HDL Cholesterol

Direct. Enzymatic , Clearance Method **1 x 80 mL**

Clinical Significance

HDL particles serve to transport lipoproteins in the blood-stream. HDL is known 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. Clinical diagnosis should not be made on a single test result; it should integrate clinical and other laboratory data.

Principle

The assay consists of distinct reaction steps:

1. Elimination of chylomicron (CM), LDL-cholesterol and VLDL-cholesterol by cholesterol esterase, cholesterol oxidase and catalase in Reagent 1. This is colorless reaction.
2. Specific reaction of HDL-cholesterol after release of HDL-C by detergent in Reagent 2.

Method

Direct Enzymatic Colorimetric method

Reagent

R1	Cholesterol esterase Cholesterol oxidase Catalase TOOS	≥1000U/L ≥800U/L ≥900U/L 100mmol/L
R2	4-aminoantipyrine Detergent Peroxidase Sodium azide	0.5% ≥4000U/L 100mmol/L
HDLc/LDLc Cal	Calibrator. Lyophilized human serum	

Storage and Stability

All the components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8ºC and contaminations are prevented during their use. Do not freeze the reagents.
- Do not use reagents over the expiration date

Signs of reagent deterioration:
- Presence of particles and turbidity.

Warnings and Precautions

HDLc/ LDLc CAL Components from human origin have been tested and found to be negative for the presence of HBsAg, HCV, and antibody to HIV (1/2). However handle cautiously as potentially infectious.

Preparation

- R 1 and R 2: Are ready to use.
- HDLc/ LDLc CAL: Dissolve the contents with 0.50 mL of distilled water. Cap vial and mix gently to dissolve contents.

Specimen and Stability

Serum or heparinized plasma, free of hemolysis[1]: Anticoagulants containing citrate should not be use. Removed from the blood clot as soon as possible.

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

Materials Required but not Provided

- Spectrophotometer or colorimeter measuring at 600 nm.
- Matched cuvettes 1.0 cm light path.
- General laboratory equipment

Assay Procedure

1. Assay conditions:
   Wavelength: . . . . . 600 -700 nm
   Cuvette: . . . . . .1 cm light path
   Temperature 37ºC
2. Adjust the instrument to zero with distilled water.
3. Pipette into a cuvette:

	Blank	Calibrator	Sample
Sample (µL)	--	--	10
Calibrator (µL)	--	10	--
Water (µL)	10	--	--
R1 (µL)	450	450	450

4. Mix and incubate for 5 min at 37ºC.
5. Add:

	Blank	Calibrator	Sample
R2 (µL)	150	150	150

6. Mix and incubate for 5 min. at 37ºC.
7. Adjust the absorbance of the blank to zero.
8. Read the absorbance of the samples ($A_{Samples}$) and calibrator ($A_{Calibrator}$), against the Blank.
8. Calculate the result by following formula:

Calculation

$$\text{mg/dL HDLc in Sample} = \frac{A_{calibrator}}{A_{sample}} \times \text{Conc. of Calibrator (mg/dl)}$$

(Absorbance should be taken immediately after 5 minutes).
Application sheets for automated systems are available on request
Conversion factor: mg/dL x 0.02586= mmol/L.
mmol/L×38.67=mg/dL

Quality Control

Commercially available normal and pathological control sera are recommended to monitor the performance of the procedure.
If the controls are found outside the defined range, check the instrument, reagents and calibrator for problems.

Serum controls are recommended for internal Quality control. Each laboratory should establish its own Quality Control scheme and corrective actions

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

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

Performance Characteristics

Measuring Range

Measuring range: This method is liear up to linearity limit of 100 mg/dL. If the results obtained were greater than linearity limit, dilute the sample 1/2 with NaCl 9 g/L and multiply the result by 2.

SYSTEM PARAMETERS

Mode	:	End Point
Reaction	:	Ascending
Wavelength	:	600 - 700 nm
Blank with	:	Reagent
Sample Volume	:	10 µL
Reagent Volume	:	600 µL
Incubation	:	5 min + 5 min
Calibrator	:	stated on the vial
Linearity limit	:	100 mg/dL
Unit	:	mg/dL

Notes

1. Use clean disposable pipette tips for dispensation

Only for invitro use in Clinical laboratory (IVD)

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