CK

CREATINE KINASE

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

2°C – 8°C

REF 1419-0090 **Packaging:** 6 x 12 mL (R1) + 6 x 3 mL (R2)

Σ 375

INTENDED USE

Reagents for In Vitro quantitative automated determination of Creatine Kinase - CK (EC 2.7.3.2) in samples of human serum or plasma from the general patient population. Measurements of CK are to be used along with other in vitro and in vivo tests and physical examination by licensed physicians, as an aid to diagnosis and monitoring of conditions related to muscle damage.

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

Creatine Kinase is an enzyme that catalyzes the conversion of creatine to phosphocreatine, by converting ATP to ADP, found in all muscle tissues. Increased CK levels are observed in trauma, surgery, myocardial infarction, loss of blood supply to any muscle, myopathic disorders and muscular dystrophies of any type, Reye's syndrome, malignant hyperpyrexia, prolonged hypothermia, hypothyroidism, infectious diseases (e.g. typhoid fever), arrhythmias (infrequently), direct-current countershock, congestive heart failure, tachycardia, pulmonary embolism, tetanus, generalized convulsions, extensive brain infarction. Lower than normal levels probably have no meaning but reflect either small muscle mass, sedentary lifestyle or both. Bed rest even overnight can lower CK activity by 20% or more. CK activity may be used for cardiac muscle evaluation; however, its low specificity requires evaluation in conjunction with other in Vivo and in Vitro tests.

METHOD PRINCIPLE

The IFCC method is applied. The kinetic determination of CK is based on the following reactions:

$$\text{Phosphocreatine} + \text{ADP} \xrightarrow{\text{CK}} \text{Creatine} + \text{ATP}$$

$$\text{ATP} + \text{D-Glucose} \xrightarrow{\text{HK}} \text{D- Glucose-6-Phosphate} + \text{ADP}$$

$$\text{D- Glucose-6-Phosphate} + \text{NAD}^+ \xrightarrow{\text{G6PDH}} \text{6-Phosphogluconolactone} + \text{NADH}$$

CK: Creatine Kinase HK: Hexokinase G6PDH: Glucose-6-Phosphate Dehydrogenase

The rate of absorbance change at 340/380 nm is proportional to the CK activity 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)	
Imidazole buffer (pH 6,7):	125 mM	Tris buffer (pH 7,5):	25 mM
Diadenosine pentaphosphate:	12.5 mM	Phosphocreatine:	166 mM
D-Glucose:	25 mM	ADP:	15 mM
NADP:	2.5 mM	G6PDH:	≥ 10 kU/L
Magnesium Acetate:	12.5 mM	Non reacting ingredients, preservative	
AMP:	6.5 mM		
NAC:	25 mM		
Hexokinase:	≥ 4.0 kU/L		
Non reacting ingredients, 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 with special caution.
- This reagent contains sodium azide (NaN_3) ≤ 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**

Reagents R1 and R2 are liquid and ready-to-use when placed in 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.
- After prolonged exposure to sunlight or high temperature.

⚠ Unopened reagents are stable at 2 – 8°C up to the expiry date stated on the label. Once opened, they remain stable for 1 month when stored in the cooled reagent tray of the Diatron Pictus® P700 or P500 analyzers.

⚠ **SAMPLE** Serum, or Li-heparin plasma 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. ATP, adenylic kinase and glucose-6-phosphate dehydrogenase are abundant in red blood cells and they may interfere severely in the reaction, if hemolysis exists. 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. CK is stable in serum and plasma samples for 4 hours at 15 – 25°C, 8 – 12 hours at 2 – 8°C and 2 – 3 days at –20°C. Do not freeze thawed samples.

CALIBRATION Diatron offers MEDICON MEDI-CAL (1578-0891) traceable to the IFCC method, for calibration. Calibrate the assay when a new lot of reagent is installed. The analyzer will automatically perform a Reagent Blank measurement every 2 weeks. Calibration should be repeated when a new lot of reagent is used, 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 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

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

REFERENCE INTERVALS

Serum/Plasma:	25°C	30°C	37°C
Men:	10 – 60 U/L	15 – 105 U/L	38 – 174 U/L
Women:	7 – 55 U/L	10 – 80 U/L	26 – 140 U/L

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

This product contains sodium azide (NaN_3), which forms sensitive explosive compounds with copper or lead. Flush waste pipes with water after the disposal of undiluted reagent in order to avoid azide build up in the drain pipes.

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 2000 U/L

Lowest detection limit: 1.5 U/L

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 (U/L)	**%CV**
66.3	2.10
311.0	2.20
Level (U/L)	**TOTAL %CV**
66.3	2.40
311.0	4.00

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

	(Insignificant up to)
Triglycerides	3000 mg/dL
Hemoglobin	125 mg/dL
Bilirubin	20 mg/dL
Conj. Bilirubin	20 mg/dL
Ascorbate	3 mg/dL

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:

Y = 1.028X + 2.464 R=0.9990 N=40 Sample range = 9.9 – 1211 U/L

SHELF LIFE

BIBLIOGRAPHY

MEDICON HELLAS S.A. - Melitona 5-7, 153 44 Gerakas, Greece. Tel: +302106606000 - Fax: +302106612666 – www.mediconsa.com

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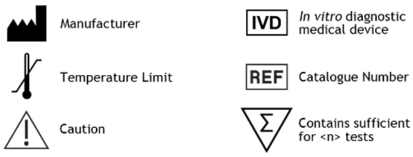
CE IVD

1. The German Society for Clinical Chemistry (1977) Standard Method for the Determination of Creatine Kinase Activity.
2. The Committee on Enzymes of the Scandinavian Society for Clinical Chemistry and Clinical Physiology (1979) Recommended Method for the determination of creatine kinase in blood modified by the inclusion of EDTA. Scand. J. Clin. Lab. Invest. 39. 1-5.
3. Mayene PD, ed. Clinical chemistry in diagnostics and treatment, 6th ed. London: Arnold, 1994:304-310.
4. Moss DW, Henderson RA. Clinical enzymology. In Burtis CA, Ashwood ER, eds. Tietz textbook of clinical chemistry. Philadelphia: WB Saunders Company, 1999;657-662.
5. Tietz NW. Clinical guide to laboratory tests 2nd ed. WB Saunders Company Philadelphia,1990.
6. Moss DW, Henderson RA, Kachmar JF. Enzymes In Tietz NW ed. Fundamentals of clinical chemistry. WB Saunders Company Philadelphia,1987 376pp.
7. Schumann G, Klauke R. New IFCC reference procedures for the determination of catalytic activity concentrations of five enzymes in serum Clin Chim Acta 2003;27:69-79.
8. Young DS. Effects of drugs on clinical laboratory tests, 5th ed. AACC Press 2000.

LABEL ELEMENTS

Precautionary Statements (P Phrases)	Hazardous Statements (H Phrases)
P201: Obtain special instructions before use. **P202**: Do not handle until all safety precautions have been read and understood. **P280**: Wear protective gloves/protective clothing/eye protection/face protection. **P308+313**: IF exposed or concerned: Get medical attention. **P405**: Store locked up. **P501**: Dispose of contents/container to hazardous or special waste collection point.	**H300**: Fatal if swallowed. **H302**: Harmful if swallowed. **H310**: Fatal in contact with skin. **H314**: Causes severe skin burns and eye damage. **H351**: Suspected of causing cancer **H360D**: May damage the unborn child. **H361d**: Suspected of damaging the unborn child. **H373**: May cause damage to organs through prolonged or repeated exposure **H400**: Very toxic to aquatic life. **H410**: Very toxic to aquatic life with long lasting effects. **H411**: Toxic to aquatic life with long lasting effects.

SYMBOLS



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