LP(a) CALIBRATOR

2°C 8°C

REF 1478-0530 **Packaging:** 6 x 1 mL

INTENDED USE

Material for the preparation of reference curves for the quantitative determination of Lipoprotein(a) using Medicon reagent with Diatron Pictus® P700 and P500 analyzers. For in vitro Diagnostic use only by trained laboratory professionals.

COMPOSITION

Sterilized, filtered, delipidated, declotted pool of normal human plasma, containing stabilizers and sodium azide (NaN3).

⚠ WARNINGS – PRECAUTIONS

- For in vitro use only
- The material contains sodium azide (NaN3) ≤ 0.1%. Avoid swallowing and contact with skin and mucous membranes.
- Biological materials of human origin contained in this product were tested for Anti-HCV, HbsAg and Anti-HIV 1 and 2 using FDA approved methods and were found to be non-reactive. As there is no known test method that can offer complete assurance that products derived from human blood will not transmit infectious agents this product should be handled as a potentially infectious material.
- 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!

⚠ MATERIAL PREPARATION

Material ready for use. Invert the vials gently to acquire homogenous mix before use. Avoid foaming.
Replace cap immediately after use and store at 2-8°C. Unsuitable storage, handling, or errors during the analytical procedure may give erroneous results.

MATERIALS REQUIRED BUT NOT PROVIDED WITH THE KIT

- Lp(a) reagent kit.
- Automated biochemistry analyzer
- Common laboratory equipment.

⚠ STORAGE - STABILITY

Unopened vials are stable up to the expiry date stated on the label when stored at 2-8ºC. Once opened, the material remains stable for 1 month when stored tightly capped at 2-8ºC.

⚠ DETERIORATION

The material should not be used:

- After prolonged exposure to sunlight or high temperature.

⚠ 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. Dispose of all waste material in accordance with local guidelines. Safety data sheet is available for professional use on request.

ASSIGNED VALUES – Lot specific

Please refer to the value sheet for the specific lot available at https://medicondoc.com

CALIBRATION PROCESS

6-point calibration curve. The following dilutions are proposed:

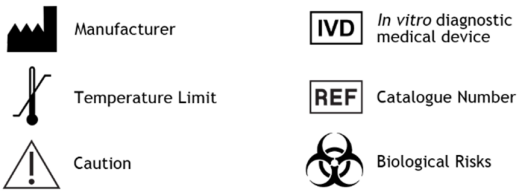
	Dilution	Calibrator	H_2O / Serum Blank
Level 1	0%	0 µL	450 µL
Level 2	12.5%	50 µL	350 µL
Level 3	25.0%	100 µL	300 µL
Level 4	50.0%	200 µL	200 µL
Level 5	75.0%	300 µL	100 µL
Level 6	100.0%	350 µL	0 µL

For the calibration process refer to the User's manual of the analyzer. The recovery of control values during quality control should lie inside expected range. Make sure the LOT on the vial is the same as on the value sheet accompanying the material.

BIBLIOGRAPHY

1. Blirup-Jensen S, Johnson AM, Larsen M. Protein standardization IV: value transfer procedure for the assignment of serum protein values from a reference preparation to a target material.Clin Chem Lab Med 2001; 39:1110-1122.
2. Baudner S, Bienvenu J, Blirup-Jensen S, Carlström A, Johnson AM, Milford Ward A, et al. The certification of a matrix reference material for immunochemical measurement of 14 human serum proteins. EUR 15243 EN,1993.

SYMBOLS



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