diatron

CK

CREATINE KINASE

For use on Diatron Pictus® series analyzers
Method: IFCC
Product code: 1419-0092, 1419-0090
Package: 6 x 32 ml (R1) + 6 x 8 ml (R2), 6 x 12 ml (R1) + 6 x 3 ml (R2)
Store at: 2° – 8°C
For *in vitro* use only

INTENDED USE
Ready to use reagents for the quantitative determination of Creatine Kinase (CK) in human serum or plasma specifically for use with Diatron Pictus® series analyzers. For in vitro diagnostic use only.

CLINICAL SIGNIFICANCE[3,4,5]
Creatine Kinase is an enzyme that catalyzes the conversion of creatine to phosphocreatine, by converting ATP to ADP. Increased CK levels are observed at 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.

METHOD PRINCIPLE[1,2,7]
The kinetic determination of CK is based on the following reactions:

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

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

D- Glucose-6-Phosphate + NAD^+ $\xrightarrow{G6PDH}$ 6-Phosphogluconolactone + 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".
The reagent is designed especially for use with the Diatron PICTUS® series of chemistry analyzers. For chemistry protocols and further information please contact the customer support unit at Diatron.

REAGENT COMPOSITION
Reagent 1 (R1):

Imidazole buffer (pH 6,7):	125 mM
Diadenosine pentaphosphate:	12.5 μM
D-Glucose:	25 mM
NADP:	2.5 mM
Magnesium Acetate:	12.5 mM
AMP:	6.5 mM
NAC:	25 mM
Hexokinase:	≥ 8.0 kU/L

Non reacting ingredients, preservative

Reagent 2 (R2):

Tris buffer (pH 7,5):	25 mM
Phosphocreatine:	166 mM
ADP:	2.5 mM
G6PDH:	≥ 20 kU/L

Non reacting ingredients, preservative

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 sodium azide (NaN_3) ≤ 0.1%. Avoid swallowing and contact of the reagent with skin and mucous membranes.
- Dispose all waste according to national laws.
- MSDS is available by Diatron or MEDICON HELLAS (manufacturer) upon request.

REAGENT 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 Pictus® series 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 reagents are stable at 2 – 8°C up to the expiry date stated on the label. Once opened, they remain stable for 56 days when stored in the cooled reagent tray of the Pictus® series analyzers.

SAMPLE [4]
Non hemolysed serum or plasma with EDTA or heparin. Hemolyzed samples should be avoided because ATP, adenylic acid kinase and glucose-6-phosphate dehydrogenase are abundant in red blood cells and they may interfere severely in the reaction. CK activity in serum remains stable for 4 hours at 15 – 25°C, 8 – 12 hours at 2 – 8°C and 2 – 3 days at –20°C.

CALIBRATION
Diatron provides MEDI-CAL (1578-0891) for calibration. Calibrate the assay when a new lot of reagent is installed. The analyzer will automatically perform a Reagent Blank measurement every 14 days. 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 provides 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 SUPPLIED WITH THE KIT
- CK calibrator
- Quality control materials.
- Diatron Pictus® P400/P700/P500
- Common laboratory equipment.

REFERENCE INTERVALS [7]

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® series 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.

	Pictus® P400	Pictus® P700/P500
Linearity	Up to 2000 U/L	Up to 2000 U/L
Lowest detection limit	7.2 U/L	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 in one run 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® P400			Pictus® P700/P500		
	Level (U/L)	Within Run CV%	Total CV%	Level (U/L)	Within Run CV%	Total CV%
	173	2.71	3.66	138	2.52	3.25
	442	2.67	3.50	396	2.32	3.19

Interferences: Criterion: recovery within ±20% from target value

	Pictus® P400	Pictus® P700/P500
Lipemia	No interference up to 1000 mg/dL Intralipid®	No interference up to 1000 mg/dL Intralipid®
Heamoglobin	No interference up to 25 mg/dL	No interference up to 125 mg/dL
Non conj. Bilirubin	No interference up to 20 mg/dL	No interference up to 20 mg/dL
Conj. Bilirubin	No interference up to 20 mg/dL	No interference up to 20 mg/dL
Ascorbate	No interference up to 3 mg/dL	No interference up to 3 mg/dL

Correlation: A comparison was performed between this reagent on a Pictus® series analyzer, and a BECKMAN COULTER AU-series system. The results were as follows;

Pictus® P400			
Y = 1.110X + 8.722	R=0.9930	N=59	Sample range = 24.6 – 286 U/L
Pictus® P700/P500			
Y = 1.028X + 2.464	R=0.9990	N=40	Sample range = 9.9 – 1211 U/L

BIBLIOGRAPHY

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.

SYMBOLS ON THE LABEL
Temperature Limits (L/H)
Manufacturer
Read the Instructions
REF Catalog Number (ISO 15223 / rev. EN980)
LOT Batch Code (ISO 15223 / rev. EN980)
IVD For in vitro use (ISO 15223 / rev. EN980)
Date of Expiry (ISO 15223 / rev. EN980)

CE IVD