CORALYZER
System Pack

HDL-D CHOLESTEROL KIT

(Direct Enzymatic Method)

For the determination of HDL Cholesterol in serum.
(For Invitro Diagnostic Use Only)

Summary

HDL particles serve to transport lipoproteins in the blood-stream. HDL is known as "good cholesterol" because high levels are thought to lower the risk of heart disease and coronary artery disease. Low HDL cholesterol levels, are considered a greater heart disease risk. Clinical diagnosis should not be made on a single test result but should integrate clinical and other laboratory data.

Principle

Direct determination of serum HDLc (high-density lipoprotein cholesterol) levels without the need for any pre-treatment or centrifugation of the sample. The method depends on the properties of a detergent which solubilizes only the HDL so that the HDLc is released to react with the cholesterol esterase, cholesterol oxidase and chromogens to give colour. The non HDL lipoproteins LDL, VLDL and chylomicrons are inhibited from reacting with the enzymes due to absorption of the detergents on their surfaces. The intensity of the color formed is proportional to the HDLc concentration in the sample.

Normal reference values

	Male	Female
Low Risk	> 50 mg/dl	> 60 mg/dl
Normal Risk	35 - 50 mg/dl	45 - 60 mg/dl
High Risk	< 35 mg/dl	< 45 mg/dl

It is recommended that each laboratory establish its own normal range representing its patient population.

Contents

Coralyzer 100 System Packs	**40 ml**	**100 ml**
L1 : HDL-D Reagent 1	30 ml	3 x 25 ml
L2 : HDL-D Reagent 2	10 ml	25 ml

Coralyzer 200 System Packs	**40 ml**	**100 ml**
L1 : HDL-D Reagent 1	30 ml	2 x 37.5 ml
L2 : HDL-D Reagent 2	10 ml	2 x 12.5 ml

Storage / stability

Contents are stable at 2 - 8°C till the expiry mentioned on the labels.

Reagent preparation

Reagents are ready to use.

Sample material

Serum or Heparinized plasma. HDL is reported to be stable in the sample for 1 week when stored at 2-8°C

Calibration

Calibrator is recommended for calibration of this assay.

Linearity

This procedure is linear upto 150 mg/dl.

Note

Do not use the reagents if there are particles or turbidity. Control sera are recommended to monitor the performance of assay procedures. If control values are found outside the defined range, check the instrument, reagents and calibrator for problems. Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

References

Naito H K HDL Cholesterol. Kaplan A et al. Clin Chem The C.V. Mosby Co. St Louis. 1984; 1207-1213 and 437.
US National Cholesterol Education Program of the National Institutes of Health.
Young DS. Effects of drugs on Clinical Lab. Tests, 4th ed AACC Press, 1995.
Young DS. Effects of disease on Clinical Lab. Tests, 4th ed AACC 2001.
Burtis A et al. Tietz Textbook of Clinical Chemistry, 3rd ed AACC 1999.
Tietz N W et al. Clinical Guide to Laboratory Tests, 3rd ed AACC 1995. PCT/JP97/04442

Programming on	**CORALYZER 100/200**
Item	HDL
Full Name	HDL DIRECT
Test Method	End Point
Base Information	
Unit	mg/dl
Filter	578 nm
Sub. Filter	670 nm
Decimal	xx.xx
High pollute	No
Reagent Blank	
Blank Medium	Reagent
Blank Value	0
Blank Low	0
Blank High	2
Sample	
Sample Volume	3
Dilution Times	1
Range Setup	
Reagent	
Rgt. 1 Volume	225
Rgt. 2 Volume	75
Linearity	150
Read data for check	
Assistant Start	12
Assistant End	13
Range Low	0
Range High	2
Test Point Start	31
Test Point End	32
Standard	
Number of standard	1
Factor	1
Correct Factor	1
Standard Cup	User Defined
Conc.	See Calibrator

Manufactured by :
Coral Clinical Systems
A Division of Tulip Diagnostics (P) Ltd.
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