

HDL-C Immuno FS*

Diagnostic reagent for quantitative in vitro determination of high density lipoprotein cholesterol (HDL-C) in serum or plasma on BioMajesty JCA-BM6010C

Order Information

Cat. No. 1 3521 99 10 962

R1: 6 x 315 tests

R2: 6 x 315 tests

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

HDL-cholesterol + H₂O + O₂ $\xrightarrow{\text{CHE \& CHO}}$ Cholest-4-en-3-one + fatty acid + H₂O₂

H₂O₂ + 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 on 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

Freeze only once. Discard contaminated specimens.

Calibrators and Controls

For calibration, DiaSys TruCal Lipid has to be used. The assigned values of the calibrator have been made traceable to the reference material NIST-SRM®-1951 Level 2. 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 180 mg/dL (4.8 mmol/L) 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 (0.03 mmol/L) HDL-C
On-board stability	6 weeks
Calibration stability	6 weeks

Interferences < 10% by	
Ascorbate up to 30 mg/dL	
Hemoglobin up to 500 mg/dL	
Bilirubin (conjugated and unconjugated) up to 60 mg/dL	
Lipemia (triglycerides) up to 1400 mg/dL	
For further information on interfering substances refer to Young DS [7].	

Precision			
Within run (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	35.6	54.7	68.9
Mean [mmol/L]	0.92	1.42	1.78
Coefficient of variation [%]	1.01	0.67	1.18
Between run (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	41.4	58.3	67.9
Mean [mmol/L]	1.07	1.51	1.76
Coefficient of variation [%]	1.79	1.77	1.52

Method comparison (n=99)	
Test x	DiaSys HDL-C Immuno FS Hitachi 917
Test y	DiaSys HDL-C Immuno FS BioMajesty JCA-BM6010C
Slope	0.965
Intercept	2.47 mg/dL (0.064 mmol/L)
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 [4]

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.

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

Manufacturer



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HDL-C Immuno FS

Chemistry code 10 352

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.

Analytical Conditions	
R1 volume	80
R2e volume	0
R2 volume	20
R1 diluent vol	0
R2e diluent vol	0
R2 diluent vol	0
Sample vol (S)	1.0
Sample vol (U)	1
Reagent 1 mix	weak
Reagent 2e mix	weak
Reagent 2 mix	weak
Reaction time	10

Sub-analy. Conditions	
Name	HDLC
Digits	2
M-wave L.	596
S-wave.L	694
Analy.mthd.	EPA
Calc.mthd.	STD
Qualit. judge	No

Analysis Test Condition Setting (M)		
Sample Type	Serum	Urine
Reac. sample vol.	1.0	1.0
Diluent method	No dil	No dil
Undil. sample vol.	0	0
Diluent volume	0	0
Diluent position	0	0

entered by user

Endpoint method	
Re.absorb (u)	9.999
Re. Absorb (d)	-9.999

Calculation Method Setting	
M-DET.P.l	0
M-DET.P.m	41
M-DET.P.n	42
S-DET.P.p	17
S-DET.P.r	18
Check D.P.l.	0
Limit value	0.003
Variance	10
Reac.type	Inc

Reaction Rate Method	
Cycle	2
Factor	2
E2 corre	Not do
Blank (u)	9.999
Blank (d)	-9.999
Sample (u)	9.999
Sample (d)	-9.999

Standards Setting	
FV	#
BLK H	9.999
BLK L	-9.999
STD H	9.999
STD L	-9.999