LIQUI STAT DIRECT

HDL CHOLESTEROL

BIO LAB DIAGNOSTICS

ISO 9001:2015
ISO 13485:2016
CE

COLORIMETRIC (END POINT)

CLINICAL SIGNIFICANCE

Total Cholesterol: Increased levels are associated with atherosclerosis, nephrosis, diabetes mellitus, myxoedema, obstructive jaundice. Decreased levels are observed in cases of hyperthyroidism, certain anaemias, malabsorption and wasting syndrome.

HDL Cholesterol: Decreased levels are associated with increased risk of developing coronary artery diseases and other atherosclerotic diseases.

PRINCIPLE

Serum is reacted with a detergent which is selectively absorbed by non-HDL lipoproteins, ie., LDL, VLDL and Chylomicrons. Thus, only HDL lipoproteins are available to be solubilized and released to react with the cholesterol esterase, cholesterol oxidase and chromogens (to give color). The color that is produced is proportional to the amount of HDL cholesterol present in the sample.

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REAGENTS COMPOSITION

1. HDL DIRECT Reagent1: R1

Magnesium chloride	100 mM,
Aminoantipyrene	1 mmol/L,
buffer, pH 7.0 ± 0.1,	
preservatives	

2. HDL DIRECT Reagent R2

Peroxidase	> 4 KU/L,
C O. (PEG-CO)	>1 KU/L,
C E (PEG-CE)	>1 KU/L,
HDAOS:	0.3 g/L
Buffer, pH 7.0 + 0.1,	
Surfactant, preservative.	

3. HDL CALIBRATOR

Calibrator	As on Label.

Working Reagent Preparation

Reconstitute Calibrator with 1 mL distilled water. Swirl gently and the reagent is ready to use after 10 minuts.

STORAGE AND STABILITY

HDL Cholesterol Reagent is stable unit the date of expiration on the kit when stored tightly capped at 2-8°. The reagent should be clear and colorless as packaged. Discard if turbid. Once opened, the Direct HDLCholesterol Reagent is stable for 30 days. Reconstituted Calibrator is stable 5 days at 2-8°C and 30 days at -20 °C. Avoid repeated freezing and thawing.

SAMPLE

Sample can be serum or plasma which has no sign of haemolysis. Common anticoagulants have no interference on this assay. Cholesterol is affected by food intake. Hence, keep the patient fasting for atleast 8 hrs. prior to sample collection.(All samples should be handled as potential infective agents as no laboratory methods make conclusive findings for its safely. Therefore, adequate protective laboratory measures should be taken while handling such materials).

MANUAL METHOD

		Blank	CAL	Test
1.	**Pipette into 3 Test Tubes**			
2.	**HDL DIRECT Reagent R1** µL	400	400	400
3.	Distilled Water..... µL	5	-	-
4.	Calibrator Reagent 3..... µL	-	5	-
5.	Sample..... µL	-	-	5
	Incubate 5 minutes at 37 °C and add			
6.	**HDL DIRECT Reagent R2** µL	100	100	100

Incubate 5 minutes at 37 °C and read at 520-550 nM or GREEN filter against Blank. Final colour is stable for 30 minutes.

SYSTEM PARAMETERS

Reaction type	End point
Wave length	546 nM
Light Path	1 Cm
Reaction Temperature	37°C
Blank / Zero Setting	Reagent
Reagent Volume	**400 + 100 µL**
Sample Volume	**5 µL**
Incubation Time	10 Min.
Calibrator Concentration	Printed on vial
Low Normal at 37°C	40 mg/dL
High Normal 37°C	60 mg/dL
Linearity	150 mg/dL

RESULT CALCULATION

(Δ A = Absorbance against blank)

$$\text{HDL in mgs/dL} = \frac{\Delta \text{ A Test} \times \text{Concentration of Calibrator}}{\Delta \text{ A Calibrator}}$$

Example:

Δ A (Sample) = 0.40,
Δ A (calibrator) = 0.32,
if the Concentration of calibrator = 33 mg/dL.

$$\frac{0.4 \times 33}{0.32} = \textbf{41.25 mg/dL}$$

To convert from conventional units to SI units, multiply the conventional units by 0.02586.
mg/dL × 0.02586 = mmol/L HDL cholesterol

EXPECTED VALUES

The expected values for serum HDL cholesterol are as follows:

< 40 mg/dl Low
> 60 mg/dl High

It is recommended that each laboratory establish its own range of expected values, since differences exist between instruments, laboratories, and local populations.
According to the NCEP, HDL values greater than or equal to 35 mg/dl are considered desirable, and values greater than or equal to 60 mg/dl are considered to offer some protection against coronary heart disease. Values below 35 mg/dl are considered to be a significant independent risk factor for coronary heart disease. As with all diagnostic methods, the final diagnosis should not be made on the result of a single test as well as laboratory diagnosis must be confirmed with clinical manifestations must be confirmed with clinical manifestations.

LIMITATIONS

This assay is liner up to 150mGs/dL. For higher values sample must be diluted with 0.9% sodium Chloride and the result multiplied by dilution factor e.g.by 2 for 1:1 dilution.

WARNING

This reagent System is for in vitro use only. This reagent system contains preservatives and components that have not established for safety if Contacted on broken skin or eye or taken orally. In case of such incidents was off with plenty of water or consult a physician.

QUALITY CONTROL

To ensure adequate quality control,each kit should be tested against astandard controlsera, it should be realized that the use of quality control material checks both instrument and reagent function together. Factors which might affect the performance of this test include proper instrument function, temperature control, cleanliness of glass wares and accuracy of pipetting. It is appropriate to establish each laboratory's accuracy costant interpret values accordingly. Similarly laboratory findings should be established by clinical manifestations.

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