diatron

URINARY PROTEIN - CSF

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

2°C – 8°C

REF 1419-0189 **Packaging:** 6 x 14.5 mL **Urine/CSF calibrator** 1 x 3 mL

Σ 300

INTENDED USE

Reagents for In Vitro quantitative automated determination of Protein in samples of human urine or cerebrospinal fluid (Microprotein) from the general patient population. Measurements of Microprotein are to be used along with other in vitro and in vivo tests and physical examination by licensed physicians, as an aid for the diagnosis and management of renal, cardiac, thyroid function diseases (urine), infections and inflammatory conditions of the spinal cord (CSF).

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

Measurement of total protein in urine is important in the diagnosis and treatment of diseases associated with renal, cardiac and thyroid function. These diseases cause proteinuria which is attributed to: (a) increased glomerular permeability (glomerular proteinuria), (b) defective tubular reabsorption (tubular proteinuria), (c) increased concentration of low molecular weight protein (overload proteinuria), (d) abnormal secretion of the protein into the urinary tract (postrenal proteinuria). Healthy people may exceed normal protein excretion levels after strenuous exercise or with dehydration. Some foods may affect protein levels. Drugs that can cause increased excretion level include: acetaminophen, antibiotics, gentamycin and non-steroid anti-inflammatory drugs (when associated with analgesic nephropathy). Measurement of total protein in CSF is indicative of increased permeability of blood-CSF barrier to plasma proteins or increased local synthesis of immunoglobulins. The increased permeability of the blood-CSF barrier may be attributed to brain tumor, endocerebral hemorrhage, bacterial or viral meningitis or poliomyelitis. Increased immunoglobulin synthesis may occur due to demyelinating diseases such as multiple sclerosis.

METHOD PRINCIPLE

The Pyrogallol Red method is applied. The assay is based on the shift in absorbance that occurs when the pyrogallol red-molybdate complex binds basic amino groups of protein molecules. A blue-purple complex is formed with a maximum absorbance at 590/750 nm. The absorbance of this complex is proportional to the protein concentration 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

For *in vitro* diagnostic use only.

Components	Final Concentration in the Test
Pyrogallol red	47 μM
Sodium molybdate	320 μM
Succinic acid	50 mM
Sodium benzoate	3.5 mM
Sodium oxalate	1 mM
Methanol	0.8% w/v
Preservative	
Calibrator Human Albumin in buffer. 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 according to the universal precautions and good laboratory practices.
- Biological materials of human origin contained in this product were tested for 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!
- Dispose all waste according to national laws.
- MSDS is available by Diatron or MEDICON upon request.

PREPARATION

The reagent is liquid and 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 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
- After prolonged exposure to high temperature.

SHELF LIFE

Unopened, the reagent is stable at 2 – 8°C up to the stated expiry date. Once opened, the reagent is stable for 2 months, if stored in the cooled reagent tray on Diatron Pictus® P700 or P500 analyzers. Calibrator: Unopened, the calibrator is stable at 2 – 8°C up to the stated expiry date. Once opened, the calibrator is stable up to the expiry date stated on the label, as long as the elastic cover and cap are placed on the vial immediately after each use, so contamination is avoided, and the calibrator is kept stored at 2° – 8°C.

SAMPLE 24-hour urine or CSF may be used as specimen. Clinically relevant results have not been validated with random urine samples. Use established Good Laboratory Practices for sampling and transport. Use no preservative for urine collection. Patients don't need to have fasted for sample gathering. During urine collection, avoid sample contamination by contact with hands or other objects. Keep collection container at 2 – 8°C during sample collection. Analyze fresh, otherwise store at 2 – 8°C for up to 24 hours. Urine samples pH must be adjusted to 7 prior to analysis. Urine samples contaminated by hemoglobin will result in falsely elevated values. CSF: Blood contamination should be avoided during sample collection. Analyze the sample when fresh, otherwise store it at 2 – 8°C for no more than 72 hours, or for up to 6 months at -20°C.

CALIBRATION Diatron offers MEDICON Urinary protein/CSF calibrator is provided inside the kit. Calibrate the assay every 1 month on 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 (1478-0188). Control values and limits should fall within acceptable intervals adjusted to the requirements of each laboratory. Target values for Urinary protein should be verified with the corresponding working protocol. Results outside the specified values even after recalibration could be due to reagent deterioration, instrument malfunction or error during test procedure.

MATERIALS REQUIRED BUT NOT PROVIDED WITH THE KIT

- Quality control material
- Diatron Pictus® analyzer
- Common laboratory equipment

REFERENCE INTERVALS

Urine: 50 – 80 mg/24h at rest.
The value may increase up to 300 mg/24h after exercise.
CSF (adults): 15 – 45 mg/dL
CSF (new-born<1 month): 15 – 130 mg/dL
Each laboratory should determine its own expected values as dictated by good laboratory practice.

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 200 mg/dL
Lowest detection limit 0.76 mg/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 EP5-A (20 consecutive days, 2 runs per day, 2 repeats per run).

Pictus® P700 and P500	
Level (mg/dL)	**%CV**
16.3	4.74
59.9	3.22
Level (mg/dL)	**TOTAL %CV**
16.3	5.28
59.9	3.34

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

	(Insignificant up to)
Bilirubin	20 mg/dL
Ascorbate	250 mg/dL
Creatinine	300 mg/dL
Glucose	1000 mg/dL
Gentamycin	4 mg/dL
Uric acid	2.5 g/L
Urea	7.5 g/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 = 0.948X – 3.011 R=0.9923 N=32 Sample range = 7.00 – 195 mg/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)
P280: Wear protective gloves/protective clothing/eye protection/face protection.	**H318:** Causes serious eye damage **H225:** Highly flammable liquid and vapor.
P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.	**H301:** Toxic if swallowed. **H302:** Harmful if swallowed. **H311:** Toxic in contact with skin. **H312:** Harmful in contact with skin.
P310: Immediately call a POISON CENTER or doctor.	**H318:** Causes serious eye damage. **H319:** Causes serious eye irritation. **H331:** Toxic if inhaled. **H370:** Causes damage to organs

SYMBOLS

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

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

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