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
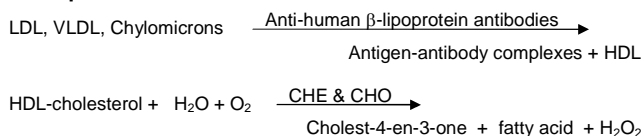
Order Information

Cat. No. 1 3521 99 10 920
4 twin containers for 200 tests each

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

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

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

$$H_2O_2 + F\text{-DAOS} + 4\text{-Aminoantipyrine} \xrightarrow{POD} \text{Blue complex} + H_2O$$

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. DiaSys respons containers provide protection from light. Do not freeze the reagents!

Warnings and Precautions

1. Reagent R1 is irritating. R43: May cause sensitisation by skin contact. S24: Avoid contact with skin. S37: Wear suitable gloves.
2. In very rare cases, samples of patients with gammopathy might give falsified results.
3. 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.

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 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]

≥ 35 mg/dL (≥ 0.9 mmol/L)

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

Clinical Interpretation

Epidemiological studies have observed that low HDL-cholesterol concentrations < 39 mg/dL (1.0 mmol/L) in men and < 43 mg/dL (1.0 mmol/L) in women, especially if associated with fasting triglycerides > 180 mg/dL (2.0 mmol/L), predict a high risk of coronary heart disease [5].

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. 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.
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.

Manufacturer

IVD CE

DiaSys Diagnostic Systems GmbH
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respons®910

HDL-C Immuno FS

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
Name:	HDLC
Shortcut:	
Reagent barcode reference:	025
Host reference:	

Technic	
Type:	Endpoint
First reagent:[µL]	180
Blanc correction	Yes
Second reagent:[µL]	45
Blanc correction	Yes
Main wavelength:[nm]	600
Secondary wavelength:[nm]	700
Polychromatic factor:	1.000
1 st reading time [min:sec]	(04:24)
Last reading time [min:sec]	10:00
Reaction way:	Increasing
Linear Kinetics Substrate deplation: absorbance limit	
Linearity: Maximum deviation [%]	
Fixed Time Kinetics Substrate deplation: absorbance limit	
Endpoint Stability: largest remaining slope	-
Prozone Limit [%]	-

Sample	
Diluent	NaCl
Concentration technical limits-Lower	1
Concentration technical limits-Upper	145
SERUM	
Normal volume [µL]	2
Normal dilution (factor)	1
Below normal volume [µL]	4
Below normal dilution (factor)	1
Above normal volume [µL]	2
Above normal dilution (factor)	6
URIN	
Normal volume [µL]	2
Normal dilution (factor)	1
Below normal volume [µL]	4
Below normal dilution (factor)	1
Above normal volume [µL]	2
Above normal dilution (factor)	6
PLASMA	
Normal volume [µL]	2
Normal dilution (factor)	1
Below normal volume [µL]	4
Below normal dilution (factor)	1
Above normal volume [µL]	2
Above normal dilution (factor)	6
CSF	
Normal volume [µL]	2
Normal dilution (factor)	1
Below normal volume[µL]	4
Below normal dilution (factor)	1
Above normal volume [µL]	2
Above normal dilution (factor)	6

Results	
Decimals	2
Units	mg/dL
Correlation factor-Offset	0.000
Correlation factor-Slope	1.000

Range	
Genre	All
Age	
SERUM	>=35
URINE	
PLASMA	>=35
CSF	
Genre	
Age	
SERUM	
URINE	
PLASMA	
CSF	

Contaminants	
Contaminant 1	
Wash with	
Cycle	
Volume [µL]	
Contaminant 2	
Wash with	
Cycle	
Volume [µL]	

Calibrators details	
Calibrator list	Concentration
Cal. 1	0
Cal. 2	*
Cal. 3	*
Cal. 4	*
Cal. 5	*
Cal. 6	*

	Max delta abs.
Cal. 1	0.015
Cal. 2	0.010
Cal. 3	
Cal. 4	
Cal. 5	
Cal. 6	
Drift limit [%]	0.8

Calculations	
Model	X degree
Degree	1

* Enter calibrator value