L. L., Badimon L., Fuester V., Regression of atherosclerotic lesions by HDL plasma fraction in the Cholesterol-fed rabbit, Journal of clinical investigation, (1990), 85, p.1234-1241.*

(2) *Clinical Guide to Laboratory Test, 4th Ed., N.W. TIETZ (2006) p. 564-569*

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

(4) *Warnick, G. Russel, Wood, Peter D., National Cholesterol Education Program Recommendations for Measurement of High-Density Lipoprotein Cholesterol: Executive Summary, Clinical Chemistry, Vol. 41, No 10, 1427-1433 (1995)*

(5) *National Committee for Clinical Laboratory Standards, National Evaluation Protocols for Interference Testing, Evaluation Protocol No 7, Vol. 6, No 13, (Aug. 1986).*

(6) *Recommandations de l'AFSSAPS sur la prise en charge thérapeutique du patient dyslipémique, p.9 (Mars 2005).*

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