UREA

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

2°C – 8°C | REF 1419-0022 | **Packaging:** 6 x 23.5 mL (R1) + 6 x 23.5 mL (R2) | Σ 1410

INTENDED USE

Reagents for In Vitro quantitative automated quantitative measurement of Urea in samples of human serum, plasma or urine from the general patient population. Measurements of Urea are to be used along with other in vitro and in vivo tests and physical examination by licensed physicians, as an aid in the assessment of kidney status and screening, differential diagnosis, severity assessment and management of conditions associated with azotemia.

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

Urea is synthesized in the liver as the final product of protein and amino acid metabolism. Urea synthesis is therefore dependent both on daily protein intake and endogenous protein metabolism. Most of the urea produced during these metabolic processes is eliminated by glomerular filtration. During diuresis a large quantity of urea is excreted in the urine and plasma urea concentration is normally low. During antidiuresis, which may occur in oliguric heart failure, exsiccosis or thirst, urea rediffuses in the tubules at an increased rate and plasma urea is increased. Prerenal elevation of urea occurs in cardiac decompensation, increased protein catabolism, and water depletion. Urea levels may be elevated due to renal causes such as acute glomerulonephritis, chronic nephritis, polycystic kidney, tubular necrosis, and nephrosclerosis. Post renal elevation of urea may be caused by obstruction of the urinary tract. In dialysis patient's urea concentration is representative of protein degradation and is also an indicator of metabolic status.

METHOD PRINCIPLE

The Urease UV method is applied. Urea is determined according to the following reactions:

$$Urea + H_2O \xrightarrow{Urease} 2NH_3 + CO_2$$

$$2NH_4^+ + 2\text{-}\alpha\text{-Ketoglutarate} + 2NADH \xrightarrow{GLDH} 2\text{-L-Glutamate} + 2NAD^+ + 2H_2O$$

GLDH: Glutamate dehydrogenase
The rate of absorbance change at 340/380 nm is proportional to the concentration of urea 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)
Tris buffer (pH 7,4):150 mM Urease: ≤ 30 kU/L GLDH: ≤ 1 kU/L ADP: 10 mM α-Ketoglutarate: 10 mM Non-reactive ingredients and preservatives.	Tris buffer (pH 7.7):20 mM NADH: 0.32 mM Non-reactive ingredients and preservatives.

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.
- This reagent contains sodium azide (NaN3) ≤ 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

The reagents are ready-to-use. 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 this reagent is stable at 2-8°C up to the expiry date stated on the label. After opening it remains stable for 1 month when stored in the cooled reagent tray of the Diatron Pictus® P700 or P500 analyzers.

SAMPLE Serum, Li-heparin plasma or urine may be used as specimen. Use established Good Laboratory Practices for sampling, transport and separation from blood cells. Do not use hemolyzed, contaminated or turbid sample specimens. Anti-coagulants other than Li-heparin have not been tested and should not be used. Centrifuge sample as soon as possible and store at room temperature if analysis cannot take place right after sample separation. do not freeze or refrigerate samples. Urea is stable in serum and plasma for 24 hours at 25°C, several days when stored at 2 – 4°C, and 2 – 3 months at least if frozen. Urine: 24-hour collection without preservatives is recommended. Urea is stable in urine for 7 days when stored at 2 – 8°C and for 2 days when stored at 15 – 25°C.

CALIBRATION Diatron offers MEDICON MEDI-CAL (1578-0891) traceable to SRM 909b NIST for serum calibration. Calibrate the assay when a new lot of reagent is installed. 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. Urine Applications are pre-programmed on the analyzer to automatically acquire a calibration factor after every successful serum calibration.

QUALITY CONTROL Diatron offers MEDICON Clinical Chemistry Control Level 1 & 2 (code 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

- Urea calibrator
- Quality control materials
- Diatron Pictus® analyzer
- Common laboratory equipment.

REFERENCE INTERVALS

Serum or plasma: 15 – 45 mg/dL
Urine: 15000 – 34200 mg/24h
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: Serum: up to 400 mg/dL Urine: up to 5000 mg/dL
Lowest detection limit: Serum: 2.4 mg/dL Urine: 21.27 mg/dL
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			
SERUM		**URINE**	
Level (mg/dL)	**%CV**	**Level (mg/dL)**	**%CV**
29.0	2.80	858	1.25
109.0	2.90	1743	1.60
Level (mg/dL)	**Total %CV**	**Level (mg/dL)**	**Total %CV**
29.0	6.10	858	1.77
109.0	3.80	1743	1.56

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

Serum	(Insignificant up to)	**Urine**	(Insignificant up to)
Triglycerides	3000 mg/dL	Bilirubin	50 mg/dL
Hemoglobin	500 g/dL	Glucose	10 g/L
Bilirubin	20 mg/dL	Creatine	3 g/L
Conj. Bilirubin	20 mg/dL	Uric Acid	2.5 g/L
Ascorbic acid	3 mg/dL	Ascorbic Acid	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:

Serum: Y = 1.024X + 4.635 R=0.9983 N=40 Sample range = 23.0 – 196 mg/dL
Urine: Y = 1.063X – 19.78 R=0.9940 N=26 Sample range = 402 – 2807 mg/dL

BIBLIOGRAPHY

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3. Ehret W, Heil W, Schmitt Y, Topfer G, Wisser H, Zawta B, et al. Use of anticoagulants in diagnostic laboratory investigations and stability of blood, plasma and urine samples. WHO/DIL/LAB/99.1 Rev.2:44pp, 49pp.
4. Young DS. Effect of drugs on clinical laboratory tests, 5th ed. AACC Press 2000.

SYMBOLS

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

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