SBio HDL-D CHOLESTEROL KIT

(Direct Enzymatic Method)

(For invitro diagnostic use only)

REF	90910040
Pack Size	40 ml

CE

8C 2C Store at 2-8°C	Manufacturer	IVD *In vitro* Diagnostic Medical Device	L1 HDL-D Reagent 1	Direct Enzymatic Direct Enzymatic Method
Use by (Last day of stated month)	Consult Instructions for use	LOT Batch Number	L2 HDL-D Reagent 2	This way up
Date of Manufacture	REF Catalogue Number	EC REP Authorised Representative in the European Community	C Calibrator (for 1ml)	

INTENDED USE

HDL-D Cholesterol Kit is used for the determination of HDL Cholesterol in serum.

PRINCIPLE OF THE TEST

Direct 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 HDLc 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.

CLINICAL SIGNIFICANCE

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. Low HDL cholesterol levels, are considered a greater heart disease risk. Clinical diagnosis should not be made on a single test result but should integrate clinical and other laboratory data.

PRESENTATION	40 ml
L1 : HDL-D Reagent 1	30 ml
L2 : HDL-D Reagent 2	10 ml
C : Calibrator (for 1ml)	1 No.

COMPOSITION

Goods Buffer 30 mM ; Dextran Sulphate ; Magnesium Sulphate Heptahydrate; 4-Aminoantipyrine 3 mM; Cholesterol Esterase 6000 U; Cholesterol Oxidase 10000 U; Peroxidase 15000 U; Surfactant and Preservatives.

STORAGE / STABILITY

Contents are stable at 2-8°C till the expiry mentioned on the labels.

SAMPLE REQUIRED

Serum or Heparinized plasma. Serum should be separated from the clot, as soon as possible. HDL is reported to be stable in the sample for 1 week when stored at 2-8°C

REAGENT PREPARATION

Reagents L1 and L2 are ready to use. Cap the bottles immediately after use and avoid contamination.

Calibrator : Reconstitute with 1 ml of D.W. Mix gently to dissolve the contents. Once reconstituted the calibrator is stable for 2 weeks at 2-8° C or 3 months at -20°C. Do not repeatedly thaw and refreeze.

SAMPLE WASTE AND DISPOSAL

Do not reuse the reagent containers, bottles, caps or plugs due to the risks of contamination and the potential to compromise reagent performance.

This product requires the handling of human specimens. It is recommended that all human sourced material are considered potentially hazardous and are handled in accordance with the OSHA standard on blood borne pathogens.

Appropriate biosafety practices should be used for materials that contain or are suspected of containing infectious agents.

Handle specimens, solid and liquid waste and test components in accordance with local regulations and NCCLS guidelines M29, or other published biohazard safety guidelines.

PROCEDURE

Wavelength / filter : 578 nm / 630 nm (Bichromatic)
Temperature : 37°C
Light path : 1 cm

MATERIALS REQUIRED BUT NOT PROVIDED

Photometer analyzer with standard thermostatic cuvette holder, micropipette and appropriate laboratory equipment.

Pipette into clean dry test tubes labelled as Blank (B), Calibrator (C) and Test (T)

Addition Sequence	B (ml)	C (ml)	T (ml)
HDL-D Reagent 1 (L1)	0.450	0.450	0.450
Calibrator	-	0.006	-
Sample	-	-	0.006
Mix and incubate for 5 mins. at 37° C and			
HDL-D Reagent 2 (L2)	0.150	0.150	0.150

Mix well and incubate for 5 mins. at 37°C and read the absorbance of the Calibrator and the Test against Blank at 578 nm / 630 nm.

CALCULATIONS

$$\text{HDLc in mg/dl} = \frac{\text{Absorbance of Test}}{\text{Absorbance of Calibrator}} \times \text{Conc. of Calibrator}$$

QUALITY CONTROL

The following process is recommended for QC during the assay of HDL-D Cholesterol. Define and establish acceptable range for your laboratory.

1. Two levels of control (Normal and Abnormal) are to be run on a daily basis.
2. If QC results fall outside acceptance criteria, recalibration may be necessary.
3. Review QC results and run acceptance criteria following a change of reagent lot.

SPECIFIC PERFORMANCE CHARACTERISTICS

Linearity:

The procedure is linear upto 150 mg/dl. If values exceed this limit dilute the serum 1+ 1 with normal saline and repeat the assay (Results x 2).

Interferences:

For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

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 = 0.002 A.

Accuracy : Results obtained 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. The results of the performance characteristics depend on the analyzer used.

Method of comparison:

Comparative studies were done to compare our reagent with another commercial HDL-D Cholesterol Assay. No significant differences were observed. Details of the comparative study are available on request.

REFERENCE RANGE

	Male	Female
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

It is recommended that each laboratory establish its own normal range representing its patient population.

NOTE

In vitro diagnostic reagent for laboratory and professional use only Not for medicinal use. The reagent contain sodium azide 0.1% as preservative. Avoid contact with skin and mucosa. On disposal flush with large quantity of water. Only clean and dry glassware must be used. Components from human origin in the calibrator 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.

Do not use the reagents if there are particles or turbidity.

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. The reagent may be used in several automated analyzers. Instruction are available on request . Do not use turbid, deteriorated or leaking reagents.

REFERENCES

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EC REP

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