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A Division of Orchard Medical

HDL Cholesterol Direct

Order Information

Cat. No.	Kit Configuration
OMR1100	Reagent 1: 1 x 40 mL Reagent 2: 1 x 14 mL Calibrator: 1 x 1 mL

Summary

High Density Lipoproteins (HDL) are molecules that transport cholesterol from the body tissues to the liver. Since HDLs can remove cholesterol from the arteries and carry them back to the liver for excretion, HDL is also called as "good cholesterol" because high levels are thought to lower the risk of heart disease and coronary artery disease.
A low HDL cholesterol levels, is considered a greater heart disease risk.

Method

Photometric test using enzymatic cholesterol.

Principle

The HDL Ultra Cholesterol assay is a homogeneous method for directly measuring HDL-C concentrations in serum or plasma without the need for any off-line pretreatment or centrifugation steps. The method is in a two reagent format and depends on the properties of a unique detergent, as illustrated. This method is based on accelerating the reaction of cholesterol oxidase (CO) with non-HDL unesterified cholesterol and dissolving HDL selectively using a specific detergent. In the first reaction, non- HDL unesterified cholesterol is subject to an enzyme reaction and the peroxide generated is consumed by a peroxidase reaction with DSBmT yielding a colorless product. The second reagent consists of a detergent capable of solubilizing HDL specifically, cholesterol esterase (CE) and chromogenic coupler to develop color for the quantitative determination of HDL-C. This may be referred to as the Accelerator Selective Detergent methodology.

Reagents

Storage Instructions and Reagent Stability

Reagent and Calibrator are stable up to the end of the indicated month of expiry, if stored at 2 – 8°C, protected from light and contamination is avoided. Do not freeze the reagents! Reagent 1: Enzyme Solution
Reagent 2: Substrate Solution
Calibrator: HDL Calibrator- (Separate Pack)

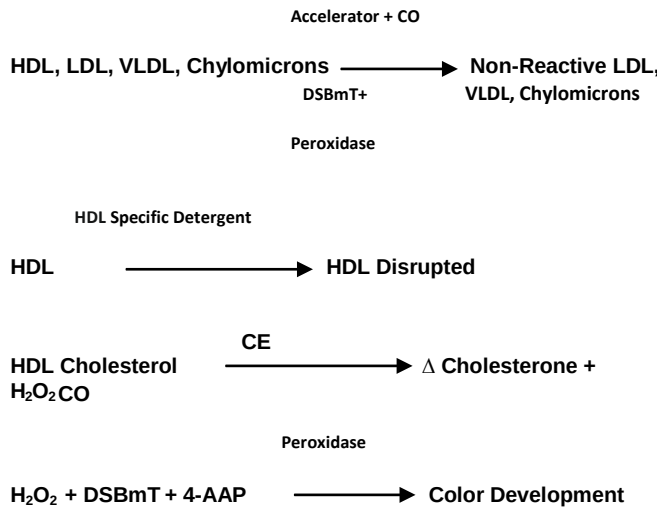
Reagent Preparation

The reagents are ready to use.

Materials required but not provided

NaCl solution 9 g/L
General laboratory equipment

Accelerator Selective Detergent Methodology



Composition

Reagent : Buffer Cholesterol oxidase (Fr: E. Coli) ≤1000 U/L, Peroxidase (Fr: Horseradish) ≤1000 U/L, N,N-bis(4-sulphobutyl)-mtoluidine-disodium(DSBmT) ≤1 mM, Accelerator ≤1Mm, Preservative ≤ 0.06%, Ascorbic Oxidase (Fr: Curcubita sp.) ≤ 3000 U/L, Cholesterol Esterase ≤ 1500 U/L, 4-Aminoantipyrine ≤ 1mm, Detergent ≤ 2%, Preservative.
Calibrator – Lyophilized Serum - HDL Cholesterol value on Label

Warnings and Precautions

1. Please take the necessary precautions for the use of laboratory reagents.
2. For diagnostic purposes, the results should always be assessed with the patient`s medical history, clinical examinations and other findings
3. Avoid direct contact with skin and do not swallow.
4. In very rare cases, samples of patients with gammopathy might give falsified results.
5. For professional use only!

Waste Management

Please refer to local regulatory requirements.

Specimen

Serum, heparin, plasma or EDTA plasma separate at the latest 1h after blood collection from cellular contents.

7 days	at	2 –8°C
30 days	at	–20°C

Only freeze once! Discard contaminated specimens.

Assay Procedure

Wavelength 600 nm to 700 nm
Optical Path 10 mm
Temperature 37°C

	Blank	Sample or Calibrator
Sample or Calibrator	--	3 µL
Reagent 1	300 µL	300 µL
Mix and incubate for 5 min. at 37°C and read absorbance A1.		
Reagent 2	100 µL	100 µL
Mix and incubate for 5 min. at 37°C and read absorbance A2.		

(Note: For Semi-Auto Analyzers: R1: 450 µL, R2: 150 µL and Sample volume: 4 µL)

ΔA = (A1-A2) sample or Calibrator

Calculation:

With Calibrator

$$\text{HDL-C (mg/dL)} = \frac{\Delta A \text{ Sample}}{\Delta A \text{ Calibrator}} \times \text{Conc. Calibrator (mg/dL)}$$

Conversion Factor
HDL-C (mg/dL) x 0.02586 = HDL-C (mmol/L)

Quality Controls

For internal quality control any normal and abnormal controls should be assayed with each batch of samples. Each laboratory should establish corrective action in case of deviations in control recovery.

Performance Characteristics Measuring Range

The test has been developed to determine the quantity of HDL Cholesterol within a measuring range from 5-150 mg/dL. When values exceed this range samples should be diluted 1 + 4 with NaCl solution (9 g/L) and the result multiplied by 5.

Specificity/Interferences

No interference was observed by, Bilirubin upto 30 mg/dL and triglycerides upto 1200 mg/dL.

Sensitivity/Limit of Detection

The lower limit of detection is 5 mg/dL.

Linearity

The higher limit of detection is 150 mg/dL.

Precision

Intra-assay n = 20	Mean [mg/dL]	SD [mg/dL]	CV [%]
Sample 1	23.96	1.19	4.97
Sample 2	65.36	1.54	2.35

Inter-assay n = 20	Mean [mg/dL]	SD [mg/dL]	CV [%]
Sample 1	35.19	1.00	2.84
Sample 2	54.85	1.16	2.12

Method Comparison

A comparison of Nucleus Diagnosys HDL Cholesterol (y) with a commercially available test (x) using 15 samples gave following results:
$y = 0.954x + 1.768$; $r^2 = 0.978$

Reference Range

	Men	Women
Low Risk	> 50 mg/dL	> 60 mg/dL
Normal Risk	35 – 50 mg/dL	45 – 60 mg/dL
High Risk	< 35 mg/dL	< 45 mg/dL

Each laboratory should check if the references range are transferable to its own patient population and determine own reference ranges if necessary.

Literature

1. **National Institutes of Health Consensus Development Conference Statement: Triglyceride, High Density Lipoprotein and Coronary Heart Disease. Washington D.C. Feb 26-28, 1992.**
2. **Izawa S., Okada M., Matsui H., and Horita Y. J. Medicine and Pharmaceutical Sci., 1385 -1388, 37 (1997).**
3. **Shih WJ, Bachorik PS, Haga JA, Myers GL, Stein EA; Clinical Chemistry, 2000; 46:3:351 – 364 Third Report of the National Cholesterol Education Programme (NCEP) Expert Panel on Detection, Evaluation and treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III). JAMA Publication, Vol 285, No. 19, P2486 - 2497; 2001.**
4. **Jacobs, D. et al. In Laboratory and Test Handbook; Jacobs, D.S; Kasten, B.L., De Mott, W.R., Wolfson, W.L., Eds; Lexi - Comp Inc: Hudson (Cleveland), 1990; P. 219.**

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