CK (NAC) Reagent

PRODUCT SUMMARY

Stability	:	Until expiry at 2-8°C
Linear Range	:	Up to 1500 U/L
Specimen Type	:	Serum
Method	:	Kinetic
Reagent Preparation	:	Add specified volume of distilled or deionised water.

SYMBOLS IN PRODUCT LABELLING

EC REP	Authorised Representative		Temperature Limitation
IVD	For in vitro diagnostic use		Use by/Expiration Date
LOT	Batch code/Lot number		CAUTION. CONSULT INSTRUCTIONS FOR USE.
REF	Catalogue number		
	Consult instructions for use		Manufactured by
REAG A	Reagent A	REAG B	Reagent B

INTENDED USE
For in vitro diagnostic use and for the quantitative determination of Creatine Kinase in serum on the Olympus Demand® and Reply®.

SUMMARY
Serum creatine kinase (CK), sometimes referred to as creatine phosphokinase (CPK), levels have proven valuable in the assessment of cardiac and skeletal muscle diseases, including myocardial infarction and muscular dystrophy. There may also be an increase in CK values associated with diseases of the central nervous system. Diseases of the thyroid show an inverse relationship to CK values.[1] A combined analysis of creatine kinase and lactate dehydrogenase isoenzymes provides a definitive diagnosis of acute myocardial infarction.[2]
The Thermo CK Procedure employs a Szasz[3] modification of Oliver-Rosalki,[4] which optimizes the reaction by reactivation of CK activity with the addition of N-acetyl-L-cysteine (NAC).

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

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

$$\text{glucose-6-phosphate} + \text{NAD} \xrightarrow{\text{G-6-PD}} \text{6-phosphogluconate} + \text{NADH}$$

CK specifically catalyzes the transphosphorylation of ADP to ATP. Through a series of coupled enzymatic reactions, NADH is produced at a rate directly proportional to the CK activity and is measured bichromatically at 340/380 nm.[1]

REAGENTS

Reactive Ingredients	Initial Conc.	Final Conc.
CK Reagent A		
creatine phosphate	300 mmol/L	30 mmol/L
ADP	20 mmol/L	2 mmol/L
hexokinase	80,000 U/L	8,000 U/L
G-6-PD	40,000 U/L	4,000 U/L
NAC	10 mmol/L	1 mmol/L
buffer		
preservative		
surfactant		
CK Reagent B		
glucose	200 mmol/L	20 mmol/L
NAD	20 mmol/L	2 mmol/L
NAC	200 mmol/L	20 mmol/L
buffer		
surfactant		
preservative		

PRECAUTIONS
1. For in vitro diagnostic use. Do not ingest. Toxicity has not been established. Avoid contact with eyes, skin and clothing.
2. California state regulations require the following precaution for this product.
   WARNING: This product contains a chemical known to the State of California to cause cancer.
3. The Packaging of This Product Contains Dry Natural Rubber.
4. Exercise precaution in handling crimps and broken glass vials, as sharp edges can injure the user.

For further information, consult the CK Reagent Material Safety Data Sheet.

PREPARATION
Add 9 mL deionized water to each vial of CK-A and CK-B. Swirl gently to dissolve. Allow 20 minutes for reconstitution.

STORAGE AND STABILITY
1. The unopened reagents are stable until the expiration date stated on the label when stored at 2-8°C.
2. After reconstitution the reagents are stable for 7 days when stored on the Olympus Demand or Reply at 2-8°C

DETERIORATION
1. The dry reagents should have a uniform white to off white appearance.
2. Failure to achieve assay values on freshly prepared control sera could indicate deterioration.

SPECIMEN COLLECTION[1]
1. Clear, non-hemolyzed serum is the recommended sample. Citrate and fluoride inhibit CK activity.
2. Intramuscular injections or strenuous physical exercise may elevate serum CK.

SAMPLE STORAGE
CK in serum is stable for 4 hours at ambient temperature, about 8-12 hours at 4°C and 2-3 days when frozen.[1]

INTERFERING SUBSTANCES
1. No interference was observed at a Triglyceride concentration of 1100 mg/dL.
2. No interference was observed at a Bilirubin concentration of 14 mg/dL.
3. At a CK level of 250 U/L, a negative interference was observed at a Hemoglobin concentration of 331 mg/dL.
4. Young has reviewed drug effects on serum CK levels.[5]

PROCEDURE
Test Parameters
Refer to the Thermo Reagent Applications for the Olympus Demand or Reply.

MATERIALS PROVIDED

CK Reagent A	5 x 9 mL
CK Reagent B	5 x 9 mL

MATERIALS REQUIRED BUT NOT PROVIDED
1. Olympus Demand or Reply system with Operator's Manual and Accessories.
2. Thermo Reagent Applications for the Olympus Demand or Reply.
3. Thermo Data-Trol N and Data-Trol A (Cat. No. 1902-050 or TR40001 and 1901-050 or TR41001) or equivalent.

P/N: PI147041en.01 Revised March 2004

Thermo
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CALIBRATION
A calibrator is not required for the CK Procedure. One U/L of CK activity is that amount of enzyme which produces one µmol/L of NADH per minute.

STABILITY OF FINAL REACTION MIXTURE
The instrument automatically computes every determination at the same time interval.

LINEARITY
Linearity extends to 1500 U/L Samples exceeding linearity should be diluted with normal saline and repeated. Multiply the result by the dilution factor when calculating the unknown.

QUALITY CONTROL
Normal and abnormal control serum of known concentrations of CK should be analyzed routinely with each group of unknown samples. Thermo's Data-Trol N and Data-Trol A (Cat. No. 1902-050 or TR40001 and 1901-050 or TR41001) are recommended for this purpose.

CALCULATION OF RESULTS
Results, expressed as U/L at 37°C, are automatically calculated.

LIMITATIONS
See Storage and Stability, Deterioration, Specimen Collection, Interfering Substances, Sample Storage, and Linearity sections for limitations to this procedure.

EXPECTED VALUES
An observed range of CK, derived from a study of 48 asymptomatic adults in the Southwest USA, was found to be 36 - 213 U/L. A reference range of 26 - 174 U/L has been reported in the literature.[1] These ranges should serve only as guidelines. Each laboratory should establish its own range of expected values since differences exist between laboratories and local populations.

PERFORMANCE CHARACTERISTICS
Precision

WITHIN RUN:	Level 1	Level 2
No. of data points	40	40
Mean U/L	145	273
SD	1.1	1.2
CV%	0.8	0.4

TOTAL:	Level 1	Level 2
No. of data points	40	40
Mean U/L	145	273
SD	4.4	10.2
CV%	3.0	3.7

COMPARISON STUDIES
A comparison of the Thermo CK reagent (y) with a commercial reagent of the same methodology (x) was performed on 40 human samples in a range of 28 -214 U/L. A correlation coefficient of 0.9968 was obtained; the linear regression equation was y = 1.179 x- 3.1.

SENSITIVITY
Based on an instrument resolution of A= 0.001, this Thermo CK Procedure has a sensitivity of 11 U/L

REFERENCES

1. Tietz, N. W, Textbook of Clinical Chemistry, W.B. Saunders Co., Philadelphia, 1986, p. 678-686.
2. Roe, C. R., Limbird, L.E., Wagner, G.S., and Nerenber, S.T., J. Lab. CIIn. Med., Vol. 80, 1972, p. 577.
3. Szasz, G., Proceedings of the Second International Symposium on Clinical Enzymology, Chicago, Oct. 1975.
4. Rosalki, S. B., J. Lab. Clin. Med., Vol. 69, 1967, p. 696.
5. Young, D. S., Effects of Drugs on Clinical Laboratory Tests, 3rd ed., AACC Press, Washington, D.C, 1990, p. 3-120 — 3-122.

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P/N: PI147041en.01 Revised March 2004

REF ***Reorder Information and Technical Support***

Catalogue No.	Configuration	
7200-014	Reagent A	5 x 9 mL
	Reagent B	5 x 9 mL

	Australia	International	U.S.A.
Phone	1800 333 110	61 3 9790 4100	(800) 558 9115
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