BioMajesty

LDL-C Select FS*

Diagnostic reagent for quantitative in vitro determination of low density lipoprotein cholesterol (LDL-C) in serum or plasma on BioMajesty JCA-BM6010/C

Order Information

Cat. No. 1 4121 99 10 964
R1: 6 x 150 tests
R2: 6 x 150 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

1) LDL + reagent 1 ⟶ protected LDL

HDL, VLDL, Chylomicrons $\xrightarrow{\text{CHE \& CHO}}$ Cholestenone + H_2O_2

$H_2O_2 \xrightarrow{\text{Catalase}} H_2O$

2) Protected LDL + reagent 2 ⟶ LDL

LDL-C $\xrightarrow{\text{CHE \& CHO}}$ Cholestenone + H_2O_2

H_2O_2 + 4-Aminoantipyrine + H-DAOS $\xrightarrow{\text{POD}}$ Color

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

1. Reagent 2 contains sodium azide (0.95 g/L). Do not swallow! Avoid contact with skin and mucous membranes.
2. Reagent 1 contains animal material. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practices.
3. Artificial lipid mixtures (e.g. Intralipid®) may interfere with the test. Serum samples from patients treated with such solutions should not be used.
4. Patient samples with a rare type of Hyperlipoproteinemia (Hyperlipoproteinemia Type III) can bring false results.
5. In very rare cases, samples of patients with gammopathy might give falsified results [7].
6. N-acetylcysteine (NAC), acetaminophen and metamizole medication leads to falsely low results in patient samples.
7. 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.
8. 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 400 mg/dL (10.3 mmol/L) LDL-C (in case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function).	
Limit of detection**	1 mg/dL (0.03 mmol/L) LDL-C
On-board stability	4 weeks
Calibration stability	4 weeks

Interferences < 10% by
Ascorbate up to 30 mg/dL
Hemoglobin up to 500 mg/dL
Bilirubin (conjugated and unconjugated) up to 60 mg/dL
Lipemia (triglycerides) up to 200 mg/dL
For further information on interfering substances refer to Young DS [6].

Precision			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	59.8	93.7	125
Mean [mmol/L]	1.55	2.42	3.22
Coefficient of variation [%]	1.10	1.17	0.94
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	68.0	96.8	119
Mean [mmol/L]	1.76	2.50	3.08
Coefficient of variation [%]	1.38	1.15	1.85

Method comparison (n=29)	
Test x	DiaSys LDL-C Select FS Hitachi 917
Test y	DiaSys LDL-C Select FS BioMajesty JCA-BM6010/C
Slope	1.03
Intercept	1.20 mg/dL (0.031 mmol/L) LDL-C
Coefficient of correlation	0.997

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

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].

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Literature

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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.
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IVD CE

Manufacturer

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LDL-C Select FS

Chemistry code 10 412

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	80
R2e volume	0
R2 volume	20
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	LDLC
Digits	2
M-wave L.	596
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.I	0
M-DET.P.m	41
M-DET.P.n	42
S-DET.P.p	17
S-DET.P.r	18
Check D.P.I.	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