SPECTRUM

The Creative Approach to Bioscience

HDL CHOLESTEROL - Precipitant

REF: 266 001 (1 X 50 ml) **100 test**
REF: 266 002 (4 X 100 ml) **800 test**
REF: 266 003 (2 X 50 ml) **200 test**
REF: 266 004 (5 X 50 ml) **500 test**

SYMBOLS IN PRODUCT LABELLING

EC REP Authorised Representative	Use by/Expiration Date
IVD For in-vitro diagnostic use	CAUTION. Consult instructions for use
LOT Batch Code/Lot number	Manufactured by
REF Catalogue Number	(Xi) - Irritant
Consult instructions for use	
Temperature Limitation	

Intended Use

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

Background

High density lipoprotein measurement, in conjunction with other lipid determination, has been shown to be useful in assessing the risk of coronary heart disease. HDL is responsible for carrying cholesterol back from preipheral cells to the liver , therefore the risk of coronary heart disease is lowered with increased levels of HDL. Usually, very low density lipoprotein (VLDL) and low density lipoprotein (LDL) are selectively precipitated from serum or plasma samples followed by determination of cholesterol in the HDL-containing supernatant.

Method

Precipitation Method .

Assay Principle

Low density lipoproteins (LDL) and very low density lipoproteins (VLDL) in sample precipitate with phosphotungstate and magnesium ions. After centrifugation, the cholesterol concentration in the HDL fraction, which remains in the supernatant, is determined.

Cholesterol esters + H_2O $\xrightarrow{\text{chol. esterase}}$ Cholesterol + Fatty acid

Cholesterol + 1\2 O_2 + H_2O $\xrightarrow{\text{chol. oxidase}}$ Cholestenone + H_2O_2

$2H_2O$ + 4-Aminoantipyrine + phenol $\xrightarrow{\text{peroxidase}}$ Quinoneimine + $4H_2O$

Reagents

Reagent (R)

Phosphotungstate	0.52 mmol/L
Magnesium chloride	30 mmol/L

Reagents also contain non-reactive stabilizers and surfactants .

* **Supplementary reagents :** A pack of Spectrum liquizyme cholesterol reagent is required

Precautions and Warnings

Do not ingest or inhalate. In case of contact with eyes or skin; rinse immediately with plenty of soap and water. In case of severe injuries; seek medical advice immediately.

Reagent Preparation, Storage and Stability

Spectrum HDL cholesterol reagent is supplied ready-to-use and stable up to the expiry date labeled on the bottles when properly stored at 2 - 8 °C .Once opened, the reagent is stable for 6 months at 2 - 8 °C if contamination is avoided.

Deterioration

Do not use The HDL cholesterol reagents if precipitate forms . Failure to recover control values within the assigned range may be an indication of reagent deterioration .

Specimen Collection and Preservation

Serum or plasma
EDTA and Heparin may be used as anticoagulants.

Stability : 7 days at 2 - 8 °C
4 days at 20 - 25 °C

System Parameters

Reagent Blank Limits	Low	0.00 AU
	High	0.15 AU

Procedure

1 - Precipitation

Pipette into centrifuge tubes :	
Reagent	0.5 ml
Specimen	0.2 ml

Mix and incubate for 10 minutes at room temperature, then centrifuge for 10 minutes at 4000 rpm .
Carefully collect the supernatant .
Stability : the supernatant may be stored up to five days at 2 - 8 °C.

2 - Cholesterol - Liquizyme

Pipette into test tubes :

	Blank	Specimen
Distilled water	50 µl	------
Specimen supernatant	------	50 µl
Cholesterol Reagent	1 ml	1 ml

Mix and incubate for 10 minutes at 20 – 25 °C or 5 minutes at 37°C.
Measure the absorbance of the specimen ($A_{specimen}$) against reagent blank at 546 nm (500 – 550 nm) within 60 minutes.

Calculation

HDL cholesterol conc. (mg/dL) = A_{sample} x 570

To calculate LDL cholesterol in mg/dL

$$\text{LDL Cholesterol} = \text{Total Cholesterol} - \frac{\text{Triglycerides}}{5} - \text{HDL Cholesterol}$$

in mmol/L

$$\text{LDL Cholesterol} = \text{Total Cholesterol} - \frac{\text{Triglycerides}}{2.2} - \text{HDL Cholesterol}$$

Performance Characteristics

Precision

Within run (Repeatability)

	Level 1	Level 2
n	20	20
Mean (mg/dL)	62.8	106.2
SD	3.46	4.29
CV%	5.51	4.04

Run to run (Reproducibility)

	Level 1	Level 2
n	20	20
Mean (mg/dL)	58.7	100.2
SD	3.08	3.27
CV%	5.25	3.36

Quality Control

Normal and abnormal commercial control serum of known concentrations should be analyzed with each run.

Sensitivity

When run as recommended, the minimum detection limit of the assay is 5 mg/dL (0.13 mmol/L).

Linearity

The reaction is linear up to a cholesterol concentration of 750 mg/dl; specimens showing higher concentration should be diluted 1+1 using physiological saline and repeat the assay (result × 2).

Clinical Interpretation

	Desirable	Standard Risk Level	Increased Risk Level
HDL Cholesterol			
Females (mg/dL)	> 65	45 - 65	< 45
(mmol/L)	>1.68	1.16 -1.68	<1.16
Males (mg/dL)	> 55	35 - 55	< 35
(mmol/L)	>1.42	0.90 -1.42	< 0.90
LDL Cholesterol			
(mg/dL)	<150	150 - 190	> 190
(mmol/L)	<3.38	3.88 - 4.91	> 4.91
Total Cholesterol			
(mg/dL)	<200	200 - 300	>300
(mmol/L)	<5.17	5.17 - 7.76	>7.76

Spectrum Diagnostics does not interpret the results of a clinical laboratory procedure; interpretation of the results is considered the responsibility of qualified medical personnel. All indications of clinical significance are supported by literature references.

Waste Disposal

This product is made to be used in professional laboratories.
Please consult local regulations for a correct waste disposal.
S56: dispose of this material and its container at hazardous or special waste collection point.
S57: use appropriate container to avoid environmental contamination.
S61: avoid release in environment. refer to special instructions/safety data sheets.

References

1. National Cholesterol Education Program Recommendation for Measurement of High-Density Lipoprotein Cholesterol: Executive Summary. Clin Chem. 1995;41:1427 - 1433.
2. Friedewald , W.T. et al. Clin. Chem. 1972; 18: 499.
3. Lopes- Virella, M.F. et al. Clin. Chem. 1977; 23: 882.

ORDERING INFORMATION	
CATALOG NO.	**QUANTITY**
266 001	**1 x 50 ml**
266 002	**4 x 100 ml**
266 003	**2 x 50 ml**
266 004	**5 x 50 ml**

Egyptian Company for Biotechnology (S.A.E)
Obour city industrial area. block 20008 piece 19 A. Cairo. Egypt.
Tel: +202 4489 2248 - Fax: +202 4489 2247
www.spectrum-diagnostics.com
E-mail:info@spectrum-diagnostics.com

EC REP **MDSS GmbH**
Schiffgraben 41
30175 Hannover, Germany

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TÜV SÜDWEST CERTIFIED ISO 13485:2016

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