



HDL Cholesterol Precipitant

IVD

REF.	Pack size
113 01 050	(1 x 50 ml) 100 Tests

Intended Use

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

Introduction

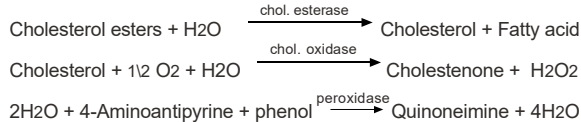
High density lipoprotein measurement, in conjunction with other lipid determination, has been shown to be useful in assessing the risk of coronary heart disease. HDL is responsible for carrying cholesterol back from peripheral cells to the liver, therefore the risk of coronary heart disease is lowered 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 .

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.



Reagents

Reagent (R)

Phosphotungstate	0.52 mmol/L
Magnesium chloride	30 mmol/LI.

Supplementary reagents :

A pack for SDI cholesterol reagent is required

Reagents preparation, storage and stability

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 opened vial 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 .

Precautions and Warnings

Do not ingest or inhale. 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.

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

Pipette into test tubes :

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

Mix, incubte 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

$$\text{HDL cholesterol conc. (mg/dL)} = A_{\text{specimen}} \times 570$$

Expected Values

Females	48.6 - 75 mg/dL	1.26 - 1.94 mmol/L
Males	41.0 - 58.7 mg/dL	1.06 - 1.52 mmol/L
Children	51.8 - 71.9 mg/dL	1.34 - 1.86 mmol/L

To calculate LDL cholesterol

$$\text{LDL Cholesterol (mg/dL)} = \text{Total Cholesterol (mg/dL)} - \frac{\text{Triglycerides (mg/dL)}}{5} - \text{HDL Cholesterol (mg/dL)}$$

in mmol/L

$$\text{LDL Cholesterol (mmol/L)} = \text{Total Cholesterol (mmol/L)} - \frac{\text{Triglycerides (mmol/L)}}{2.2} - \text{HDL Cholesterol (mmol/L)}$$

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.

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

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 x 2).

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.

SYMBOLS IN PRODUCT LABELLING

	For in-vitro diagnostic use
	Batch Code/Lot number
	Catalogue Number
	Consult instructions for use
	Temperature Limitation
	Use by/Expiration Date
	CAUTION. Consult instructions for use
	Manufactured by

 Spectrum For Diagnostic Industries - Free Zone
Ismailia Free Zone , Block 5 .
Cairo- Port said Avenue.
Ismailia, Egypt
Tel: +2 064 3488 013 - +2 064 3488 014 Fax: +2 064 3488 015
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