# Cholesterol FS

## Cholesterol Reagent Test Kit

### Intended Use

Diagnostic reagent for in vitro quantitative determination of Cholesterol in human serum or plasma on photometric analyzers.

### Reagent Kits

| Item Code. | Pack Size |
|---|---|
| 113009934840 | R: 4 x 60 mL |

### Summary

Cholesterol is a component of cell membranes and a precursor for steroid hormones and bile acids synthesized by body cells and absorbed with food. Cholesterol is transported in plasma via lipoproteins, namely complexes between lipids and apolipoproteins. There are four classes of lipoproteins: high density lipoproteins (HDL), low density lipoproteins (LDL), very low density lipoproteins (VLDL) and chylomicrons. While LDL is involved in the cholesterol transport to the peripheral cells, HDL is responsible for the cholesterol uptake from the cells. The four different lipoprotein classes show distinct relationship to coronary atherosclerosis. LDL-cholesterol (LDL-C) contributes to atherosclerotic plaque formation within the arterial intima and is strongly associated with coronary heart disease (CHD) and related mortality. Even with total cholesterol within the normal range an increased concentration of LDL-C indicates high risk. HDL-C has a protective effect impeding plaque formation and shows an inverse relationship to CHD prevalence. In fact, low HDL-C values constitute an independent risk factor. The determination of the individual total cholesterol (TC) level is used for screening purposes while for a better risk assessment it is necessary to measure additionally HDL-C and LDL-C.

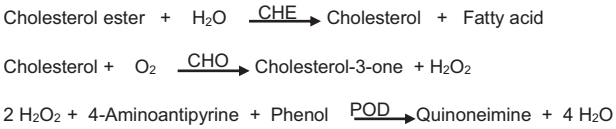
In the last few years several controlled clinical trials using diet, life style changes and/or different drugs (especially HMG CoA reductase inhibitors [statins]) have demonstrated that lowering total cholesterol and LDL-C levels reduce drastically CHD risk [2].

### Method

"CHOD-PAP": enzymatic photometric test

### Principle

Determination of cholesterol after enzymatic hydrolysis and oxidation [3,4]. The colorimetric indicator is quinoneimine which is generated from 4-aminoantipyrine and phenol by hydrogen peroxide under the catalytic action of peroxidase (Trinder's reaction) [3].




### Reagents

#### Components and Concentrations

**Reagent:**

| | |
|---|---|
| Pipes Buffer | 100mmol/L |
| Phenol | 1 g/L |
| 4-Amino Antipyrine | 0.1mmol/L |
| Cholesterol Esterase | >150 U/L |
| Cholesterol Oxidase | >100 U/L |
| Peroxidase | >500 U/L |
| Preservatives & Stabilizers | q.s. |

### Storage Instructions and Reagent Stability

Reagent stable up to the end of the indicated month of expiry, if stored at 2 – 8°C, protected from light and contamination is avoided. Do not freeze the reagents!

**Note:** It has to be mentioned, that the measurement is not influenced by occasionally occurring color changes, as long as the absorbance of the reagent is < 0.3 at 546 nm.

### Traceability

The assigned values of the calibrator have been made traceable to the reference method gas chromatography-isotope dilution mass spectrometry (GC-IDMS).

### Warnings and Precautions

1. The reagent contains sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
2. May cause an allergic skin reaction. Causes serious eye irritation. Wash hands and face thoroughly after handling. Wear protective gloves/protective clothing/eye protection/face protection. If on skin: Wash with plenty of soap and water. If eye irritation persists: Get medical advice/attention.
3. In very rare cases, samples of patients with gammopathy might give falsified results [8].
4. N-acetylcysteine (NAC), acetaminophen and metamizole medication leads to falsely low results in patient samples.
5. Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.
6. For professional use only!

### Waste Management

Please refer to local legal requirements.

### Reagent Preparation

Reagent is ready to use.

### Specimen

Serum, heparin plasma or EDTA plasma

| | | | |
|---|---|---|---|
| Stability [6]: | 7 days | at | 20 – 25°C |
| | 7 days | at | 4 – 8°C |
| | 3 months | at | –20°C |

Discard contaminated specimens! Freeze only once!

### Assay Procedure

| | |
|---|---|
| Wavelength | 546 nm |
| Optical path | 1 cm |
| Temperature | 20 – 25°C/37°C |
| Measurement | Against reagent blank |

| | Blank | Sample or Calibrator |
|---|---|---|
| **Sample or standard** | - | 10 µL |
| **Dist. water** | 10 µL | - |
| **Reagent** | 1000 µL | 1000 µL |
| Mix, incubate for 10 min. at 20 – 25°C or for 5 min. at 37°C. Read absorbance within 60 min against reagent blank. | | |

### Calculation

With standard or calibrator

$$\text{Cholesterol [mg / dL]} = \frac{\text{A Sample}}{\text{A Std / Cal}} \times \text{Conc. Std / Cal [mg / dL]}$$

### Conversion factor

Cholesterol [mg/dL] x 0.02586 = Cholesterol [mmol/L]

### Calibrators and Controls

For the calibration of automated photometric systems, DiaSys TruCal U calibrator is recommended. The assigned values of the

calibrator have been made traceable to the reference method gas chromatography-isotope dilution mass spectrometry (GC-IDMS). DiaSys TruLab N and P or TruLab L controls should be assayed for internal quality control. Each laboratory should establish corrective action in case of deviations in control recovery.

### Performance Characteristics

#### Measuring range

The test has been developed to determine cholesterol concentrations within a measuring range from 3 – 750 mg/dL (0.08 – 19.4 mmol/L). When values exceed this range samples should be diluted 1 + 4 with NaCl solution (9 g/L) and the result multiplied by 5.

#### Specificity/Interferences

No interference was observed by ascorbic acid up to 5 mg/dL, bilirubin up to 20 mg/dL, hemoglobin up to 200 mg/dL and lipemia up to 2000 mg/dL triglycerides. For further information on interfering substances refer to Young DS [7].

#### Sensitivity/Limit of Detection

The lower limit of detection is 3 mg/dL (0.08 mmol/L).

#### Precision (at 37°C)

| Intra-assay precision n = 20 | Mean [mg/dL] | SD [mg/dL] | CV [%] |
|---|---|---|---|
| **Sample 1** | 108 | 1.76 | 1.62 |
| **Sample 2** | 236 | 1.45 | 0.61 |
| **Sample 3** | 254 | 1.57 | 0.62 |

| Inter-assay precision n = 20 | Mean [mg/dL] | SD [mg/dL] | CV [%] |
|---|---|---|---|
| **Sample 1** | 104 | 1.19 | 1.14 |
| **Sample 2** | 211 | 2.57 | 1.22 |
| **Sample 3** | 245 | 2.28 | 0.93 |

#### Method Comparison

A comparison of DiaSys Cholesterol FS (y) with a commercially available test (x) using 78 samples gave following results:
y = 1.00 x – 2.50 mg/dL; r = 0.995

#### Reference Range

| | |
|---|---|
| Desirable | 200 mg/dL (5.2 mmol/L) |
| Borderline high risk | 200 – 240 mg/dL (5.2 – 6.2 mmol/L) |
| High risk | > 240 mg/dL (> 6.2 mmol/L) |

Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

#### Limitations

Eventual Cholesterol CHOD-PAP carry-over to reagents Magnesium (Xylidyl blue), Iron(Ferrene), Lipase(Enzymatic, colorimetric) and Protein Total in Urine/CSF (Pyrogallol red). The actual carry-over depends on the analyzer.

#### Clinical Interpretation

The European Task Force on Coronary Prevention recommends to lower TC concentration to less than 190 mg/dL (5.0 mmol/L) and LDL-cholesterol to less than 115 mg/dL (3.0 mmol/L) [2].

#### Literature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3. Artiss JD, Zak B. Measurement of cholesterol concentration. In: Rifai N, Warnick GR, Dominiczak MH, eds. Handbook of lipoprotein testing. Washington: AACC Press, 1997: 99–114.
4. Deeg R, Ziegenhorn J. Kinetic enzymatic method for automated determination of total cholesterol in serum. Clin Chem 1983;29:1798-802.
5. Schaefer EJ, McNamara J. Overview of the diagnosis and treatment of lipid disorders. In: Rifai N, Warnick GR, Dominiczak MH, eds. Handbook of lipoprotein testing. Washington: AACC press, 1997:25–48.
6. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001. p. 22-3.
7. Young DS. Effects of Drugs on Clinical Laboratory Tests. 5th ed. Volume 1 and 2. Washington, DC: The American Association for Clinical Chemistry Press 2000.
8. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed 2007;45(9):1240–1243.


## *Notes on Symbols and Marks*

| | |
|---|---|
| | Consult instruction for use |
| | Use-by date |
| LOT | Batch code |
| REF | Catalogue number |
| | Caution |
| | Manufacturer |
| IVD | In vitro diagnostic medical device |
| | Temperature limit |
| | Do not reuse |
| CONT. | The pack contains |
| | Recycle |
| | Date of manufacture |

ISO 9001, ISO 13485 and ICMED 13485 Certified Company


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