MALB/UPROT CONTROL

2°C – 8°C

REF 1478-0188 **Packaging:** (2 x 3) x 3 mL

INTENDED USE
Material for internal quality control of Microalbumin and Urine Albumin assays using Medicon reagent with Diatron Pictus® P700 and P500 analyzers. For in vitro diagnostic use only by trained laboratory professionals.

COMPOSITION
Albumin of human origin and animal-derived proteins in aqueous buffer solution. Preservatives.

⚠ **WARNINGS – PRECAUTIONS**

- Follow the normal precautions required to handle all laboratory reagents.
- Dispose of all waste according to national regulations.
- Biological materials of human origin contained in this product have been tested and shown to be free from hepatitis B surface antigen (HbsAg), hepatitis C (HCV) antibodies, and antibodies to human immunodeficiency virus (HIV-1 and HIV-2).
- Since there is no known control method that can offer full assurance that products derived from human blood do not transmit infectious agents, you should treat this product as a potentially infectious material. The material contains sodium azide (NaN3) <0.1%. Avoid contact with skin, eyes and mucous membranes.
- 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. Allow the material to reach room temperature. 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.

⚠ **STORAGE - STABILITY**
The content of the sealed vial is stable up to the indicated expiration date, stored at 2-8 ° C. Once opened, the material remains stable for 2 months when stored tightly capped after use at 2-8ºC.

TEST PROCESS
Refer to the user's manual of the analyzer for calibration and quality control process.
Each laboratory should establish its own control frequency, however proper laboratory practice suggests that the controls be tested each day when patient samples are measured and each time a 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.

SYMBOLS

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

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