APO A1/B CONTROL LEV2

2°C – 8°C

REF 1578-0554 **Packaging:** 3 x 3 mL

INTENDED USE

Material for internal quality control of Apolipoprotein A1 and Apolipoprotein B assays when using the corresponding Medicon reagent with Diatron Pictus® P700 and P500 analyzers. For in vitro diagnostic use only by trained laboratory professionals.

COMPOSITION

Liquid, human serum based control material with additives and preservative.

⚠ **WARNINGS – PRECAUTIONS**

- For in vitro use only.
- Every donor used for the preparation of the material was tested and found negative for HbsAg, anti-HCV and anti-HIV 1 and 2 with FDA approved methods. 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 to use. Swirl the vials gently to acquire homogenous mix. Avoid foaming. Replace cap immediately after use and store at 2-8ºC. Unsuitable storage, handling, or errors during the analytical procedure may give erroneous results.

MATERIALS REQUIRED BUT NOT PROVIDED WITH THE KIT

- APO A1 / APO B reagents
- Automated biochemical analyzer
- Common laboratory equipment.

⚠ **STORAGE – STABILITY**

The material is stable, unopened up to the expiry date stated on the label when stored at 2-8ºC. Once opened the material is stable for 1 month when stored tightly capped at 2-8ºC.

⚠ **DETERIORATION**

The material should not be used:

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

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**

Dispose of all material according to local guidelines. Material safety data sheet is available by MEDICON on request.

ASSIGNED VALUES – Lot specific

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

SYMBOLS

Manufacturer

IVD *In vitro* diagnostic medical device

Temperature Limit

REF Catalogue Number

Caution

Biological Risks

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CE IVD