HDL PREC

Cat. No.	Pack Name	Packaging (Content)
BLT00032	HDL PREC 100	R1: 2 x 50 ml, R2 standard: 1 x 5 ml

EN

CE IVD

INTENDED USE
Diagnostic reagent for quantitative *in vitro* determination of HDL Cholesterol in human serum and plasma.

CLINICAL SIGNIFICANCE
High-density lipoproteins (HDL) compose one of the major classes of plasma lipoproteins. They are synthesized in liver as complexes of apolipoprotein and phospholipid and are capable of picking up cholesterol and carrying it from arteries to the liver, where the cholesterol is converted to bile acids and excreted into the intestine.
An inverse relationship between HDL Cholesterol (HDL-C) levels in serum and the incidence/prevalence of coronary heart disease (CHD) has been demonstrated in a number of epidemiological studies. The importance of HDL-C as a risk factor for CHD is now recognized.[1-8]
Accurate measurement of HDL-C is of vital importance when assessing patient's risk for CHD.

PRINCIPLE
Chylomicrons, LDL and VLDL (low and very low density lipoproteins) are precipitated from serum by phosphotungstate in the presence of divalent cations such as magnesium. The HDL cholesterol remains unaffected in the supernatent and is estimated using ERBA Cholesterol reagent.

$$\text{Serum/plasma} \xrightarrow[Mg^{2+}]{\text{Phosphotungstate}} \underset{\text{(Supernatent)}}{\text{HDL}} + \underset{\text{(Precipitate)}}{\text{(LDL + VLDL + Chylomicrons)}}$$

REAGENT COMPOSITION
R1

Phosphotungstic Acid	0.77 mmol/l
Magnesium Chloride	17.46 mmol/l
R2 standard	See bottle label

REAGENT PREPARATION
Reagent is liquid, ready to use.

STABILITY AND STORAGE
The unopened reagents are stable till the expiry date stated on the bottle and kit label when stored at 2–8°C.

SPECIMEN COLLECTION AND HANDLING
Use serum, plasma (EDTA).
It is recommended to follow NCCLS procedures (or similar standardized conditions).
Stability in serum/plasma: 24 hours at 20–25°C
7 days at 4–8°C
12 weeks at -20°C
Discard contaminated specimens.

CALIBRATION
Calibration with the standard included in the kit.

QUALITY CONTROL
To ensure adequate quality control, it is recommended to use controls with assayed values.

UNIT CONVERSION
mg/dl x 0.026 = mmol/l

EXPECTED VALUES [2]
Adults male: 35.3 - 79.5 mg/dl
Adults female: 42.0 - 88.0 mg/dl
It is recommended that each laboratory verify this range or derives reference interval for the population it serves.

WARNING AND PRECAUTIONS
For in vitro diagnostic use. To be handled by entitled and professionally educated person.
Reagents of the kit are not classified like dangerous but contain less than 0.1% sodium azide - classified as very toxic and dangerous substance for the environment.

WASTE MANAGEMENT
Please refer to local legal requirements.

ASSAY PROCEDURE

1. PRECIPITATION
Precipitation of LDL, VLDL and Chylomicrons.

Pipette	Volumes
Sample or Calibrator	250 µl
Precipitating Reagent	500 µl

Mix well and allow the reaction mixture to stand for 10 minutes at room temperature, Centrifuge at 4000 r.p.m. (1800 x g) for 10 minutes to obtain a clear supernatent. Use the supernatent to determine the concentration of HDL cholesterol in the sample.

2. CHOLESTEROL DETERMINATION

Wavelength: 500 (546) nm
Cuvette: 1 cm

Pipette into tubes marked	Blank	Calibrator	Test
Cholesterol Working Reagent	1000 µl	1000 µl	1000 µl
Distilled water	50 µl	--	--
Calibrator	--	50 µl	--
Supernatent	--	--	50 µl

Mix well, incubate for 10 min. at 37°C, or 12 min. at 30°C. Read the absorbance of the Calibrator and each test at 500 (546) nm or 505/670 nm for bichromatic analysers against reagent blank.

CALCULATIONS

$$\text{HDL Cholesterol (mg/dl)} = \frac{\text{Abs. of Test}}{\text{Abs. of Cal.}} \times \text{Concentration of Calibrator (mg/dl)}$$

Applications for automatic analysers are available on request.

ASSAY PARAMETERS FOR PHOTOMETERS

Mode	End Point
Wavelength 1 (nm)	505
Wavelength 2 (nm)	670
Sample Volume (µl)	25/50
Working Reagent Volume (µl)	500/1000
Incubation time (min.)	5
Incubation temp. (°C)	37
Normal Low (mg/dl)	42
Normal High (mg/dl)	79,5
Linearity Low (mg/dl)	0
Linearity High (mg/dl)	125
Concentration of Standard	See bottle label
Blank with	Reagent
Absorbance limit (max.)	0.2
Units	mg/dl

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REFERENCES

1. Burstein M., Scholnic H.R., Morfin R. (1970). J. Lipid Res.
2. Tietz Textbook of Clinical Chemistry and Molecular Diagnostics. Burtis, C.A., Ashwood, E.R., Bruns, D.E.; 5th edition, WB Saunders Comp., 2012.

SYMBOLS USED ON LABELS

REF Catalogue Number	Manufacturer	See Instruction for Use
LOT Lot Number	CE Mark - Device comply with the Directive 98/79/EC	Storage Temperature
Expiry Date	IVD In Vitro Diagnostics	CONT Content

QUALITY SYSTEM CERTIFIED
ISO 9001 ISO 13485

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