BIOLABO
www.biolabo.fr

MANUFACTURER:
BIOLABO SAS,
Les Hautes Rives
02160, Maizy, France

CHOLESTEROL CHOD PAP

Reagent for quantitative determination of Total Cholesterol in human serum and plasma

I REF K1106	**R1** 5 x 17 mL
I REF K2106	**R1** 4 x 30 mL

TECHNICAL SUPPORT AND ORDERS
Tel: (33) 03 23 25 15 50
support@biolabo.fr
Latest revision: www.biolabo.fr

CE

IVD

Made in France
I: corresponds to significant modifications

INTENDED USE

This reagent is designated for professional use in laboratory. It may be used with manual procedure on spectrophotometer or with Biochemistry Clinical Analyzer.
This quantitative test is to determine the concentration of Total Cholesterol in human serum or plasma.

GENERALITIES (1) (2)

I Hypercholesterolemia can be observed in case of dietary imbalance, in in hepatic and thyroid disorders, certain cases of diabetes, nephrotic syndrome, pancreatitis, myeloma or familial hypercholesterolemia.
Total cholesterol increased levels may be isolated or associated to other increased lipids (hyperlipidemia).
A decreased level of cholesterol may be due to deficiencies or malnutrition, cancer or hyperthyroidism.

PRINCIPLE (4)

Enzymatic method described by Allain and al., which reaction scheme is as follows:

Cholesterol esters $\xrightarrow{CE}$ Cholesterol + free fatty acids

Cholesterol + O_2 $\xrightarrow{CO}$ Cholesten 4 one 3 + H_2O_2

2 H_2O_2 + Phenol + PAP $\xrightarrow{POD}$ Quinoneimine (pink) + 4 H_2O

REAGENTS

R1 CHO CHOLESTEROL Reagent

Phosphate buffer	100	mmol/L
Chloro-4-phenol	5	mmol/L
Sodium Cholate	2.3	mmol/L
Triton x 100	1.5	mmol/L
Preservative		
Cholesterol oxidase (CO)	≥ 100	IU/L
Cholesterol esterase (CE)	≥ 170	IU/L
Peroxidase (POD)	≥ 1200	IU/L
4 - Amino – antipyrine (PAP)	0.25	mmol/L
PEG 6000	167	µmol/L

According to 1272/2008 regulation, this reagent is 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.

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 cap in the original vial at 2-8°C, reagent is stable when stored and used as described in the insert:

Unopened:
- Until the expiry date stated on the label of the Kit.

Once opened:
- Reagent is stable at least 3 months when free from contamination.
- Discard reagent if cloudy or if absorbance at 505 nm > 0.400.

SPECIMEN COLLECTION AND HANDLING (2)

Serum or plasma (Heparin or EDTA). Do not use oxalate, fluoride or citrate. Collect on fasting patient. Separate serum from cells within 2 h.

Cholesterol is stable in the specimen for:
- 5-7 days at 2-8°C
- 3 months at –20°C
- Many years at –70°C.
- Avoid repeated freezing and thawing

LIMITATIONS (2) (3) (5)

Enzymatic methods increase analytic specificity. Cholesterol oxidase also reacts with 3β-hydroxycholesterols (insignificant quantity in human serum – i.e. DHEA, pregnenolone).

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

MATERIALS REQUIRED BUT NOT PROVIDED

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

QUALITY CONTROL

- REF 95010 EXATROL-N Level I.
- REF 95011 EXATROL-P Level II.
- 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 calibrator or a fresh calibrator and repeat the test.
3. If control is still out of range, repeat with a new vial of reagent.

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

REFERENCE INTERVAL (2)

Values for adults, in term of risk for atherosclerotic diseases:

Total cholesterol	mg/dL	[mmol/L]
Recommended values	< 200	[< 5.18]
Low risk	200-239	[5.18-6.19]
High risk	≥ 240	[≥ 6.22]

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

PERFORMANCES

On KENZA ONE, 37°C, 505 nm

Linearity Range: between 4 and 400 mg/dL

Detection limit: approx. 0.1 mg/dL

Precision:

Within-run N = 20	*Low level*	*Normal level*	*High level*
Mean (mg/dL)	107	199	270
S.D. mg/dL	1.6	1.8	1.5
C.V. %	1.5	0.9	0.6

Between run N = 20	*Low level*	*Normal level*	*High level*
Mean (mg/dL)	112	212	290
S.D. mg/dL	2.7	5.0	7.3
C.V. %	2.4	2.3	2.5

Analytical Sensitivity: approx. 0.3312 abs for 100 mg/dL

Clinical comparison study with commercially available reagent, using serum specimens between 64 and 323 mg/dL (n=101)

y = 1.0292 x – 3.94 R= 0.9882

Interferences:

Turbidity	No interference up to 0.295 OD
Total bilirubin	Negative interference from 293 µmol/L
Direct bilirubin	Negative interference from 271 µmol/L
Ascorbic acid	Negative interference from 855 mg/dL
Glucose	No interference up to 1212 mg/dL
Haemoglobin	No interference up to 162 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 240TX/ISE are available on request

CALIBRATION (6)

- REF 95015 Multicalibrator traceable *to SRM 1951*

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

PROCEDURE

Refer to validated application of the Kenza Analyzer used

CALCULATION

The analyzer provides directly result in units (mg/dL).

Refer to the instruction of use of Kenza analyzer.

REFERENCES

(1) *TIETZ N.W. Textbook of clinical chemistry, 3rd Ed. C.A. Burtis, E.R. Ashwood, W.B. Saunders (1999) p. 826-835.*
(2) *Clinical Guide to Laboratory Test, 3rd Ed., N.W. TIETZ (1995) p. 130-131.*
(3) *YOUNG D.S., Effect of Drugs on Clinical laboratory Tests, 4th Ed. (1995) p. 3-143 to 3-164*
(4) *Allain C. C. et al., Clin. Chem. (1974), 20/4, p.470-475*
(5) *Allan C., Deacon et Peter J. G. Dawson, Clin. Chem. (1979) 25/6, p.976-984*
(6) *SRM: Standard Reference material ®*

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