

Intended Use

This reagent is intended for *in vitro* quantitative determination of Creatine Kinase in human serum or plasma.

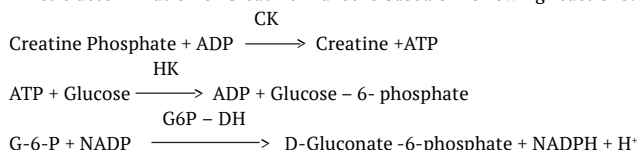
- Optimized IFCC Method
- Linear up to 1700 U/L
- Working Reagent can be prepared as per requirements

Clinical Significance

It is mainly found in all muscle (Cardiac & Skeletal) & brain tissues. It plays an important role in energy storing mechanism of the tissues. It's iso-enzymes: CK-MB mainly exists in cardiac muscle tissues, CK-MM in skeletal muscle tissues & CK-BB in brain. Increased levels are found in myocardial infarction, muscular dystrophy, cerebrovascular-disease, pulmonary infarction, electrical shocks & hypothyroidism. Decreased levels are, sometimes seen in early pregnancy, alcoholic liver diseases and RA.

Principle

Kinetic determination of Creatine Kinase is based on following reactions:-



CK – Creatine Kinase

HK – Hexokinase

G-6-P-Glucose-6-phosphate

G-6-PDH-Glucose-6-Phosphate dehydrogenase.

Kit Components

Reagent/Component	Product code: 11404001	Product code: 11404005	Description
CK-NAC (S.L) R1	2 x 8 mL	2 x 24 mL	Imidazole buffer 125 mmol/L D-Glucose 25 mmol/L N-Acetyl-L-cysteine 25 mmol/L Magnesium acetate 12.5 mmol/L NADP 2.4 mmol/L EDTA 2.0 mmol/L Hexokinase >6800 U/L
CK-NAC (S.L) R2	2 x 2 mL	2 x 6 mL	Creatine Phosphate 250 mmol/L

Risk & safety

Material Safety data sheets (MSDS) will be provided on request.

Reagent Preparation

Mix 4 volume of Reagent 1 (R1) with 1 volume of Reagent 2 (R2)

The working reagent is stable for 14 days at 2-8°C.

Note: Discard the working reagent if the blank absorbance exceeds 1.0 at 340 nm.

Reagent Storage

The sealed reagents are stable up to the expiry date stated on the label, when stored at 2- 8°C and protected from light.

Open Vial Stability

Once opened, the reagent is stable up to 4 weeks at 2-8°C if contamination is avoided.

On-board Calibration Stability

On-board Calibration stability is 20 days.

Reagent Deterioration

Turbidity or precipitation in any kit component indicates deterioration and the component must be discarded. Values outside the recommended acceptable range for the Agappe Qualicheck Norm & Path control may also be an indication of reagent instability and associated results are invalid. Sample should be retested using fresh vial of reagent.

Precaution

To avoid contamination, use clean laboratory wares. Use clean, dry disposable pipette tips for dispensing. Close reagent bottles immediately after use.

Avoid direct exposure of reagent to light. Do not blow into the reagent bottles.

This reagent is only for IVD use and follow the normal precautions required for handling all laboratory reagents.

Waste Management

Reagents must be disposed off in accordance with local regulations.

Sample

Serum / Plasma (Free of haemolysis).

Interferences

No interference for	
Ascorbic acid up to	40 mg/dL
Haemoglobin up to	5 g/L
Turbidity up to	600 mg/dL

Materials Provided

CK-NAC reagent R1 & R2

Materials required but not provided

- Pipettes & Tips
- Test Tubes & racks
- Timer
- Incubator
- Analyzer

Test Parameter

Mode of Reaction	Kinetic
Slope of reaction	Increasing
Wavelength	340 nm
Temperature	37°C
Factor	4127
Linearity	1700 U/L
Blank	Distilled Water
Delay time	100 sec.
No of readings	3
Interval	60 sec
Reagent volume	1000 µL
Sample volume	40 µL
Cuvette	1 cm light path

Application parameters for various instrument are available. Please contact customer support department for specific information.

Unit Conversion

Traditional Unit	SI Unit	Conversion from Traditional to SI
U/L	µKat/L	x 0.017

Calibration

Agappe multicalibrator is recommended for calibration of this assay on fully auto analyzers.

Use provided factor (4127) for estimation of this assay on Semi automated analyzer.

Procedure notes

Laboratory procedure for Semi Auto Analyzer.(Mono reagent Procedure)	
Working reagent	1000 µL
Sample	40 µL
Mix and incubate at 37°C for 1 minute. Measure the change in absorbance per minute (OD/min) during 3 minutes.	

SYMBOLS USED ON THE LABELS

IVD IN VITRO DIAGNOSTIC USE  SEE PACKAGE INSERT FOR PROCEDURE  LOT LOT NUMBER  MANUFACTURER'S ADDRESS  MANUFACTURING DATE  EXPIRY DATE  TEMPERATURE LIMIT

**AGAPPE DIAGNOSTICS LTD.**

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REV. NO.: ADL/IFU/CKNAC/LIQ/R02

CE ISO 9001 : 2015
EN ISO 13485: 2016

Two reagent Procedure

Reagent R1	200 µL
Reagent R2	50 µL
Mix and wait for 25 second and add sample 10 µL. mix well and incubate for 2 minutes at 37°C. measure the variation of absorbance per minute during 3 minute	

Calculation

Creatine Kinase Activity (U/L) = (Δ OD /min.) x 4127

Quality control

It is recommended to use Agappe Qualicheck Norm & Path (11601001) to verify the performance of the assay. Each laboratory has to establish its own internal quality control scheme and procedure for corrective action, if control do not recover within the acceptable range.

Reference Range

It is recommended that each laboratory establish its own reference value.

The following value may be used as guide line.

Men upto : < 171 U/L

Women upto : < 145 U/L

Results obtained for patient samples are to be correlated with clinical findings of patient for interpretation and diagnosis.

Performance**1. Linearity**

This reagent is linear upto 1700 U/L.

If the concentration is greater than linearity (1700 U/L) dilute the sample with normal saline and repeat the assay. Multiply the result with dilution factor.

2. Comparison

A comparison study has been performed between Agappe reagent and another internationally available reagent yielded a correlation coefficient of $r^2=0.9802$ and a regression equation of $y=1.035x$.

3. Precision

Intra Run		
	Control Level 1	Control Level 2
n	20	20
Mean (U/L)	130.2	445.4
SD	4.20	15.19
CV(%)	3.23	3.41

Inter Run

	Control Level 1	Control Level 2
n	20	20
Mean (U/L)	126.9	434.9
SD	4.8	16.7
CV(%)	3.8	3.8

Accuracy (U/L)

Control	Expected Value	Measured Value
Control Level 1	141 ± 28	131.8
Control Level 2	457 ± 91	435
Qualicheck Norm	145 ± 22.3	152.1
Qualicheck Path	510 ± 80	490

4. Sensitivity

Lower detection Limit is 2.0 U/L.

Bibliography

1. DGKC, J.Clin. chem.Clin. Bioch.15, 255 (1977).
2. Di. Witt, C. Tren delenburg, J. Clin chemie, Clin. Bioch. 20,235 (1982).


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