HDL PPT LS

Quantitative determination of HDL Cholesterol in Serum or Plasma. Method with precipitation.

REF CC1100 – 4x100 mL + 1x3 mL

METHOD AND PRINCIPLE

Determination of HDL Cholesterol with precipitating reagent. The phosphotungstic acid precipitates in serum or plasma lipoproteins VLDL and LDL. After centrifugation, the supernatant are only the HDL lipoprotein, and on it is possible to run the common dosage of total cholesterol.

CLINICAL SIGNIFICANCE

Cholesterol is a soft, waxy substance found among the lipids (fats) in the bloodstream and in all your body's cells. It is transported to and from the cells by special carriers called lipoproteins. LDL is the major Cholesterol carrier in the blood. If too much LDL Cholesterol circulates in the blood, it can cause atherosclerosis and/or clotting. HDL is known as "good Cholesterol" because a high HDL level seems to protect against a heart attack. About one-third to one-fourth of blood Cholesterol is carried by HDL.

REAGENT COMPOSITION

Reagent (R1)

Phosphotungstic Acid	0,55 mmol/L
Magnesium chloride	25 mmol/L

Reagent (R2)

Cholesterol Standard	value on label

REAGENT PREPARATION AND STABILITY

Liquid and ready to use Reagents, stable up to the end of the expiry, if stored at +15° to +25°C, protected from light and contamination is avoided. Do not freeze the reagents.
Discard if signs of deterioration appear:
- Presence of particles and turbidity.
- Failure to recover control values within the assigned range.

SPECIMEN

Serum or plasma free of hemolysis.
Do not use anticoagulants containing citrate.
HDL in Serum or Plasma is stable:

- Up to 7 days at 2 -8 °C.
- 1 month at -20 °C.

Shake gently and bring samples at room temperature before use.
Discard contaminated specimens.

PROCEDURE

Pipette as follow:

Reagent	1000 µL
Sample	500 µL

Mix well, leave for 10 minutes at room temperature, centrifuge for 2 minutes at 10,000 rpm, or 10 minutes at 4,000 rpm.
After centrifugation, separate the supernatant and on it determine the concentration of Cholesterol with the normal method used in the laboratory, using the enclosed standard to calibrate.
Volumes can be proportionally modified. This methodology describes the manual procedure to use the kit. For automated procedure, ask for specific application.

CALCULATION

HDL Cholesterol (mg / dL) = Cholesterol measured in supernatant x 3

The result obtained by the normal Cholesterol dosage should be multiplied by 3 since the test sample was diluted 1: 3 (1 + 2) with the reagent R1 in the pre-analytical phase.

Conversion Factor: mg/dL x 0.02586 = mmol/L

For LDL Cholesterol Calculation use this equation (if the value of Triglycerides is in the normal range):

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

QUALITY CONTROL

Normal and abnormal control sera of known HDL activities should be analysed routinely with each group of unknown samples utilizing **MTD Diagnostics** Quality Control Material:

Chemistry Control N - REF CNN1010 10 x 5 mL (Level 1)
Chemistry Control P - REF CNP1020 10 x 5 mL (Level 2)

EXPECTED VALUES

HDL

Women	30 – 85 mg/dL
Men	30 – 70 mg/dL

LDL

Adults	66 – 178 mg/dL

Each laboratory should investigate the transferability of the expected values to its own patient population and if necessary determine its own reference range.
For diagnostic purposes, HDL results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

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PERFORMANCE
Precision

Intra-assay precision n = 20	Mean [mg/dL]	CV [%]
Sample1	30.20	1.50
Sample2	42.70	1.18
Sample3	75.60	1.04

Inter-assay precision n = 20	Mean [mg/dL]	CV [%]
Sample1	29.40	2.68
Sample2	41.90	1.89
Sample3	73.20	3.22

Method Comparison (Accuracy)
A comparison between **MTD Diagnostics HDL PPT LS** and a commercially available test using 50 samples gave following results: r=0.99. The analytical performances have been generated using automatic instrument. Results may vary depending on the instrument.

Linearity: 6 – 300 mg/dL
Sensitivity: 6 mg/dL

SPECIFICITY / INTERFERENCES
No interference was observed by, bilirubin up to 20 mg/dL, haemoglobin up to 0.4 g/dL. Triglycerides up to 2000 mg/dL do not interfere. Ascorbic Acid up to 40 mg/dL and Glucose up to 500 mg/dL do not interfere.
If Triglycerides levels are higher than 2000 mg/dL, repeat the measure on a sample diluted 1:2 with physiological solution and multiply the results by 2.

NOTES
1. This method may be used with different instruments. Any application to an instrument should be validated to demonstrate that results meet the performance characteristics of the method. It is recommended to validate periodically the instrument. Contact your distributor for any question on the application method.
2. Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

PRECAUTIONS
The products do not contain dangerous substances or mixtures, according to the EC Regulation n ° 1272/2008 or their concentrations are such as not to be considered persistent, bioaccumulative or toxic (PBT). The product is classified and labeled in accordance with EC directives or respective national laws. Sodium azide, less than 0.1%.
However, in compliance with the normal prudential rules that everyone has to keep managing any chemical or laboratory reagent, in case of contact of reagents with the operator, you must apply the following first aid:
S26 (P305 – P351 – P338): In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S28 (P302 – P352): After contact with skin, wash immediately with plenty of water.
S36/37/39 (P280): Wear suitable protective clothing, gloves and eye/face protection.
S46 (P301 – P310): If swallowed, seek medical advice immediately and show container or label. If victim is conscious and alert, wash out mouth with water.
S56 (P273): Dispose of this material and its container at hazardous or special waste collection point.
S63 (P304 – P340): In case of accident by inhalation: remove casualty to fresh air and keep at rest. If breathing is difficult, give oxygen and get medical aid.
FOR MORE INFORMATION, REQUEST SAFETY DATA SHEET FOR REAGENT (MSDS) AT THE MANUFACTURER.

SIMBOLOGY

CE	CE Mark (EC Directive 98/79)		
IVD	In Vitro Diagnostic		Temperature Limitation
	Consult instructions for use		Contains sufficient for <n> test
REF	Catalog Number		Use By
LOT	Batch Code		Manufacturer

BIBLIOGRAPHY
Burstein M., J. Lipid Res. 11, 583 (1970)

Castelli, W.P. et al.Circulation 55, 767-772 (1986)

Vassault, A. Et al. Ann. Biol. Clin., 44,686, (1986)