LP(a) CONTROL HIGH

2°C 8°C

REF 1478-0532 **Packaging:** 6 x 1 mL

INTENDED USE

Material for internal quality control of Lipoprotein Lp(a) assays 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 normal human pool 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!

⚠ **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**

The unopened material is 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 after use at 2-8ºC.

⚠ **DETERIORATION**

The material should not be used:

- After the expiration date.
- When microbial growth is evident
- After prolonged exposure to direct sunlight or high temperature

TEST PROCEDURE

Refer to the user's manual of the analyzer for calibration and quality control process.
Each laboratory should establish its own control frequency, however good laboratory practice suggests that controls be tested each date patient samples are tested and each time calibration is performed.
The results obtained by any individual laboratory may vary from the given mean value but should fall within the corresponding acceptable ranges given in the enclosed table.
If any trends or sudden shifts in values are detected, review all operating parameters. Each laboratory should establish guidelines for corrective actions to be taken if controls do not recover within the specified limits.
Make sure the LOT on the vial is the same as on the value sheet accompanying the material.

⚠ **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.

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. CRM 470. EUR 15243 EN, 1993.

SYMBOLS

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

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