TOTAL PROTEIN

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

2°C – 25°C

REF 1419-0185 **Packaging:** 6 x 15 mL (R1) + 6 x 15 mL (R2) Σ 450

REF 1419-0186 **Packaging:** 6 x 25 mL (R1) + 6 x 25 mL (R2) Σ 750

INTENDED USE
Reagents for In Vitro quantitative automated determination of Total Protein in samples of human serum or plasma from the general patient population. Measurements of Total Protein 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 diseases involving liver, kidney or bone marrow, and metabolic and nutritional 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
Total serum protein is the sum of all circulating proteins and is a major component of blood. Measurements of total protein are used in the diagnosis and treatment of a variety of diseases involving liver, kidney or bone marrow as well as other metabolic and nutritional disorders. Increased levels of total protein are seen in hyperimmunoglobulinemia, polyclonal or monoclonal gammapathies. Reduced levels are observed at protein-depleting gastroenteropathies, acute burns, nephrotic syndrome. Miscellaneous decreases due to decrease synthesis of the proteins are seen at severe protein deficiency, chronic liver disease, malabsorption syndrome, malnutrition, agammaglobulinemia.

METHOD PRINCIPLE
The Biuret method is applied. Copper ions react with proteins in an alkaline medium for the formation of a colored complex. The reaction is end-point. The absorbance of the test solution at 550/700 nm is proportional to the concentration of protein 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

Final reagent concentrations in the cuvette:	
NaOH:	600 mmol/L
Sodium potassium tartrate:	50 mmol/L
CuSO4:	12.5 mmol/L
Potassium iodine:	12.5 mmol/L

⚠ **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 according to the universal precautions and good laboratory practices.
- The reagent contains highly alkaline $CuSO_4$. 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**
Reagents R1 and R2 are liquid, ready to use, when placed in the corresponding positions of the analyzer. 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.
- When it appears cloudy or decolorized.
- After prolonged exposure to sunlight or high temperature.

⚠ **SHELF LIFE**
Unopened, reagents are stable at 2 – 25°C up to the stated expiry date. Once opened, they are stable for 3 weeks stored in the cooled reagent tray on Diatron Pictus® P700 or P500 analyzers.

⚠ **SAMPLE** Serum or EDTA plasma may be used as specimen. Values in plasma are higher due to the presence of coagulation proteins. Use established Good Laboratory Practices for sampling, transport and separation from blood cells. Do not use hemolyzed, contaminated or turbid sample specimens. Centrifuge sample as soon as possible, and store properly if analysis cannot take place right after sample separation. Total protein remains stable in serum or plasma for 3 days at 2 – 8°C and for 6 months at –20°C. Do not freeze thawed samples.

CALIBRATION Diatron offers MEDICON MEDI-CAL (1578-0891) traceable to SRM 927c NIST for serum calibration. Calibrate the assay every 3 weeks. Perform a Reagent Blank measurement every 1 week. 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 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
- Total Protein Calibrator
- Quality control materials
- Diatron Pictus® analyzer
- Common laboratory equipment

REFERENCE INTERVALS
Serum: 6.2 – 8.5 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.

⚠ **WASTE DISPOSAL**
Flush waste pipes with copious amounts of water after discarding reagents. Unused reagent should be discarded following procedure for hazardous chemical waste.

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 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 14.0 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).

Pictus® P700 and P500	
Level (g/dL)	**%CV**
3.80	6.50
6.90	1.20
Level (g/dL)	**TOTAL %CV**
3.80	1.80
6.90	2.30

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

	(Insignificant up to)
Triglycerides	3000 mg/dL
Hemoglobin	500 mg/dL
Bilirubin	50 mg/dL
Conj. Bilirubin	50 mg/dL
Ascorbic Acid	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 = 0.970X + 0.050 R=0.9917 N=198 Sample range = 5.10 – 12.6 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, DC: The American Association for Clinical Chemistry Press, 1997.
5. Henry, RJ. Clinical Chemistry, Principles and Technics. New York: Harper & Row, 1974.

⚠ **LABEL ELEMENTS**

Precautionary Statements (P Phrases)	Hazardous Statements (H Phrases)
P260: Do not breathe dust/fumes/gas/mist/vapors/spray.	**H302:** Harmful if swallowed.
P280: Wear protective gloves/protective clothing /eye protection/face protection.	**H314:** Causes severe skin burns and eye damage.
P301+330+331: IF SWALLOWED: rinse mouth. Do NOT induce vomiting.	**H315:** Causes skin irritation.
P303+361+353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.	**H319:** Causes serious eye irritation.
P304+340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.	**H400:** Very toxic to aquatic life.
P305+351+338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.	**H410:** Very toxic to aquatic life with long lasting effects.
	H412: Harmful to aquatic life with long lasting effects

SYMBOLS

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

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Version 4 - Last updated 2020.06.30

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