diatron

LDL-CHOLESTEROL

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

2°C – 8°C

REF 1419-0220 **Packaging:** 6 x 13.5 mL (R1) + 6 x 4.5 mL (R2) Σ 360

REF 1419-0222 **Packaging:** 6 x 35.1 mL (R1) + 6 x 11.7 mL (R2) Σ 936

INTENDED USE

Reagents for In Vitro quantitative automated measurement of the concentration of Low-Density Lipoprotein Cholesterol - LDL-C in samples of human serum or plasma from the general patient population. Measurements of LDL-Cholesterol are to be used along with other in vitro and in vivo tests and physical examination by licensed physicians, as an aid for 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

LDL-C has a major role in the development of coronary heart disease (CHD). High levels of LDL-C increase the risk of atherosclerosis and cardiovascular diseases. A diet high in saturated and trans fats raises LDL cholesterol. Lowering LDL-C levels is a primary target of prevention and therapy of conditions like heart attack and stroke, especially in high-risk populations, like diabetics.

METHOD PRINCIPLE

The Selective Detergent method is applied. The method is in a two-reagent format and depends on the properties of a unique detergent. The detergent solubilizes only the non-LDL lipoprotein particles. The cholesterol released is consumed by cholesterol esterase and cholesterol oxidase in a non-color forming reaction. A second detergent solubilizes the remaining LDL particles and a chromogenic coupler allows for color formation. The enzyme reaction with LDL-C in the presence of the coupler produces color that is proportional to the amount of LDL cholesterol present in the sample.

METHOD LIMITATIONS

Refer to the book "Effects of Preanalytical Variables on Clinical Laboratory Tests" for possible interference of her 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

Detergent 1	<1%
4-Aminoantipyrine:	<0.1%
Cholesterol Oxidase (CHO):	<1500 U/L
Cholesterol Esterase (CHE):	<2500 U/L
Peroxidase (POD):	<1300 U/L
Ascorbic oxidase:	<3000 U/L
Detergent 2:	<1%
N, N-bis(4-sulfobytul)-m-toluidine, disodium (DSBmT):	
<1 mM	Non-reactive ingredients, preservative

WARNINGS – PRECAUTIONS

- This 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.
- Antisera are raised in clinically healthy animals in monitored facilities under constant surveillance.
- 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!
- Dispose all waste according to national laws.
- MSDS is available by Diatron or MEDICON upon request.

PREPARATION

The reagents are ready-to-use when placed in the corresponding positions of 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.
- After prolonged exposure to sunlight or high temperature
- When reagent 1 (R1) has been accidentally frozen.

SHELF LIFE

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

SAMPLE Serum, or EDTA plasma may be used as specimen. Patient must fast for 12 hours prior to sampling. Patient must be sitting for at least 5 min before sampling. Application of tourniquet should be limited to a minimum prior to sampling. Use established Good Laboratory Practices for sample transport and separation from blood cells. Do not use hemolyzed, contaminated or turbid sample specimens. Anti-coagulants other than EDTA have not been tested and should not be used. Centrifuge sample as soon as possible and store properly if analysis cannot take place right after sample separation. LDL-C remains stable in serum or plasma for 7 days at 2 - 8°C. Do not freeze thawed samples. A significant statistical but not clinical reduction of LDL may be observed when EDTA plasma samples are used or when the assay takes place after samples have been frozen.

CALIBRATION Diatron offers MEICON MEDI-CAL (1578-0891) traceable to Medicon Master Lot for calibration. Calibrate the assay when a new lot of reagent is installed. Perform a Reagent Blank measurement every 2 weeks. Calibration should also be repeated after major maintenance is performed on the analyzer, 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 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

- LDL-Cholesterol Calibrator
- Quality control materials
- Diatron Pictus® analyzer
- Common laboratory equipment

REFERENCE INTERVALS

Serum or plasma:	Desirable:	60 – 130 mg/dl
	Moderate risk:	130 – 159 mg/dl
	High risk:	> 160 mg/dl

The NCEP-ATP III2 guidelines emphasize LDL-C as a major factor for the identification of risk and ask for more aggressive cholesterol-lowering treatments. The guidelines classify LDL - Cholesterol levels as follows:

Optimal	< 100 mg/dL
Near optimal/above optimal	100 – 129 mg/dL
Borderline high risk	131 – 159 mg/dL
High risk	160 – 189 mg/dL
Very high risk	≥ 190 mg/dL

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, especially for high-risk patient populations with diabetes.

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 270 mg/dL

Lowest detection limit 1.6mg/dL

The limit of detection (LoD) is measured following procedure according to the CLSI protocol namely EP17-A2.

Precision: Precision is estimated on two concentration levels of analyte according to CLSI protocol EP05-A3 (20 consecutive days, 2 runs per day, 2 repeats per run).

Pictus® P700 and P500	
Level (mg/dL)	**%CV**
44.5	4.10
98.0	2.80
Level (mg/dL)	**TOTAL %CV**
44.5	6.50
98.0	6.50

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

	(Insignificant up to)
Triglycerides	3000 mg/dL
Hemoglobin	500 mg/dL
Bilirubin	20 mg/dL
Conj. Bilirubin	20 mg/dL
Ascorbate	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 = 0.953X + 0.068 R=0.982 N=66 Sample range = 57 – 249.2 mg/dL

BIBLIOGRAPHY

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SYMBOLS

Manufacturer

In vitro diagnostic medical device

Temperature Limit

Catalogue Number

Caution

Contains sufficient for <n> tests

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