HDLc

Direct HDL Cholesterol Liquid

Product information

24LDL01-UN	**Meditest HDL**	**4x40 mL 2x20 mL**
24LDL01-AU	**Meditest HDL**	**3x30 mL 3x10 mL**
24LDL01-AB	**Meditest HDL**	**4x40 mL 2x20 mL**
24LDL01-ER	**Meditest HDL**	**3x30 mL 3x10 mL**
24LDL01-AR	**Meditest HDL**	**3x30 mL 3x10 mL**

Purpose

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

Summary

High-density lipoproteins are one of the main classes of plasma lipoproteins. HDL Cholesterol is known as the "good cholesterol" because high levels of it can help reduce the risk of heart disease and coronary artery disease (CHD). A low level of HDL-C is considered a greater risk of heart disease. Accurate measurement of HDL-C is an important parameter when assessing patient risk from CHD.

Test principle

After the addition of magnesium ions, dextran sulfate selectively forms water-soluble complexes with LDL, VLDL and chylomicrons, which are resistant to PEG-modified enzymes. HDL-C in human serum is dissolved with a specific detergent and performs color reactions with Cholesterol esterase, Cholesterol oxidase and Peroxidase. Non-HDL lipoproteins such as chylomicron (CM), low-density lipoprotein (LDL), very low-density lipoprotein (VLDL) are inhibited by detergents, so they do not react with said enzymes. HDL Cholesterol concentration is determined by color intensity following the Trinder reaction.

Reagents - working solutions

R 1 Buffer	Dextran Sulfate Magnesium Chloride Hegzahydrate Preservative Brij 35	≤ 10 gr/dL ≤ 5 gr/dL ≤ 10 gr/dL
R 2 Substrate	Detergent PEG-Cholesterol Esterase PEG-Cholesterol Oxidase 4 AAP Peroxidase	≤ 2 % ≤ 5 KU/L ≤ 5 KU/L ≤ 1 gr/dL ≤ 8000 U/L

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# 24LIP01-DC Meditest Diachem Lipid 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. Assay conditions:

Wavelength:. . . . . 550-650 nm
Cuvette: . . . . . .1 cm light path
Temperature: . . . . . 37 ^{0}C

2. Adjust the instrument to zero with distilled water.
3. Pipette into a cuvette:

	Blank	Calibrator	Sample
R1 (µL)	300	300	300
Calibrator (µL)	--	3	--
Sample (µL)	--	--	3

4. Mix and incubate for 5 min at 37ºC and read the absorbance (A1) of the samples and calibrator.
5. Add:

	Blank	Calibrator	Sample
R2 (µL)	100	100	100

6. Mix and incubate for 5 min at 37ºC and read the absorbance (A2) of the samples and calibrator, against the Blank.

Calculation

$$\frac{\text{(A2-A1) Sample - (A2-A1) Blank}}{\text{(A2-A1) Calibrator - (A2-A1) Blank}} \times \text{Calibrator conc=mg/dL}$$

Conversion factor:
mg/dL*0.02586=mmol/L

Expected values

Levels in terms of coronary heart disease risk:

National Cholesterol Education Program (NCEP) guidelines:
<40 mg/dL: Low HDL (important risk factor for CHD)
≥60 mg/dL: High HDL ("negative" CHD risk factor)

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

Limitations

No interference was observed in bilirubin T. and D. up to 60 mg/dL, haemoglobin up to 30 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: 3 - 200 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			Inter-assay		
Mean (mg/dL)	%CV	n	Mean (mg/dL)	%CV	n
106	1.70	20	80	1.90	20
22	2.80	20	22	2.95	20

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

References

1. Young DS. Effects of drugs on clinical laboratory tests, 4thed. AACC Press, 1995.
2. Tietz NW. Clinical guide to laboratory tests, 2nd ed. Saunders Co, 1991.1988; 26:783-790
3. Rifai N, Warnick GR, McNamara JR, Belcher JD, Grinstead GF,Expected Values Handbook of Laboratory Medicine, Li-hua Zhu 1998
4. Frantz Jr ID. Measurement of Low-Density-Lipoprotein Cholesterol in Serum: a Status
5. Report. Clin Chem 1992; 38:150-160.
6. Kannel, W.B., Castelli W.P., Gordon, T., Cholesterol in the Prediction of Artherios clerotic
7. Disease; New Perspectives Based on the Framingham Study, Am. Intern. Med., 90:85 (1979).
8. Bachoric P. Measurement of Low-Density-Lipoprotein. 245-263. In: Handbook of
9. Lipoprotein Testing (eds. Rifai, Warnick and Dominiczak), 2nd edition, AACC press, 2000.
10. National Cholesterol Education Program. Expert Panel on Detection, Evaluation, and
11. Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel II). NIH Publication No. 93-3095, 1995.
12. Naito HK, Strong JP, Scott MG, Roheim PS, Asztalos BF, Zilversmit DB, Srinivasan SR,
13. Berenson GS, Wilson PWF, Scanu AM, Malikow MR. Atherogenesis: current topics on etiology andrisk factors. Clin. Chem 1995; 41:132-133 No. 1.
14. National Committee for Clinical Laboratory Standards, National Evaluation Protocols for
15. Interference Testing, Evaluation Protocol Number 7, Vol. 4, No.8, June 1984.
16. Wieland H, Seidel D. Quantitative Lipoprotein Electrophoresis.
17. Westgard, J.O., Carey, R.N., Wold, S., Criteria for judging precision and accuracy in method development and evaluation. ClinicalChemistry1974:20:825-833.
18. Armstrong V, Seidel D. Evaluation of a Commercial Kit for the Determination of LDLCholesterol in Serum Based on Precipitation of LDL with Dextran Sulfate. Arztl. Lab. 1985;31:325-330.
19. National Institutes on Health Publicationno. 93-3095, September 1993.
20. Stone NJ, Robinson JG, Lichtenstein AH, et al. 2013 ACC/AHA guideline on the treatment of blood cholesterol to reduce atherosclerotic cardiovascular risk in adults: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol 2014;63:2889-2934.

Medios Medical Informatics Consultancy Trade Ltd.
Güzelevler Mah. Çınar Cad. No: 5 Yüreğir/Adana