



Presentation:

Cod. SU014 CONT: R 3 x 10 mL.

Store at: +2+8°C.

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 removed by centrifugation the clear supernatant containing high density lipoproteins (HDL) is used for the determination of HDL cholesterol^{1,2}.

REAGENTS COMPOSITION

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

REAGENT PREPARATION AND STABILITY

R is ready to use.

All the components of the kit are stable until the expiration date on the label when stored at 2-8°C, protected from light and contamination prevented during their use.

Do not use reagents over the expiration date.

Signs of reagent deterioration:

- Presence of particles and turbidity.

All the reagents of the kit are stable up to the end of the indicated month and year of expiry. Store tightly closed at 2-8°C. Do not use reagents over the expiration date

SPECIMEN

Serum or plasma, free of hemolysis¹. Removed from the blood clot as soon as possible

Stability of the sample: 7 days at 2-8°C.

MATERIAL REQUIRED BUT NOT PROVIDED

- Spectrophotometer or colorimeter measuring at 505 nm.
- Matched cuvettes 1.0 cm light path.

General laboratory equipment.

TEST PROCEDURE

Precipitation:

1. Pipette into a centrifuge 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 test HDLc.

Test:

Following the Cholesterol reagent instructions.

CALCULATIONS

With Calibrator:

$$\text{HDL Cholesterol (mg/dL.)} = \frac{(A)\text{Sample}}{(A)\text{Standard}} \times \text{Calibrator conc.}$$

With Factor:

$$\text{HDL (mg/dL.)} = (A_{505 \text{ nm}}) \text{ Sample} \times 320$$

$$\text{HDL (mg/dL.)} = (A_{546 \text{ nm}}) \text{ Sample} \times 475$$

LDL Cholesterol

According to the Friedewald Formula:

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

QUALITY CONTROL

Control sera are recommended to monitor the performance of the procedure, Control Normal Ref. QC001 and Control Pathological Ref. QC002. If control values are found outside the defined range, check the instrument, reagents and calibrator for problems.

Serum controls are recommended for internal quality control. Each laboratory should establish its own Quality Control scheme and corrective actions

REFERENCE VALUES

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 1/2 with NaCl 9 g/L. and multiply 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 GPL reagents did not show systematic differences when compared with other commercial reagents. The results of the performance characteristics depend on the analyzer used.

INTERFERING SUBSTANCES

- No interferences were observed with triglycerides up to 4 g/L¹.
- 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. Use clean disposable pipette tips for its dispensation.

BIBLIOGRAPHY

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