TECO DIAGNOSTICS
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CREATINE KINASE (CK-NAC) REAGENT (KINETIC METHOD)
TC MATRIX-160

INTENDED USE
For the quantitative determination of creatine kinase activity in serum or plasma on TC Matrix analyzers.

SUMMARY AND EXPLANATION OF THE TEST
Creatine kinase (CK) catalyzes the reversible reaction of creatine and ATP to form creatine phosphate and ADP which plays very important role in the function of energy storage in the human tissue. It presents mostly in skeletal muscle, heart and brain. Damage of muscle and heart tissues will release CK to the blood stream and result in the increase of CK activity. Determination of CK activity in serum or plasma is a good diagnosis of muscular dystrophy and other skeletal muscle disease myocardial infarction, renal damage and dysfunction.
CK catalyzes the conversion of creatine phosphate and ADP to creatine and ATP. The ATP and glucose are converted to ADP and glucose-6-phosphate by hexokinase (HK). Glucose-6-phosphate dehydrogenase (G-6-PDH) oxidizes at the D-glucose-6-phosphate and reduces the nicotinamide adenine dinucleotide (NAD). The rate of NADH formation, measured at 340nm, is directly proportional to serum CK activity.
The TC Matrix System automatically proportions the appropriate sample and reagent volumes into the cuvette. The system monitors the change in absorbance at 340 nanometers. This change in absorbance is directly proportional to the activity of creatine kinase in the sample and is used by the TC Matrix System to calculate and express creatine kinase activity.

$$\text{Creatine phosphate} + \text{ADP} \xrightarrow{\text{CK}} \text{creatine} + \text{ATP}$$

$$\text{ATP} + \text{D-glucose} \xrightarrow{\text{Hexokinase}} \text{glucose-6-phosphate} + \text{ADP}$$

$$\text{Glucose-6-phosphate} + \text{NAD}^+ \xrightarrow{\text{G-6-PDH}} \text{6-phosphogluconate} + \text{NADH} + \text{H}^+$$

REAGENT PREPARATION
No preparation is required.

REAGENT COMPOSITION
Creatine phosphate: 30mmol/L
ADP: 2 mmol/L
D-glucose: 20 mmol/L
NAD^+: 2 mmol/L
N-acetylcysteine: 20 mmol/L
Hexokinase: 3000 U/L
G-6-PDH: 3000 U/L
Also non-reactive chemicals for optimal system performance.

REAGENT STORAGE AND STABILITY
Creatine Kinase Reagent stored at 2ºC to 8ºC is stable until the expiration date shown on the bottle label.
DO NOT FREEZE.

SPECIMEN COLLECTION AND HANDLING
1. The test can be performed on serum or plasma. For serum, blood is drawn into a tube which does not contain anticoagulant and it is allowed to clot. The serum should then be separated from the clot within two hours from the time of collection.
2. Stability of creatine kinase activity in sera is not well defined, but is generally poor. Specimens should be assayed as soon after collection as possible since activity loss may occur after specimens have been stored for 4 hours at room temperature, 8 to 12 hours at 4ºC or 2-3 days when frozen.
3. For plasma, add whole blood directly into a tube containing anticoagulant. Acceptable anticoagulants are listed in the "LIMITATIONS" section.

CALIBRATION
Calibration required.(Not provided in the kit)

MATERIALS NEEDED BUT NOT SUPPLIED WITH REAGENT KIT
At least two levels of control material.

LIMITATIONS
1. The anticoagulants Potassium Oxalate, Sodium Fluoride and Sodium Citrate were found to be incompatible with this method.
2. The anticoagulants Ammonium Heparin, EDTA, Lithium Heparin and Sodium Heparin were found to be compatible with this method.

INTERFERENCE
1. Samples showing evidence of hemolysis should not be used.
2. Lipemic samples >3+ should be ultra-centrifuged and the analysis performed on the infranate.
3. On this method, refer to the work of Young for a review of drug and comprehensive list of substances which have an effect on creatine kinase level.

EXPECTED VALUE
33 to 186 IU/L or 0.6 to 3.1 µkat/L

PRECAUTIONS:
1. For in vitro diagnostic use only.
2. Since all specimens are potentially infectious, they should be handled with appropriate precautions and practices in accordance with Biosafety level 2 as recommended by USA NIH Biosafety in Microbiological and Biomedical Laboratories manual, and in accordance with national or local regulations related to the safety precautions of such materials.
3. Each laboratory should perform the quality control testing to ensure the results are reliable before testing the specimens.

PROCEDURE:

Test Name:	CK-NAC	R1:	120
Full Name :	Creatine Kinase	R2:	25
Pri. Wave:	340 nm	Sample volume:	6.6
Sec. Wave:	700 nm	Calibration Type:	2 point linear
Assay/ Point:	Kinetic	K Value:	/
Start - End:	15 - 21	Point:	2
Decimal place:	1	Blank Type:	Water
Unit:	U/L	Point 0 (Blank) Con.:	0.0
Linearity Range:	2.0 - 2000.0	Point 1 (STD) Con.:	Standard/
Correlation Factor:	1.0000 - 0.0000		Calibrator

PERFORMANCE CHARACTERISTICS

Analytical Range: 2-2000 U/L

For Creatine Kinase analysis by Creatine Kinase Reagent on TC Matrix System, this method has been demonstrated to be linear from 2-2000 U/L

Accuracy: Comparison study was performed on TC Matrix System from 40 samples. Beckman Coulter Creatine Kinase Reagent was used to compare with Creatine Kinase Reagent. The results of this study yielded a correlation coefficient of 0.99 with a regression equation of y=0.99x -4.1

Precision: Within Run precision for Creatine Kinase Reagent Set was determined following a modification of NCCLS EP5-A. Two commercial human sera were assayed on TC Matrix System for 25 times.

Sample	Sample 1	Sample 2
N	25	25
Mean (U/L)	151	492
Standard Deviation (U/L)	4.9	5.6
Coefficient of Variation (%)	3.5	3.4

Run-Day precision for Creatine Kinase Reagent was determined following a modification of NCCLS EP5-A. Two commercial human serum were assayed on TC Matrix Systems five times per day for five days for the total of 25 values.

Sample	Sample 1	Sample 2
N	25	25
Mean (U/L)	150	490
Standard Deviation (U/L)	5.2	7.8
Coefficient of Variation (%)	3.8	3.7

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Manufactured by:

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