diatron

CREATININE

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

2°C – 8°C

REF 1419-0030 **Packaging:** 6 x 6 mL (R1) + 6 x 6 mL (R2) Σ 360

REF 1419-0032 **Packaging:** 6 x 20 mL (R1) + 6 x 20 mL (R2) Σ 1200

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 prostatitis, 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 loss of muscle mass, in amputees and elderly people.

METHOD PRINCIPLE

The Jaffé Kinetic method is applied. Creatinine forms a yellow-orange complex with picrate anions in alkaline medium. The rate of change of absorbance of the complex at 505/700 nm is proportional to creatinine concentration in the sample.

Creatinine + Picrate anion ⟶ Creatinine-Picrate complex

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)	
NaOH:	0.45 M	Picric acid:	22 mM
Detergent:	0.4 %	Non- reactive components and preservatives	
Non-reactive components 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.
- The reagent contains NaOH ≤ 1.0 %. Avoid ingestion and contact 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 ready to use when placed at the corresponding positions of the analyzer. The vials bear bar codes for automatic recognition by Diatron Pictus® P700 / P500 analyzers. Please use a vial tube insert in the R1 vial as instructed below.

⚠ **VIAL TUBE INSERTS**

1. Always use a clean and dry insert tube. Insert the tube into the R1 reagent vial until it clicks in place. The tube top should come flush with the vial top and the tube end should reach a few millimeters from the R1 vial bottom.
2. Handle the tube with clean gloves. Avoid touching the tube body during this operation to eliminate the risk of contaminating the reagent.
3. When discarding the R1 bottle please remove the tube and wash it thoroughly with tap water. Rinse internal and external surfaces with plenty of DI water before allowing the tube to dry.
4. Never use scratched, deformed or vial tube inserts with dried reagent residue. Discard the tube when it shows signs of deterioration like scratches, deformation or permanent salt or color deposits.
5. Once the bottle insert tube is put into the reagent vial, you may cap the reagent vial while it is on-board the instrument or you may maintain the reagent vial un-capped.

⚠ **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 reagents are stable at 2 – 8°C up to the expiry date stated on the label. Once opened, they remain stable for 1 week when stored in the cooled reagent tray of the Diatron Pictus® P700 or P500 analyzers, provided that vial tube inserts are used with R1. Failure to use a vial tube insert with R1 vial will cause fast reagent deterioration.

⚠ **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. Perform a Reagent Blank measurement and calibrate the assay every 2 days when used on Diatron Pictus® P700 or P500 analyzers, with vial tube insert in R1 vial. 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

- Vial tube inserts
- Creatinine Calibrator.
- Diatron Pictus® analyzer
- Quality control materials.
- Common laboratory equipment.

REFERENCE INTERVALS

Serum or plasma:	0.73 – 1.45 mg/dl (men)	0.59 – 1.11 mg/dl (women)
Urine:	14 – 26 mg/kg/24h (men)	11 – 20 mg/kg/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.
NOTE: Performance characteristics were determined with vial tube inserts in R1 vials.

Linearity:	Serum: up to 30 mg/dL	Urine: up to 500 mg/dL
Lowest detection limit	Serum: 0.06 mg/dL	Urine: 3.8 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**
1.34	1.17	74.3	1.26
5.20	0.80	171	0.99
Level (mg/dL)	**Total %CV**	**Level (mg/dL)**	**Total %CV**
1.34	2.61	74.3	1.70
5.20	1.99	171	1.35

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

Serum	(Insignificant up to)	**Urine**	(Insignificant up to)
Triglycerides	1200 mg/dL	Bilirubin	50 mg/dL
Hemoglobin	220 g/dL	Glucose	10 g/L
Bilirubin	5 mg/dL	Uric Acid	2.5 g/L
Conj. Bilirubin	3 mg/dL	Ascorbic Acid	5 g/L
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:

Serum: Y = 0.963X + 0.306	R=0.9991	N=40	Sample range = 1.00 – 12.9 mg/dL
Urine: Y = 1.006X – 0.963	R=0.9977	N=26	Sample range = 17.6 – 225.4 mg/dL

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⚠ **LABEL ELEMENTS**

Precautionary Statements (P Phrases)	Hazardous Statements (H Phrases)
P260: Do not breathe dust/ fumes/ gas/ mist/ vapors/ spray.	**EUH208**: Contains <Picric acid Solution>. May produce an allergic reaction.
P280: Wear protective gloves/protective clothing/eye protection/face protection.	**H201**: Explosive; mass explosion hazard.
P301+330+331: IF SWALLOWED: rinse mouth. Do NOT induce vomiting.	**H301**: Toxic if swallowed.
P303+361+353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.	**H311**: Toxic in contact with skin.
P304+340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.	**H314**: Causes severe skin burns and eye damage.
P305+351+338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.	**H317**: May cause an allergic skin reaction.
	H331: Toxic if inhaled.

SYMBOLS

Manufacturer

Temperature Limit

Caution

IVD *In vitro* diagnostic medical device

REF Catalogue Number

Σ Contains sufficient for <n> tests

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