LP(a)

LIPOPROTEIN-(a)

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

2°C – 8°C

REF 1419-0530 **Packaging:** 4 x 7.2 mL (R1) + 4 x 3.6 mL (R2)

Σ 120

INTENDED USE
Reagents for In Vitro quantitative automated measurement of the concentration of Lipoprotein (a) - Lp(a) in samples of human serum or plasma from the general patient population. Measurements of Lp(a) are to be used along with other in vitro and in vivo tests and physical examination by licensed physicians, as an aid in the stratification and reclassification of genetically determined lifelong risk associated with the development of cardiovascular diseases.

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
Lp(a) is closely connected to the probability of coronary disease, as high Lp(a) levels have been related to increased risk of atherosclerosis. The probability of coronary disease increases when high levels of Lp(a) coexist with increased LDL cholesterol.

METHOD PRINCIPLE
The immunoturbidimetric method is applied. When the sample is mixed with the appropriate buffer (R1) and latex particles coated with anti-Lp(a) antibodies (R2), Lp(a) reacts with the antibodies leading to agglutination of latex particles. This agglutination is detected as increase of turbidity at 700 nm, and is proportional to the concentration of Lp(a) 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

Reagent 1 (R1)	Reagent 2 (R2)
Tris Buffer (pH 8,2):65 mM Non-reactive ingredients, preservative.	Latex particles coated with rabbit anti-human Lp(a) antibodies. 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.
- This reagent contains sodium azide (NaN_3) ≤ 0.1%. Avoid swallowing and contact of the reagent with skin and mucous membranes
- 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
Reagent 1 (R1) is ready to use and can be placed directly on the analyzer. Reagent 2 (R2) should be mixed with inversion 5 – 10 times before placement on the analyzer, for re-dispersion of Latex particles and again at weekly intervals. Avoid foaming. The vials bear barcodes for automatic recognition by Diatron Pictus® P700 / P500 analyzers.

REAGENT DETERIORATION
The reagent should not be used:
- When it does not exhibit the specified linearity or recovery of control values lies outside the acceptable range after recalibration.
- After prolonged exposure to sunlight or high temperature.

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

SAMPLE Serum may 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. Centrifuge sample as soon as possible and store properly if analysis cannot take place right after sample separation. LP(a) is stable for up to 24 hours at 2 - 8°C. Freezing may affect immunoreactivity of LP(a).

CALIBRATION Diatron offers MEDICON Lp(a) Calibrator (1478-0530) traceable to the WHO/IFCC SRM 2b. Calibrate the assay every 2 weeks on Diatron Pictus® P700 or P500 analyzers. 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 the MEDICON Lp(a) Control Low (1478-0531) and Lp(a) Control High (1478-0532) 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
- LP(a) calibrator
- Quality control materials
- Diatron Pictus® analyzer
- Common laboratory equipment

REFERENCE INTERVALS
Reference intervals for Lp(a) have not been determined. Current bibliographic data report that values above 30 mg/dL indicate increased risk of coronary disease. 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 100 mg/dL
Hook Effect: >400 mg/dL
Lowest Detection Limit: 1.1 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 EP5-A (20 consecutive days, 2 runs per day, 2 repeats per run).

Pictus® P700 and P500	
Level (mg/dL)	**%CV**
22.4	1.82
64.8	1.31
Level (mg/dL)	**TOTAL %CV**
22.4	2.87
64.8	3.04

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 = 1.007X + 2.20 R=0.9920 N=25 Sample Range: 0.9 – 113 mg/dL

BIBLIOGRAPHY

1. Tietz, NW, ed. Clinical Guide to Laboratory Tests. 3rd. ed. Philadelphia: W.B. Saunders Company Ltd., 1995.
2. Burtis, CA and Ashwood, ER, ed. Tietz Textbook of Clinical Chemistry. 2nd. ed. Philadelphia: W.B. Saunders Company Ltd., 1994.
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.

SYMBOLS

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

*PICTUS®: Registered Trademark of Diatron Medical Instruments Limited, Táblás utca 39, H-1097 Budapest, Hungary, used here after contractual agreement.

MEDICON HELLAS S.A. - Melitona 5-7, 153 44 Gerakas, Greece. Tel: +302106606000 - Fax: +302106612666 – www.mediconsa.com

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