Reactivos GPL

Barcelona, España

CE

- Cholesterol LS -

CHOLESTEROL
Liquid. CHOD-POD

Store at: +2+8º 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 8 x 125 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:

$$\text{Cholesterol esters} + H_2O \xrightarrow{\text{CHE}} \text{Cholesterol} + \text{fatty acids}$$

$$\text{Cholesterol} + O_2 \xrightarrow{\text{CHOD}} \text{4-Cholestenona} + H_2O_2$$

$$2H_2O_2 + \text{Phenol+4-Aminophenazone} \xrightarrow{\text{POD}} \text{Quinonimine} + 4H_2O$$

The intensity of the color formed is proportional to the cholesterol concentration in the sample[1,2].

REAGENTS COMPOSITION

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

REAGENT PREPARATION AND STABILITY

All the reagents are ready to use.
CHOLESTEROL CAL: Proceed carefully with this product because due its nature it can get contamined easily.
Signs of Reagent deterioration:
- Presence of particles and turbidity.
- Blank absorbance (A) at 505 nm. ≥ 0.26

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[1,2]: Stability of the sample for 7 days at 2-8º C or freezing at –20º 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
   - Wavelenght: ..... 505 nm. (500-550)
   - Cuvette: ..... 1 cm light path
   - Temperature .....37ºC /15-25º C
2. Adjust the instrument to zero with Blank of reagent.
3. Pipette into a cuvette: (Note 3)

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

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

CALCULATIONS

$$\frac{(A)\text{SAmple} - (A)\text{Blank}}{(A)\text{Standard} - (A)\text{Blank}} = 200\ (\text{Standard Conc.}) = \text{mg/dL cholesterol min sample}$$

Conversion Factor. mg/dL. x 0.0258 = mmol/L.

QUALITY CONTROL

Control sera are recommended to monitor the performance of the procedure, H Normal (Ref. QC003) and H Pathological. (Ref. QC004)
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 a 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 0.113 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 ½ with NaCl 9 g/L. and multiply result by 2.

– *Precision*:

	Intra-assay n= 20		Inter-assay n= 20	
Mean (mg/dL)	99.789	185.309	96.346	184.962
SD	1.213	1.405	4.196	12.773
CV	1.216	0.758	4.355	6.906

- *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 obtained using 50 samples were the following:
  Correlation coefficient $(r)^2$: 0.9968
  Regression equation: y= 0.9797x + 2.2803
  The results of the performance characteristics depend on the analyzer used.

INTERFERING SUBSTANCES

- No interferencess 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. LDF (Lipid Clearing Factor) is integrated in the reagent.
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. Use clean disposable pipette tips for its dispensation.

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