HDL Cholesterol P

HDL cholesterol precipitating reagent

CE IVD

PACKAGING

Ref.: 101-0352	Cont.: 4 x 5 mL

Store at 2-8º C

CLINICAL SIGNIFICANCE

HDL particles carry cholesterol from the cells back to the liver.
HDL is known as "good cholesterol" because high levels are thought to lower the risk of heart disease. A low HDL cholesterol levels, is considered a greater heart disease risk[1,6,7].
Clinical diagnosis should not be made on a single test result; it should integrate clinical and other laboratory data.

PRINCIPLE OF THE METHOD

The very low density (VLDL) and low density (LDL) lipoproteins from serum or plasma are precipitated by phosphotungstate in the presence of magnesium ions. After centrifugation the supernatant contains high density lipoproteins (HDL). The HDL cholesterol fraction is determined using the total cholesterol enzymatic reagent[1,2].

REAGENTS

R Precipitating Reagent	Phosphotungstic acid Magnesium chloride	14 mmol/L 2 mmol/L
OPTIONAL REAGENT	Cholesterol (CHOD-PAP) Ref: 101-0237, 101-0012, 101-0267, 101-0050, 101-0051	

PRECAUTIONS

Corrosive (C):R35: Causes severe burns.

PREPARATION

The reagent is ready to use.

STORAGE AND STABILITY

All the components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8º C, protected from light and contaminations prevented during their use. Do not use reagents over the expiration date.
Signs of reagent deterioration:
- Presence of particles and turbidity.

ADDITIONAL EQUIPMENT

- Spectrophotometer or colorimeter measuring at 505 nm (500 - 550).
- Matched cuvettes 1.0 cm light path.
- General laboratory equipment.

SAMPLES

Serum or plasma[1]: Free of hemolysis. Removed from the blood clot as soon as possible.
Stability : HDL Cholesterol is stable for 7 days at 2-8º C .

PROCEDURE

Notes: CHRONOLAB SYSTEMS has instruction sheets for several automatic analyzers. Instructions for many of them are available on request.
The Precipitation procedure can be also performed with the half of reagent and sample volume.
Calibration with the aqueous Standard may cause a systematic error in automatic procedures. In these cases, it is recommended to use a serum Calibrator.
Precipitation NOTE 1

1. Pipette into a centrifuge tube:

R (µL)	100
Sample (mL)	1.0

2. Mix well; allow to stand for 10 min at room temperature.
3. Centrifuge at 4000 r.p.m. for 20 min or 2 min at 12000 r.p.m..
4. Collect the supernatant and proceed it as a sample in the total cholesterol determination.

CALCULATIONS

Follow the instructions of the total cholesterol insert.**Calculated LDL-cholesterol (Friedewald)**

LDLc = Total cholesterol - HDLc + (/5)

QUALITY CONTROL

Follow the Cholesterol reagent instructions of use.

REFERENCE VALUES[3]

HDL-cholesterol:

	Men	Women
Lower risk	> 55 mg/dL	> 65 mg/dL
Standard risk	35-55 mg/dL	45-65 mg/dL
Increased risk	< 35 mg/dL	< 45 mg/dL

LDL-cholesterol:
Suspected above: 150 mg/dL
Increased above: 190 mg/dL
These values are for orientation purpose; each laboratory should establish its own reference range.

PERFORMANCE CHARACTERISTICS

Measuring range: From detection limit of 1.57 mg/dL to linearity limit of 275 mg/dL.
If the results obtained were greater than linearity limit, dilute the sample 1/2 with NaCl (9 g/L) and multiply the result by 2.

Precision:

	Intra-assay (n=20)		Inter-assay (n=20)	
Mean (mg/dL)	75.8	33.9	95.2	182
SD	0.89	0.85	2.59	3.04
CV (%)	1.18	2.51	2.72	1.68

Sensitivity: 1 mg/dL = 0.0015 A.

Accuracy: Results obtained using CHRONOLAB reagents (y) did not show systematic differences when compared with other commercial reagents (x).
The results obtained using 50 samples were the following:
Correlation coefficient (r): 0.99.
Regression equation: y= 0.9944x – 1.2346.
The results of the performance characteristics depend on the analyzer used.

INTERFERENCES

No interferences were observed with triglycerides up to 4 g/L[1].
A list of drugs and other interfering substances with HDL cholesterol determination has been reported by Young et. al[4,5].

BIBLIOGRAPHY

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