AGD

CliniPak

LDL-CHOLESTEROL

(Selective Detergent Technique)

Code	AGDSP - LDL40
Pack Size	R1 : 2 X 15 mL R2 : 2 X 5 mL

INTENDED USE

This reagent kit is intended for inVitro quantitative determination of Low-Density lipoprotein cholesterol (LDL-C) in serum & plasma.

CLINICAL SIGNIFICANCE

The LDL- particles are lipoproteins that transport cholesterol to the cells. Often called 'bad Cholesterol'

Increased levels : High levels are risk factor for coronary heart disease and are associated with obesity, diabetes and nephrosis.

Clinical diagnosis should not be made on the single test result, it should integrate with clinical and other laboratory data.

PRINCIPLE

When a sample is mixed with reagent 1, the protecting (masking) reagent binds to LDL and protects LDL from enzyme reactions. Cholesterol esterase (CHE) and cholesterol oxidase (CO) react with non-LDL lipoproteins. When reagent 2 is added , the protecting reagent is removed from LDL. Hydrogen peroxide is produced by the enzyme yields a color complex with oxidative condensation with dimethoxyaniline and 4-Aminoantipyrine. By measuring the absorbance of the blue color complex produced at 546nm the LDL-C concentration in the sample can be calculated and compared with calibrator.

PROCEDURE

Reagent1 + Sample + Incubation
(220µL) (3µL) (300Sec)

Reagent2 ⟶ Measurement
(80µL) (600 Sec) (546nm)

REAGENT COMPOSITION

REAGENT 1

Goods Buffer pH 7	≈ 0 mmol/L
Cholesterol Esterase	380 U/L
Cholesterol Oxidase	980 U/L
Catalyse	400 U/L
TOOS	0.45mmol/L

REAGENT 2

Goods Buffer pH 7	≈ 0 mmol/L
4- AminoAntipyrine	≈ 1 mmol/L
Peroxidase	1000 U/L
LDL -C Calibrator	Concentration printed on label

LDL-C Calibrator : Dissolve with distilled water (QTY printed on label). Cap and mix gently to dissolve contents. Reconstituted calibrator is stable for 7days at 2 to 8°C.

WORKING REAGENT

Reagent 1 & Reagent 2 are ready to use and stable up to the expiry date stated in the label.

STORAGE AND STABILITY

When stored tightly closed at 2-8°C temperature protected from light and contamination prevented during their use.

SAMPLES

Serum or hepairinized plasma, free of hemolysis, removed from blood clot as soon as possible. Anticoagulants containing citrate should not be used.

BASIC PARAMETERS

SHORT NAME	LDL
NAME	LDL CHOLESTEROL
METHOD	SELECTIVE DETERGENT
ASSAY	End point (two point reagent blank)
MAIN WAVE	546 nm
SUB WAVE	0
DECIMAL	2
UNIT	mg/dL
R1 VOLUME	220µL
INCUBATION	36 secs
R2 VOLUME	80µL
SAMPLE VOLUME	3µL
INCUBATION	300 secs
MIXING SPEED	0
REACTION TIME (Delay)	560 secs
CHECK TIME (Read)	40 secs
LINEAR RANGE	0-600mg/dL
ABSORBANCE RANGE	2.5
CALIBRATION TYPE	SINGLE SPOT LINEARITY
DILUTION RATIO	6
SAMPLE VOLUME	50

LINEARITY

Reagent is linear up to 600 mg/dL
Dilute the sample appropriately and re-assay if LDL-C Concentration exceeds 600mg/dL.Multiply result with dilution factor.

REFERENCE NORMAL VALUE

Desirable value : < 130 mg/dL
Increased risk of coronary heart disease : 130-159 mg/dL High risk of coronary heart disease : >160mg/dL
It is recommended that each laboratory should assign its own normal range.

QUALITY CONTROL

To ensure adequate quality control,it is recommended that the laboratory should use a normal and abnormal commercial reference control serum.The quality control material is used to check the function of reagents and the machine together.

LIMITATIONS & PRECAUTIONS

- Do not freeze or expose the reagents to higher temperature as it may affect the performance of the kit.
- Storage condition as mentioned on the kit to be adhered.
- Before the assay bring all the reagents to the room temperature.
- Avoid contamination of the reagent during assay process.
- Use clean glassware free from dust and debris.
- Reagent to sample ratio as mentioned above must be strictly adhered, as any changes it affects the factor and result.
- In case reagent comes in contact with eyes,immediately rinse with plenty of water and seek medical advice.

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