HDL-C

High density lipoprotein cholesterol Assay Kit (PPD)

Intended Use

The Snibe HDL-C reagent is an assay intended for the in vitro direct quantitative determination of high density lipoprotein cholesterol in human serum.

Package

Catalogue NO.	Kit size	
130501001L	R1: 60 ml×3	R2: 60 ml×1
130501001S	R1: 60 ml×1	R2: 20 ml×1

Assay Principle

The Snibe Direct HDL assay accurately measures HDL in the specimen using a two-step procedure. First, non-HDL, including chylomicrons, VLDL, IDL and LDL, are suppressed by polyanion polymer and detergent. Then, an HDL-specific surfactant is used to release the cholesterol and the enzymes react with HDL to produce H_2O_2 which is detected through a Trinder reaction.

Reactive Ingredients

Reagent 1 (R1)	Good's buffer	50 mmol/L
	Cholesterol esterase	2000 U/L
	2,4,6-tribromo-3-hydroxybenzoic acid	0.96 mmol/L
	Cholesterol oxidase	1600 U/L
	Catalase	3000 U/L
Reagent 2 (R2)	4-aminoantipyrine	2.5 mmol/L
	Peroxidase	2000 U/L
	Sodium azide	0.013 w/v%

Reagent Preparation

1. The Snibe HDL-C reagents (R1, R2) are liquid stable, ready to use reagents.
2. Reagents with different lot numbers should not be interchanged or mixed.

Materials Required But Not Provided

1. Automated clinical chemistry analyzer (reading at 546 nm).
2. Controls, calibrators and purified water for validating the performance of the HDL-C reagents are not provided.

Reagent Stability and Storage

Store the Snibe HDL-C assay reagents at 2°C to 8°C protect from light. Unopened reagents can be used at any time before the expiration date indicated on the labels. Reagent on-board (5°C to 15°C) stability is least 28 days. The reagent solutions should be clear. If turbid, the reagents may have deteriorated.

Specimen Collection and Stability

Use fresh human serum. After sampling, the test should be performed without delay. If the test cannot be done immediately, the sample should be placed in a tightly sealable container and stored at -20°C or below. Repeated freezing and thawing should be avoided. If samples contain HDL-C exceed 150 mg/dL, they should be diluted with saline.

Test Procedure

R1: 240 µL
Sample: 5 µL

R2: 80 µL
A1

A2

37°C   546 nm (sub: 660 nm)

0 min   3 min   10 min
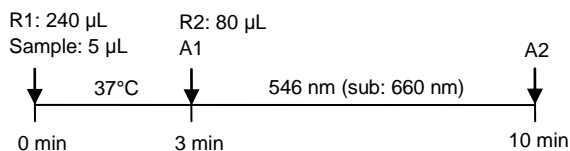
Calibration

Calibration is required. An aqueous standard or serum based calibrator, with an assigned value traceable to a primary standard (e.g. NIST or IRMM) is recommended. For calibration frequency on automated instruments, refer to the instrument manufacturers specifications. However, calibration stability is contingent upon optimum instrument performance and the use of reagents which have been stored as recommended in the stability and storage section of this package insert. Recalibration is recommended at any time if one of the following events occurs:
• The Lot number of reagent changes.
• Preventative maintenance is performed or a critical component is replaced.
• Control values have shifted or are out of range and a new vial of control does not rectify the problem.

Quality Control

To ensure adequate quality control, normal and abnormal control with assayed values for this methodology should be run as unknown samples:
• At least once per day or as established by the laboratory.
• When a new bottle of reagent is used.
• After preventative maintenance is performed or a critical component is replaced.
• With every calibration.

Calculations and Results

$$\Delta A = A_2 - A_1$$

$$\text{Concentration of HDL-C} = \frac{\Delta A_{sample} - \Delta A_{blank}}{\Delta A_{standard} - \Delta A_{blank}} \times C_{standard}$$

To convert results into SI unit (mmol/L), multiply results obtained in mg/dL by 0.0259 [mg/dL×0.0259 = mmol/L.]

Expected Values

0.7 ~ 1.7 mmol/L (27 ~ 66 mg/dL)
It is strongly recommended that each laboratory establish its own range of expected values, since differences exist between instruments, laboratories, and local populations.

Clinical Significance

HDL-C 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-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.
Accurate measurement of HDL-C is of vital importance when assessing patient's risk for CHD.

Limitations

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

Performance Characteristics

All Performance Characteristics were determined at Snibe Co., Ltd using a Snibe BC1200 chemistry analyler.

Absorbance of Blank

When purified water is used as a sample, the absorbance at 546 nm is under 0.10.

Sensitivity

When standard solution (74.5 mg/dL) is used as a sample, the range of absorbance change (at a wavelength of 546 nm) is greater than 0.300.

Linearity

When run as recommended the assay is linear between 0 and 150 mg/dL.

Precision

Within-Run Precision:

Batch code	Batch NO.1	Batch NO.2	Batch NO.3
Mean value	75.41 mg/dl	75.71 mg/dl	75.43 mg/dl
Standard deviation	0.51	0.72	0.66
CV	0.68%	0.95%	0.87%

Inter-Batch Precision:

Batch code	Batch NO.1	Batch NO.2	Batch NO.3
Mean value	74.45 mg/dl	74.56 mg/dl	74.56 mg/dl
Mean value of 3 batches	74.52 mg/dl		
relative deviation	0.16%		

Interference

The following substances normally present in serum produced less than 10% deviation at the listed concentrations: triglycerides at 1200 mg/dL, ascorbic acid at 30 mg/dL, bilirubin at 40 mg/dL, and hemoglobin at 500 mg/dL.

Precautions

1. For in vitro diagnostic use and professionals only.
2. Before tests, please read the effective version of reagent (kits) user manual thoroughly, make sure all program are clear.
3. Do not intermix reagents from different package. Do not use the reagents after the expiration date labeled on the outer box.
4. Avoid ingestion and contact with skin or mucous membranes, wear clean gloves when operating with a reagent kit or sample.

Security Warning

All samples, calibration serums and Quality control serums used in the test must be considered as potential infectious substances, whose disposal should be in accordance with the current regulations and guidelines of jurisdictional agency of laboratory, as well as the corresponding state regulations.

References

1. Henry RJ, Cannon DC, Winkelman JW. *Clinical Chemistry Principles and Technics*, 2nd ed. Hangerstown, MD: Harper and Row, 1974.
2. US Department of Health and Human Services. *Biosafety in Microbiological and Biomedical Laboratories. HHS Publication (CDC)*, 4th ed. Washington, DC: US Government Printing Office, May 1999.
3. Heins M, Heil W, Withold W. *Storage of serum and whole blood samples? Effects of time and temperature on 22 serum analytes.* Eur J Clin Chem Clin Biochem 1995; 33:231–8.
4. Dale JC, Pruett SK. *Phlebotomy–a minimalist approach.* Mayo Clin Proc 1993; 68 (3):249–55.
5. Elfath D, Cooney J, McDaniel R, et al. *Effect of frozen storage of serum on the level of 22 chemistry analytes.* Clin Chem 1991; 37:931.
6. Faulkner AM, Lukes-Hall AM, White GW. *Evaluation of the Grenier plasma separator blood tube.* Ann Clin Biochem 1990; 27:386–7.
7. Young DS. Effects of Drugs on Clinical Laboratory Tests, 4th ed. Washington, DC: AACC Press, 1995:3-6 – 3-16.

EC REP	Authorized Representative	Manufacturer	R1 Reagent 1	Keep upright	Consult instructions for use
CONT	Contents of kit	Keep away from sunlight	R2 Reagent 2	store at 2-8 °C	
REF	Catalogue number	SN Serial Number	Use-by date	LOT Batch code	IVD In vitro diagnostic medical device

Shenzhen New Industries Biomedical Engineering Co., Ltd
4/F,Wearnes Tech Bldg,
Science & Industry Park,
Nanshan,Shenzhen,518057CHINA
Tel. + 86-755-86028224
Fax.+ 86-755-26654850

EC REP
Lotus Global Co., Ltd
1 Four Seasons Terrace，West Drayton，Middlesex London，UB7 9GG，United Kingdom
Tel. + 44-20-75868010
Fax.+ 44-20-79006187

High density lipoprotein cholesterol   List No.501
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