respons®920

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®920

Order Information

Cat. No. 1 4121 99 10 921
4 twin containers for 120 determinations 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. Patient samples with a rare type of Hyperlipoproteinemia (Hyperlipoproteinemia Type III) can bring false results.
5. To avoid carryover interference, please take care of efficient washing especially after use of interfering reagents. Please refer to the DiaSys respons®920 Carryover Pair Table. Carryover pairs and automated washing steps with the recommended cleaning solution can be specified in the system software. Please refer to the user manual.
6. In very rare cases, samples of patients with gammopathy might give falsified results [7].
7. N-acetylcysteine (NAC), acetaminophen and metamizole medication leads to falsely low results in patient samples.
8. 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.
9. 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

DiaSys TruCal Lipid calibrator is recommended for calibration. The assigned values of the calibrator have been made traceable to the NIST-SRM®-1951 Level 2 reference material. For internal quality control, 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**	1 mg/dL LDL-C
On-board stability	4 weeks
Calibration stability	4 weeks

Interferences < 10% by
Ascorbate up to 30 mg/dL
Hemoglobin up to 700 mg/dL
Conjugated Bilirubin up to 60 mg/dL
Unconjugated Bilirubin up to 60 mg/dL
Lipemia (triglycerides) up to 500 mg/dL
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]	72.8	118	146
Coefficient of variation [%]	2.03	1.66	0.99
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	73.7	115	147
Coefficient of variation [%]	2.04	1.79	1.77

Method comparison (n=112)	
Test x	DiaSys LDL-C Select FS (Hitachi 917)
Test y	DiaSys LDL-C Select FS (respons®920)
Slope	1.02
Intercept	2.20 mg/dL
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-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 - 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].

* fluid stable

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: mechanisms, detection and prevention. ClinChemLabMed 2007;45(9):1240–1243.

IVD CE

Manufacturer

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respons®920

LDL-C Select FS

Application for serum and plasma

Test Details			Test Volumes			Reference Ranges		
Test	:	LDLC				Auto Rerun	☐	
Report Name	:	LDL – C				Online Calibration	☐	
Unit	:	mg/dL	Decimal Places	:	2	Cuvette Wash	☐	
Wavelength-Primary	:	578	Secondary	:	700	Total Reagents	:	2
Assay Type	:	2-Point	Curve Type	:	Linear	Reagent R1	:	LDLC R1
M1 Start	:	15	M1 End	:	15	Reagent R2	:	LDLC R2
M2 Start	:	33	M2 End	:	33			
Sample Replicates	:	1	Standard Replicates	:	3	Consumables/Calibrators:		
Control Replicates	:	1	Control Interval	:	0	Blank/Level 0	:	o
Reaction Direction	:	Increasing	React. Abs. Limit	:	0.00	Calibrator 1	:	*
Prozone Limit %	:	0	Prozone Check	:	Lower			
Linearity Limit %	:	0	Delta Abs./Min.	:	0.00			
Technical Minimum	:	1.00	Technical Maximum	:	400.00			
Y = aX + b a=	:	1.00	b=	:	0.00			

* Enter calibrator value.

Test Details			Test Volumes	Reference Ranges
Test	:	LDLC		
Sample Type	:	Serum		

Sample Volumes

Normal	:	2.00 µL	Dilution Ratio	:	1 X
Increase	:	4.00 µL	Dilution Ratio	:	1 X
Decrease	:	2.00 µL	Dilution Ratio	:	2 X
Standard Volume	:	2.00 µL			

Reagent Volumes and Stirrer Speed

RGT-1 Volume	:	180 µL	R1 Stirrer Speed	:	High
RGT-2 Volume	:	45 µL	R2 Stirrer Speed	:	High

Sample Types

- ☑ Serum
- ☐ Urine
- ☐ CSF
- ☑ Plasma
- ☐ Whole Blood
- ☐ Other

Test Details			Test Volumes	Reference Ranges
Test	:	LDLC		
Sample Type	:	Serum		
Reference Range	:	DEFAULT		
Category	:	Male		

Reference Range

		Lower Limit (mg/dL)	Upper Limit (mg/dL)
Normal	:	0.00	130.00
Panic	:	0.00	0.00

Sample Types

- ☑ Serum
- ☐ Urine
- ☐ CSF
- ☑ Plasma
- ☐ Whole Blood
- ☐ Other