Spectrum For Diagnostic Industries

LDL CHOLESTEROL

Direct Enzymatic colorimetric, Liquid

IVD

REF.	Pack size
119 01 040	R1 30ml/R2 10ml 100 Tests

Intended Use

LDL-Cholesterol Assay is intended for the in-vitro quantitative determination of Low Density Lipoprotein Cholesterol in human serum or plasma. The reagents can assist in the diagnosis and treatment of patients at risk of developing coronary heart disease. Elevated LDL cholesterol is the primary target of cholesterol-lowering therapy.

Introduction

Low Density Lipoproteins (LDL) are synthesized in the liver by the action of various lipolytic enzymes on triglyceride-rich Very Low Density Lipoproteins (VLDLs). Specific LDL receptors exist to facilitate the elimination of LDL from plasma by liver parenchymal cells. It has been shown that most of the cholesterol stored in atherosclerotic plaques originates from LDL. For this reason, the LDL-Cholesterol concentration is considered to be the most important clinical predictor, of Coronary atherosclerosis.

Method

Enzymatic colorimetric method.

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 chylomicron (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), whereas HDL reacts with the enzymes. Addition of R2 containing a specific detergent releases LDL from the PVS/PEGME complex. The released LDL reacts with the enzymes to produce H_2O_2 which is quantified by the Tinder reaction.

Reagents

Reagent (R1)
Reagent (R2)

LDL Calibrator

Standard, Lyophilized Human Serum

LDL actual concentration is stated on the vial label.

Reagents preparation, storage and stability

Unopened reagents are stable till the expiration date printed on the outer box when stored at 2– 8°C. The reagent solutions should be clear. If turbid, the reagents may have deteriorated. Do not freeze the reagents.R1 and R2: Once opened, is stable 8 weeks at 2-8°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

Use fresh patient serum or plasma samples (EDTA, Citrate). If samples contain LDL cholesterol greater than 250 mg/dL, they should be diluted with saline.

LDL CAL: Dissolve the contents with the amount of distilled water indicated on Label. Cap vial and mix gently to dissolve contents, and wait for 30 minutes.

Stability: 7 days at 2-8°C and 4 weeks at - 20°C.

Procedure

This reagent can be used manually (see method below) and on most analyzers. Applications are available on request.

Wavelength	600 nm (580 nm is an option)
Optical path	1 cm
Temperature	37 °C or 20 – 25 °C
Measurement	Against distilled water
Reagent Blank Limits	Low 0.00 AU High 0.2 AU
Calibrator	Vial dependent

	Reagent blank	Calibrator	Specimen
Reagent(R1)	300 µl	300 µl	300 µl
Calibrator	____	4 µl	____
Specimen	____	____	4 µl
Mix and incubate for 5 minutes at 37°. Then add:			
Reagent(R2)	100 µl	100 µl	100 µl

Mix Read **immediately** the absorbance (A_1) of the specimens and calibrator, against the Blank, then Read the absorbance (A_2) of the Specimens and calibrator after 5 mins, against the Blank.

Calculate the Increase of the absorbance $A = A_2 - A_1$.

Calculation

$$\frac{\textbf{A Sample}}{\textbf{A Calibrator}} \times \text{Calibrator conc.} = \text{mg/dL of LDL-C in the sample}$$

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

Performance Characteristics

Dynamic range:
The measuring range is from 1.0 mg/dl to linearity
Limit of 250 mg/dl. If the results obtained were greater than linearity limit, dilute the sample 2 times with NaCl 9 g/L and multiply the result by 2.

Accuracy
Results obtained using reagents (y) did not show systematic differences when compared with other commercial reagents. (x).The results obtained using 92 samples were the following.
Correction coefficient (r): 0.996.
Regression equation: y =4.6+0.940x.
The results of the performance characteristics depend on the analyzer used.

Sensitivity
1 mg/dL

Linearity
250 mg/dL

Quality control

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.

Interference

No Interferences were observed with ascorbic acid up to 50 mg/dL, haemoglobin up to 500 mg/dL or bilirubin up to 30 mg/dL. A list of drugs and other interfering substances with LDL cholesterol determination has been reported by Young et al 8.4.

NOTES

Spectrum has Instrument application sheets for several automatic analyzers. Instructions for many of them are available on request.

Expected Values

Levels of the risk:

Desirable	<100 mg/dL
Medium	100 – 160 mg/dL
High	>160mg/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. Kaplan A et al. Lipoprotein Clin Chem the C. V. Masby Co. St Louis.
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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. Teitz Texbook of Clinical Chemistry, 3rd ed AACC 1999.
6. Tietz N W et al, Clinical Guide 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

Spectrum For Diagnostics Industries - Free Zone
Ismailia Free Zone , Block 5 .
Cairo- Port said Avenue.
Ismailia,Egypt
Tel: +2 064 3488 013 - +2 064 3488 014 Fax: +2 064 3488 015
www.sdi-fz.com

EC REP **MDSS GmbH**
Schiffgraben 41
30175 Hannover, Germany