GENESIS

Instructions For Use

HDL Cholesterol (Preciptating Method)

Cat no.	Size
1106 101	1*50

INTENDED USE

The HDL Cholesterol reagent is intended for in vitro Quantitative diagnostic determination of HDL cholesterol in human serum and plasma.

DIAGNOSTIC CHARACTERISTICS

HDL play an important role in the removal of cholesterol from tissues and its transportation to the liver for removal as bile acids. Decreased plasma HDL-cholesterol concentrations are positively correlated with the incidence of atherosclerosic diseases, basis of myocardial infarction and cerebrovascular accidents. There are several disease states or environmental influences associated with reduced levels of HDL: acute or chronic hepatocellular diseases, intravenous hyperalimentation, severe malnutrition, diabetes, chronic anemia, myeloproliferative disorders, Tangier disease, analphalipopro-teinemia, acute stress, some drugs and smoking.

PRINCIPLE OF THE METHOD

Very low density lipoproteins (VLDL) and low density lipoproteins (LDL) in the sample precipitate with phosphotungstate and magnesium ions. The supernatant contains high density lipoproteins (HDL). The HDL cholesterol is then spectrophotometrically measured by means of the coupled reactions described below

Cholesterol ester + H_2O $\xrightarrow{\text{chol. Esteras}}$ Cholesterol + Fatty acid

Cholesterol + ½ O_2 + H_2O $\xrightarrow{\text{chol. Oxidas}}$ Cholestenone + H_2O_2

2 H_2O_2 + 4-Aminoantipyrine + Phenol $\xrightarrow{\text{Peroxidase}}$ Quinoneimine

COMPOSITION

Reagent(R)	
Phosphotungstate	0.4 mmol/L
magnesium chloride	20.0 mmol/L

STORAGE

Store at 15-25ºC.

HDL Reagent is stable until the expiry date shown on the vial label when stored tightly closed and if contaminations are prevented during their use.

REAGENT PREPARATION

Reagent provided ready to use.

ADDITIONAL EQUIPMENT

− Desktop centrifuge.
− Thermostatic water bath at 37º
− Analyzer, spectrophotometer able to read at 546 nm.

SPECIMEN

1.Serum or plasma collected by standard procedures.
2.HDL cholesterol in serum or plasma is stable for 7 days at 2-8ºC.
3.Heparin, EDTA, oxalate and fluoride may be used as anticoagulants.

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

PROCEDURE

1- Precipitation

A-Pipette into test tube

Reagent(R)	0.5 ml
sample	0.2 ml

B. Mix thoroughly and let stand for 10 minutes at room temperature.
C. Centrifuge at a minimum of 4000 r.p.m. for 10 minutes.
D. Carefully collect the supernatant.

2-Colorimetry

- Pipette into labeled test tubes:

	Blank	Sample
Cholesterol Reagent	1.0 mL	1.0 mL
sample	-	50 µL

3- Mix thoroughly and incubate the tubes for **10 minutes** at room temperature (16-25ºC) or for **5 minutes** at 37ºC.

4- Measure the absorbance (A) of the Sample at 546 nm against the Blank. The color is stable for one hour.

CALCULATIONS

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

A sample-A Blank= A sample

A sample x 570 = concentration of HDL cholesterol

REFERENCE VALUES

Female	48.6 - 75 mg/dL
Male	41 - 58.7 mg/dL
Children	51.8 - 71.9 mg/dL

QUALITY CONTROL

It is recommended to use the Control Serum level Iand II to verify the performance of the measurement procedure.

Each laboratory should establish its own internal Quality Control

METROLOGICAL CHARACTERISTICS

- Detection limit: 3.0 mg/dL = 0.078 mmol/L
- Linearity limit: 150 mg/dL = 3.9 mmol/L

For higher values dilute sample **1/2** with physiological saline and repeat measurement.

Precision:

− Repeatability (within run):

Mean Concentration	CV	n
30 mg/dL = 0.78 mmol/L	3.3 %	20
55 mg/dL = 1.42 mmol/L	2.0%	20

− Reproducibility (run to run):

Mean Concentration	CV	n
121 mg/dL = 3.13 mmol/L	4.2 %	25
257 mg/dL = 6.66 mmol/L	3.2 %	25

− INTERFERENCES:

Lipemia (triglycerides 10 g/L) does not interfere. Bilirubin (>10 mg/dL) and hemoglobin (>5 g/L) may affect the results.

Other drugs and substances may interfere.

These metrological characteristics have been obtained using an analyzer. Results may vary if a different instrument or a manual procedure are used.

BIBLIOGRAPHY

1. Grove TH. Effect of reagent pH on determination of high-density lipoproteincholesterolbyprecipitationwith sodium phosphotungstate-magnesium. Clin Chem 1979; 25: 560-564.

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CE

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