Reactivos GPL

Barcelona, España

CE

- HDLc -

HDL CHOLESTEROL
Precipitating Method

Store at: +2+8ºC.

<u>Presentation:</u>
Cod. SU014   CONT: *R 3 x 10 mL.*

Procedure

HDL Cholesterol precipitating reagent.

Only for *in vitro* use in clinical laboratory (IVD)

TEST SUMMARY
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 COMPOSITION

R Precipitating reagent	Phosphotungstic acid Magnesium chloride	14 mmol/L 2 mmol/L
Opcional	Cholesterol Reagent	Ref. SU011 Ref. SU012 Ref. SU013

PRECAUTIONS
R: H314-Causes severe skin burns and eye damage.
Follow the precautionary statements given in MSDS and label of the product.

REAGENT PREPARATION AND STABILITY
The reagent is ready to use.
Signs of reagent deterioration:
- Presence of particles and turbidity.

All the components of the kit are stable until the expiration date on the label when stored at 2-8ºC, protected from light and contamination prevented during their use. Do not use reagents over the expiration date.

SPECIMEN
Serum or plasma, free of hemolysis[1]. Removed from the blood clot as soon as possible
Stability of the sample: 7 days at 2-8ºC.

MATERIAL REQUIRED BUT NOT PROVIDED
- Spectrophotometer or colorimeter measuring at 505 nm. (500-550)
- Matched cuvettes 1.0 cm light path.

General laboratory equipment.

TEST PROCEDURE
Precipitation (note1)
1.   Pipette into a centriguge tube:

R (µL)	100
Sample (mL)	1.0

2.   Mix well: allow to stand for 10 minutes at room temperature.
3.   Centrifuge at 4000 rpm for 20 minutes 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 - (TG/5)

QUALITY CONTROL
Follow the Cholesterol reagent instructions of use.

REFERENCE VALUES3
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).

It is suggested that each laboratory establish its own reference range.

CLINICAL SIGNIFICANCE
HDL particles serve to transport lipoproteins in the blood-stream. HDL is known as "good cholesterol" because high levels are thought to lower the risk of heart disease and coronary artery disease.
A low HDL cholesterol levels, is considered a greater heart disease risk[1,5,6].
Clinical diagnosis should not be made on a single test result; it should integrate clinical and other laboratory data.

REAGENT PERFORMANCE
–   *Measuring Range*:
    From detection limit of 1.57 mg/dL. to linearity limit of 275 mg/dL., under the described assay conditions.
    If results obtained were greater than linearity limit, dilute the sample ½ with NaCl 9 g/L. and multiply result by 2.
–   *Precision*:

	Intra-assay (n=20)		Inter-assay (n=20)	
Mean (mg/dL)	33.9	75.8	34.8	75.4
SD	0.85	0.89	1.25	1.95
CV (%)	2.51	1.18	3.60	2.59

-   *Sensitivity:* 1 mg/dL. = 0.0015 A
-   *Accuracy:* Results obtained with GPL reagents did not show systematic differences when compared with other commercial reagents.
    The results obtained using 50 samples were the following:
    Correlation coefficient $(r)^2$: 0.99
    Regression equation : y=0.9944x – 1.2346
    The results of the performance characteristics depend on the analyzer used.

INTERFERING SUBSTANCES
-   No interferes were observed with triglycerides up to 4 g/L[1].
-   Other substances may interfere. A list of drugs and other substances that could interfere has been reported by Young et. al[3,4].

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

BIBLIOGRAPHY
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3.   US National Cholesterol Education Program of the National Institutesof Health.
4.   Young DS. Effects of drugs on Clinical Lab. Tests, 4th ed AACC Press, 1995.
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6.   Burtis A et al. Tietz Textbook of Clinical Chemistry, 3rd ed AACC 1999.
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