diatron

# ALBUMIN

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

REF 1419-0192 **Packaging:** 8 x 21 mL Σ 840

**INTENDED USE**
Reagents for In Vitro quantitative automated determination of Albumin in samples of human serum from the general patient population. Measurements of Albumin are to be used along with other in vitro and in vivo tests and physical examination by licensed physicians, as an aid for diagnosis and management of liver disease, malnutrition and acute diseases.

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**
Human serum albumin is produced in the liver and plays a very significant role in maintaining oncotic pressure (colloid osmotic pressure), transporting thyroid and other hormones, fatty acids, unconjugated bilirubin, and regulating (buffering) pH. Serum albumin levels can also affect drugs catabolism rate, as it transports many drugs. Low blood albumin levels (hypoalbuminemia) can be caused by liver disease, decreased production due to malnutrition or malabsorption, in nephrotic syndrome, protein losing enteropathy, burns, redistribution (hemodilution) as in pregnancy, increased vascular permeability or decreased lymphatic clearance, acute disease states, mutations causing analbuminemia (very rare). Hyperalbuminemia can occur in any condition that results in decrease of plasma water.

**METHOD PRINCIPLE**
The BCG method is applied, without serum blank. The bichromatic photometric determination of albumin is based on albumin binding the anionic dye bromocresol green in mildly acidic pH. The raise in absorbance at 620/750 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**

| | |
|---|---|
| Succinic acid buffer (pH 4.2±0.1): | 500 mM |
| Bromocresol green: | 0.75 mM |
| Brij 35: | 0.9% |
| Non-reactive ingredients, preservative | |

**WARNINGS – PRECAUTIONS**
- The 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.
- Avoid swallowing and contact of the reagent with skin and mucous membranes.
- Dispose all waste according to national laws.
- 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!
- MSDS is available by Diatron or MEDICON upon request.

**PREPARATION**
Reagent ready to use when placed in the corresponding position on the analyzer. The vials bear barcodes for automatic recognition by Diatron Pictus® P700 / P500 analyzers.

**REAGENT DETERIORATION**
The reagents should not be used:
- When they do not exhibit the specified linearity or control values lie outside the acceptable range after recalibration.
- When they appear turbid.
- After prolonged exposure to sunlight or high temperature.

**SHELF LIFE**
Unopened, the reagent is stable at 2 – 25°C up to the expiry date stated on the label. Once opened, it remains stable for 2 months when stored in the cooled reagent tray of the Diatron Pictus® P700 or P500 analyzers.

**SAMPLE** Serum may be used as specimen. Use established Good Laboratory Practices for sampling, transport and separation from blood cells. Fasting before sampling is desirable, since lipemia may interfere with this assay. During sampling there should be no blood flow retention because an increase in the concentration of albumin and other plasma proteins takes place due to water diffusion from the vein pores. Centrifuge sample as soon as possible, and store properly if analysis cannot take place right after sample separation. Albumin is stable in serum samples for 3 days when stored at 2 – 8°C, and up to 6 months at –20°C. Allow capped frozen samples in room temperature to thaw. Mix carefully thawed samples before analysis. Do not freeze thawed samples.

**CALIBRATION** Diatron offers MEDICON MEDI-CAL (1578-0891) traceable to CRM470 for serum calibration. Calibrate the assay every 1 month when used on Diatron Pictus® P700 or P500. Perform a Reagent Blank measurement every 2 weeks. 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 Clinical Chemistry Control Level 1 & 2 (1578-0901-12 & 1578-0902-12 respectively) for serum 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**
- Albumin calibrator
- Quality control material
- Diatron Pictus® analyzer
- Common laboratory equipment

**REFERENCE INTERVALS**
Serum: 3.5 – 5.2 g/dl
Expected values may vary with age, sex, sample type, diet and geographical location. Each laboratory should determine its own expected values as dictated by good laboratory practices.

**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** Up to 6.0 g/dL
**Lowest detection limit** 0.05 g/dL
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 EP-5T (20 consecutive days, 2 runs per day, 2 repeats per run).. The results taken in your laboratory may differ from these values.

| Pictus® P700 and P500 | |
|---|---|
| **Level (g/dL)** | **CV%** |
| 2.8 | 3.5 |
| 4.1 | 2.4 |
| **Level (g/dL)** | **TOTAL %CV** |
| 2.8 | 3.7 |
| 4.1 | 3.5 |

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

| | (Insignificant up to) |
|---|---|
| Triglycerides | 3000 mg/dL |
| Hemoglobin | 500 mg/dL |
| Bilirubin | 20 mg/dL |
| Conj. Bilirubin | 20 mg/dL |
| Ascorbate | 3 mg/dL |

**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 = 0.951X + 0.249 R=0.9920 N=40 Sample range = 2.85 – 5.23 g/dL

**BIBLIOGRAPHY**

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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.
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**SYMBOLS**

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

* PICTUS®: Registered Trademark of Diatron Medical Instruments Limited, Táblás utca 39, H-1097 Budapest, Hungary, used here after contractual agreement.


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