APO A1/B CALIBRATOR

2°C 8°C

REF 1478-0550 **Packaging:** 3 x 1 mL

INTENDED USE
Material for the preparation of reference curves for the quantitative determination of Apolipoprotein A1 or Apolipoprotein B using the corresponding Medicon reagent with Diatron Pictus® P700 and P500 analyzers. For in vitro Diagnostic use only by trained laboratory professionals.

COMPOSITION
Liquid defibrinated human plasma with stabilizers and preservative.

⚠ **WARNINGS – PRECAUTIONS**
- For in vitro use only.
- Every donor used for the preparation of this control was tested and found negative for HbsAg, anti-HCV, anti-HIV 1 and 2 by FDA approved methods. However, since no test method can offer complete assurance that infectious agents are absent, this product should be handled observing the same precautions employed when handling any 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 gently 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
- Apolipoprotein A1/B reagents
- Automated biochemical analyzer
- Common laboratory equipment.

⚠ **STORAGE - STABILITY**
Unopened, the material is stable up to the expiry date stated on the label when stored at 2-8°C. Once opened, the material remains stable for 1 month when stored capped after use at 2-8°C.

⚠ **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 appropriate User's Guide and the accompanying Instrument Setting Sheet for analyzer-specific assay instructions for calibration.
If any trends or sudden shifts in values are detected, review all operating parameters. Control recovery should lie within the acceptable intervals. Results outside the specified values even after recalibration could be due to reagent/calibrator/control deterioration, unsuitable storage conditions, instrument malfunction, or error during test procedure. Every laboratory should establish its own corrective measures in case control recovery lies outside acceptable intervals.
Make sure the LOT on the vial is the same as on the value sheet accompanying the material.

⚠ **WASTE DISPOSAL**
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.

SYMBOLS

Manufacturer	IVD *In vitro* diagnostic medical device
Temperature Limit	REF Catalogue Number
Caution	Biological Risks

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

Version 2 - Last updated 2020.06.30

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