REF. HDL-MC-100 (1X30 ML, 1X10 ML)
HDL-MC-200 (2X15 ML, 1X10ML +CALIBRATOR)
HDL-MC-C200 (3X20 ML, 1X20 ML+CALIBRATOR)

INTENDED USE

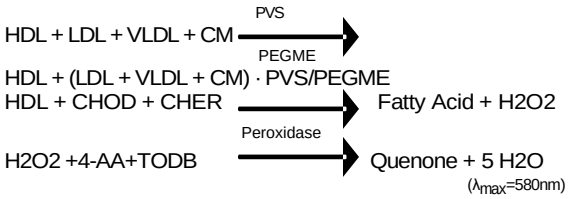
NS Biotec HDL cholesterol reagent is intended for in-vitro quantitative determination of HDL cholesterol in human serum, heparinized or EDTA plasma.

CLINICAL SIGNIFICANCE

HDL particles serve to transport in the blood-stream.
HDL is known as "good cholesterol" because high levels ae 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.

ASSAY 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 H2O2 which is detected through a Tinder reaction.



EXPECTED 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
These values are for orientation purpose; each laboratory should establish its own reference range.		

REAGENTS

Reagent 1: (R1)
Reagent 2: (R2)
Reagent 3: (R3) HDL Calibrator
HDL Calibrator
Standard, Lyophilized Human Serum
HDL actual concentration is stated on the vial label.

REAGENT PREPARATION AND STABILITY

- R1 and R2: Are ready to use.
- HDL Calibrator: 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 Calibrator: Once reconstituted 2 weeks at -20°C.
- Do not use reagents over the expiration date.
- Sign of reagent deterioration :
  Presence of particles and turbidity.

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.

SPECIMEN

Serum or heparinized or EDTA 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.

PRECAUTIONS

HDL. Calibrator
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.

PROCEDURE

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

	Blank	Calibrator	Sample
R1 (µL)	300	300	300
R3Calibrator(µL)	-	4	-
Sample (µL)	-	-	4
Mix and Incubate for 5 min at 37°C. Then add :			
R2(µL)	100	100	100

Mix Read ***immediately*** the absorbance (A_1) of the samples and calibrator, then Read the absorbance (A_2) of the Samples and calibrator after 5 mins.

Calculate the Increase of the absorbance $\Delta A = A_2 - A_1$.

CALCULATION

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

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

LINEARITY

When run as recommended, the assay is linear up to 150 mg/dl If result exceeds 150 mg/dl, dilute the sample 2 times with 0.9% NaCl solution and reassayed , Multiply the result by 2

Sensitivity

When run as recommended the sensitivity of this assay is 1 mg/dl

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.

Accuracy

Results obtained using 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.

	Consult Instruction 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

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