Cat. No 4-179 and 4-479

PRESTIGE 24i HDL DIRECT

II GENERATION

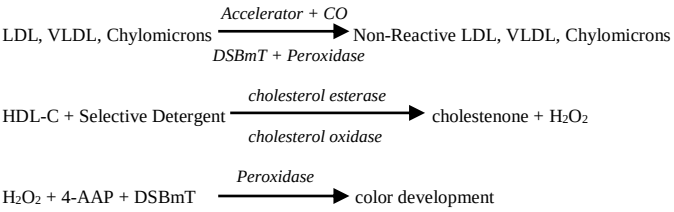
DIAGNOSTIC KIT FOR DETERMINATION OF HDL-CHOLESTEROL CONCENTRATION (DIRECT METHOD)

INTRODUCTION

Plasma lipoproteins are spherical particles containing varying amounts of cholesterol, triglycerides, phospholipids and proteins. The relative protein and lipid determine the density of these lipoproteins and provide the basis on which to begin their classification. The classes are: chylomicron, very-low-density lipoprotein (VLDL), low-density-lipoprotein (LDL) and high-density lipoprotein (HDL). The principle role of HDL in lipid metabolism is the uptake and transport of cholesterol from peripheral tissues to the liver. Low HDL cholesterol (HDL-C) levels are strongly associated with an increased risk of coronary artery disease. The HDL-C determination is used to identify high-risk patients.

METHOD PRINCIPLE

The assay is a homogeneous method for directly measuring HDL-cholesterol concentration in serum or plasma, without any off-line pretreatment or centrifugation steps.
Accelerator selective detergent methodology.
During the first phase, LDL, VLDL particles and Chylomicrons generate free non-HDL cholesterol, which through an enzymatic reaction, produce hydrogen peroxide. The generated peroxide is consumed by a peroxidase reaction with DSBmT yielding a colourless product.
During the second phase, specific detergent solubilises HDL-Cholesterol. In conjuction with cholesterol oxidase (CO) and cholesterol esterase (CE) action, peroxidase and 4-AAP develop a coloured reaction which is proportional to HDL-Cholesterol concentration.



REAGENTS

Package

	Cat. No 4-179 (24-TRAY)	Cat. No 4-479 (36-TRAY)
1-Reagent	4 x 40 ml	6 x 23 ml
2-Reagent	4 x 15 ml	6 x 9 ml

The reagents are stable up to the kit expiry date printed on the package when stored at 2-8°C. Stability on board of the analyser at 2-10°C: Prestige 24i - 12 weeks, Biolis 24i Premium - 12 weeks. Protect from light and contamination!

Concentrations in the test

1-Reagent	
Buffer	
Cholesterol oxidase (*E.coli*)	< 1000 U/l
Peroxidase (horseradish)	< 1300 ppg U/l
N,N-bis(sulfobutyl)-toluidine, disodium (DSBmT)	< 1 mM
Accelerator	< 1 mM
Preservative	< 0.06 %
Ascorbic acid oxidase (*Curcubita sp.*)	< 3000 U/l
2-Reagent	
Buffer	
Cholesterol esterase (*Pseudomonas sp.*)	< 1500 U/l
4–aminoantipyrine (4-AAP)	< 1 mM
Detergent	< 2 %
Preservative	< 0.06 %

Warnings and notes

- Product for in vitro diagnostic use only.

SPECIMEN

Serum, heparinized or EDTA plasma.
Anticoagulants containing citrate should not be used.
Blood should be collected only if the patient has been fasting for 12 -14 hours.
Serum: Collect whole blood by venepuncture and allow to clot. Centrifuge and remove the serum as soon as possible after collection (within 3 hours).
Plasma: Specimens may be collected in EDTA or lithium or sodium heparin. Centrifuge and remove the plasma as soon as possible after collection (within 3 hours).
Serum and plasma should not remain at 15-30°C longer than 14 hours. If assays are not completed within 14 hours, serum or plasma should be stored at 2 - 8°C for up to 1 week. If specimens need to be stored for more than 1 week, they may be preserved at less than -20°C for up to 3 months. Samples may be frozen once.
Nevertheless it is recommended to perform the assay with freshly collected samples.

PROCEDURE

These reagents may be used in the automatic analysers Prestige 24i, Biolis 24i, Sapphire 400 and Prestige 24i Premium, Biolis 24i Premium, Sapphire 400 Premium.
1-Reagent and 2-Reagent are ready to use.
1-Reagent put on basic position in reagent tray.
2-Reagent put on start position in reagent tray.
For reagent blank deionized water is recommended.

REFERENCE VALUES [4]

serum/ plasma	40 – 60 mg/dl 1.04 – 1.55 mmol/l

As HDL cholesterol is affected by a number of factors such as smoking, exercise, hormones, age and sex, each laboratory should establish its own reference ranges for local population.

QUALITY CONTROL

For internal quality control it is recommended to use CORMAY LIPID CONTROL 1 (Cat. No 5-179) and CORMAY LIPID CONTROL 2 (Cat. No 5-180) or CORMAY SERUM HN (Cat. No 5-172) and CORMAY SERUM HP (Cat. No 5-173) with each batch of samples.
For the calibration of automatic analysers the CORMAY HDL/LDL CALIBRATOR (Cat. No 5-178) is recommended.
The calibration curve should be prepared every 12 weeks (Prestige 24i, Biolis 24i Premium) with change of reagent lot number or as required e.g. quality control findings outside the specified range.

PERFORMANCE CHARACTERISTICS

These metrological characteristics have been obtained using automatic analysers Prestige 24i and Biolis 24i Premium. Results may vary if a different instrument or manual procedure is used.

- **Sensitivity (Prestige 24i):** 1.8 mg/dl (0.047 mmol/l).
  Sensitivity (Biolis 24i Premium): 1.1 mg/dl (0.028 mmol/l).

- **Linearity (Prestige 24i):** up to 168 mg/dl (4.35 mmol/l).
  Linearity (Biolis 24i Premium): up to 200 mg/dl (5.18 mmol/l).
  For higher concentration of HDL cholesterol dilute the sample with physiological saline before assaying. Multiply the result obtained from the manual dilution by the appropriate dilution factor.

- **Specificity / Interferences**
  Bilirubin conjugated up to 60 mg/dl, bilirubin total up to 60 mg/dl, haemoglobin up to 1 g/dl, ascorbic acid up to 100 mg/dl, Intralipid up to 1800 mg/dl, triglycerides up to 2000 mg/dl and gamma-globulins up to 5000 mg/dl do not interfere with the test.

- **Precision (Prestige 24i)**

Repeatability (run to run) n = 10	Mean [mg/dl]	SD [mg/dl]	CV [%]
level 1	23.69	0.60	2.54
level 2	60.55	0.50	0.82

Reproducibility (day to day) n = 10	Mean [mg/dl]	SD [mg/dl]	CV [%]
level 1	43.91	1.68	3.84
level 2	58.02	1.06	1.83

Precision (Biolis 24i Premium)

Repeatability (run to run) n = 10	Mean [mg/dl]	SD [mg/dl]	CV [%]
level 1	43.30	0.61	1.42
level 2	58.20	0.88	1.51

Reproducibility (day to day) n = 10	Mean [mg/dl]	SD [mg/dl]	CV [%]
level 1	43.91	1.68	3.84
level 2	58.02	1.06	1.83

- **Method comparison**

A comparison between HDL cholesterol values determined at Prestige 24i (y) and at Olympus AU 400 (x) using 26 samples gave following results:
y = 0.9843 x + 0.1911 mg/dl;
R= 0.991 (R - correlation coefficient)

A comparison between HDL cholesterol values determined at Biolis 24i Premium (y) and at ADVIA 1650 (x) using 58 samples gave following results:
y = 0.8436 x + 3.2579 mg/dl;
R= 0.984 (R - correlation coefficient)

WASTE MANAGEMENT
Please refer to local legal requirements.

LITERATURE

1. Gotto, A.M. Lipoprotein metabolism and the etiology of hyperlipidemia. Hospital Practice 1988; 23 Suppl:1 4-13.
2. Badimon, J. J., Badimon, L., Fuester V. Regression of Atherosclerotic Lesions by High Density Lipoprotein Plasma Fraction in the Cholesterol-Fed Rabbit. J Clin Invest 1990; 85:1234-41.
3. Warnick, G. Russell, Wood, Peter D. National Cholesterol Education Program Recommendations for Measurement of High-Density Lipoprotein Cholesterol: Executive Summary. Clin Chem 1995; 41(10):1427-1433.
4. Alan H.B. Wu: Tietz Clinical Guide to Laboratory Tests, 4th ed. WB Saunders, 564 (2006).
5. Camps, J, Altered Composition of Lipoproteins in Liver Cirrhosis Compromises Three Homogeneous Methods for HDL-Cholesterol, Clinical Chemistry, 1999; 45:685-688.

APPLICATION for Prestige 24i, Biolis 24i and Sapphire 400

Item name	6	HDL-D

Data information

Units	**mg/dl**
Decimals	**1**

Analysis

Type	**END**
Main W.Length1	**600**
Sub W.Length2	**700**
Method	**Direct**

Corr

	Slope		Inter
Y=	**1.000**	X+	**0.000**

Calibration

Type	**Linear**		
Standard			
#1	*	#4	
#2		#5	
#3		#6	

Normal Range

	Male		Female	
	Low	High	Low	High
Serum	**40**	**60**	**40**	**60**
Urine				
Plasma	**40**	**60**	**40**	**60**
CSF				
Dialysis				
Other				

Item name	6	HDL-D

Aspiration

Kind	**Double**

	Volume	
Sample	**3**	µl
Reagent1	**210**	
Reagent2	**70**	

Third Mix.	**OFF**
R1 Blank	**Water-Blank**

Monitor

0 Level Point	**1**
Span	**3.000**

Data Process

Read

	Start	End
Main	**51**	**52**
Sub	**29**	**31**

Factor

Blank correction	**1.0000**

Dilution

Diluent	**100:Dil2**

Prozone Check

	Start	End	Limit (%)	
First				
Second				**Low**
Third				**Low**

Absorbance Limit

Low	**-0.200**
High	**2.000**

Endpoint Limit	**2.000**
Linear Check (%)	

Item name	6	HDL-D

Auto Rerun SW

ON

Auto Rerun Range (Result)

	ON	ON
	Lower	Higher
Serum	**1.8**	**168**
Urine		
Plasma		
CSF		
Dialysis		
Other		

Auto Rerun Condition (Absorbance)

Absorbance Range	
Lower	**OFF**
Higher	**OFF**

Prozone Range	**OFF**

APPLICATION for Prestige 24i Premium, Biolis 24i Premium and Sapphire 400 Premium

Item No.	6	Item Name	HDL-D	Optical

Data information

Units	**mg/dl**
Decimals	**1**

Analysis

Type	**END method**
Main Wave Length	**600nm**
Sub Wave Length	
Method	**Direct**

Correlation

	Slope		Intercept
Y=	**1**	X+	**0**

Calibration

Type	**Linear1**				
Std sample conc.					
Blank	**0**	#1	*	#2	
#3		#4		#5	
#6					

Item No.	6	Item Name	HDL-D	Optical

Aspiration

Kind	**Double**
Vol.	

Kind	Vol.	Add	Units
Sample	**4**	**5**	µl
Reagent 1	**180**	**10**	µl
Reagent 2	**60**	**10**	µl

Blank value

Water Blank

Reaction Monitor

0 Level Point	**1**
Span	**3**

Third mixing

OFF

Data Process

Read		Start	End
	Main	**51**	**52**
	Sub	**29**	**31**

Abs.Limit Low **-0.2** ~ High **2**

Correction value

Blank correction	
End Point Limit	**2**
Linear Check (%)	

Prozone Check

	Start	End	Limit (%)	
First				
Second				**Low**

Item No.	6	Item Name	HDL-D	Optical

Normal Range

	Male		Female	
	Low	High	Low	High
Serum	**40**	**60**	**40**	**60**
Urine				
Plasma	**40**	**60**	**40**	**60**
CSF				
Dialysis				
Other				

Panic Range

	Male		Female	
	Low	High	Low	High
Serum				
Urine				
Plasma				
CSF				
Dialysis				
Other				

Item No.	6	Item Name	HDL-D	Optical

Auto Rerun SW

ON

Auto Rerun Range (Conc.)

	First Dil	Low Re	Low Value	Low Dil	High Re	High Value	High Dil
Serum			**1.1**			**200**	
Urine							
Plasma							
CSF							
Dialysis							
Other							

Auto Rerun Condition (Absorbance)

Lower	**OFF**
Higher	**OFF**

Auto Rerun Condition (Prozone)

OFF

Dilution

100:Dil2

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MANUFACTURER

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