Spectrum For Diagnostic Industries

HDL Cholesterol

Direct Enzymatic colorimetric, Liquid

IVD

REF.	Pack size
116 01 040	R1 30 ml/R210 ml 100 Tests

Intended Use

HDL cholesterol reagent is intended for in-vitro quantitative determination of HDL cholesterol in human serum, heparinized or EDTA plasma.

Introduction

High density lipoprotein measurement, in conjunction with other lipid determination, has been shown to be useful in assessing the risk of coronary heart disease. HDL is responsible for carrying cholesterol back from preipheral cells to the liver , therefore the risk of coronary heart disease is lowered with increased levels of HDL. A low HDL cholesterol level, is considered a greater heart disease risk.Clinical diagnosis should not be made on a single test result; it should integrate clinical and other laboratory data.

Method

Direct Enzymatic colorimetric

Principle

The assay is based on a modified polyvinyl sulfonic acid (PVS) and polyethylene-glycol-methyl ether (PEGME) coupled classic precipitation method with the improvements in using optimized quantities of PVS/ PEGME and selected detergents. LDL, VLDL and chylomicrons (CM) react with PVS and PEGME and the reaction results in inaccessibility of LDL, VLDL and CM by cholesterol Oxidase (CHOD) and cholesterol esterase (CHER). The enzymes selectively react with HDL to produce H_2O_2 which is detected through a Tinder reaction.
The series of the reactions involved in the assay system is as follows:

HDL+LDL+VLD +CM $\xrightarrow{\text{PVS PEGME}}$ HDL+(LDL+VLDL+CM)· PVS/PEGME

HDL + CHOD + CHER $\xrightarrow{\text{Peroxidase}}$ Fatty Acid + H_2O_2

H_2O_2 +4-AA+TODB $\xrightarrow{\text{Peroxidase}}$ Quinone + 5 H_2O

Reagents

Reagent 1 (R1): MES buffer (pH 6.5), TODB N, N-Bis (4- sulfobutyl)-3- methylaniline), Polyvinyl sulfonic acid, Polyethylene-glycol-methyl ester, MgCl2, Detergent, EDTA

Reagent 2 (R2): MES buffer (pH 6.5), Cholesterol esterase, Cholesterol Oxidase, Peroxidase, 4-aminoantipyrine, detergent.

HDL CAL
Standard, Lyophilized Human Serum
Actual concentration of calibrator is stated on the vial label.

Reagents preparation, storage and stability

-HDL Cholesterol reagents are supplied ready-to-use and stable up to the expiry date labeled on the bottles. Once opened,the reagent is stable for 8 weeks at 2 - 8 °C if contamination is avoided. Do NOT freeze.

HDL Calibrator: Dissolve the contents with distilled water, as mentioned on vial label. Cap vial and mix gently to dissolve contents. Wait for 30 minutes before use.
Once reconstituted, calibrator is stable for 2 weeks at -20°C.

Deterioration

Failure to recover the control values within assigned range may indicate reagent deterioration.

Precautions and Warnings

Do not ingest or inhalate. In case of contact with eyes or skin; rinse immediately with plenty of soap and water. In case of severe injuries; seek medical advice immediately.

Specimen collection and preservation

Non haemolysed serum or plasma can be stored at 4 °C up to 7 days prior to analysis.
The only acceptable anticoaglulant is heparin.Anticoagulants containing citrate should not be used.

Procedure

System Parameters

Wavelength	600 nm (580 nm is an option)
Optical path	1 cm
Temperature	37 °C
Zero adjustment	Distilled water
Incubation time	5 minutes at 37 °C
Sensitivity	1 mg/dL

	Reagent blank	Calibrator	Specimen
Reagent1	300µl	300µl	300µl
Calibrator	____	4µl	____
Specimen	____	____	4µl

Mix and incubate for 5 minutes at 37 °C. Then add:

Reagent2	100µl	100µl	100µl

Mix and read immediately the absorbance (A_1) of the samples and calibrator .After 5 mins read the absorbance (A2) of the samples and calibrator.
Calculate the Increase of the absorbance A = A2 - A1.

Calculation

$$\frac{\text{(A) Sample}}{\text{(A) Calibrator}} \times \text{Calibrator conc.} = \text{mg/dL of HDL-C}$$

Conversion factor: mg/dL x 0.0259 = mmol/L

Quality control

Control sera are recommended to monitor the performance of assay procedures. If control values are found outside the defined range, check the reagents and / or calibrator.

Performance Characteristics

Accuracy
Results obtained using reagents (y) did not show systematic difference when compared with other commercial reagents. (x).

The results obtained using 50 samples were the following:
Correlation coefficient (r): 0.996.
Regression equation: y 0.98 + 3.42 mg/dL.

Sensitivity

When run as recommended, the minimum detection limit of the assay is 1 mg/dL .

Linearity

The reaction is linear up to a concentration of 150 mg/dl; specimens showing higher concentration should be diluted 1+1 using physiological saline and repeat the assay (result × 2).

Interference

No Interferences were observed to bilirubin T. and D. up to 60 mg/dL. Hemoglobin up to 1000 mg/dL or lipaemia up to 1800 mg/dL.

Expected Values

	Men	Women
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

These values are for orientation purpose; each laboratory should establish its own reference range.

Waste Disposal

This product is made to be used in professional laboratories. Please consult local regulations for a correct waste disposal.
S56: dispose of this material and its container at hazardous or special waste collection point.
S57: use appropriate container to avoid environmental contamination.
S61: avoid release in environment. refer to special instructions/safety data sheets.

References

1. Natio H KCholesterol Kaplan A et al. Clin Chem the C.V. Mosby Co. St Louis. Toronto. Princeeton 1984; 1207-1213 and 437.
2. US National Cholestrol Educatiopn Program of the National Institutes of Health.
3. Young DS. Effects of Drugs on Clinical Lab. Tests, 4th ad AACC Press, 1995.
4. Young DS. Effects of diseases on Clinical Lab. Tests 4th ad AACC 2001.
5. Burlis A et al. Tietz Texbook of Clinical Chemistry, 3rd ed AACC 1999.
6. Tietz N W et al, Clinical to Laboratory Tests, 3rd ed AACC 1995.

SYMBOLS IN PRODUCT LABELLING

IVD	For in-vitro diagnostic use
LOT	Batch Code/Lot number
REF	Catalogue Number
	Consult instructions for use
	Temperature Limitation
	Use by/Expiration Date
	CAUTION. Consult instructions for use
	Manufactured by

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