Biomaghreb

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CE

CHOLESTEROL

Enzymatic Colorimetric test

(CHOD- PAP)

Reagent for the quantitative determination of Total Cholesterol in human plasma

IN VITRO DIAGNOSTIC USE

IVD

REF	**21014**	**3 x 120 ml** (360 T)	**R1:** 3 x 120 ml	**R2:** 3 lyophilisates	**R3:** 1 x 5 ml
REF	**21021**	**2 x 200 ml** (400 T)	**R1:** 2 x 200 ml	**R2:**2 lyophilisates	**R3:** 1 x 5 ml
REF	**21038**	**4 x 30 ml** (120 T)	**R1:** 4 x 30 ml	**R2:**4 lyophilisates	**R3:** 1 x 4 ml
REF	**21045**	**2 x 30 ml** (60 T)	**R1:** 2 x 30 ml	**R2:**2 lyophilisates	**R3:** 1 x 4 ml
REF	**21052**	**5 x 120 ml** (600 T)	**R1:** 5 x 120 ml	**R2:**5 lyophilisates	**R3:** 2 x 5 ml

CLINICAL SIGNIFICANCE

Cholesterol is a molecule essential to the proper functioning of the body, which comes from food where is synthesized in the liver. It is an insoluble molecule in the blood, transported by proteins called «lipoproteins»: LDL, HDL and VLDL. Cholesterol levels are measured in order to detect hypercholesterolemia, which could lead to the development of atheromatous plaques (atherosclerosis), and can also be used to diagnose liver and thyroid diseases. In some cases, cholesterol levels are monitored before initiating drug therapy.

PRINCIPLE

The cholesterol level is measured after enzymatic hydrolysis and then oxidation. The quinoneimine indicator is formed from hydrogen peroxide and amino 4 antipyrine in the presence of phenol and peroxidase according to the following reactions:

Cholesterol esterase

Cholesterol esters + H_2O ⟶ Cholesterol + Fatty Acid

Cholesterol oxidase

Cholesterol + O_2 ⟶ Cholestene-4-one-3 + H_2O_2

Peroxidase

H_2O_2 + Phenol +Amino-4–antipyrine ⟶ Quinoneimine rose

The quantity of quinoneimine formed is proportional to the concentration of cholesterol.

REAGENT COMPOSITION

Reagent 1 Buffer solution	Pipes pH 6.9 Phenol	90 mmol/l 26 mmol/l
Reagent 2 Enzymes	Cholesterol oxidase Peroxidase Cholesterol esterase Amino-4-antipyrine	300 U/l 1250 U/l 300 U/l 0.4 mmol/l
Reagent 3 Standard	Standard Cholesterol	200 mg/dl 2 g/l 5.17 mmol/l

SAFETY CAUTIONS

Biomaghreb reagents are intended for use by qualified personnel for in vitro use (do not pipette by mouth).

- Refer to the current SDS available on request or at www.biomaghreb.com;
- Verify the integrity of the reagents before use; and
- Disposal of waste: comply with the legislation in force.

For safety reasons, treat any specimen or reagent of biological origin as potentially infectious. Respect the legislation in force.

REAGENT PREPARATION

Working solution: Dissolve the lyophilisate R2 with the contents of a Buffer R1 vial.

SAMPLE PREPARATION

Serum, plasma heparinized non-hemolyzed.

PRESERVATION AND STABILITY

- Before opening: Until the expiry date indicated on the label of the box at 2-8°C;
- After opening (Working Solution) :
  1 month at 20-25°C;
  4 months at 2-8°C.

ADDITIONAL EQUIPMENT

- Basic equipment of the medical analysis laboratory ;
- Spectrophotometer or Clinical Biochemistry Analyzer.

QUALITY CONTROL

External quality control program.
It is recommended to control in the following cases:

- At least one test per series.
- Change of reagent bottle.
- After maintenance work on the analyzer.

If a control value is outside the confidence limits, repeat the procedure using the same control. Use normal and pathological control sera.

CALIBRATION

The standard of the kit (Reagent 3) or any calibrator connected to a method or reference material. The frequency of calibration depends on analyzer performance and reagent storage conditions. Recalibration is recommended in the following cases:

1. Changing the reagent lot;
2. After maintenance work on the analyzer; and
3. Control values are outside the confidence limits.

LINEARITY

The method is linear up to 6 g/l (600 mg/dl - 15.4 mmol/l). If the cholesterol concentration is higher than 6 g/l, dilute the sample 1/2 with 9 g/l NaCl solution and repeat the test. Multiply the result by 2.

PROCEDURE

Wavelength: 505 nm (500-550);
Temperature: 37°C ;
Tank: 1 cm thick;
Adjust the spectrophotometer zero on the reagent blank.

	Blank	Standard	Sample
Standard	- -	10 µl	- -
Sample	- -	- -	10 µl
Working solution	1 ml	1 ml	1 ml
Mix, read absorbances after incubation for 5 minutes at 37°C or 10 minutes at 20 - 25°C. Staining is stable 30 minutes.			

CALCUL

$$\text{Cholesterol} = \frac{\text{OD. Sample}}{\text{OD. Standard}} \times n$$

n = Standard value

n = 200 mg/dl;
n = 2 g/l;
n = 5, 17 mmol/l.

REFERENCE VALUES

Serum or plasma	3,6 at 5,7 mmol/l 1,4 at 2,2 g/l 140 at 220 mg/dl

REFERENCES

Trinder P., Ann. Clin. Biochem. 6, 24 (1969) ;
Richmond, Clin. Chem. 19, 1350 (1973) ;
Fasce C.F., Clin. Chem. 18901 (1982).

Manufacturer | Use by | In Vitro Diagnostic | Temperature Limitation | Catalogue number | See insert | Store away from light | Sufficient for < n > essais | Batch number