LDLc

Direct LDL Cholesterol Liquid

Product information

24LDL01-UN	**Meditest LDL**	**4x40 mL 2x20 mL**
24LDL01-AU	**Meditest LDL**	**4x40 mL 2x20 mL**
24LDL01-AB	**Meditest LDL**	**4x40 mL 2x20 mL**
24LDL01-ER	**Meditest LDL**	**4x40 mL 2x20 mL**

Purpose

This reagent is designed for the quantitative determination of the concentration of LDL Cholesterol (LDL-C) in human serum and plasma.

Summary

LDL-C particles are lipoproteins that transport cholesterol into cells. It's often called "bad cholesterol" because high levels are a risk factor for coronary heart disease and are associated with obesity, diabetes, and nephrosis.

Test principle

The specific detergent contained in Reagent 1 dissolves only non-LDL lipoprotein particles (CM, HDL, VLDL). The released cholesterol will be used by the enzymatic reagent in a reaction that does not produce color. Another specific detergent contained in Reagent 2 dissolves LDL-C. LDL Cholesterol concentration is determined by color intensity following the Trinder reaction.

Reagents - working solutions

R 1 Buffer	Polyaniondetergent 1 Cholesterol esterase Cholesterol oxidase Peroxidase 4-aminoantipyrine TOOS	 ≤ 200,000 U/L ≤ 200,000 U/L ≤ 200,000 U/L
R 2 Substrate	Detergent TOOS Tris Buffer	

Precautions warnings

It is intended for in vitro diagnostic use by healthcare professionals. Follow the normal precautions necessary in handling all laboratory reagents.
Infectious or microbial waste:
Warning: handle waste as potentially biohazardous. Dispose of waste according to accepted laboratory instructions and procedures.
Environmental hazards: Follow all relevant local disposal regulations to determine that it has been disposed of safely. If requested, a safety data sheet can be provided to professional users.

Inhibit foam formation in all reagents and sample types (sample, calibrator and control).
If there is any damage on the package, do not use Read the user manual carefully before use, do not use the expired assay kit. Do not mix different lot reagents.

All samples should be considered epidemic material, please dispose of them in accordance with the laboratory working standard of infectious diseases.
Take the necessary protective measures to prevent users from becoming infected during operation.

Use of reagents

Ready to use.

Storage and stability

All components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8ºC, protected from light and contamination is avoided during their use.
Do not use reagents after the expiration date. Signs of reactive deterioration: Presence of particles and turbidity.

Sample collection and preparation

Fresh Serum or EDTA and heparinized plasma.
Note: Separate the serum or plasma as soon as possible (within 3 hours) after collection. Store the serum at room temperature for a maximum of 12 hours and at 2-8 ºC for a maximum of 7 days. The serum is stable at (-60)-(-80)°C for 30 days.

Required Materials (not included in the kit)

1. Cat# 24BIO01-DC Meditest Diachem Calibrator
2. Cat# 24BIO01-DQ Meditest Diacheck Control L1
3. Cat# 24BIO02-DQ Meditest Diacheck Control L2
4. General laboratory equipment
5. Distilled or deionized water

Working Procedure

If you are using a spectrophotometer to perform this test, work with the following procedure. Ask your representative for the application data for fully automatic devices.

1.Test Conditions:
Wavelength: . 572 nm
Cuvette: . . . . . 1 cm light path
Temperature: .

Conversion factor: mmol/L x 38.61=mg/dL

Expected values

Levels in terms of coronary heart disease risk:
Levels in adults:

Optimum	<2.59 mmol/L (<100 mg/dL)
Near-optimal/optimal above level	2.59-3.34 mmol/L (100-129 mg/dL)
Borderline high	3.37-4.12 mmol/L (130-159 mg/dL)
High	4.14-4.89 mmol/L (160-189 mg/dL)
Very high	≥ 4.92 mmol/L (≥ 190 mg/dL)

The risk classification of patients and treatments is described in international guidelines26.
These values are for orientation purposes; Each laboratory should establish its own reference range

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Limitations

Bilirubin T. and D. up to 15 mg/dL,
No interference was observed with hemoglobin up to 10 g/L or lipemia up to 2500 mg/dL. A list of drugs and other substances that interfere with the determination of HDL cholesterol was reported by Young et al.

Performance characteristics

Measuring range: 5 - 600 mg/dL
If the results obtained are greater than the linearity limit, dilute the sample by 1/10 with 9 g/L NaCl and multiply the result by 10.

Precision

Intra-assay		
Mean (mg/dL)	%CV	n
45	4.6	20
65	3.4	20

Inter-assay		
Mean (mg/dL)	%CV	n
45	4.2	25
65	3.9	25

The results of the performance characteristics depend on the analyzer used.

References

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