GENESIS

Instructions For Use

HDL Direct (Enzymatic Method)

Cat no.	size
1112 101	1*40
1112 102	2*40

Intended use

HDL Direct Reagent is intended for the in vitro Quantitative diagnostic determination of HDL Cholesterol in human serum and plasma.

DIAGNOSTIC CHARACTERISTICS

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 OF THE METHOD

Directly determination of serum HDLc (high-density lipoprotein cholesterol) levels without the need for any pre-treatment or centrifugation of the sample. The method depends on the properties of a detergent which solubilizes only the HDL so that the HDL-c is released to react with the cholesterol esterase, cholesterol oxidase and chromogens to give colour. The non HDL lipoproteins LDL, VLDL and chylomicrons are inhibited from reacting with the enzymes due to absorption of the detergents on their surfaces. The intensity of the color formed is proportional to the HDLc concentration in the sample.

COMPOSITION

Reagent (**R1**)	GOOD pH 7.0 Cholesterol oxidase Peroxidase DSBmT	50.0 mmol/L < 1000 U/L < 1300 U/L < 1 mM
Reagent (**R2**)	GOOD pH 7.0 Cholesterol esterase 4 – Aminoantipyrine (4-AP) Detergent Ascorbate oxidase	50.0 mmol/L < 1500 U/L < 1 mM < 2% < 3000 U/L
Calibrator	Lyophilized human serum	83.8 mg/dL

STORAGE

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.
HDLc CAL: Once reconstitute
-Stable for 1 week at 2-8ºC or 5 weeks at –20ºC.
- Do not use reagents over the expiration date.

REAGENT PREPARATION

-R 1 and R 2: Are ready to use.
- HDLc CAL: Dissolve the contents with 1 mL of distilled water.

ADDITIONAL EQUIPMENT

– Analyzer, spectrophotometer able to read at (578) nm.
- General laboratory equipment.

SPECIMEN AND STABILITY

-Serum or heparinized plasma, free of hemolysis
-Anticoagulants containing citrate should not be used.
-Remove from the blood clot as soon as possible
- Stability of the sample: 7 days at 2-8ºC.

Precautions and Warnings

Do not ingest or inhalate. In case of contact with eyes or skin; rinse immediately with plenty of soap and water. In case of severe injuries; seek medical advice immediately.

Symbols in Product Labeling

EC REP	Authorized Representative		Expiration date
IVD	For in-vitro diagnostic use		CAUTION, consult instructions for use
REF	Catalogue number		
LOT	Lot number		Manufactured by
	Consult instructions for use		Temperature Limit

PROCEDURE

1. Assay Parameters:
Mode:……fixed time
Wavelength……..578 nm
Cuvette:……...1 cm light path
2. Pipette into labeled test tubes:

	Blank	Standard	Sample
REAGENT (R1)	300 µL	300 µL	300 µL
STANDARD (S)	---	4 µL	---
SAMPLE	---	---	4 µL

3. Mix thoroughly and incubate the tubes for 5 minutes at (37ºC).

	Blank	Standard	Sample
REAGENT (R2)	100 µL	100 µL	100 µL

Mix and Read immediately the absorbance (A1) of the samples and calibrator.
After 5 minutes, read the absorbance (A2) of the samples and calibrator.
Calculate the increase of the absorbance ΔA= A2 – A1.

CALCULATIONS

HDL Cholesterol concentration in the sample is calculated using the following general formula:

$$\frac{\text{A Sample}}{\text{A Calibrator}} \times \text{CAL conc.} \times 0.0259 = \text{mg/dL HDL} = \text{mmol/l HDL}$$

REFERENCE VALUES

	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

QUALITY CONTROL

It is recommended to use the Control Serum level I and II to verify the performance of the measurement procedure.
Each laboratory should establish its own internal Quality Control.

METROLOGICAL CHARACTERISTICS

Measuring range :(2.5 mg/dL - 200 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.

Precision:

	Intra-assay			Inter-assay		
Mean (mg/dL)	32.9	50.6	101.4	32.8	50.0	100.1
SD	0.3	0.2	0.7	0.4	0.7	1.1
CV (%)	0.8	0.5	0.7	1.3	1.5	1.1

Sensitivity: 1 mg / dL = 0.0016 A.
Accuracy: Results obtained using genesis reagents (y) did not show systematic differences when compared with other commercial reagents (x).
The results obtained using 50 samples were the following: Correlation coefficient (r): 0.996.
Regression equation: y= 0.98 + 3.42 mg/dL.

INTERFERENCES+

No interferences were observed to
bilirubin T. and D. up to 60 mg/dL,
hemoglobin up to 1000 mg/dL or
lipemia up to 1800 mg/dL.
Drugs and substances may interfere.

BIBLIOGRAPHY

1. Naito H K HDL Cholesterol. Kaplan A et al. Clin Chem the C.V. Mosby Co.St Louis.Toronto.Princeton 1984;1207-1213 and 437.
2. US National Cholesterol Education Program of the National Institutes of Health.

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