# CHOLESTEROL

Specifically for use with Diatron PICTUS® 700 and PICTUS® 500 Analyzers

REF 1419-0042 **Packaging:** 6 x 60 mL

2°C – 8°C

Σ 1800

**INTENDED USE**

Reagents for In Vitro quantitative automated measurement of the concentration of Cholesterol in samples of human serum or plasma from the general patient population. Measurements of total cholesterol are to be used along with other in vitro and in vivo tests and physical examination by licensed physicians, as an aid for preventative screening, diagnosis and management of atherosclerotic cardiovascular disease (ASCVD) risk assessment.

This reagent is formulated specifically for use with Diatron Pictus® P700 and P500 analyzers.
For in vitro diagnostic use only by trained laboratory professionals.

**CLINICAL SIGNIFICANCE**

Cholesterol is present in the cell membrane of all body tissues, and transported in blood plasma. Cholesterol is found in high concentrations in tissues which either produce more or have more densely-packed membranes, for example, the liver, spinal cord, brain and also in atheromas. Cholesterol is best known for the association of cardiovascular disease to various lipoprotein cholesterol transport patterns and to high levels of cholesterol in the blood.

Total cholesterol provides only a baseline value that indicates whether further investigation of the lipoprotein metabolism should be carried out. Increased levels of cholesterol are found in familial or polygenic hyperlipoproteinemia type IIa and IIb, familial combined hyperlipidemia, intra and extra hepatic cholestasis, glomerulonephritis, nephrotic syndrome, chronic renal failure, malignant neoplasms of the pancreas and prostate, hypothyroidism, ischemic heart disease, diabetes, dysglobulinemia, anorexia nervosa. Reduced levels of cholesterol are observed in a-lipoprotein deficiency, hypo a- and β-lipoproteinemias, hepatocellular necrosis, malignant neoplasm of the liver, hyperthyroidism, malabsorption, malnutrition, megaloblastic anemias, sideroblastic anemia, thalassemia, severe acute illness, extensive burns, rheumatoid arthritis, and intestinal lymphangiectasia.

**METHOD PRINCIPLE**

The CHOD-POD method is applied. Cholesterol is determined according to the following reaction scheme:

$$\text{Cholesterol esters} + H_2O \xrightarrow{CHE} \text{Cholesterol} + \text{Fatty acids}$$

$$\text{Cholesterol} + O_2 \xrightarrow{CHOD} \text{4-cholesten-3-one} + H_2O_2$$

$$2H_2O_2 + \text{4-aminophenazone} + \text{phenol} \xrightarrow{POD} \text{Quinone} + 4H_2O$$

CHE: Cholesterol esterase CHOD: Cholesterol oxidase POD: Peroxidase

The absorbance at 550/620 nm is proportional to the concentration of cholesterol in the sample.

**METHOD LIMITATIONS**

Refer to the book "Effects of Preanalytical Variables on Clinical Laboratory Tests" for possible interference of other pharmaceutical agents in this particular test. Interference of other agents is described in the "Clinical Guide to Laboratory Tests". This reagent is formulated specifically for use with Diatron Pictus® P700 and P500 analyzers. For additional information please contact customer support at Diatron or Medicon.

**REAGENT COMPOSITION**

| | | | |
|---|---|---|---|
| Buffer pH. =7.6 | 100 mM | Peroxidase (POD) | ≥ 1000 U/L |
| Cholesterol esterase (CHE) | ≥ 500 U/L | 4-Aminophenazone | 1 mM |
| Cholesterol oxidase (CHOD) | ≥ 500 U/L | 4-Chlorophenol | 4 mM |
| Non-reactive ingredients, preservative | | | |

⚠ **WARNINGS – PRECAUTIONS**

- The reagent is designed for in vitro diagnostic use. In vitro diagnostic reagents can be hazardous. They should be handled according to good laboratory techniques. Avoid inhalation and contact with eyes and skin.
- Samples should be considered as potentially infectious. Handle with special caution.
- This reagent contains sodium azide ($NaN_3$) ≤ 0.1%. Avoid swallowing and contact of the reagent with skin and mucous membranes.
- Dispose all waste according to national laws.
- Any serious incident that may occur in relation to this device must be reported by the user to the manufacturer and the competent authority of the country in which the user and/or the patient is established!
- MSDS is available by Diatron or MEDICON upon request.

⚠ **PREPARATION**

Reagent ready to use when placed in the corresponding position on the analyzer. The vials bear barcodes for automatic recognition by Diatron Pictus® P700 / P500 analyzers.

⚠ **REAGENT DETERIORATION**

**The reagents should not be used:**

- When they do not exhibit the specified linearity or control values lie outside the acceptable range after recalibration.
- When they appear cloudy or decolorized.
- after prolonged exposure to sunlight or high temperature.

⚠ **SHELF LIFE**

Unopened, the reagent is stable at 2 – 8°C up to the expiry date stated on the label. After opening it remains stable for 1 month when stored in the cooled reagent tray of the Diatron Pictus® P700 or P500 analyzers.

⚠ **SAMPLE** Serum, EDTA or Li-heparin plasma can be used as specimen. Use established Good Laboratory Practices for sampling, transport and separation from blood cells. Do not use hemolyzed, contaminated or turbid sample specimens. Anti-coagulants other than EDTA or Li-heparin have not been tested and should not be used. Centrifuge sample as soon as possible, separate serum or plasma from blood cells and store properly if analysis cannot take place right after sample separation. Cholesterol is stable in serum and plasma for 5 days at 20 – 25°C, 3 months at 2 – 8°C and several years at –20°C. Avoid repeated freezing-thawing of samples.

**CALIBRATION** Diatron offers MEDICON MEDI-CAL (code 1578-0891) traceable to SRM 909b (NIST) for serum calibration. Calibrate the assay every 2 weeks when used on Diatron Pictus® P700 or P500 analyzers. The analyzer will perform an automatic blank calibration every 1 week. Recalibration should also be repeated after a major maintenance is performed on the analyzer or after a critical part is replaced or when a significant shift in control values occurs.

**QUALITY CONTROL** Diatron offers MEDICON Clinical Chemistry Control Level 1 & 2 (1578-0901-12 & 1578-0902-12 respectively) for serum quality control. Control recovery should lie within the acceptable range. Results outside the acceptable range even after recalibration could be due to reagent deterioration, unsuitable storage conditions or control deterioration, instrument malfunction, or error during test procedure.

**MATERIALS REQUIRED BUT NOT PROVIDED WITH THE KIT**

- Cholesterol calibrator
- Quality control material
- Diatron Pictus® analyzer
- Common laboratory equipment

**REFERENCE INTERVALS**

According to the European Atherosclerosis Society:

| | | |
|---|---|---|
| Cholesterol<br>Triglycerides | < 200 mg/dL<br>< 200 mg/dL | No lipid metabolism anomaly |
| Cholesterol | 200 – 300 mg/dL | Anomaly in lipid metabolism if HDL Cholesterol is < 35 mg/dL |
| Cholesterol<br>Triglycerides | > 300 mg/dL<br>> 200 mg/dL | Anomaly in lipid metabolism |

The European Atherosclerosis Society suggests reduction of cholesterol levels at around 180 mg/dl for adults up to 30 years old, and around 200 mg/dl for adults above 30. Expected values may vary with age, sex, sample type, diet and geographical location. Each laboratory should determine its own expected values as dictated by good laboratory practices.

⚠ **WASTE DISPOSAL**

This product contains sodium azide ($NaN_3$), which forms sensitive explosive compounds with copper or lead. Flush waste pipes with water after the disposal of undiluted reagent in order to avoid azide build up in the drain pipes.

**SPECIFIC PERFORMANCE CHARACTERISTICS**

The following values are representative of the reagent performance on Diatron Pictus® P700 or P500 analyzers. The reagent performance has been evaluated on other types of analyzers, covering all requirements of the 98/79 IVD Directive. A list of analyzers with the corresponding performance characteristics is available in the special leaflet accompanying the insert. The results taken in your laboratory may differ from these values.

**Linearity** Up to 800 mg/dL
**Lowest detection limit:** 2.6 mg/dL

The lowest detection limit (LDL) is defined as the lowest concentration of analyte that is distinguishable from zero. A sample free of analyte is assayed 20 times within the assay and the LDL is calculated as the absolute mean plus three standard deviations.

**Precision:** Precision is estimated on two concentration levels of analyte according to CLSI protocol EP-5T (20 consecutive days, 2 runs per day, 2 repeats per run). The results taken in your laboratory may differ from these values.

| Pictus® P700 and P500 | |
|---|---|
| **Level (mg/dL)** | **%CV** |
| 133.0 | 2.80 |
| 313.0 | 2.10 |
| **Level (mg/dL)** | **Total CV%** |
| 133.0 | 3.20 |
| 313.0 | 2.60 |

**INTERFERENCES -** Criterion: recovery within ±10% from target value

| | (Insignificant up to) |
|---|---|
| Triglycerides | 3000 mg/dL |
| Hemoglobin | 500 g/dL |
| Bilirubin | 20 mg/dL |
| Conj. Bilirubin | 20 mg/dL |
| Ascorbic acid | 3 mg/dL |

**Correlation:** A comparison was performed between this reagent on a Diatron Pictus® P700 and P500 analyzer, and another commercially available product. The results were as follows:
Y = 1.017X + 0.320 R=0.9975 N=40 Sample Range = 91 – 305 mg/dL

**BIBLIOGRAPHY**


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3. Jacobs, DJ, Demott, WR, Grady, HJ, Horvat, RJ, Huestis, DW and Kasten, BL, JR, eds. Laboratory Test Handbook. 4th. ed. Ohio, Hudson: Lexi-Comp Inc., 1996.
4. Young DS. Effects of Preanalytical Variables on Clinical Laboratory Tests. 2nd. ed. Washington, DC: The American Association for Clinical Chemistry Press, 1997.
5. Henry, RJ. Clinical Chemistry, Principles and Technics. New York: Harper & Row, 1974.
6. National Cholesterol Education Program, Expert Panel: Report on the detection, evaluation and treatment of high blood cholesterol in adults. Arch Intern Med 1988; 148: 36-69.


**SYMBOLS**

Manufacturer
IVD *In vitro* diagnostic medical device
Temperature Limit
REF Catalogue Number
Caution
Σ Contains sufficient for <n> tests




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