SPECTRUM

The Creative Approach to Bioscience

LDL CHOLESTEROL

Direct Enzymatic colorimetric, Liquid

REF : 280 001	R1 30ml/R2 10ml 100 Tests
REF : 280 002	R1 60ml/R2 20ml 200 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.

Background

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.Accurate measurement of LDL-Cholesterol is of vital importance in therapies which focus on lipid reduction to prevent atherosclerosis or reduce its progress and to avoid plaque rupture.

Method

Enzymatic colorimetric method.

Assay 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 resulting 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) : Enyme reagent
Reagent (R2) : Buffer reagent

LDL Calibrator

Standard, Lyophilized Human Serum

LDL actual concentration is stated on the vial label.
For further information, refer to the material safety data sheet.

Precautions and Warnings

Do not ingest or inhale. 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.

Reagent Preparation, Storage and Stability

Spectrum LDL-Cholesterol Assay Reagent (R1,R2) are liquid ready to use reagent . Reagents are stable till the expiration date printed on the label when stored at 2– 8°C.

SYMBOLS IN PRODUCT LABELLING

EC REP Authorised Representative	Use by/Expiration Date
IVD For in-vitro diagnostic use	CAUTION. Consult instructions for use
LOT Batch Code/Lot number	Manufactured by
REF Catalogue Number	(Xi) - Irritant
Consult instructions for use	
Temperature Limitation	

Once opened, the reagent is stable for 2 months at 2-8°C.The reagent solutions should be clear. Do not freeze the reagents.

LDL Calibrator: 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 is 2 weeks at -20°C

Deterioration

The reagent is normally clear . Do not use reagent if it is turbid.Failure to recover the control values within assigned range may indicate reagent deterioration.

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.

System Parameters

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

Procedure

	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 and read **immediately** the absorbance (A_1) of the specimens and calibrator against the Blank. After 5 minutes, read the absorbance (A_2) of the Specimens and calibrator against the Blank.

Calculation

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

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

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

Quality Control

Normal and abnormal commercial control serum of known concentrations should be analyzed with each run.

Performance Characteristics

Precision
Within run (Repeatability)

	Level 1	Level 2
n	20	20
Mean (mg/dL)	66.2	11.07
SD	4.26	4.64
CV%	6.44	4.19

Run to run (Reproducibility)

	Level 1	Level 2
n	20	20
Mean (mg/dL)	72.7	110.7
SD	4.02	4.64
CV%	5.53	4.44

Accuracy

Results obtained using Spectrum 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.

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.

Sensitivity

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

Linearity

250 mg/dL

Interfering Substance

No Interferences were observed up to the following
Ascorbic acid 50 mg/dL
Haemoglobin 500 mg/dL
Bilirubin 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

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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.
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ORDERING INFORMATION	
CATALOG NO.	QUANTITY
280 001 280 002	100 Test 200 Test

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