

# LDL DIRECT

(Selective Detergent)

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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).

## 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.

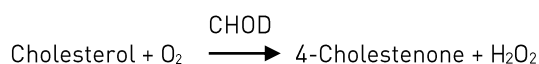
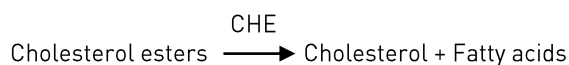
Clinical diagnosis should not be made on a single test result; it should integrate with clinical and other laboratory data.

## PRINCIPLE

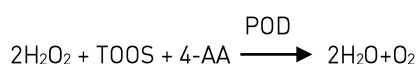
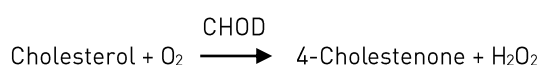
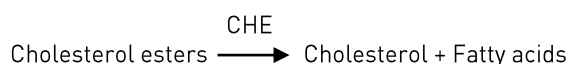
Determination of serum LDL Cholesterol (low-density lipoprotein cholesterol) (Direct) levels without the need for any pre-treatment or centrifugation steps.

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 U/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 and contamination are prevented during their use.

R1 and R2: Once opened is stable for 4 weeks 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         | : Fix Time             |
| Wavelength               | : 578 nm               |
| Flow cell temperature    | : 37°C                 |
| Delay Time               | : 300 Sec              |
| Interval Time            | : 300 Sec              |
| No. of Reading           | : 2                    |
| 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 |
|------------------------|-------|------------|--------|
| R1 (µL)                | 375   | 375        | 375    |
| Calibrator (µL)        | -     | 5          | -      |
| Sample (µL)            | -     | -          | 5      |

Mix and Incubate for 5 min at 37°C.

Add:

|         |     |     |     |
|---------|-----|-----|-----|
| R2 (µL) | 125 | 125 | 125 |
|---------|-----|-----|-----|

Mix and read absorbance (A1) after 5 second. Incubate for 5 min at 37°C. Read the absorbance (A2).

**TEST RESULT**

$$\text{LDL Chol. (mg/dl)} = \frac{(\text{A2-A1}) \text{ of Unknown}}{(\text{A2-A1}) \text{ of calibrator}} \times \text{Calibrator Value}$$

**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, hemoglobin 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.

**NORMAL VALUES**

Level of the risk

<154.68 mg/DL

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

**LINEARITY**

The method is linear upto a concentration of 610 mg/dL. Specimens with LDL values above 610 mg/dL should be diluted with isotonic saline and reassayed. Multiply results by the dilution factor.

**PRECISION**

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

**REFERENCES**

- Kaplan a et al. Lipoprotein Clin Chem The C.V. Masby Co. St Louis.
- Okada M. et al Low-density lipoprotein can be chemically measured J. Lab. Clin. Mad., 1996; 132, 195-201.
- Young DS. Effects of Drugs on Clinical Lab. Tests, 4th ad AACC Press, 1995.
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- Burlis A et al. Teitz Texbook of Clinical Chemistry, 3rd ed AACC 1999.
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