diatron

LP(a)

For use on Diatron Pictus® series analyzers
Method: **Immunoturbidimetry**
Product code: **1419-0532, 1419-0530**
Package: **4x21.6 ml (R1) + 4x10.8 ml (R2), 4x7.2 ml (R1) + 4x3.6 ml (R2)**
Store at: **2 – 8°C**
For *in vitro* use only

INTENDED USE
Ready to use reagent for the quantitative determination of Lipoprotein (a) in human serum specifically for use with Diatron Pictus® series analyzers. For in vitro diagnostic use only

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 LIMITATION
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".
The reagent is designed especially for use with the Diatron Pictus® series of chemistry analyzers. For chemistry protocols and further information please contact the customer support unit at Diatron.

REAGENT COMPOSITION
Reagent 1 (R1):
Tris Buffer (pH 8,2): 65 mM
Non reactive ingredients, preservative.
Reagent 2 (R2):
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
- Dispose all waste according to national laws.
- MSDS is available by Diatron or MEDICON HELLAS (manufacturer) upon request.

REAGENT 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 7 day intervals. Avoid foaming. The vials bear barcodes for automatic recognition by Pictus® series analyzers.

REAGENT DETERIORATION
The reagent should not be used:
- When it does not exhibit the specified linearity or control values lie 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 28 days when stored in the cooled reagent tray of the Pictus®\ series analyzers.

SAMPLE
Serum specimens, from patients fasting at least 12 hours must be used. The sample is stable for 2 days at 2°–8°C.

CALIBRATION
Diatron provides Lp(a) Calibrator (1478-0530) traceable to the WHO/IFCC SRM 2b. Calibrate the assay every 14 days on Pictus® series 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 provides the Lp(a) Control Low (1478-0531) and Lp(a) Control High (1478-0532).
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 SUPPLIED WITH KIT
- Lp(a) calibrator
- Quality control materials
- Diatron Pictus® P400/P700/P500
- 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.

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® series 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

	Pictus® P400	Pictus® P700/P500
Linearity	Up to100 mg/dL	Up to 100 mg/dL
Hook effect	> 400 mg/dL	> 400 mg/dL
Lowest Detection Limit	0 mg/dL	0 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® P400			Pictus® P700/P500		
Επίπεδο (mg/dL)	Within Run CV%	Total CV%	Επίπεδο (mg/dL)	Within Run CV%	Total CV%
112.3	2.98	4.42	22.4	2.82	3.87
215.6	2.41	3.98	64.8	2.31	4.04

Interference: Criterion: recovery within ±20% from target value

	Pictus® P400	Pictus® P700/P500
Lipemia	Insignificant up to Intralipid® 1000 mg/dl	Insignificant up to 1000 mg/dl Intralipid®
Haemoglobin	Insignificant up to 500 mg/dL	Insignificant up to 500 mg/dL
Non conj. Bilirubin	Insignificant up to 20 mg/dL	Insignificant up to 20 mg/dL
Conj. Bilirubin	Insignificant up to 20 mg/dL	Insignificant up to 20 mg/dL
Ascorbate	Insignificant up to 3 mg/dL	Insignificant up to 3 mg/dL

Correlation: A comparison was performed between this reagent on a Pictus® series analyzer, and a BECKMAN COULTER AU-series system. The results were as follows:

Pictus® P400			
Y = 0.751X – 4.412	R=0.970	N=48	Sample range = 0.0 – 162.8 mg/dL
Pictus® P700/P500			
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
Temperature Limits (L/H)
Manufacturer
Read the Instructions
REF Catalog Number (ISO 15223 / rev. EN980)
LOT Batch Code (ISO 15223 / rev. EN980)
IVD For in vitro use (ISO 15223 / rev. EN980)
Date of Expiry (ISO 15223 / rev. EN980)

CE IVD

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