Cholesterol

Cholesterol.CHOD-POD. Liquid

Product information

24CHOL01-UN	**Meditest CHOL**	**6x40 mL**
24CHOL01-AU	**Meditest CHOL**	**6x40 mL**
24CHOL01-AB	**Meditest CHOL**	**6x40 mL**
24CHOL01-ER	**Meditest CHOL**	**6x40 mL**
24CHOL01-AR	**Meditest CHOL**	**6x40 mL**

Purpose

This reagent is intended for the quantitative determination of total cholesterol concentration in human serum and plasma.

Summary

Cholesterol is a fat-like substance found in all body cells and is called a lipid. The liver produces all the cholesterol that the body needs to build cell membranes and make certain hormones. 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 based on a single test result, but clinical and other laboratory data should be integrated.

Test principle

The cholesterol present in the sample forms a colored complex according to the following reactions:

Cholesterol esters + H_2O —**CHE**→ Cholesterol + fatty acids

Cholesterol + O_2 —**CHOD**→ 4-Cholestenona + H2O2

2 H2O2+ Phenol + 4-AP —**POD**→ Quinonimine + $4H_2O$

The intensity of the resulting colour is proportional to the cholesterol concentration in the sample[1,2]

Reagents - working solutions

R 1	PIPES pH 6.9	<90 mmol/L
	Phenol	<26 mmol/L
	Cholesterol esterase (CHE)	>1000 U/L
	Cholesterol oxidase (CHOD)	<300 U/L
	Peroxidase (POD)	<650 U/L
	4 – Aminophenazone (4-AP)	<0.4 mmol/L

Precautions warnings

It is intended for in vitro diagnostic use by healthcare professionals. Follow the normal precautions necessary in handling all laboratory reagents.
Infectious or microbial waste:
Warning: handle waste as potentially biohazardous. Dispose of waste according to accepted laboratory instructions and procedures.
Environmental hazards: Follow all relevant local disposal regulations to determine that it has been disposed of safely. If requested, a safety data sheet can be provided to professional users.
Inhibit foam formation in all reagents and sample types (sample, calibrator and control).
If there is any damage on the package, do not use Read the user manual carefully before use, do not use the expired assay kit. Do not mix different lot reagents.
All samples should be considered epidemic material, please dispose of them in accordance with the laboratory working standard of infectious diseases.
Take the necessary protective measures to prevent users from becoming infected during operation. This kit contains components classified according to Regulation (EC) No 1272/2008 as follows:

Warning

H319 Causes severe irritation of the eye.
Prevention:
P264 Wash the skin thoroughly after handling.
P280 Wear eye protection/face protection.
Answer:
P305 + P351 + P338 IF IN EYES: Rinse carefully with water for a few minutes. Remove the lenses if they are present and easy to remove. Continue washing.
P337 + P313 If eye irritation persists: Seek medical advice/help.

Use of reagents

Ready to use.

Storage and stability

All components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8ºC, protected from light and contamination is avoided during their use.
Do not use reagents after the expiration date. Signs of reactive deterioration: Presence of particles and turbidity.

Sample collection and preparation

Fresh Serum or EDTA and heparinized plasma.
Note: Separate the serum or plasma as soon as possible (within 3 hours) after collection. Store the serum at room temperature for a maximum of 12 hours and at 2-8 ºC for a maximum of 7 days. The serum is stable at (-60)-(-80)°C for 30 days.

Required Materials (not included in the kit)

1. Cat# 24BIO01-DC Meditest Diachem Calibrator
2. Cat# 24BIO01-DQ Meditest Diacheck Control L1
3. Cat# 24BIO02-DQ Meditest Diacheck Control L2
4. General laboratory equipment
5. Distilled or deionized water

Working Procedure

If you are using a spectrophotometer to perform this test, work with the following procedure. Ask your representative for the application data for fully automatic devices.

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1.Test Conditions:
Wavelength: . 505 nm
Cuvette: . . . . . 1 cm light path
Temperature: . .
2. Set the appliance to zero with distilled water
3. Pipette into cuvettes in the following ratio.

	Blank	Standard	Sample
R (mL)	1.0	1.0	1.0
Standard(Note 1-2) (µL)	--	10	--
Sample (µL)	--	--	10

4. Stir and incubate at 37ºC for 5 minutes or at 15-25ºC for 10 minutes.
5. Read the absorbance of the samples and the calibrator (A) against the gap. The color is stable for at least 60 minutes.

Calculation:
(A) Sample- (A)Blank
——————————x 200 (Standard conc.) = mg/dL cholesterol
(A) Standard- (A)Blank

Flip factor:
mmol/L*38.67= mg/dL
mg/dL*0.02586=mmol/L

Expected values
Levels in terms of coronary heart disease risk:

Risk assessment[5,6]:

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

The risk classification of patients and treatments is described in international guidelines[2,6]
These values are for orientation purposes; Each laboratory should establish its own reference range.

Limitations
No interference was observed at values of hemoglobin up to 5 g/L and bilirubin up to 10 mg/dL[1,2]. A list of drugs and other substances that interfere with cholesterol determination has been reported by Young et al [3,4]

Performance characteristics
Measuring range: 1 - 1000 mg/dL
If the results obtained are greater than the linearity limit, dilute the sample by 1/2 with 9 g/L NaCl and multiply the result by 2.

Precision

	Intra-assay (n=20)		Inter-assay (n=20)	
Mean (mg/dL)	99	201	96	197
SD	0,83	1,41	1,75	6,41
CV (%)	0,84	0,70	1,82	3,26

Sensitivity: 1 mg/dL = 0.0019 ΔA/min
Accuracy: Results obtained using Meditest reagents (y) showed no systematic differences when compared to other commercial reagents (x). The results obtained using 50 samples are as follows:
Correlation coefficient (r)²: 0.99549
Regression equation y= 0.911x + 2.624

The results of the performance characteristics depend on the analyzer used.

References

1. Naito H.K. Cholesterol. Kaplan A et al. Clin Chem The C.V. Mosby Co. St Louis. Toronto. Princeton 1984; 1194-11206 and 437.
2. Meiattini F. et al. The 4-hydroxybenzoate/4-aminophenazone Chromogenic System. Clin Chem 1978; 24 (12): 2161-2165.
3. Young DS. Effects of drugs on Clinical Lab. Tests, 4th ed AACC Press, 1995.
4. Young DS. Effects of disease on Clinical Lab. Tests, 4th ed AACC 2001.
5. Burtis A et al. Tietz Textbook of Clinical Chemistry, 3rd ed AACC 1999.
6. Tietz N W et al. Clinical Guide to Laboratory Tests, 3rd ed AACC 1995.

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