CREATININE

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

2°C – 8°C | REF 1419-0038 | **Packaging:** 6 x 36 mL (R1) + 6 x 12 mL (R2) | Σ 1440

INTENDED USE
Reagents for In Vitro quantitative automated measurement of the concentration of Creatinine in samples of human serum, plasma, or urine from the general patient population. Measurements of Creatinine are to be used along with other in vitro and in vivo tests and physical examination by licensed physicians, as an aid in the evaluation of kidney function and screening, diagnosis and monitoring of acute and chronic renal disease.

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
Creatinine is a metabolic product of creatine phosphate in muscle and it is usually produced at a fairly constant rate by the body. Measuring serum creatinine is the most commonly used indicator of renal function. It is useful in the evaluation of kidney glomerular function and in monitoring renal dialysis. In post renal conditions where obstruction of the urine flow is present, e.g. malignancy, nephrolithiasis and prostatism both plasma and urine creatinine will be increased. Serum creatinine varies with the subject's age, body weight and sex.
Increased levels of creatinine are observed in acute or chronic renal function deficiency of any cause, in active acromegaly, gigantism, hyperthyroidism and diet rich in meat. Low levels of creatinine are observed during pregnancy, (especially in the 1st and 2nd semester), in cases of increased muscle mass loss, in amputees and elderly people.

METHOD PRINCIPLE
The determination of Creatinine is performed with a first-order kinetic enzymatic method, according to the following reactions:

$$\text{Creatinine} + H_2O \xrightarrow{\text{Creatinine amidohydrolase}} \text{Creatine}$$

$$\text{Creatine} + H_2O \xrightarrow{\text{Creatinase}} \text{Sarcosine} + \text{Urea}$$

$$\text{Sarcosine} + O_2 + H_2O \xrightarrow{\text{Sarcosine oxidase}} \text{Glycine} + HCHO + H_2O_2$$

$$H_2O_2 + \text{4-AA} + \text{Tops} \xrightarrow{\text{Peroxidase}} \text{benzoquinoneimine color}$$

Creatinine concentration is calculated from the change of absorbance at 590/700 nm. This method is superior to typical end-point methods, as the co-determination of pseudocreatinines is avoided.

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)
MOPS Buffer: 25 mM Sarcosine oxidase: ≤ 7.5 kU/L Ascorbate oxidase: ≤ 4.7 kU/L Creatinase: ≤ 27 kU/L Catalase: ≤ 200 kU/L Non-reactive components and preservatives	MOPS Buffer: 100 mM Creatinine Amidohydrolase: ≤ 300kU/L Peroxidase III: ≤ 10kU/L Non-reactive components and preservatives

⚠ **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.
- The reagent contains NaOH ≤ 1.0 %. Avoid ingestion and contact 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**
Reagents R1 and R2 are ready-to-use when placed on the corresponding positions of 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.

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

⚠ **SAMPLE** Serum, Li-heparin plasma or 24-hour 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 properly if analysis cannot take place right after sample separation. Creatinine remains stable in serum or plasma for 7 days at 2 – 8°C and for 12 months at -20°C. Do not freeze thawed samples. Creatinine in 24-hour urine samples is stable for at least 1 day at room temperature (18 – 25°C) and for 7 days at 2 – 8°C.

CALIBRATION Diatron offers MEDICON MEDI-CAL (1578-0891) traceable to SRM 909b NIST for serum calibration. Calibrate the assay every 2 weeks when used 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. 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 (1578-0901-12 & 1578-0902-12 respectively) for serum quality control. Any commercially available quality control can be used for other types of samples. 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
- Creatinine calibrator
- Quality control material
- Diatron Pictus® analyzer
- Common laboratory equipment

REFERENCE INTERVALS

Serum or plasma:	0.74 – 1.25 mg/dl (men)	0.57 – 1.09 mg/dl (women)
Urine:	1.0 – 2.8 g/ 24h (men)	0.9 – 1.6 g/24h (women)

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 150 mg/dL	Urine: up to 1000 mg/dL
Lowest detection limit:	Serum: 0.09 mg/dL	Urine: up to 0.54 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 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			
SERUM		**URINE**	
Mean (mg/dL)	**%CV**	**Mean (mg/dL)**	**%CV**
0.90	7.80	90.5	0.71
4.50	1.50	220	0.60
Mean (mg/dL)	**TOTAL %CV**	**Mean (mg/dL)**	**TOTAL %CV**
0.90	1.80	90.5	1.34
4.50	1.90	220	1.10

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	Hemoglobin	500 mg/dL
Bilirubin	20 mg/dL	Ascorbic Acid	20 mg/dL
Conj. Bilirubin	20 mg/dL	Glucose	30 g/L
Ascorbic acid	3 mg/dL	Urea	50 g/L

Correlation: A comparison was performed between this reagent on a Diatron Pictus® P700 and analyzer, and another commercially available product. The results were as follows:

Serum:	Y = 0.990X + 0.028	R=0.9990 N=95	Sample range = 0.49 – 10.7 mg/dL
Urine:	Y = 0.982X + 1.11	R=0.9985 N=82	Sample range = 17.4 – 214 mg/dL

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SYMBOLS

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

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