



Store at: +2+8°C.

Presentation:

- Cod. SU011 CONT: R 2 x 50 mL. + CAL 1 x 5 mL.
- Cod. SU012 CONT: R 2 x 125 mL. + CAL 1 x 5 mL.
- Cod. SU013 CONT: R 4 x 250 mL. + CAL 1 x 5 mL.

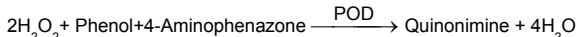
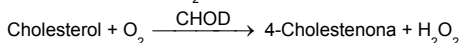
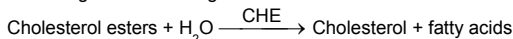
Procedure

Quantitative determination of Cholesterol.

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

TEST SUMMARY

The cholesterol present in the sample originates a coloured complex, according to the following reaction:



The intensity of the color formed is proportional to the cholesterol concentration in the sample^{1,2}.

REAGENTS COMPOSITION

R	PIPES pH 6.9	90 mmol/L.
	Phenol	26 mmol/L.
	Cholesterol esterase (CHE)	1000 U/L.
	Cholesterol oxydase (CHOD)	300 U/L.
	Peroxidase (POD)	650 U/L.
	4-Aminophenazone (4-AP)	0.4 mmol/L.
Cholesterol Cal	Cholesterol aqueous primary Calibrator	200 mg/dL.

REAGENT PREPARATION AND STABILITY

All the reagents are 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.

Cholesterol Cal: Once open is stable up to 1 month when stored tightly closed at 2-8°C, protected from light and contamination prevented during their use.

Signs of Reagent deterioration:

- Presence of particles and turbidity.
- Blank absorbance (A) at 505 nm. ≥ 0.26

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^{1,2}: Stability of the sample for 7 days at 2-8°C or freezing at -20°C will keep samples stable for 3 months.

MATERIAL REQUIRED BUT NOT PROVIDED

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

General laboratory equipment.

TEST PROCEDURE

1. Assay Conditions
 - Wavelength : 505 nm. (500-550).
 - Cuvette: 1 cm light path.
 - Temperature 37°C. 15-25°C.
2. Adjust the instrument to zero with Blank of reagent.
3. Pipette into a cuvette:

	Blank	Standard	Sample
R (mL.)	1.0	1.0	1.0
Calibrator ^(note1-2) (μL.)	--	10	--
Sample (μL.)	--	--	10

4. Mix and incubate for 5 minutes at 37°C or 10 minutes at room temperature (15-25°C).
5. Read the absorbance (A) of the samples and calibrator, against the Blank. The colour is stable at least 60 minutes.

CALCULATIONS

$$\text{Cholesterol (mg/dL.)} = \frac{(A)\text{Sample}}{(A)\text{Standard}} \times 200 \text{ (Calibrator conc.)}$$

$$\text{Conversion Factor. mg/dL.} \times 0.0258 = \text{mmol/L.}$$

QUALITY CONTROL

Control sera are recommended to monitor the performance of the procedure, Normal (Ref. QC001) and 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

Risk evaluation^{5,6}:

Less than 200 mg/dL	Normal
200-239 mg/dL	Borderline
240 mg/dL and above	High

(These values are for orientation purpose).

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

CLINICAL SIGNIFICANCE

Cholesterol is a fat-like substance that is found in all body cells. The liver makes all of the cholesterol the body needs to form cell membranes and to make certain hormones.

The determination of serum cholesterol is one of the important tools in the diagnosis and classification of lipemia. High blood cholesterol is one of the major risk factors for heart disease^{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 0.46 mg/dL. to linearity limit of 600 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:

Mean (mg/dL)	Intra-assay n= 20		Inter-assay n= 20	
	93.95	200	92.2	195
SD	0.76	1.22	1.88	5.97
CV	0.80	0.61	2.04	3.05

Sensitivity: 1 mg/dL. = 0.0017 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 to bilirubin up to 10 mg/L, hemoglobin up to 5 g/L^{1,2}.
- 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. Calibration with the aqueous standard may cause a systematic error in automatic procedures. In these cases, it is recommended to use a serum Calibrator.
2. Use clean disposable pipette tips for its dispensation.

BIBLIOGRAPHY

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