respons®920

HDL-C Immuno FS*

Diagnostic reagent for quantitative in vitro determination of high density lipoprotein cholesterol (HDL-C) in serum or plasma on DiaSys respons®920

Order Information

Cat. No. 1 3521 99 10 920
4 twin containers for 200 determinations each
Cat. No. 1 3521 99 10 921
4 twin containers for 120 determinations each

Method

Previous HDL-cholesterol determinations were performed by time consuming precipitation methods [1]. HDL-C Immuno FS is a homogeneous method for HDL-cholesterol measurement without centrifugation steps. Antibodies against human lipoproteins are used to form antigen-antibody complexes with LDL, VLDL and chylomicrons in a way that only HDL-cholesterol is selectively determined by an enzymatic cholesterol measurement [2].

Principle

LDL, VLDL, Chylomicrons $\xrightarrow{\text{Anti-human β-lipoprotein antibodies}}$ Antigen-antibody complexes + HDL

HDL-cholesterol + $H_2O + O_2$ $\xrightarrow{\text{CHE \& CHO}}$ Cholest-4-en-3-one + fatty acid + H_2O_2

H_2O_2 + F-DAOS + 4-Aminoantipyrine $\xrightarrow{\text{POD}}$ Blue complex + H2O

Reagents

Components and Concentrations

R1:	Good's buffer	pH 7.0	25 mmol/L
	4-Aminoantipyrine		0.75 mmol/L
	Peroxidase	(POD)	2 kU/L
	Ascorbate oxidase		2.25 kU/L
	Anti-human β - lipoprotein antibody (sheep)		
R2:	Good's buffer	pH 7.0	30 mmol/L
	Cholesterol esterase	(CHE)	4 kU/L
	Cholesterol oxidase	(CHO)	20 kU/L
	N-Ethyl-N-(2-hydroxy-3-sulfopropyl)-3,5-dimethoxy-4-fluoroaniline, sodium salt	(F-DAOS)	0.8 mmol/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. Do not freeze the reagents!

Warnings and Precautions

1. Reagent 1: Warning. Contains: Mixture of 5-chlorine-2-methyl-2H-isothiazol-3-on and 2-methylen-2H-isothiazol-3-on (3:1). H317 May cause an allergic skin reaction. H412 Harmful to aquatic life with long lasting effects. P273 Avoid release to the environment. P280 Wear protective gloves/protective clothing/eye protection. P302+P352 If o skin: Wash with plenty of water/soap. P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
2. The reagents contain animal material. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practices.
3. 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.
4. In very rare cases, samples of patients with gammopathy might give falsified results [8].
5. N-acetylcysteine (NAC), acetaminophen and metamizole medication leads to falsely low results in patient samples.
6. 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.
7. 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 [3]:
2 days 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 has to be used 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 the 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 180 mg/dL HDL-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 HDL-C
On-board stability	4 weeks
Calibration stability	4 weeks

Interferences < 10% by
Ascorbate up to 30 mg/dL
Hemoglobin up to 800 mg/dL
Bilirubin up to 60 mg/dL
Lipemia (triglycerides) up to 1000 mg/dL
For further information on interfering substances refer to Young DS [4].

Precision			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	13.3	35.2	54.3
Coefficient of variation [%]	2.48	2.32	2.12
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	12.9	34.0	53.9
Coefficient of variation [%]	4.36	3.00	3.12

Method comparison (n=112)	
Test x	DiaSys HDL-C Immuno FS (Hitachi 917)
Test y	DiaSys HDL-C Immuno FS (respons®920)
Slope	0.989
Intercept	–0.450 mg/dL
Coefficient of correlation	0.998

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

Conversion factor

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

Reference Range [5]

National Cholesterol Education Program (NCEP) guidelines:

Low HDL-cholesterol (major risk factor for coronary heart disease (CHD)):
< 40 mg/dL (< 1.04 mmol/L)

High HDL-cholesterol ("negative" risk factor for CHD):
≥ 60 mg/dL (≥ 1.55 mmol/L)

A number of factors contribute to low HDL-cholesterol levels: e.g. overweight and obesity, smoking, physical inactivity, drugs such as beta-blockers and progestational agents, genetic factors.

Each laboratory should check if reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

* fluid stable

Literature

1. Wiebe DA, Warnick GR. Measurement of high-density lipoprotein cholesterol. In: Rifai N, Warnick GR, Dominiczak MH, eds. Handbook of lipoprotein testing. Washington: AACC Press, 1997. p. 127-44.
2. Nauck M, Maerz W, Wieland H. New immunoseparation-based homogenous assay for HDL-cholesterol compared with three homogenous and two heterogeneous methods for HDL-cholesterol. Clin Chem 1998; 44: 1443-51.
3. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001; p. 22-3.
4. 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.
5. Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III). NIH Publication No 02-5215; September 2002.
6. 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.
7. 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.
8. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed 2007;45(9):1240–1243.

Manufacturer

IVD CE

DiaSys Diagnostic Systems GmbH
Alte Strasse 9 65558 Holzheim Germany

respons®920

HDL-C Immuno FS

Application for serum and plasma

Test Details			Test Volumes			Reference Ranges		
Test	:	HDLC				Auto Rerun		☐
Report Name	:	HDL–C				Online Calibration		☐
Unit	:	mg/dL	Decimal Places	:	1	Cuvette Wash		☐
Wavelength-Primary	:	578	Secondary	:	700	Total Reagents	:	2
Assay Type	:	2-Point	Curve Type	:	Linear	Reagent R1	:	HDLC R1
M1 Start	:	15	M1 End	:	15	Reagent R2	:	HDLC R2
M2 Start	:	33	M2 End	:	33			
Sample Replicates	:	1	Standard Replicates	:	3	Consumables/Calibrators:		
Control Replicates	:	1	Control Interval	:	0	Blank/Level 0	:	0
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	:	180.00			
Y = aX + b a=	:	1.00	b=	:	0.00			

* Enter calibrator value.

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

Reference Range

		Lower Limit (mg/dL)	Upper Limit (mg/dL)
Normal	:	40.00	180.00
Panic	:	0.00	0.00

Sample Types

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