Cat. No 4-504

DIAGNOSTIC KIT FOR DETERMINATION OF TOTAL CHOLESTEROL CONCENTRATION

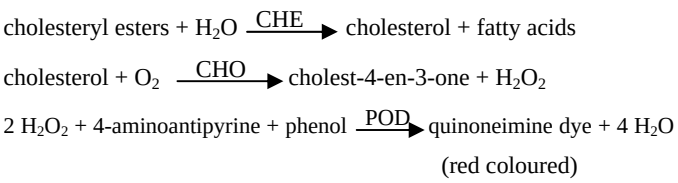
HC – CHOL

INTRODUCTION

Cholesterol is essential structural component of cell membranes and precursor of bile acids and all steroids hormones. This is why cholesterol has enormous significance for organism normal functioning. But there is also well established association between blood cholesterol concentration and coronary heart disease. Measurement of cholesterol serum level is valuable in prevention and monitoring cardiovascular disease. This determination is useful also for evaluation of intestine absorption, liver and gallbladder function.

METHOD PRINCIPLE

Enzymatic, colorimetric method with cholesterol esterase and cholesterol oxidase.



The colour intensity is proportional to the cholesterol concentration.

REAGENTS

Package

1-Reagent	6 x 96.5 ml

The reagent when stored at 2-8°C is stable up to expiry date printed on the package. The reagent is stable for 12 weeks on board the analyser at 2-10°C. Protect from light and avoid contamination!

Concentrations in the test

Good's buffer (pH 6.4)	100 mmol/l
phenol	5 mmol/l
4-aminoantipyrine	0.3 mmol/l
cholesterol esterase (CHE)	> 3.2 µkat/l
cholesterol oxidase (CHO)	> 1.67 µkat/l
peroxidase (POD)	> 50 µkat/l

Warnings and notes

- Product for in vitro diagnostic use only.
- The reagent contains sodium azide (< 0.1%) as a preservative. Avoid contact with skin and mucous membranes.

SPECIMEN

Serum, EDTA or heparinized plasma (recommended: heparine lithium, sodium or ammonium salt) free from hemolysis.
Blood should be collected only if the patient has been fasting for minimum of 12 hours. Before blood collection patient should stay in rest position for about 30 minutes. Venous blood is recommended for cholesterol measurement.
Plasma cholesterol values have been reported to be 3% to 5% lower than serum cholesterol values.
Serum should be separated from red blood cells as soon as possible after blood collection.
Serum and plasma can be stored up to 3 days at 2-8ºC or 6 months at -20ºC.
Nevertheless it is recommended to perform the assay with freshly collected samples!

PROCEDURE

The reagent is ready to use.
This reagent may be used in automatic analyser Hitachi 911/912.
Application should be entered using handheld barcode scanner and attached barcodes sheet, according to procedure described below:

1. Delete previous version of application and calibrators assigned to it and restart the analyser.
2. Enter codes of calibrators according to the attached list.
3. Enter barcoded application and assign proper values to calibrators.
4. To activate entered application go to the tab UTILITY | APPLICATION | RANGE and change value of field DATA MODE from INACTIVE to ON BOARD. Confirm the change using UPDATE button.
5. Put reagents on board the analyser – they will be assigned to relevant tests automatically. Perform also measurement of level of reagents inside the bottles.
6. After calibration analyser is ready to use.

REFERENCE VALUES [9]

serum / plasma		mg/dl	mmol/l
children	≤ 4 wk	50 – 170	1.3 – 4.4
	2 – 12 mo	60 – 190	1.6 – 4.9
	≥1 y	110 – 230	2.8 – 6.0
adults		< 200	< 5.2

It is recommended for each laboratory to establish its own reference ranges for local population.

QUALITY CONTROL

For internal quality control it is recommended to use the CORMAY SERUM HN (Cat. No 5-172) and CORMAY SERUM HP (Cat. No 5-173) with each batch of samples.
For the calibration of automatic analysers systems the CORMAY MULTICALIBRATOR LEVEL 1 (Cat. No 5-174; 5-176) is recommended. **Calibrator and 0.9% NaCl** should be used for calibration.
The calibration curve should be prepared every 12 weeks, with change of reagent lot number or as required e.g. quality control findings outside the specified range.

PERFORMANCE CHARACTERISTICS

These metrological characteristics have been obtained using the automatic analyser Hitachi 912. Results may vary if a different instrument or a manual procedure is used.

- **Sensitivity:** 0.8 mg/dl (0.021 mmol/l).
- **Linearity:** up to 820 mg/dl (21.2 mmol/l).
- **Specificity / Interferences**
  Haemoglobin up to 0.31 g/dl, ascorbate up to 62 mg/l, bilirubin up to 20 mg/dl and triglycerides up to 1000 mg/dl do not interfere with the test.
- **Precision**

Repeatability (run to run) n = 20	Mean [mg/dl]	SD [mg/dl]	CV [%]
level 1	251.56	1.08	0.43
level 2	105.83	0.54	0.51

Reproducibility (day to day) n = 80	Mean [mg/dl]	SD [mg/dl]	CV [%]
level 1	258.40	2.78	1.08
level 2	109.90	1.15	1.05

- **Method comparison**

A comparison between cholesterol values determined at Hitachi 912 (y) and at COBAS INTEGRA 400 (x) using 100 samples gave following results:
y = 1.0268 x + 5.4927 mg/dl;
R = 0.9983 (R – correlation coefficient)

WASTE MANAGEMENT
Please refer to local legal requirements.

LITERATURE

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