respons®910

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®910

Order Information

Cat. No. 1 3521 99 10 920
4 twin containers for 200 tests each
Cat. No. 1 3521 99 10 921
4 twin containers for 120 tests 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 + H_2O

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. In very rare cases, samples of patients with gammopathy might give falsified results [8].
4. N-acetylcysteine (NAC), acetaminophen and metamizole medication leads to falsely low results in patient samples.
5. 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.
6. 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 [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

For calibration, DiaSys TruCal Lipid calibrator has to be used. 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 145 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	10 days

Interfering substance	**Interferences < 10%**	**HDL [mg/dL]**
Ascorbate	up to 30 mg/dL	49.1
Hemoglobin	up to 550 mg/dL	43.4
	up to 550 mg/dL	71.4
Bilirubin, conjugated	up to 70 mg/dL	40.0
	up to 70 mg/dL	67.1
Bilirubin, unconjugated	up to 80 mg/dL	42.5
	up to 80 mg/dL	69.3
Lipemia (triglycerides)	up to 1700 mg/dL	36.6
	up to 1700 mg/dL	62.9
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]	43.8	69.3	103
Coefficient of variation [%]	1.94	2.33	2.84
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	48.2	75.0	116
Coefficient of variation [%]	3.37	3.30	2.19

Method comparison (n=120)	
Test x	DiaSys HDL-C Immuno FS (Hitachi 917)
Test y	DiaSys HDL-C Immuno FS (respons®910)
Slope	1.042
Intercept	–1.698 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.

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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: Mechanism, detection and prevention. Clin Chem Lab Med 2007; 45(9): 1240–1243.

IVD CE

Manufacturer

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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:	HDL-C
Shortcut:	
Reagent barcode reference:	025
Host reference:	025

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	1.0000
Concentration technical limits-Upper	145.0000
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	>=40.00 <=145.00
URINE	
PLASMA	>=40.00 <=145.00
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	0.010
Cal. 3	
Cal. 4	
Cal. 5	
Cal. 6	
Drift limit [%]	0.80

Calculations	
Model	X
Degree	1

* Enter calibrator value