HDL-Cholesterol

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

2°C – 8°C

REF 1419-0240 **Packaging:** 6 x 13.5 mL (R1) + 6 x 4.5 mL (R2) Σ 360

REF 1419-0242 **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 High-Density Lipoprotein Cholesterol - HDL-C in samples of human serum or plasma from the general patient population. Measurements of HDL-C are to be used along with other in vitro and in vivo tests and physical examination by licensed physicians, as a direct and indirect aid for the preventative screening, risk assessment, diagnosis, and management of atherosclerotic cardiovascular disease (ASCVD).

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

HDL-cholesterol plays an important role in the transportation of cholesterol from tissue storage areas to the liver where it is removed in the form of cholic acids. Low levels of HDL-cholesterol suggest dysfunction of the liver and intestines, where HDL is produced, and increased risk for atherosclerosis and cardiovascular diseases.

METHOD PRINCIPLE

The Accelerator Selective Detergent is applied. The determination of HDL-Cholesterol is based on the following reactions:

LDL, VLDL, chylomicrons —(Accelerator + CO / DSBmT+Peroxidase)→ Non-Reactive LDL, VLDL, Chylomicrons

HDL —(HDL Specific Detergent)→ HDL Disrupted

HDL-Cholesterol —(CE + CO)→ Δ4 Cholesterone +H2O2

H2O2 + DSBmT+ 4-AAP —(Peroxidase)→ Color Development

CE: Cholesterol esterase **CO:** Cholesterol oxidase **4-AA**: 4-aminoantipyrine
DSBmT: N, N-bis(4-sulphobutyl)-m-toluidine-disodium
The absorbance at 590/750 nm is proportional to the concentration of HDL-Cholesterol in the sample.

METHOD LIMITATIONS

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

Cholesterol esterase:	<1500 U/L
Cholesterol oxidase:	<1000 U/L
Peroxidase:	<1300ppg U/L
Ascorbate oxidase:	<3000U/L
Accelerator:	<1mM
DSBmT:	<1mM
4-aminoantipyrine:	<1mM
Non-reactive ingredients, preservative	

WARNINGS – PRECAUTIONS

- These reagents are 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, skin, and mucus membranes.
- Samples should be considered as potentially infectious. Handle with special caution.
- 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. HDL-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 HDL may be observed when EDTA plasma samples are used or when the assay takes place after samples have been frozen.

CALIBRATION Diatron offers MEDICON 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

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

REFERENCE INTERVALS

Increased risk factor: < 35 mg/dL
Negative risk factor: > 60 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.

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 180.0 mg/dL
Limit of detection 1.5 mg/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**
51.80	1.40
103.0	2.00
Level (mg/dL)	**TOTAL %CV**
51.80	3.90
103.0	3.90

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 = 1.02X - 0.09 R=0.96 N=93 Sample range = 31.5– 92 mg/dL

BIBLIOGRAPHY

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4. Young DS. Effects of Preanalytical Variables on Clinical Laboratory Tests. 2nd. ed. Washington: The American Association for Clinical Chemistry Press, 1997.
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SYMBOLS

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

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