

LDL-C Select FS*

Diagnostic reagent for quantitative in vitro determination of low density lipoprotein cholesterol (LDL-C) in serum or plasma on Sysmex BX-Series

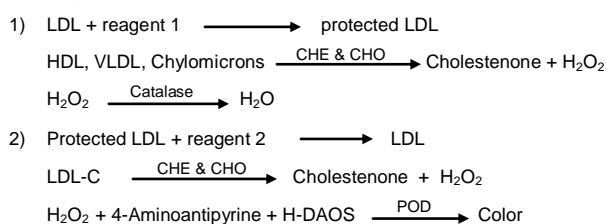
Order information

Cat. No.	Kit size	Number of tests
1 4121 99 10 972	R1 3 x 12.3 mL	BX-3010 3 x 80 tests BX-4000 3 x 61 tests
	R2 3 x 5.1 mL	BX-3010 3 x 80 tests BX-4000 3 x 61 tests

Method

Previous LDL-cholesterol determinations were performed indirectly by calculation from the combined results of total cholesterol, HDL cholesterol and triglycerides using the Friedewald equation [1]. LDL-C Select FS is a homogeneous method without centrifugation steps for the direct measurement of LDL-cholesterol. In a first step, LDL is selectively protected while non-LDL-lipoproteins are enzymatically processed. In a second step, LDL is released and LDL-cholesterol selectively determined in a color producing enzymatic reaction.

Principle



Reagents

Components and Concentrations

R1:	Good's buffer	pH 6.8	20 mmol/L
	Cholesterol esterase (CHE)		≥ 2.5 kU/L
	Cholesterol oxidase (CHO)		≥ 2.5 kU/L
	N-(2-hydroxy-3-sulfopropyl)-3,5-dimethoxyaniline (H-DAOS)		0.5 mmol/L
	Catalase		≥ 500 kU/L
R2:	Good's buffer	pH 7.0	25 mmol/L
	4-Aminoantipyrine		3.4 mmol/L
	Peroxidase (POD)		≥ 15 kU/L

Storage Instructions and Reagent Stability

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

Warnings and Precautions

- Reagent 2 contains sodium azide (0.95 g/L). Do not swallow! Avoid contact with skin and mucous membranes.
- Reagent 1 contains animal material. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practices.
- Artificial lipid mixtures (e.g. Intralipid®) may interfere with the test. Serum samples from patients treated with such solutions should not be used.
- Patient samples with a rare type of Hyperlipoproteinemia (Hyperlipoproteinemia Type III) can bring false results.
- In very rare cases, samples of patients with gammopathy might give falsified results [7].
- N-acetylcysteine (NAC), acetaminophen and metamizole medication leads to falsely low results in patient samples.
- 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 examination and other findings.
- For professional use only!

Waste Management

Please refer to local legal requirements.

Reagent Preparation

The reagents are ready to use. The bottles are placed directly into the reagent trays.

Specimen

Serum or heparin plasma

Stability [2]:

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

Discard contaminated specimens. Only freeze once.

Calibrators and Controls

For calibration, DiaSys TruCal Lipid calibrator is recommended. The assigned values of the calibrator have been made traceable to NIST-SRM®-1951 Level 2. For internal quality control a DiaSys TruLab L control should be assayed. Each laboratory should establish corrective action in case of deviations in control recovery.

	Cat. No.	Kit size
TruCal Lipid	1 3570 99 10 045	3 x 2 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 340 mg/dL (8.79 mmol/L) LDL (in case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function).	
Limit of detection**	0.5 mg/dL (0.013 mmol/L) LDL
On-board stability	3 weeks
Calibration stability	3 weeks

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

Interfering substance	Interferences < 10 %	Analyte concentration
Ascorbate	up to 30 mg/dL	88.3 mg/dL (2.28 mmol/L)
Hemoglobin	up to 500 mg/dL	88.2 mg/dL (2.28 mmol/L)
Bilirubin, conjugated	up to 60 mg/dL	89.0 mg/dL (2.30 mmol/L)
Bilirubin, unconjugated	up to 60 mg/dL	88.7 mg/dL (2.29 mmol/L)
Lipemia (triglycerides)	up to 200 mg/dL	140 mg/dL (3.63 mmol/L)

For further information on interfering substances refer to Young DS [6].

Precision BX-3010

Within run (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	89.6	125	143
Mean [mmol/L]	2.32	3.23	3.70
Coefficient of variation [%]	1.58	1.49	2.08
Between run (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	85.9	116	142
Mean [mmol/L]	2.22	3.00	3.67
Coefficient of variation [%]	1.86	1.54	1.84

Method comparison (n=120)

Test x	DiaSys LDL-C Select FS (BioMajesty BM6010C)
Test y	DiaSys LDL-C Select FS (BX-3010)
Slope	1.00
Intercept	-2.23 mg/dL (-0.058 mmol/L)
Coefficient of correlation	0.997

Conversion factor

LDL-C [mg/dL] x 0.02586 = LDL-C [mmol/L]

Reference Range [3]

Desirable	≤ 130 mg/dL (3.4 mmol/L)
Borderline high risk	130 – 160 mg/dL (3.4 – 4.1 mmol/L)
High risk	> 160 mg/dL (> 4.1 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) [4].

Literature

1. Bachorik PS. Measurement of low-density lipoprotein cholesterol. In: Rifai N, Warnick GR, Dominiczak MH, eds. Handbook of lipoprotein testing. Washington: AACC Press; 1997. p. 145-60.
2. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001; p. 22-3.
3. 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.
4. 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.
5. 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.
6. 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.
7. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: Mechanism, detection and prevention. Clin Chem Lab Med 2007; 45(9): 1240–1243.



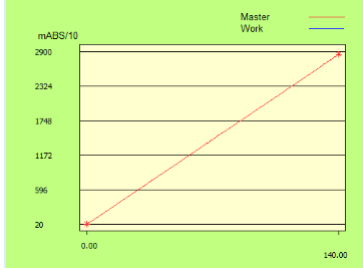
Manufacturer

DiaSys Diagnostic Systems GmbH
Alte Strasse 9 65558 Holzheim Germany

Chemistry Parameters 1				Sysmex BX-3010 Chemistry Analyzer Analytical Parameters																						
Method No.	* <input type="text"/>	Method Name	<input type="text" value="LDL"/>	Reagent Name	Reagent (µL)	Water (µL)																				
Print Name	<input type="text" value="LDL"/>	MethodColor		R1	<input type="text" value="LDL"/>	<input type="text" value="120"/>																				
Sample Type	<input type="text" value="Serum"/>			R2	<input type="text" value="LDL"/>	<input type="text" value="30"/>																				
Unit	<input type="text" value="mg/dL"/>			Diluent	<input type="text" value="Disable"/>																					
Assay Type	<input type="text" value="End"/>			Sample Ppt. Wash	<input type="text" value="Disable"/>																					
Measuring points		Start	End	Stirring Speed R1	<input type="text" value="Middle"/>	R2 <input type="text" value="Middle"/>																				
		1 <input type="text" value="22"/>	- <input type="text" value="23"/>																							
		2 <input type="text" value="45"/>	- <input type="text" value="46"/>																							
Wave Length	Prim. <input type="text" value="600"/>	Sec. <input type="text" value="700"/>		<table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th>No.</th> <th>Normal Range Name</th> <th>Min</th> <th>Max</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>Male-G1</td> <td>*</td> <td>*</td> </tr> <tr> <td>2</td> <td>Male-G2</td> <td>*</td> <td>*</td> </tr> <tr> <td>3</td> <td>Male-G3</td> <td>*</td> <td>*</td> </tr> <tr> <td>4</td> <td>Female-G1</td> <td>*</td> <td>*</td> </tr> </tbody> </table>			No.	Normal Range Name	Min	Max	1	Male-G1	*	*	2	Male-G2	*	*	3	Male-G3	*	*	4	Female-G1	*	*
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1	Male-G1	*	*																							
2	Male-G2	*	*																							
3	Male-G3	*	*																							
4	Female-G1	*	*																							
Normal	Sample Volume (µL)	Diluted Sample (µL)	Diluent (µL)	Technical Range																						
	Low <input type="text" value="0.0"/> < Normal <input type="text" value="1.5"/> < High <input type="text" value="0.0"/>			(Conc) <input type="text" value="0.5"/> - <input type="text" value="340"/>																						
<input type="checkbox"/> Diluent				(mAbs/10) <input type="text" value="*"/> - <input type="text" value="*"/>																						
<input type="checkbox"/> Rerun (High/Prozone)				Previous Result Comparison (%) <input type="text" value="*"/> - <input type="text" value="*"/> %																						
<input type="checkbox"/> Diluent				Abnormal Range (Conc) <input type="text" value="*"/> - <input type="text" value="*"/>																						
<input type="checkbox"/> Rerun (Low)				Panic Range (Conc) <input type="text" value="*"/> - <input type="text" value="*"/>																						
<input type="checkbox"/> Diluent				Decimal Point <input type="text" value="1"/>	Profile SI <input type="text" value="Disable"/>																					

*Entered by user

Chemistry Parameters 2				Sysmex BX-3010 Chemistry Analyzer Analytical Parameters		
Method No.	* <input type="text"/>	Method Name	<input type="text" value="LDL"/>	Sample	<input type="text" value="Serum"/>	
Limit Checks				Blank measurement Blank measurement: <input type="text" value="Disable reagent blank and C1 blank"/> Measurement of Reagent Blank during Run: <input type="text" value="None"/> Reagent blank measurement at calibration: <input type="text" value="Reagent blank (No sample)"/> The number of measurement: <input type="text" value="Duplicate"/> Reagent blank limit checks: <input checked="" type="checkbox"/> Duplicate Limit <input type="text" value="20"/> mAbs/10		
<input checked="" type="checkbox"/> Duplicate Limit	<input type="text" value="100"/>	mAbs/10				
<input checked="" type="checkbox"/> Sensitivity Limit	<input type="text" value="2100"/>	mAbs/10				
<input checked="" type="checkbox"/> Linearity Limit	<input type="text"/>	%				
	<input type="text"/>	(mAbs/10)/min				
<input type="checkbox"/> Prozone Limit	<input type="text" value="Higher"/>	%				
	<input type="text"/>					
	SL1-S <input type="text"/>	-	SL1-F <input type="text"/>			
	SL2-S <input type="text"/>	-	SL2-F <input type="text"/>			
	Sensitivity <input type="text"/>	mAbs/10				
<input checked="" type="checkbox"/> Absorbance Limit				Instrument Factor		
	Abs. in reaction <input type="text" value="Increase"/>			a <input type="text" value="1.00"/>	b <input type="text" value="0.00"/>	
	Limit <input type="text" value="25000"/>	mAbs/10				

Calibration Registration		Sysmex BX-3010 Chemistry Analyzer Analytical Parameters			
Method No.	<input type="text" value="*"/>	Reagent Lot No. (R1)	<input type="text" value="*"/>		
Method Name	<input type="text" value="LDL"/>	Reagent Lot No. (R2)	<input type="text" value="*"/>		
Sample Type	<input type="text" value="Serum"/>	Last	<input type="text"/>		
Replication	<input type="text" value="Duplicate"/>	 <p>The calibration curve is lot dependent</p>			
Check Interval	<input type="text" value="21"/>				
Test without calibration	<input type="text" value="Disable"/>				
Calibration Type	<input type="text" value="Linear"/>				
Reagent Lot	<input type="text" value="New"/> <input type="button" value="Add"/>				
Calibrator Name	<input type="text" value="TruCal Lipid"/>				
Conc.	WORK			MASTER	Calibr. Lot No.
C1	<input type="text" value="0"/> Automatic entry			<input type="text" value="Automatic entry"/>	<input type="text" value="*"/>
C2	<input type="text" value="*"/> Automatic entry			<input type="text" value="Automatic entry"/>	<input type="text" value="*"/>
C3	<input type="text" value="*"/>			<input type="text"/>	<input type="text"/>
C4	<input type="text" value="*"/>	<input type="text"/>	<input type="text"/>		
C5	<input type="text" value="*"/>	<input type="text"/>	<input type="text"/>		
C6	<input type="text" value="*"/>	<input type="text"/>	<input type="text"/>		
C7	<input type="text" value="*"/>	<input type="text"/>	<input type="text"/>		
K	<input type="text" value="Automatic entry"/>	<input type="checkbox"/> C1 Blank <input type="checkbox"/> Reagent Blank for C1			
<p>*Entered by user</p>					
		Reagent blank	<input type="text"/> mAbs/10 Last <input type="text"/>		
		Blank	<input type="text" value="Automatic entry"/> mAbs/10 Last <input type="text"/>		
		Calibration Curve	<input type="text"/> Conc. <input type="text"/>		
		Absorbance	<input type="text"/> mAbs/10 <input type="button" value="Recalculation"/>		

LDL-C Select FS

Chemistry Code 100 57

Chemistry Parameters		Sysmex BX-4000 Chemistry Analyzer Analytical Parameters																								
Method	*	Name	LDL	Reagent Name	Reagent (µL)	Water (µL)																				
Print Name	LDL	R1	LDL	160																						
Sample	Serum	R2	LDL	40																						
Unit	mg/dL	✓ Enable																								
Assay Type	End	Diluent	<input type="checkbox"/> Enable																							
Measuring points		Start	End	Decimal Points	0																					
	1	33	34																							
<input type="checkbox"/> Enable	2	67	68																							
Wave Length	Prim.	600	Sec	<input type="checkbox"/> Disable	700																					
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3	Male-G3	*	*																							
4	Female-G1	*	*																							
<input type="checkbox"/> Normal Dilution 2.0		Sampling	Sample (µL)	Diluent (µL)	Technical Range (Conc) 0.5 - 340 (mAbs/10)																					
<input type="checkbox"/> Rerun (High/Prozone)																										
<input type="checkbox"/> Dilution 2.0																										
<input type="checkbox"/> Rerun (Low)																										
<input type="checkbox"/> Dilution 2.0																										
				SPT Wash	<input type="checkbox"/> Enable	Reagent Name																				
				Stirring Speed	R1	Middle																				
					R2	Middle																				

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Chemistry Parameters		Sysmex BX-4000 Chemistry Analyzer Analytical Parameters																																																																																													
Method No.	*	Name	LDL	Sample	Serum																																																																																										
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Registration Calibration

Sysmex BX-4000 Chemistry Analyzer
Analytical Parameters

Method Name

Sample

Sampling

Check Interval days

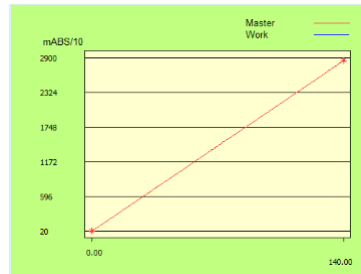
Auto

Auto Interval hours

Type Lot

Material Name

R Lot No. R1 Last
R2



The calibration curve is lot dependent

Reagent blank mAbs/10 Last

Blank mAbs/10 Last

Type Conc.

Absorbance mAbs/10

	Conc.	WORK	MASTER	Lot No. (S) <input type="checkbox"/> All
S1	<input type="text" value="0"/>	Automatic entry	Automatic entry	
S2	*	Automatic entry	Automatic entry	
S3	*			
S4	*			
S5	*			
S6	*			
S7	*			

K S1 Blank Reagent Blank for S1

*Entered by user