

Cholesterol FS*

Order Information

Cat. No.	Kit size
1 1300 99 10 960	Σ 2120 (4 x 530)
1 1300 99 10 967	Σ 1920 (6 x 320)

Intended Use

Diagnostic reagent for quantitative in vitro determination of cholesterol in human serum or heparin plasma on automated BioMajesty® JCA-BM6010/C.

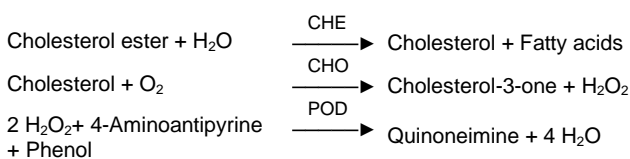
Summary

Cholesterol is a component of cell membranes and a precursor for steroid hormones and bile acids synthesized by body cells and absorbed with food. Cholesterol is transported in plasma via lipoproteins, namely complexes between lipids and apolipoproteins. Four classes of lipoproteins exist: high density lipoproteins (HDL), low density lipoproteins (LDL), very low-density lipoproteins (VLDL) and chylomicrons. While LDL is involved in the cholesterol transport to the peripheral cells, HDL is responsible for the cholesterol uptake from the cells. The four different lipoprotein classes show distinct relationship to coronary atherosclerosis [1,2]. LDL cholesterol (LDL-C) contributes to atherosclerotic plaque formation within the arterial intima and is strongly associated with coronary heart disease (CHD) and related mortality. Even with total cholesterol within the normal range, an increased concentration of LDL-C indicates high risk. HDL-C has a protective effect impeding plaque formation and shows an inverse relationship to CHD prevalence. In fact, low HDL-C values constitute an independent risk factor. The determination of the individual total cholesterol (TC) level is used for screening purposes while for a better risk assessment it is necessary to measure additionally HDL-C and LDL-C. In the last few years several controlled clinical trials using diet, lifestyle changes and / or different drugs (especially HMG CoA reductase inhibitors [statins]) have demonstrated that lowering total cholesterol and LDL-C levels reduce drastically the CHD risk [2].

Method

“CHOD-PAP”: enzymatic photometric test

Determination of cholesterol after enzymatic hydrolysis and oxidation [3,4]. The colorimetric indicator is quinoneimine, which is generated from 4-aminoantipyrine and phenol by hydrogen peroxide under the catalytic action of peroxidase (Trinder's reaction) [3].



Reagent

Components and Concentrations

Good's buffer	pH 6.7	50 mmol/L
Phenol		5 mmol/L
4-Aminoantipyrine		0.3 mmol/L
Cholesterol esterase	(CHE)	≥ 200 U/L
Cholesterol oxidase	(CHO)	≥ 50 U/L
Peroxidase	(POD)	≥ 3 kU/L

Storage and Stability

Reagent is stable up to the date of expiry indicated on the kit, if stored at 2 - 8°C and contamination is avoided. Do not freeze and protect from light.

The open-vial stability of the reagent is 18 months until expiry date.

Warnings and Precautions

- The reagent contains sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
- The reagent contains biological material. Handle the product as potentially infectious according to universal precautions and good laboratory practice.
- N-acetylcysteine (NAC), acetaminophen and metamizole medication leads to falsely low results in patient samples.
- In very rare cases, samples of patients with gammopathy might give falsified results [5].
- Measurement is not influenced by occasionally occurring color changes, as long as the absorbance of the reagent is < 0.3 at 500 - 546 nm.
- In case of product malfunction or altered appearance that could affect the performance, contact the manufacturer.
- Any serious incident related to the product must be reported to the manufacturer and the competent authority of the Member State where the user and/or patient is located.
- Please refer to the safety data sheets (SDS) and take the necessary precautions for the use of laboratory reagents. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.
- For professional use only.

Waste Management

Refer to local legal requirements for chemical disposal regulations as stated in the relevant SDS to determine the safe disposal.

Warning: Handle waste as potentially biohazardous material. Dispose of waste according to accepted laboratory instructions and procedures.

Reagent Preparation

The reagent is ready to use. The bottles are placed directly into the reagent rotor.

Materials Required

General laboratory equipment

Specimen

Human serum or heparin plasma

Only use suitable tubes or collection containers for specimen collection and preparation.

When using primary tubes, follow the manufacturer's instructions.

Stability [6]:

7 days	at	20 – 25°C
7 days	at	4 – 8°C
3 months	at	-20°C

Only freeze once. Discard contaminated specimens.

Calibrators and Controls

DiaSys TruCal U is recommended for calibration. Calibrator values have been made traceable to the reference method gas chromatography-isotope dilution mass spectrometry (GC-IDMS). Use DiaSys TruLab N and P or TruLab L Level 1 and Level 2 for internal quality control. All target values of the controls are traceable to DiaSys reagent/calibrator system. Quality control must be performed after calibration. Control intervals and limits have to be adapted to the individual requirements of each laboratory. Results must be within the defined ranges. Follow the relevant legal requirements and guidelines. Each laboratory should establish corrective action in case of deviations in control recovery.

	Cat. No.	Kit size
TruCal U	5 9100 99 10 063	20 x 3 mL
	5 9100 99 10 064	6 x 3 mL
TruLab N	5 9000 99 10 062	20 x 5 mL
	5 9000 99 10 061	6 x 5 mL
TruLab P	5 9050 99 10 062	20 x 5 mL
	5 9050 99 10 061	6 x 5 mL
TruLab L Level 1	5 9020 99 10 065	3 x 3 mL
TruLab L Level 2	5 9030 99 10 065	3 x 3 mL

Performance Characteristics

Measuring range up to 750 mg/dL, linearity is given within $\pm 5\%$. In case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function.

Limit of detection**	2 mg/dL
Onboard stability	6 weeks
Calibration stability	6 weeks

Interference by	Interferences $\leq 10\%$ up to	Analyte concentration [mg/dL]
Ascorbic acid	6 mg/dL	167
Bilirubin (conjugated)	24 mg/dL	167
Bilirubin (unconjugated)	24 mg/dL	167
Hemolysis	200 mg/dL	168
Lipemia (triglycerides)	2000 mg/dL	168

For further information on interfering substances, refer to the literature [7-9].

Precision			
Repeatability (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	139	202	284
CV [%]	1.07	0.646	0.719
Between day (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	104	171	242
CV [%]	1.77	1.50	1.47

Method comparison (n=100)	
Test x	Competitor Cholesterol (BioMajesty® JCA-BM6010/C)
Test y	DiaSys Cholesterol FS (BioMajesty® JCA-BM6010/C)
Slope	1.00
Intercept	2.13 mg/dL
Coefficient of correlation	0.999

** lowest measurable concentration which can be distinguished from zero; mean + 3 SD (n = 20) of an analyte free specimen.

Conversion Factor

Cholesterol [mg/dL] x 0.02586 = Cholesterol [mmol/L]

Reference Range [10]

Desirable	< 200 mg/dL	< 5.18 mmol/L
Borderline high risk	200 – 239 mg/dL	5.18 – 6.19 mmol/L
High risk	≥ 240 mg/dL	≥ 6.22 mmol/L

Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

Clinical Interpretation

The European Task Force on Coronary Prevention recommends to lower TC concentration to less than 190 mg/dL (5.0 mmol/L) and LDL-cholesterol to less than 115 mg/dL (3.0 mmol/L) [2].

Literature

1. Rifai N, Bachorik PS, Albers JJ. Lipids, lipoproteins and apolipoproteins. In: Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry. 3rd ed. Philadelphia: W.B Saunders Company; 1999. p. 809-61.
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3. Artiss JD, Zak B. Measurement of cholesterol concentration. In: Rifai N, Warnick GR, Dominiczak MH, eds. Handbook of lipoprotein testing. Washington: AACC Press, 1997: p. 99-114.
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* Fluid Stable

Cholesterol FS

Chemistry code 10 130

Application for serum and plasma samples

This application was set up and evaluated by DiaSys. It is based on the standard equipment at that time and does not apply to any equipment modifications undertaken by unqualified personnel.

Analytical Conditions	
R1 volume	90
R2e volume	0
R2 volume	0
R1 diluent vol	0
R2e diluent vol	0
R2 diluent vol	0
Sample vol (S)	1
Sample vol (U)	1
Reagent 1 mix	weak
Reagent 2e mix	weak
Reagent 2 mix	weak
Reaction time	10

Sub-analy. Conditions	
Name	CHOL
Digits	2
M-wave L.	505
S-wave.L	694
Analy.mthd.	EPA
Calc.mthd.	STD
Qualit. judge	No

Analysis Test Condition Setting (M)		
Sample Type	Serum	Urine
Reac. sample vol.	1	1
Diluent method	No dil	No dil
Undil. sample vol.	0	0
Diluent volume	0	0
Diluent position	0	0

entered by user

Endpoint method	
Re.absorb (u)	9.999
Re. Absorb (d)	-9.999

Calculation Method Setting	
M-DET.P.l	0
M-DET.P.m	41
M-DET.P.n	42
S-DET.P.p	0
S-DET.P.r	0
Check D.P.l.	0
Limit value	0.003
Variance	10
Reac.type	Inc

Reaction Rate Method	
Cycle	2
Factor	2
E2 corre	Not do
Blank (u)	9.999
Blank (d)	-9.999
Sample (u)	9.999
Sample (d)	-9.999

Standards Setting	
FV	#
BLK H	9.999
BLK L	-9.999
STD H	9.999
STD L	-9.999