Cholesterol FS*

Diagnostic reagent for quantitative in vitro determination of cholesterol in serum or plasma on Sysmex BX-Series

Order Information

Cat. No.	Kit size	Number of tests
1 1300 99 10 970	R1 4 x 31.7 mL	BX-3010 4 x 200 tests BX-4000 4 x 154 tests

Method

"CHOD-PAP": enzymatic photometric test

Principle

Determination of cholesterol after enzymatic hydrolysis and oxidation. 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) [1,2].

Cholesterol ester + H_2O $\xrightarrow{CHE}$ Cholesterol + Fatty acid

Cholesterol + O_2 $\xrightarrow{CHO}$ Cholesterol-3-one + H_2O_2

2 H_2O_2 + 4-Aminoantipyrine + Phenol $\xrightarrow{POD}$ Quinoneimine + 4 H_2O

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 Instructions and Reagent Stability

The reagent is stable up to the end of the indicated month of expiry, if stored at 2 – 8°C, protected from light and contamination is avoided. Do not freeze the reagent!

Warnings and Precautions

1. The reagent contains sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
2. N-acetylcysteine (NAC), acetaminophen and metamizole medication leads to falsely low results in patient samples.
3. In very rare cases, samples of patients with gammopathy might give falsified results [8].
4. Please refer to the safety data sheets 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.
5. For professional use only!

Waste Management

Please refer to local legal requirements.

Reagent Preparation

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

Specimen

Serum, heparin plasma or EDTA plasma

Stability [3]:

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

Freeze only once. Discard contaminated specimens.

Calibrators and Controls

For calibration the DiaSys TruCal U calibrator is recommended. The assigned values of the calibrator have been made traceable to the reference method gas chromatography-isotope dilution mass spectrometry (GC-IDMS). For internal quality control DiaSys TruLab N and P or TruLab L controls should be assayed. Each laboratory should establish corrective actions 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 (19.4 mmol/L) cholesterol (in case of higher concentrations re-measure samples after manual dilution with NaCl (9 g/L) or use rerun function)	
Limit of detection**	1 mg/dL (0.026 mmol/L) cholesterol
On-board stability	6 weeks
Calibration stability	6 weeks

Interfering substance	Interferences < 10%	Analyte concentration
Ascorbate	up to 6 mg/dL	166 mg/dL (4.29 mmol/L)
Hemoglobin	up to 300 mg/dL	228 mg/dL (5.90 mmol/L)
Bilirubin, conjugated	up to 13 mg/dL	193 mg/dL (4.99 mmol/L)
Bilirubin, unconjugated	up to 15 mg/dL	209 mg/dL (5.41 mmol/L)
Lipemia (triglycerides)	up to 2000 mg/dL	180 mg/dL (4.66 mmol/L)
For further information on interfering substances refer to Young DS [7].		

Precision (BX-3010)			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	82.2	137	286
Mean [mmol/L]	2.13	3.54	7.39
Coefficient of variation [%]	2.02	1.82	1.70
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	142	225	340
Mean [mmol/L]	3.67	5.83	8.79
Coefficient of variation [%]	3.01	2.07	1.49

Method comparison (n=106)	
Test x	Cholesterol FS (BioMajesty 6010C)
Test y	Cholesterol FS (BX-3010)
Slope	1.002
Intercept	–4.04 mg/dL (-0.104 mmol/L)
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 [4]

Desirable	< 200 mg/dL (< 5.2 mmol/L)
Borderline high risk	200 – 240 mg/dL (5.2 – 6.2 mmol/L)
High risk	≥ 240 mg/dL (≥ 6.2 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) [5].

Literature

1. 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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Manufacturer

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