

CK-NAC reagent

INTENDED USE

For the quantitative determination of Creatine Kinase in Serum.

SUMMARY AND EXPLANATION

Serum creatine kinase (CK) levels have proven valuable in the assessment of cardiac and skeletal muscle diseases, including myocardial infarction and muscular dystrophy.¹ A combined analysis of creatine kinase and lactate dehydrogenase isoenzymes provides a definitive diagnosis of acute myocardial infarction.²

The CK, NAC Activated Procedure employs a Szasz³ modification of Oliver-Rosalik⁴, which optimizes the reaction by reactivation of CK activity with the addition of N-acetyl-L-cysteine (NAC).

PRINCIPLE

CK specifically catalyzes the transphosphorylation of ADP to ATP. Through a series of coupled enzymatic reactions, NADH absorbance change is measured via an absorbance increase at 340 nm. The increase in absorbance is directly proportional to the CK activity.

REAGENTS PROVIDED (for in vitro diagnostic use)

REACTIVE INGREDIENTS

creatine phosphate	30 mmol/L
ADP	2.0 mmol/L
glucose	20 mmol/L
NAD	2.0 mmol/L
hexokinase (yeast)	8,000 U/L
glucose-6-phosphate dehydrogenase (microbial)	4,000 U/L
NAC	20 mmol/L

buffer

surfactant

preservative

PRECAUTIONS

- Do not ingest. Toxicity has not been established. Avoid contact with eyes, skin and clothing.
- 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. **The Packaging of This Product Contains Dry Natural Rubber.**

REAGENT PREPARATION

Add the amount of deionized water to each vial as stated on the label. Swirl gently to dissolve the contents.

STORAGE AND STABILITY

- The dry reagent is stable until the expiration date as stated on the label when stored at 2° - 8°C.
- The reconstituted reagent is stable for 21 days when stored at 2° - 8°C.

DETERIORATION

- The dry reagent should have a uniform white to off-white appearance.
- If the reagent blank absorbance without added serum exceeds 0.600 at 340 nm, the reagent may have deteriorated and should not be used. with skin, eyes and clothing.

INSTRUMENTS

The procedure may be performed by employing a suitable chemistry analyzer or spectrophotometer calibrated to read at 340 nm.

SPECIMEN COLLECTION¹

- Clear, non-hemolyzed serum is the recommended sample. No special additives or preservatives are required.
- Strenuous physical exercise may elevate serum CK.

LINEARITY

Linearity extends to 1500 U/L at 30°C and 2300 U/L at 37°C. Samples exceeding linearity should be diluted with normal saline and repeated. Multiply the activity by the dilution factor when calculating the unknown.

QUALITY CONTROL

Normal and abnormal control sera with 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

The rate of NADH production, and consequently enzyme activity, can be established from the following equation:

$$U/L = \frac{\Delta A/Min. \times Total Volume}{Absorptivity \times Sample Volume}$$

Where the absorptivity micromolar extinction coefficient of NADH at 340 nm is 0.00622.

$$U/L = \frac{\Delta A/Min. \times 2.05}{0.00622} \times 0.05$$

$$U/L = \Delta A/Min. \times 6592$$

LIMITATIONS

See Storage and Stability, Deterioration, Specimen Collection, Interfering Substances, Sample Storage, Stability of Final Reaction Mixture, and Linearity sections for limitations to this procedure.

EXPECTED VALUES

NORMAL RANGE: 7 - 114 U/L at 30°C
25 - 160 U/L at 37°C

The 30°C values were established from a study of 57 samples from persons judged clinically normal by multiphasic testing.

The 37°C values were based on a study of 35 human serum samples. Reference ranges of 26 - 140 U/L (female, 37°C) and 38 - 174 U/L (male, 37°C) have been reported in the literature.¹

These ranges should serve only as guidelines. It is recommended that each laboratory establish its own range of expected values, since differences exist between instruments, laboratories, and local populations.

PERFORMANCE CHARACTERISTICS

PRECISION

Within-run reproducibility was obtained by assaying normal and abnormal control sera 20 times.

WITHIN-RUN NORMAL ABNORMAL	MEAN	STD.DEV.	CV%
	104	2.8	2.7
	383	14.8	3.9

Run-to-run reproducibility was obtained by assaying normal and abnormal control sera for 10 testing runs.

RUN-TO-RUN NORMAL ABNORMAL	MEAN	STD.DEV.	CV%
	104	3.0	2.9
	389	16.3	4.2

SENSITIVITY

Based on an instrument resolution of A = 0.001, this CK Procedure has a sensitivity of 6.6 U/L.

BIBLIOGRAPHY

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REF

Reorder Information

Catalogue No.
1380-200
1380-500

Configuration
20 x 10 mL
10 x 50 mL



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