

# LDL-DIRECT

[Selective Detergent]

ENZOPAK

Last update 09-2020

**Ref.** CC3-LDL.022, 20ml/50 Test  
CC3-LDL.22M, 40 ml/100 Test  
CC3-LDL.22MU, 80ml/200 Test

## INTENDED USE

Quantitative Determination of LDL Cholesterol (Direct) in serum.

## DIAGNOSTIC SIGNIFICANCE

The LDL Cholesterol particles are lipoproteins that transport cholesterol to the cells.

Often called "bad cholesterol" because high levels are risk factor for coronary heart disease and are associated with obesity, diabetes and nephrosis

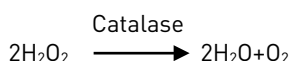
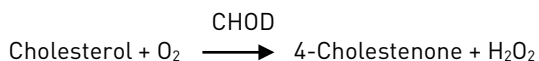
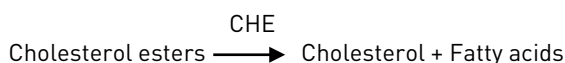
Clinical diagnosis should not be made on a single test result; it should integrate with clinical and other laboratory data.

## PRINCIPLE

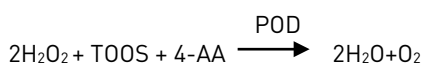
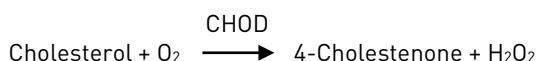
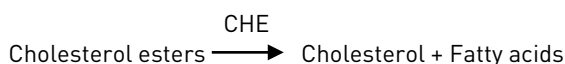
Determination of serum LDL Cholesterol (low-density lipoprotein cholesterol) (Direct) levels without the need for any pre-treatment or centrifugation steps.

The assay takes place in two steps.

Elimination of lipoprotein non-LDL Cholesterol.



Measurement of LDL Cholesterol



The Intensity of the color formed is proportional to the LDL Cholesterol concentration in the sample.

## PRESENTATION

All reagents to be stored at 2-8°C	No. of Bottles		
	20ml/50 T	40ml/100 T	80ml/200 T
• 1 LDL Direct	1	1	1
• 2 LDL Direct	1	1	1
• HDL/LDL Calibrator	1	1	1
• Distilled Water	1	1	1

## FINAL REAGENT COMPOSITION

Active Ingredients	Concentration
• GOOD pH 7.0 (2°C)	100 mmol/L
• Cholesterol esterase (CHE)	380 U/L
• Cholesterol oxidase (CHOD)	380 U/L
• Catalase	400 U/ml
• N-[2hydroxy-3-sulfopropyl]-3,5-dimethoxyaniline (TOOS)	0.45 mmol/L
• 4-Amino antipyrine (4-AA)	1.00 mmol/L
• Peroxidase (POD)	100 µ/L
• HDLc/LDLc CAL	Standard, Lyophilized human serum

## PRECAUTION

Do not use reagents over the expiration date.  
Sign of reagent deterioration.  
- Presence of particles and turbidity.

## PREPARATION OF WORKING REAGENT

LDL Direct Cholesterol Reagents are ready to use.

## HDL/LDL Calibrator Preparation & Stability

Refer the calibrator insert before use.

## REAGENT STORAGE AND STABILITY

All the components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8°C.  
R1 and R2: Once opened is stable for 30 days at 2-8°C.

## SPECIMEN COLLECTION

Serum: After Serum Separation, the test should be performed without delay.

Repeated freezing and thawing should be avoided.

Stability of the sample: 7 days at 2-8°C.

## REACTION PARAMETERS

- Type of Reaction : End Point
- Wavelength : 546 nm
- Flow cell temperature : 37°C
- Incubation : 5 + 5 min at 37°C
- Sample Volume : 5 µl
- Reagent Volume (R1+R2) : 375 + 125 µl
- Calibrator Concentration : As mentioned on vial
- Light Path : 1 cm
- Zero setting with : Distilled water

## TEST PROCEDURE

Pipette into Test Tube	Blank	Calibrator	Sample
Reagent 1 (µL)	375	375	375
Calibrator (µL)	-	5	-
Sample (µL)	-	-	5

Mix and Incubate for 5 min at 37°C than add,

Reagent 2 (µL)	125	125	125
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Mix and incubate for 5 min 37°C than read the absorbance (A), against the Blank.

## TEST RESULT

$$\text{LDL Cholesterol (mg/dl)} = \frac{\text{Abs. of Sample}}{\text{Abs. of Calibrator}} \times \text{Calibrator value}$$

## 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 tolerance.

## LIMITATIONS FOR INTERFERENCE

No Interferences were observed with ascorbic acid up to 50 mg/dl.

No Interferences were observed with Hemoglobin up to 500 mg/dl.

No Interferences were observed with 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.

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## NORMAL VALUES

Level of the risk

Desirable	<100 mg/dl
Medium	130-160mg/dl
High	> 160mg/dl

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

## LINEARITY

The method is linear upto a concentration of 1000 mg/dl. Specimens with LDL values above 1000 mg/dl should be diluted with isotonic saline and reassayed. Multiply results by the dilution factor.

## PRECISION

	Intra - assay			Inter - assay		
	Mean (mg/dl)	SD	CV	Mean (mg/dl)	SD	CV
Mean (mg/dl)	32.9	0.3	0.8	32.8	0.4	1.3
SD	50.8	0.2	0.5	50.0	0.7	1.5
CV	101.4	0.7	0.7	100.0	1.1	1.1

## REFERENCES

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5. Burlis A et al. Teitz Texbook of Clinical Chemistry, 3rd ed AACC 1999.
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Regd. Office.3/7, B.I.D.C., Gorwa, Vadodara 390 016 (INDIA)

Web: [www.reckondiagnosics.com](http://www.reckondiagnosics.com) Ph: +91-265-2281631

Email: [mail@reckondiagnosics.com](mailto:mail@reckondiagnosics.com)

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