

Creatine Kinase NAC

NAC Activated. UV. Kinetic Liquid

Store at 2 - 8 °C

Configuration

REF	HBELO3
VOL	60 + 15 mL
Reagent 1	1 x 60 mL
Reagent 2	1 x 15 mL

Intended use

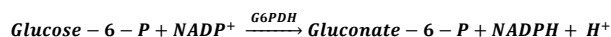
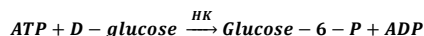
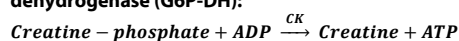
The Cypress Diagnostics kit Creatine Kinase NAC is an in vitro diagnostic medical device intended to be used for the quantitative measurement of creatine kinase in human serum free of hemolysis or heparin plasma. The device is not automated. The measurement of creatine kinase is intended to be used to aid to identify skeletal muscle disease or myocardial infarction, in patient risk population. This kit is intended to be used by healthcare professionals in a laboratory-based testing environment. For *in vitro* diagnostic use only. For professional use only.

Clinical significance

Creatine kinase (CK) is a cellular enzyme with wide tissue distribution in the body. Its physiological role is associated with adenosine triphosphate (ATP) generation for contractile or transport systems. Elevated CK values are observed in diseases of skeletal muscle and after myocardial infarction.^{1,5,6} Clinical diagnosis should not be made on a single test result; it should integrate clinical and other laboratory data.

Principle

The kinetic determination of CK is based upon IFCC and DGKC recommendations. Creatine kinase catalyzes the reversible transfer of a phosphate group from phosphocreatine to ADP. This reaction is coupled to those catalyzed by hexokinase (HK) and glucose-6-phosphate dehydrogenase (G6P-DH):



The rate of NADPH formation, measured photometrically, is proportional to the catalytic concentration of CK present in the sample.^{1,2}

Reagent composition

Reagent 1	Imidazole pH 6,7 (125 mmol/L) D-Glucose (25 mmol/L) N-acetyl-L-cysteine (25 mmol/L) Magnesium Acetate (12,5 mmol/L) NADP (2,52 mmol/L) EDTA (2,02 mmol/L) Hexokinase (≥ 6800 U/L)
Reagent 2	ADP (15,2 mmol/L) AMP (25 mmol/L) Diadenosine-5-P (103 mmol/L) G-6-PDH (≥ 8800 U/L) Creatine phosphate (250 mmol/L)

Precautions

- All body fluid samples should be considered potentially infectious materials and the appropriate precautions should be taken. Wear personal protective equipment such as gloves, safety glasses, lab coats or aprons when working with possible biohazard contaminants.
- Use Good Laboratory Practices (GLP) when handling this product.
- Please refer to the MSDS, available on our website, for further information.

Preparation

Mix 4 volumes of reagent 1 with 1 volume of reagent 2. The stability of the working reagent is 2 weeks at 2 - 8 °C or 48 hours at room temperature (15 - 25 °C).

Storage, stability and disposal

All the components of the kit are stable up to the date of expiration as specified on the label, when stored tightly closed, protected from light and contaminations prevented during their use. Storage temperature for this kit is 2 - 8 °C.

The reagent should be a clear solution. If turbidity or precipitation has occurred or if blank absorbance at 340 nm ≥ 1,0 the reagent should be discarded.

Do not use the product if deterioration or contamination is suspected or beyond the expiration date or open container stability period. Dispose unused or deteriorated product and waste in compliance with local regulations.

Additional material required but not provided

- Spectrophotometer or colorimeter. Minimum analyzer specifications:
Measuring at 340 nm
Linear measuring range: 0 - 2 AU
- Cuvettes, matching the analyzer used (1,0 cm light path)
- General laboratory equipment

Samples

Sample type: human serum free of hemolysis or heparin plasma. Stability: 7 days at 2 - 8 °C, protected from light. The creatinine kinase activity decreases 10% after 1 day at 2 - 5 °C or after 1 hour at 15 - 25 °C.

Procedure

1. Wavelength 340 nm; Temperature 25, 30, 37 °C; Cuvette (1 cm light path).
2. Adjust the instrument to zero with distilled water.
3. Pipette into a cuvette:

25 - 30 °C	40 µL Sample + 1 mL Working reagent
37 °C	20 µL Sample + 1 mL Working reagent
Mix and incubate for 2 minutes. Read initial absorbance (A), start the stopwatch and read absorbances every minute for 3 min. Calculate the difference between the absorbances and the average absorbance differences per minute (ΔA/min).	

Calculation

$$\text{At 25-30 °C} \quad \Delta A/\text{min} \times 4127 = \text{U/L CK} \text{ Note 3}$$

$$\text{At 37 °C} \quad \Delta A/\text{min} \times 8095 = \text{U/L CK} \text{ Note 3}$$

One international unit (IU) is the amount of enzyme that transforms 1 µmol of substrate per minute, in standard conditions. The concentration is expressed in units per liter of sample (U/L).

Conversion Factor: µkat/L = 0,0167 x U/L

Temperature conversion factors

To correct results to other temperatures, multiply by:

Assay Temperature	Desired Temperature		
	25 °C	30 °C	37 °C
25 °C	1,00	1,56	2,44
30 °C	0,64	1,00	1,56
37 °C	0,41	0,63	1,00

Quality control

Control sera are recommended for the qualification of the reagents and to monitor the performance of assay procedures. Next to legal requirements, we recommend to perform Quality Control on a daily basis and after each calibration.

Use Biochemistry Normal and Pathological Controls Specific (HBC01-S, HBC02-S). Also a CK (NAC & MB) Control (HBC08) is available. If other controls (not manufactured by Cypress) are used, they have to be validated by the user as they can vary. Prepare and measure these controls the same as samples. Measure at least one replicate per control.

If control values are found outside the defined range, check the instrument, reagents and calibrator for problems. Do not continue testing as the results will be invalid. Each laboratory should establish its own QC scheme and corrective actions if controls do not meet the acceptable tolerances.

Reference values

Men - 25 °C	≤ 80 U/L (≤ 1,34 µkat/L)
Women - 25 °C	≤ 70 U/L (≤ 1,17 µkat/L)
Men - 30 °C	≤ 130 U/L (≤ 2,17 µkat/L)
Women - 30 °C	≤ 110 U/L (≤ 1,84 µkat/L)
Men - 37 °C	≤ 195 U/L (≤ 3,26 µkat/L)
Women - 37 °C	≤ 170 U/L (≤ 2,84 µkat/L)

These values are for orientation purpose. Each laboratory should establish its own reference range.

Performance characteristics

Measuring range: from 2,12 U/L (detection limit) to 2000 U/L (linearity limit). If the obtained results are greater than 2000 U/L, dilute the sample



1:10 with saline solution, repeat the determination, and multiply the result by factor 10.

Precision:

	intra-assay (n=20)		inter-assay (n=20)	
Mean (U/L)	147	494	145	485
SD	1,23	3,60	2,91	8,97
CV (%)	0,84	0,73	2,01	1,85

Sensitivity: 1 U/L = 0,00012 ΔA/min

Accuracy: Results obtained using CYPRESS DIAGNOSTICS reagents did not show systematic differences when compared with other commercial reagents.

The results of the performance characteristics depend on the analyzer used.

Interferences

No interferences were observed with glucose up to 7 g/L, hemoglobin up to 5 g/L and triglycerides up to 7 mmol/L. A list of drugs and other interfering substances with CK determination has been reported by Young et al.

Notes

1. For best use of this kit on a Cypress Diagnostics analyzer, we kindly advise to follow the application sheets of the respective analyzer. Please log in to our website (www.diagnostics.be) as a registered user to download the latest application sheets, which are located under the section of the corresponding analyzer. Compatible Cypress analyzers: CYANSmart, CYANStart, CYANExpert 130, CYANVision.
2. In case other instruments (not manufactured by Cypress Diagnostics) are used, the laboratory is responsible to validate the reagents in this kit on those analyzers before testing patient samples.
3. Calibration by means of a Factor. For more accurate results, we recommend to use a serum based Biochemistry Calibrator Specific (HBC03-S) instead of a factor.

Bibliography

1. Abbot B et al. Creatine kinase. Kaplan A et al. Clin Chem The C.V. Mosby Co. St.Louis. Toronto. Princeton 1984 : 1112-1116.
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6. Tietz N W et al. Clinical Guide to Laboratory tests, 3rd ed AACC 1995
7. Mathieu M. et coll. Recommandation pour la mesure de la concentration catalytique de la créatine kinase dans la sérum humaine. Ann. Biol. Clin. 40, (1482), 87

Notice: Any serious incident that has occurred in relation to the device shall be reported to Cypress Diagnostics and the competent authority of the Member State in which the user and/or patient is established.

2022-06, Rev. 6.0

