MICROALBUMIN CALIBRATOR

2°C 8°C

REF 1578-0852 **Packaging:** 5 x 1 mL

INTENDED USE

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

COMPOSITION

The microalbumin standards are declotted human plasma solutions with phosphate salts, stabilized in liquid state and filtered through 0.2μ filters. They contain sodium azide (NaN_3).

⚠ **WARNINGS – PRECAUTIONS**

- For in vitro use only
- The material contains sodium azide (NaN_3) <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**

The material is ready to use according to appropriate work protocols. Invert the vial gently a few times to ensure a homogenous mix. 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. Make sure the LOT on the vial is the same as on the value sheet accompanying the material.

MATERIALS REQUIRED BUT NOT PROVIDED WITH THE KIT

No further reagents or materials are needed, other than the biochemistry analyzer and the MEDICON Microalbumin assay reagent.

⚠ **STORAGE - STABILITY**

The contents of vials are stable at 2-8°C until the expiry date stated on the label. After the vials have been unsealed, contents can be used for 6 weeks if vials are stored tightly capped at 2-8°C after each use. Do not freeze vials.

⚠ **DETERIORATION**

The material should not be used:

- After prolonged exposure to direct light or high temperatures
- After contents have been frozen.

⚠ **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

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

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

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