

IN VITRO DIAGNOSTIC USE



REF 22011	5 x 5 ml (500 T)	Additionnal Kit	REF 21017
REF 22028	1 x 5 ml (100 T)		REF 21021
REF 22035	10 x 10 ml (1000 T)		REF 21038
Cholesterol (CHOD- PAP)			REF 21045
			REF 21052

CLINICAL SIGNIFICANCE

High cholesterol is considered a risk factor for atherosclerosis. It can be primary or secondary to thyroid insufficiency, pancreatitis, or nephrotic syndrome.... It will be necessary to type this anomaly by determining the respective levels of the different lipid fractions (HDL, LDL, VLDL).

A high level of HDL cholesterol protects against coronary heart disease complications. It can increase with age, gender, physical activity, a diet low in cholesterol and high in polyunsaturated fatty acids, or when taking certain drugs such as lipid-lowering drugs (fibrates), vitamin C, anti-epileptics, insulin and estrogen-progestin or alcohol consumption.

PRINCIPLE

Chylomicrons and very low density (VLDL) and low density (LDL) lipoproteins contained in the sample are precipitated by addition of phosphotungstic acid in the presence of magnesium ions. The supernatant obtained after centrifugation contains the high density lipoproteins (HDL) whose cholesterol is determined by the cholesterol enzyme reagent of the complementary kit.

REAGENT COMPOSITION

Precipitant Reagent	Phosphotungstic Acid	13,9 mmol/l
	MgCl2 6H2O pH 6,2	490 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

The reagent is ready to use.

SAMPLE PREPARATION

Serum or plasma collected on EDTA.

PRESERVATION AND STABILITY

The reagent must be stored until the expiry date indicated on the package label between 2-8°C.

LIMITS

If the reagent is cloudy or colored, it must be discarded.

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.

PROCEDURE

• Precipitation

Dilute in 9 g/l NaCl solution the sera with triglyceride more than 3,5 mmol/l.

Serum.....500 µl

Precipitant reagent50 µl

Mix well, wait 10 minutes;

Centrifuge for 15 minutes at 5000 rpm.

• Cholestérol-HDL (CHOD-PAP) Assay:

Reconstitute the enzymatic cholesterol reagent according to the notice of the additional kit.

Wavelength: 505 nm (492-550);

Temperature: 37°C;

Adjust the spectrophotometer zero on the reagent blank.

	Blank	Standard	Assay
Distilled water	10 µl	--	--
Standard Cholesterol	--	10 µl	--
Supernatant	--	--	10 µl
Cholesterol enzyme Reagent	1 ml	1 ml	1 ml

Mix, read absorbances after incubation for 5 minutes at 37°C. Staining is stable 30 minutes.

N.B.: Once the vial of HDL reagent is opened, there is a possibility of the formation of shiny crystals at the bottom of the vial which do not affect the quality of the product.

CALCULATION

$$[\text{HDL-Cholesterol}] = \frac{\text{DO. Assay}}{\text{DO. Standard}} \times n$$

with n = Standard value

n = 5,17 mmol/l ;

n = 2 g/l.

Multiply the result obtained by 1.1 to take into account the dilution made during precipitation: this gives the HDL cholesterol concentration .

REFERENCE VALUES

Cholesterolemia	Evaluation du risque
< 2g/l < 5,2 mmol/l	Low risk
2,0 à 2,5 g/l 5,2 à 6,5 mmol/l	Moderate risk especially if HDL cholesterol < 0,35 g/l ; < 0,9 mmol/l.
> 2,5 g/l > 6,5 mmol/l	High risk especially if HDL cholesterol < 0,35 g/l ; < 0,9 mmol/l.

REFERENCES

BURSTEIN M. et al. Lipid Res.11. 583.(1970) ;

Study Group, European Atherosclerosis Society, European Heart Journal, 9, 571 (1988) ;

ARCOL, ISB, 1989, 15, 121 -124.



Manufacturer



Use by



In Vitro Diagnostic



Temperature Limitation



Catalogue number



See insert



Store away from light



Sufficient for < n > essais



Batch number