diatron

# MICROALBUMIN

2°C – 8°C

Specifically for use with Diatron PICTUS® 700 and PICTUS® 500 Analyzers

REF 1419-0852 **Packaging:** 6 x 10 mL (R1) + 6 x 4 mL (R2)

Σ 300

**INTENDED USE**
Reagents for In Vitro quantitative automated determination of Albumin in samples of human Urine (Microalbumin) from the general patient population. Measurements of Microalbumin are to be used along with other in vitro and in vivo tests and physical examination by licensed physicians, as an aid for screening, diagnosis and management of kidney disorders.

This reagent is formulated specifically for use with Diatron Pictus® P700 and P500 analyzers.
For in vitro diagnostic use only by trained laboratory professionals.

**CLINICAL SIGNIFICANCE**
The presence of albumin in urine is a primary evidence of renal failure. A healthy kidney infiltrates and excretes unnecessary components in urine. Valuable proteins such as albumin remain in circulating blood. In case of kidney disorder, a small quantity of albumin is detected in the urine (microalbuminuria). Where there is a severe disorder, larger amounts of albumin are excreted (macroalbuminuria). In cases of chronic conditions, such as diabetes or hypertension, where the kidney is susceptible to failure, regular testing is necessary.

**METHOD PRINCIPLE**
The method used is immunoturbidimetric. When sample is mixed with antiserum solution, Albumin reacts selectively with anti-human Albumin, leading to formation of insoluble aggregates. The absorbance of the test solution at 340/750 nm is proportional to the concentration of Albumin in the sample.

**METHOD LIMITATIONS**
Refer to the book "Effects of Preanalytical Variables on Clinical Laboratory Tests" for possible interference of other pharmaceutical agents in this particular test. Interference of other agents is described in the "Clinical Guide to Laboratory Tests". This reagent is formulated specifically for use with Diatron Pictus® P700 and P500 analyzers. For additional information please contact customer support at Diatron or Medicon.

**REAGENT COMPOSITION**

| Reagent 1 (R1) | Reagent 2 (R2) |
|---|---|
| Polyethylene glycol in Tris buffer<br>Non-reactive ingredients, preservative | Goat anti-human albumin antibodies<br>Non-reactive ingredients, preservative |

⚠ **WARNINGS – PRECAUTIONS**
- This reagent is designed for in vitro diagnostic use. In vitro diagnostic reagents can be hazardous. They should be handled according to good laboratory techniques. Avoid inhalation and contact with eyes and skin.
- Samples should be considered as potentially infectious. Handle with special caution.
- Antisera are raised in clinically healthy animals in monitored facilities under constant surveillance.
- This reagent contains sodium azide ($NaN_3$) ≤ 0.1%. Avoid swallowing and contact of the reagent with skin 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!
- Dispose all waste according to national laws.
- MSDS is available by Diatron or MEDICON upon request.

⚠ **PREPARATION**
Reagent 1 and 2 are ready to use when placed in the corresponding positions of the analyzer. Shake R2 lightly before use. Vials bear barcode for recognition by Diatron Pictus® P700 / P500 analyzers.

⚠ **REAGENT DETERIORATION**
The reagent should not be used:
- When it does not exhibit the specified linearity or recovery of control values lies outside the acceptable range after recalibration.
- After prolonged exposure to high temperature.
- When they appear cloudy.

⚠ **SHELF LIFE**
Unopened, reagents are stable up to the stated expiry date when stored at 2°– 8°C. Once opened, they can be stored for 1 month in the cooled reagent tray of the Diatron Pictus® P700 or P500 analyzers.

⚠ **SAMPLE** 24-hour urine may be used as specimen. Use established Good Laboratory Practices for sampling and transport. Clinically relevant results have not been validated with random urine samples. Patients don't need to have fasted for sample gathering. During urine collection, avoid sample contamination by contact with hands or other objects, because it may lead to false increase of albumin levels in the sample. Keep collection container at 2 – 8°C during sample collection. Analyze sample as soon as possible (within 1 hour) from last urination.

**CALIBRATION** Diatron offers MEDICON Microalbumin Calibrator (1578-0852), traceable to ERM-DA470, for calibration. Calibrate the assay every 2 weeks on the Diatron Pictus® P700 or P500 analyzers. Calibration should also be repeated after major maintenance is performed on the analyzer, after a critical part is replaced, or when a significant shift in control values occurs.

**QUALITY CONTROL** Diatron offers MEDICON MALB UPROT Control (code: 1478-0188) for urine quality control. Control recovery should lie within the acceptable range. Results outside the acceptable range even after recalibration could be due to reagent deterioration, unsuitable storage conditions or control deterioration, instrument malfunction, or error during test procedure.

**MATERIALS REQUIRED BUT NOT PROVIDED WITH THE KIT**
- Microalbumin calibrator
- Quality control material
- Diatron Pictus® analyzer
- Common laboratory equipment

**REFERENCE INTERVALS**
Urine: normal:< 20 mg/L (urine 24 hours)
Microalbuminuria:20 – 300 mg/L (urine 24 hours)
Each laboratory should determine its own expected values as dictated by good laboratory practice.

⚠ **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.

**SPECIFIC PERFORMANCE CHARACTERISTICS**
The following values are representative of the reagent performance on Diatron Pictus® P700 or P500 analyzers. The reagent performance has been evaluated on other types of analyzers, covering all requirements of the 98/79 IVD Directive. A list of analyzers with the corresponding performance characteristics is available in the special leaflet accompanying the insert. The results taken in your laboratory may differ from these values.

**Linearity** 5.4 to 450 mg/L
**Hook effect** >10000 mg/L
**Lowest detection limit** 1.68mg/L

The lowest detection limit (LDL) is defined as the lowest concentration of analyte that is distinguishable from zero. A sample free of analyte is assayed 20 times within the assay and the LDL is calculated as the absolute mean plus three standard deviations.

**Precision:** Precision is estimated on two concentration levels of analyte according to CLSI protocol EP5-A (20 consecutive days, 2 runs per day, 2 repeats per run).

| Pictus® P700 and P500 | |
|---|---|
| **Level (mg/L)** | **%CV** |
| 31.3 | 2.11 |
| 92.1 | 1.10 |
| **Level (mg/L)** | **TOTAL %CV** |
| 31.3 | 5.41 |
| 92.1 | 3.82 |

**INTERFERENCES -** Criterion: recovery within ±10% from target value

| | (Insignificant up to) |
|---|---|
| Bilirubin | 50 mg/dL |
| Urea | 50 g/L |
| Ascorbate | 5 g/L |
| Creatinine | 300 mg/dL |
| Glucose | 3 g/dL |
| Gentamycin | 10 g/L |
| Uric Acid | 2.5 g/L |

**Correlation:** A comparison was performed between this reagent on a Diatron Pictus® P700 and P500 analyzer and another commercially available product. The results were as follows:
Y = 1.156X – 1.341 R=0.9994 N=29 Sample range = 6.45 – 296 mg/L

**BIBLIOGRAPHY**

1. Tietz, NW, ed. Clinical Guide to Laboratory Tests. 3rd. ed. Philadelphia: W.B. Saunders Company Ltd., 1995.
2. Burtis, CA and Ashwood, ER, ed. Tietz Textbook of Clinical Chemistry. 2nd. ed. Philadelphia: W.B. Saunders Company Ltd., 1994.
3. Jacobs, DJ, Demott, WR, Grady, HJ, Horvat, RJ, Huestis, DW and Kasten, BL, JR, eds. Laboratory Test Handbook. 4th. ed. Ohio, Hudson: Lexi-Comp Inc., 1996.
4. Young DS. Effects of Preanalytical Variables on Clinical Laboratory Tests. 2nd. ed. Washington: The American Association for Clinical Chemistry Press, 1997.
5. Peters, T, Jr, Biamonte, GT, Doumas, BT. Protein (total protein) in serum, urine, and cerebrospinal fluid; albumin in serum. In: E. Faulkner, E and Meites, S, eds. Selected Methods of Clinical Chemistry. Vol. 9. Washington, DC: The American Association of Clinical Chemistry Press, 1982.


**SYMBOLS**

Manufacturer
IVD *In vitro* diagnostic medical device
Temperature Limit
REF Catalogue Number
Caution
Σ Contains sufficient for <n> tests




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





Version 4 - Last updated 2020.06.30


CE IVD