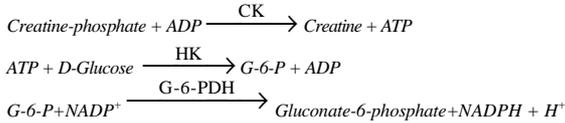


Cat. No.:	46961	46962	46963
	125 ml	600 ml	10x25 ml
	(1x100 ml+1x25ml)	(1x480 ml +1x125 ml)	(10x20 ml+ 10x5 ml)

Reagent kit for determination of creatine kinase activity in serum based upon IFCC and DGKC recommendations.

Creatine kinase (CK) is an enzyme which is found primarily in skeletal muscle, cardiac muscle and brain tissue. Elevated levels of CK are associated with myocardial infarction, various muscle disorders and diseases such as progressive Duchenne-type muscular dystrophy. In myocardial infarction, peak CK levels occur 24 to 36 hours after onset of chest pain and depending on the extent of damage can reach more than 10 times normal levels.

Principle



CK= Creatine kinase
HK= Hexokinase
G-6-P= Glucose-6-phosphate
G-6-PDH = Glucose-6-phosphate-dehydrogenase

Reference values

Female: 24-170 U/l (0,4-2,83 µkat/l)
Male: 24-195 U/l (0,4-3,25 µkat/l)

It is recommended that each laboratory should assign its own normal range.

Reagents

1 Reagent (R1)

Imidazole buffer, pH=6,70	125 mmol/l
N-Acetyl-L-Cysteine	25 mmol/l
Magnesium acetate	11 mmol/l
D-Glucose	25 mmol/l
EDTA	2 mmol/l
AMP	6,26 mmol/l
NADP	2,5 mmol/l
Diadenosine pentaphosphate	13 µmol/l
Hexokinase	6800 U/l

2 Reagent (R2)

Creatine-phosphate	166 mmol/l
ADP	15 mmol/l
G-6PDH	8800 U/l

Precaution

These reagents contain sodium azide (<0.1%). To avoid the possible build-up of azide compounds, flush waste-pipes with water after the disposal of undiluted reagent. Avoid contamination by using clean laboratory materials (pipette, plastic vial for analyzers). Discard cloudy reagent.

Sample

Serum free of haemolysis.

PROCEDURE

Preparation and stability of working reagent

• One-reagent procedure:

Mix 4 volumes of R1 with 1 volume of R2.

Stability:	20-25°C:	2 days
	2-8°C:	1 week

• Two-reagent procedure:

Reagents are ready to use.

If the absorbance of working reagent is higher than 1.0 at 334 nm the reagent can not be used.

Assay conditions

Wavelength:	340 nm
Temperature:	37°C
Cuvette:	1 cm light path
Read against:	distilled water
Method:	kinetic (increasing)

One-reagent procedure

Working reagent	1 ml
Sample	40 µl

Mix and after a 3-minute incubation, measure the change of absorbance per minute (ΔA/min) during 3 minutes.

Two-reagent procedure

Reagent 1	1 ml
Sample	50 µl

Mix and wait 3 minutes.

Reagent 2	250 µl
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Mix and after a 2-minute incubation, measure the change of absorbance per minute (ΔA/min) during 3 minutes.

Calibration: (37°C, IFCC method)

S1: Distilled water

S2: Roche C.F.A.S. (Calibrator for automated system) or

Randox Calibration Serum Level I or

Randox Calibration Serum Level II

Calibration frequency

Two point calibration is recommended:

- after reagent lot change,

- as required following quality control procedures.

Calculation

$$\frac{\Delta A_{\text{sample}}}{\Delta A_{\text{standard}}} \times C_{\text{standard}} = C_{\text{sample}}$$

A = Absorbance, C = Concentration

Calculation using factor

Activity (U/l) = ΔA/min x 6232; (µkat/l) = ΔA/min x 103,8

Quality control

A quality control program is recommended for all clinical laboratories. The analysis of control material in both the normal and abnormal ranges with each assay is recommended for monitoring the performance of the procedure. Each laboratory should establish corrective measures to be taken if values fall outside the limits.

PERFORMANCES DATA

The following data were obtained using the Olympus 600 analyzer (37°C).

Linearity

The test is linear up to 1032 U/l (17,2 µkat/l) creatine-kinase activity.

Sensitivity

It is recommended that each laboratory establishes its own range of sensitivity as this is limited by the sensitivity of the spectrophotometer used. Under manual conditions however, a change of 0.001 Abs units/min is equivalent to 4.127 U/l (0,07µkat/l) creatine-kinase activity at 334 nm.

Precision

Sample	Reproducibility		
	Average activity (U/l)	SD	CV%
sample I	148	5.50	3.71
sample II	436	8.76	2.01

	Repeatability		
	Average activity (U/l)	SD	CV%
sample I	90.1	1.28	1.42
sample II	605	4.67	0.77

Correlation

Comparative studies were done to compare our reagent with our Creatine-kinase powder reagent.

The results from these studies are detailed below.

Correlation coefficient: r=0.9999

Linear regression: y (U/l)= 0.955x-5.798

(x= powder reagent, y= liquid reagent).

Specificity

Bilirubin 855µmol/l (50mg/dl), lipid 700mg/dl, glucose 55.5mmol/l (1000mg/dl) and ascorbic acid 2.84mmol/l (50mg/dl) don't interfere with the assay up to the given levels.

NOTE

Do not use reagents after the expiry date stated on each reagent container label. Do not use products, test solutions and reagents described above for any purpose other than described herein.

For in vitro diagnostic use only.

The following symbols are used on labels

 For in vitro diagnostic use

 Use by (last day of the month)

 Temperature limitation

 Batch Code

 Code

Bibliography

1: Mathieu M. et coll Recommendation pour la mesure de la concentration catalytique de la creatinine kinase dans le serum humain. Ann. Biol. Clin., 40, (1982) 87.