

CK Reagent

INTENDED USE

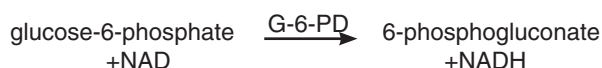
For the quantitative determination of Creatine Phosphokinase in serum.

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 Szasz³ modification of Oliver-Rosalki,⁴ which optimizes the reaction by reactivation of CK activity with the addition of N-acetyl-L-cysteine (NAC).

METHODOLOGY



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.¹

REAGENTS

Reactive Ingredients

creatine phosphate	30.0 mmol/L
ADP	2.0 mmol/L
glucose	20.0 mmol/L
NAD	2.0 mmol/L
NAC	20.0 mmol/L
hexokinase	8,000 U/L
G-6-PD	4,000 U/L
surfactant	
preservative	
buffer	

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.

Preparation

Transfer the entire contents of CK Reagent to an appropriate polyethylene bottle. Reconstitute with the required volume of deionized water. Swirl gently to dissolve.

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 reagent is stable for 21 days when stored at 2° - 15°C and kept covered.

Deterioration

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

SPECIMEN COLLECTION

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

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. Elevated bilirubin does not significantly interfere with this assay.
2. Hemolysis and lipemia will cause interference with this assay.
3. Young has reviewed drug effects on serum CK levels.⁵

PROCEDURE

Test Parameters

Refer to the Thermo Reagent Applications.

Materials Provided

** 7500-014 CK Reagent 4 x 250 mL

** Requires separate container for reconstitution and subsequent storage.

Materials Required But Not Provided

1. Analyzer with Manual and Accessories.
2. Thermo Reagent Applications.
3. Thermo Data-Trol N and Data-Trol A (Cat. No. 1902-050 or TR40001 and 1901-050 or TR41001) or equivalent.
4. Polyethylene bottles (available through Thermo Customer Service) or equivalent.

Stability of Final Reaction Mixture

The instrument automatically computes every determination at the same time interval.

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.

Linearity

Linearity extends to 2300 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 sera of known CK activities 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 for CK, derived from a study of 48 asymptomatic adults in the Southwest USA, was found to be 23 - 219 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 precision was determined by assaying control sera in replicate.

Within-run	n	Mean	Std. Dev.	CV%
Level 1	20	165	1.47	0.89
Level 2	20	452	3.61	0.80

Run-to-run precision was determined by assaying control sera in duplicate for 9 runs.

Run-to-run	n	Mean	Std. Dev.	CV%
Level 1	18	173	2.25	1.30
Level 2	18	482	16.17	3.36

Sensitivity

Based on an instrument resolution of A= 0.001, this Thermo procedure has a sensitivity of 8.2 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, LE, Wagner, G.S., and Nerenber, S.T., J. Lab. Clin. 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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REF

Reorder Information

Catalogue No.	Configuration
7500-014	4 250 mL
TR41001	10 x 5 mL
TR40001	10 x 5 mL