BioMed- HDL CHOLESTEROL

Direct Enzymatic colorimetric, Liquid

REF:

R1 2 x 15 ml	R2 1 x 10 ml	100 Test
R1 2 x 30 ml	R2 1 x 20 ml	200 Test

INTENDED FOR USE:

BIOMED HDL cholesterol reagent is intended for in-vitro quantitative determination of HDL cholesterol in human serum, heparinized or EDTA plasma.

PRINCIPLE:

The assay is based on a modified polyvinyl sulfonic acid (PVS) and polyethylene-glycol-methyl ether (PEGME) coupled classic precipitation method with the improvements in using optimized quantities of PVS/PEGME and selected detergents.LDL, VLDL, and chylomicron (CM) react with PVS and PEGME and the reaction results in inaccessibility of LDL, VLDL and CM by cholesterol Oxidase (CHOD) and cholesterol esterase (CHER). The enzymes selectively react with HDL to produce H_2O_2 which is detected through a Tinder reaction

$$\text{HDL + LDL + VLDL + CM} \xrightarrow{\text{PVS}} \text{HDL + (LDL + VLDL + CM)} \cdot \text{PVS/PEGME}$$

$$\text{HDL + CHOD + CHER} \xrightarrow{\text{PEGME}} \text{Fatty Acid + } H_2O_2$$

$$\text{H2O2 +4-AA+TODB} \xrightarrow{\text{Peroxidase}} \text{Quenone + 5 } H_2O \text{ } (\lambda max=560nm)$$

BACKGROUND

HDL particles serve to transport 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 level, is considered a greater heart disease risk.[1.5.6.]
Clinical diagnosis should not be made on a single test result; it Should integrate clinical and other laboratory data

SPECIMEN COLLECTION:

Serum or heparinized plasma, free of haemolysis; Anticoagulants containing citrate should not be used. Removed from the blood clot as soon as possible. Stability of the sample: 7 days at 2-8°C.

REAGENT COMPOSITIONS :

Reagent 1 (R1): MES buffer (pH 6.5), TODB N, N-Bis (4- sulfobutyl)-3- methylaniline), Polyvinyl sulfonic acid, Polyethylene- glycol-methyl ester, MgCl2, Detergent, EDTA

Reagent 2(R2): MES buffer (pH 6.5), Cholesterol esterase, Cholesterol Oxidase, Peroxidase, 4-aminoantipyrine, detergent

PACKAGE: Collection and storage.

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

LINEARITY: 150 mg/dl

PRECAUTIONS & WARNING :

HDL CAL
Standard, Lyophilized Human Serum

HDL. 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

REAGENT PREPARATION & STABILITY :

- R1 and R2: Are ready to use.
- HDL CAL: Dissolve the contents with distilled water, as mentioned on vial label. Cap vial and mix gently to dissolve contents. Wait for 30 minutes before use.
- R1 and R2: Once opened is stable 8 weeks at 2-8°C.
- HDL CAL: Once reconstituted 1 week at 2-8°C or 4 weeks at -20°C.
- Do not use reagents over the expiration date.
- Sign of reagent deterioration.
- Presence of particles and turbidity.

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

REQUIRED MATERIALS NOT PROVIDED:

General Laboratory Equipment and instrumentations.

PROCEDURE:

This reagent can be used manually (see method below) and on most analyzers. Applications are available on request

Wavelength:	600 nm (580 nm is an option)
Cuvette:	1 cm
Temperature:	37°C.
Measure:	Against distelled water

	SAMPLE	CALIBRATOR	BLANK
R1 (µL)	450	450	450
Calibrator(µL)	-	5	-
Sample (µL)	5	-	-
Mix and Incubate for 5 min at 37°C. Then add :			
R2(µL)	150	150	150

Mix and incubate for five minutes at 37 C read the absorbance of the samples and calibrator, against. Calculate the Increase of the absorbance $\Delta A = A_2 - A_1$.

CALCULATION:

$$\frac{(\Delta\ A)\ \text{Sample}}{(\Delta\ A)\ \text{Calibrator}} \times \text{Calibrator conc} = \text{mg/dL of HDL-C}$$

Conversion factor: mg/dL x 0.0259 = mmol/L

QUALITY CONTROL:

Control sera are recommended to monitor the performance of assay procedures.
If control values are found outside the defined range,
check the instrument reagents and calibrator for problems.
Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances

EXPECTED VALUE:

	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.

Dynamic range:
The measuring range is from 1.0 mg/dL to linearity
limit of 180 mg/dL. If the results obtained were greater than
linearity limit, dilute the sample 2 times with NaCl 9 g/L and multiply the result by 2.

Sensitivity
The sensitivity of the test is 1 mg/dl

Accuracy
Results obtained using BIOMED reagents (y) did not show systematic difference when compared with other commercial
reagents. (x).
The results obtained using 50 samples were the following. Correction coefficient (r): 0.996.
Regression equation: y 0.98 + 3.42 mg/dL

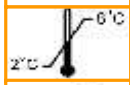
INTERFERENCES:

No Interferences were observed to bilirubin T. and D. up to 60 mg/dL Hemoglobin up to 1000 mg/dL or lipaemia up to 1800 mg/dL.

NOTES
BIOMED has Instrument application sheets for several automatic analyzers. Instructions for many of them are available on request

REFERENCES:

1. Natio H KCholesterol Kaplan A et al. Clin Chem the C.V. Mosby Co. St Louis. Toronto. Princeeton 1984; 1207-1213 and 437.
2. US National Cholestrol Educatiopn Program of the National Institutes of Health.
3. Young DS. Effects of Drugs on Clinical Lab. Tests, 4th ad AACC Press, 1995.
4. Young DS. Effects of diseases on Clinical Lab. Tests 4th ad AACC 2001.
5. Burlis A et al. Tietz Texbook of Clinical Chemistry, 3rd ed AACC 1999.
6. Tietz N W et al, Clinical to Laboratory Tests, 3rd ed AACC 1995.

	Consult Instructions for Use
	Caution, Consult accompanying Documents
IVD	In Vitro Diagnostic Medical Device
	Temperature Limitation
	Manufacturer
EC REP	Authorized Representative in the European Community
REF	Catalogue Number
LOT	Batch Code
	Use by

EGY- CHEM for lab technology
Badr City, Industrial Area Piece 170
250 Fadan In East of Elrubaki, EGYPT
Office Tel: +202 26236727 / +202 26236598
Factory Tel: +202 23108170 / +202 23108171
Fax: +202 26240986
www.egy-chem.com

CE
EC REP
MDSS GmbH
Schiffgraben 41
30175 Hannover,
Germany