Cholesterol FS*

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

Order Information

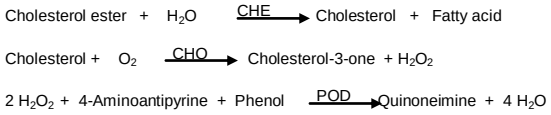
Cat. No.	Kit size	Number of tests
1 1300 99 10 970	R1 4 x 31.7 mL	BX-3010 4 x 200 tests BX-4000 4 x 154 tests

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].



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.
2. Deeg R, Ziegenhorn J. Kinetic enzymatic method for automated determination of total cholesterol in serum. Clin Chem 1983; 29: 1798-802.
3. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001. p. 22-3.
4. Schaefer EJ, McNamara J. Overview of the diagnosis and treatment of lipid disorders. In: Rifai N, Warnick GR, Dominiczak MH, eds. Handbook of lipoprotein testing. Washington: AACC press, 1997: p. 25-48.
5. Recommendation of the Second Joint Task Force of European and other Societies on Coronary Prevention. Prevention of coronary heart disease in clinical practice. Eur Heart J 1998; 19: 1434-503.
6. 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.
7. Young DS. Effects of Drugs on Clinical Laboratory Tests. 5th ed. Volume 1 and 2. Washington, DC: The American Association for Clinical Chemistry Press 2000.
8. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed 2007;45(9):1240-1243.

Manufacturer

DiaSys Diagnostic Systems GmbH
Alte Strasse 9 65558 Holzheim Germany

IVD CE

Cholesterol FS*

Chemistry Code 100 21

Chemistry Parameters 1

Sysmex BX-3010 Chemistry Analyzer
Analytical Parameters

Method No.	*	Method Name	CHOL	Reagent Name	Reagent (µL)	Water (µL)
Print Name	Cholesterol	MethodColor		R1	CHOL	136	
Sample Type	Serum			R2	Disable		
Unit	mg/dL			Diluent	Disable		
Assay Type	End			Sample Ppt. Wash	Disable		

Measuring points

	Start		End
1	45	–	46
2	Disable	–	

Stirring Speed R1: Middle R2:

Wave Length: Prim. 510 Sec. 700

Normal Range

No.	Normal Range Name	Min	Max
1	Male-G1	*	*
2	Male-G2	*	*
3	Male-G3	*	*
4	Female-G1	*	*

	Normal	Sample Volume (µL) Low	Normal	High	Diluted Sample (µL)	Diluent (µL)
☐	Diluent	0.0 <	1.5 <	0.0		
	Rerun (High/Prozone)					
☐	Diluent	0.0 <	1.5 <	0.0		
	Rerun (Low)					
☐	Diluent	0.0 <	1.5 <	0.0		

Technical Range

	(Conc)	1 –	750
	(mAbs/10)	* –	*
Previous Result Comparison (%)		*	* %
Abnormal Range	(Conc)	* –	*
Panic Range	(Conc)	* –	*

Decimal Point: 0 Profile SI: Disable

***Entered by user**

Chemistry Parameters 2

Sysmex BX-3010 Chemistry Analyzer
Analytical Parameters

Method No. * Method Name CHOL Sample Serum

Limit Checks

- ✓ Duplicate Limit: 50 mAbs/10
- ✓ Sensitivity Limit: 500 mAbs/10
- ✓ Linearity Limit: %
- (mAbs/10)/min
- ☐ Prozone Limit: Higher %
- SL1-S – SL1-F
- SL2-S – SL2-F
- Sensitivity: mAbs/10
- ✓ Absorbance Limit
  - Abs. in reaction: Increase
  - Limit: 25000 mAbs/10

Blank measurement

Blank measurement:
Disable reagent blank and C1 blank

Measurement of Reagent Blank during Run:
None

Reagent blank measurement at calibration:
Reagent blank (No sample)

The number of measurement:
Duplicate

Reagent blank limit checks:
✓ Duplicate Limit: 20 mAbs/10

Instrument Factor

a 1.00 b 0.00

Cholesterol FS*

Chemistry Code 100 21

Calibration Registration

Sysmex BX-3010 Chemistry Analyzer
Analytical Parameters

Method No. *

Method Name CHOL

Sample Type Serum

Replication Duplicate

Check Interval 42

Test without calibration: Disable

Calibration Type Linear

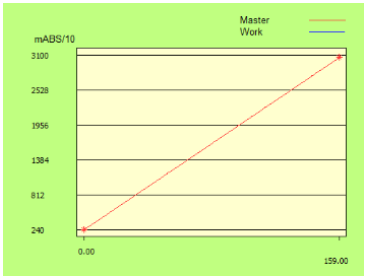
Reagent Lot New Add

Calibrator Name TruCal U

	Conc.	WORK	MASTER	Calibr. Lot No.	☐ All
C1	0	Automatic entry	Automatic entry	*	
C2	*	Automatic entry	Automatic entry	*	
C3	*				
C4	*				
C5	*				
C6	*				
C7	*				

K Automatic entry ☐ C1 Blank ☐ Reagent Blank for C1

Reagent Lot No.
(R1) *
(R2) *
Last



The calibration curve is lot dependent

Reagent blank mAbs/10 Last

Blank Automatic entry mAbs/10 Last

Calibration Curve Conc.

Absorbance mAbs/10 Recalculation

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Cholesterol FS*

Chemistry Code 100 21

Chemistry Parameters

Sysmex BX-4000 Chemistry Analyzer
Analytical Parameters

Method: * | Name: CHOL

Print Name: Cholesterol

Sample: Serum

Unit: mg/dL

Assay Type: End

	Reagent Name	Reagent (µL)	Water (µL)
R1	CHOL	180	
R2 ✓ Enable			
Diluent ☐ Enable			

Measuring points: Start / End

1: 67 – 68

☐ Enable 2: –

Decimal Points: 0

Wave Length: Prim. 510 Sec ☐ Disable 700

Normal Range

No.	Normal Range Name	Min	Max
1	Male-G1	*	*
2	Male-G2	*	*
3	Male-G3	*	*
4	Female-G1	*	*

	Sampling	Sample (µL)	Diluent (µL)
Normal ☐ Dilution	2.0		
Rerun (High/Prozone) ☐ Dilution	2.0		
Rerun (Low) ☐ Dilution	2.0		

Technical Range

(Conc): 1 – 750

(mAbs/10): –

SPT Wash ☐ Enable — Reagent Name:

Stirring Speed: R1 Middle R2

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Chemistry Parameters

Sysmex BX-4000 Chemistry Analyzer
Analytical Parameters

Method No. * | Name CHOL | Sample Serum

Limit Checks

✓ Duplicate Limit: 50 mAbs/10

✓ Sensitivity Limit: 500 mAbs/10

✓ Linearity Limit: % (mAbs/10)/min

☐ Prozone Limit: % Upper

SL1-S: – SL1-F:

SL2-S: – SL2-F:

Sensitivity: mAbs/10

✓ Absorbance Limit

Reaction: Increase

Limit: 25000 mAbs/10

Blank measurement

Blank measurement: Disable reagent blank and S1 blank

Measurement of Reagent Blank during Run: None

Reagent blank measurement at calibration: Reagent blank (No sample)

The number of measurement: Duplicate

Reagent blank limit checks:

✓ Duplicate Limit: 20 mAbs/10

Instrument Factor

a: 1.00 b: 0.00

Cholesterol FS*

Chemistry Code 100 21

Registration Calibration

Sysmex BX-4000 Chemistry Analyzer
Analytical Parameters

Method: * Name: CHOL

Sample: Serum

Sampling: Duplicate

Check Interval: 42 days

Auto: Change Lot Full Calibration

Auto Interval: hours

Type: Linear Lot: New

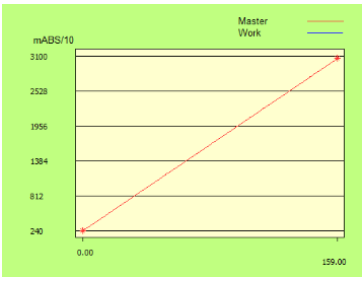
Material Name: NaCL/TruCal U

	Conc.	WORK	MASTER	Lot No. (S) ☐ All
S1	0	Automatic entry	Automatic entry	
S2	*	Automatic entry	Automatic entry	
S3	*			
S4	*			
S5	*			
S6	*			
S7	*			

K: Automatic entry ☐ S1 Blank ☐ Reagent Blank for S1

***Entered by user**

R Lot No. R1: * R2: * Last:



The calibration curve is lot dependent

Reagent blank: mAbs/10 Last:

Blank: Automatic entry mAbs/10 Last:

Type: Conc.:

Absorbance: mAbs/10 Recalculation