respons®910

LDL-C Select FS*

Diagnostic reagent for quantitative in vitro determination of low density lipoprotein cholesterol (LDL-C) in serum or plasma on DiaSys respons®910

Order Information

Cat. No. 1 4121 99 10 921
4 twin containers for 120 tests each

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, protected from light and contamination is avoided. DiaSys respons containers provide protection from light. Do not freeze the reagents!

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. Determination of samples from patients with a rare type of Hyperlipoproteinemia (Hyperlipoproteinemia Type III) may lead to 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 examinations 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 rotor.

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. Freeze only once.

Calibrators and Controls

For calibration, DiaSys TruCal Lipid calibrator is recommended. The assigned values of the calibrator have been made traceable to the NIST-SRM®-1951 Level 2 reference material. 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 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**	2 mg/dL LDL-C
On-board stability	4 weeks
Calibration stability	10 days

Interfering substance	Interferences < 10%	LDL-C [mg/dL]
Ascorbate	up to 30 mg/dL	96.1
Hemoglobin	up to 350 mg/dL	60.3
	up to 550 mg/dL	85.2
Bilirubin, conjugated	up to 70 mg/dL	64.9
	up to 70 mg/dL	93.4
Bilirubin, unconjugated	up to 80 mg/dL	62.5
	up to 80 mg/dL	88.9
Lipemia (Lipofundin)	up to 190 mg/dL	60.3
Lipemia (triglycerides)	up to 200 mg/dL	74.7
For further information on interfering substances refer to Young DS [3].		

Precision			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	62.2	84.5	127
Coefficient of variation [%]	2.66	2.62	2.25
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	63.1	88.7	127
Coefficient of variation [%]	4.05	4.40	1.73

Method comparison (n=91)	
Test x	DiaSys LDL-C Select FS (Hitachi 917)
Test y	DiaSys LDL-C Select FS (respons®910)
Slope	0.999
Intercept	0.546 mg/dL
Coefficient of correlation	0.988

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

Conversion factor:

LDL-Cholesterol [mg/dL] x 0.0259 = LDL-Cholesterol [mmol/L]

Reference Range [4]

Desirable	≤ 130 mg/dL (3.4 mmol/L)
Borderline high risk	130 – 60 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) [5].

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. 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.
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. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: Mechanism, detection and prevention. Clin Chem Lab Med 2007; 45(9): 1240–1243.

Manufacturer

IVD CE

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respons®910

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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.

Identification	
This method is usable for analysis:	Yes
Twin reaction:	No
Name:	LDL-C
Shortcut:	
Reagent barcode reference:	026
Host reference:	026

Technic	
Type:	End point
First reagent:[µL]	180
Blank reagent	Yes
Sensitive to light	
Second reagent:[µL]	45
Blank reagent	No
Sensitive to light	
Main wavelength:[nm]	600
Secondary wavelength:[nm]	700
Polychromatic factor:	1.0000
1 st reading time [min:sec]	(04:24)
Last reading time [min:sec]	10:00
Reaction way:	Increasing
Linear Kinetics Substrate depletion: Absorbance limit	
Linearity: Maximum deviation [%]	
Fixed Time Kinetics Substrate depletion: Absorbance limit	
Endpoint Stability: Largest remaining slope	
Prozone Limit [%]	

Reagents	
Decimals	
Units	

Sample	
Diluent	DIL A (NaCl)
Hemolysis:	
Agent [µL]	0 (no hemolysis)
Cleaner	
Sample [µL]	0
Technical limits	
Concentration technical limits-Lower	2.0000
Concentration technical limits-Upper	400.0000
SERUM	
Normal volume [µL]	2.0
Normal dilution (factor)	1
Below normal volume [µL]	
Below normal dilution (factor)	
Above normal volume [µL]	2.0
Above normal dilution (factor)	6
URINE	
Normal volume [µL]	2.0
Normal dilution (factor)	1
Below normal volume [µL]	
Below normal dilution (factor)	
Above normal volume [µL]	2.0
Above normal dilution (factor)	6
PLASMA	
Normal volume [µL]	2.0
Normal dilution (factor)	1
Below normal volume [µL]	
Below normal dilution (factor)	
Above normal volume [µL]	2.0
Above normal dilution (factor)	6
CSF	
Normal volume [µL]	2.0
Normal dilution (factor)	1
Below normal volume[µL]	
Below normal dilution (factor)	
Above normal volume [µL]	2.0
Above normal dilution (factor)	6
Whole blood	
Normal volume [µL]	2.0
Normal dilution (factor)	1
Below normal volume[µL]	
Below normal dilution (factor)	
Above normal volume [µL]	2.0
Above normal dilution (factor)	6

Results	
Decimals	2
Units	mg/dL
Correlation factor-Offset	0.0000
Correlation factor-Slope	1.0000

Range	
Gender	All
Age	
SERUM	<=130.00
URINE	
PLASMA	<=130.00
CSF	
Whole blood	
Gender	
Age	
SERUM	
URINE	
PLASMA	
CSF	
Whole blood	

Contaminants
Please refer to r910 Carryover Pair Table

Calibrators details	
Calibrator list	**Concentration**
Cal. 1/Blank	0
Cal. 2	*
Cal. 3	
Cal. 4	
Cal. 5	
Cal. 6	
	Max delta abs.
Cal. 1	0.003
Cal. 2	0.015
Cal. 3	
Cal. 4	
Cal. 5	
Cal. 6	
Drift limit [%]	0.80

Calculations	
Model	X
Degree	1

* Enter calibrator value