CE IVD DIALAB

Liquid Reagents – ready to use

CK-NAC

(Creatine Kinase - NAC)

opt. DGKC / IFCC

2 Reagents

Diagnostic reagent for quantitative in vitro determination of creatinkinase (CK-NAC) in human serum or plasma on photometric systems

REF Cont.

D94581	**5 x 50 ml**	4 x 50 ml	Reagent 1
		1 x 50 ml	Reagent 2

Additionally offered:

D98485	5 x 3 ml	Calibrator	Diacal Auto
D98481	12 x 5 ml	Control normal	Diacon N
D98482	12 x 5 ml	Control abnormal	Diacon P

TEST PARAMETERS

Method:	UV, Kinetic, Increasing Reaction Optimized DGKC
Wavelength:	Hg 334 nm, Hg 365 nm, 340 nm
Temperature:	37°C
Sample:	Serum, EDTA-plasma, heparin plasma
Linearity:	up to 1050 U/L
Sensitivity:	The lower limit of detection is 1 U/L.

REAGENT COMPOSITION

COMPONENTS	CONCENTRATION
Reagent 1:	
Imidazole, pH 6.5	60 mmol/L
Glucose	27 mmol/L
N-Acetylcysteine (NAC)	27 mmol/L
Magnesium acetate	14 mmol/L
EDTA-Na_2	2 mmol/L
NADP	2.7 mmol/L
Hexokinase (HK)	≥ 5 kU/L
Reagent 2:	
Imidazole	160 mmol/L
ADP	11 mmol/L
AMP	28 mmol/L
Diadenosine pentaphosphate	55 µmol/L
Glucose-6-phosphate dehydrogenaase (G6P-DH)	≥ 14 kU/L
EDTA-Na_2	2 mmol/L
Creatine phosphate	160 mmol/L

REAGENT PREPARATION

Substrate Start:

Reagents are ready for use.

Sample Start:

Mix 4 parts of Reagent 1 with 1 part of Reagent 2.
(= Working Reagent)

REAGENT STABILITY AND STORAGE

Conditions: protect from light
close immediately after use
do not freeze the reagents!

Substrate Start:

Storage: at 2 – 8°C
Stability: up to the expiration date

Sample Start (Working Reagent):

Stability:	at 2 – 8°C	3 weeks
	at 15 – 25°C	2 days

Protect from light!

SAMPLE STABILITY AND STORAGE

Stability [7]:	at 4 – 8 °C	7 days
	at 20 – 25 °C	2 day
(in the dark)	at - 20°C	4 weeks

Discard contaminated specimens.

INTERFERING SUBSTANCES

no interference up to:

ascorbic acid	30 mg/dl
bilirubin	40 mg/dl
hemoglobin	200 mg/dl
triglycerides	2000 mg/dl

MANUAL TEST PROCEDURE

Bring reagents and samples to room temperature.

Substrate Start

Pipette into test tubes:	Blank	Sample/Cal.
Sample	-	50 µl
Dist. water	50 µl	-
Reagent 1	1000 µl	1000 µl
Mix. Incubate for approximately 3 minutes. Then add:		
Reagent 2	250 µl	250 µl
Mix. Read initial absorb. after 2 min. at 37°C and start a timer. Read absorbance again after exactly 1, 2 and 3 min. at 37°C ΔA/min = [ΔA/min sample] – [ΔA/min blank]		

Sample Start

Pipette into test tubes:	Blank	Sample/Cal.
Sample	-	40 µl
Dist. water	40 µl	-
Working Reagent	1000 µl	1000 µl
Mix. Read initial absorb. after 3 min. at 37°C and start a timer. Read absorbance again after exactly 1, 2 and 3 min. at 37°C ΔA/min = [ΔA/min sample] – [ΔA/min blank]		

CALCULATION (light path 1 cm)

With factor :

CK-NAC (U/L) = ΔA/min x factor

Factors (37°C):

Factor for :	**340 nm**	**=**	4127
Factor for :	**334 nm**	**=**	4207
Factor for :	**365 nm**	**=**	7429

With calibrator :

$$\text{CK-NAC [U/L]} = \frac{\Delta A/\text{min Sample}}{\Delta A/\text{min Calibrator}} \times \text{Conc. of Cal [U/L]}$$

UNIT CONVERSION

U/L x 0,01667 = µkatal/L

REFERENCE RANGE (U/L)

Adults [3]		**Children** [1]	
Females	< 145	Umbilical cord blood	175 - 402
Males	< 171	Newborns	468 - 1200
		≤ 5 days	195 - 700
		< 6 months	41 - 330
		> 6 months	24 - 229

These reference ranges ensure high diagnostic sensitivity. The diagnostic specificity is low; however, it can be improved by additional measurement of CK-MB.
The risk of myocardial infarction is high if following three conditions are fulfilled [5]:

1. CK (men) > 190 U/L (3.12 µkat/L)*
   CK (women) > 167 U/L (2.87 µkat/L)*
2. CK-MB > 24 U/L (0.40 µkat/L)*
3. CK-MB activity is between 6 and 25% of total CK activity.

* calculated using temperature conversion factor 2.38 (25°C → 37°C)

If myocardial infarction is suspected and the conditions are not fulfilled, the infarction may be fresh. In this case the measurements should be repeated after 4 hours with fresh samples.
In healthy individuals different values are found depending on race and age [5,6].
Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary. For diagnostic purposes CK values should always be assessed in conjunction with the anamnesis, the clinical examination and other findings.

TEST PRINCIPLE

$$\text{Creatine phosphate} + \text{ADP} \xleftarrow{\text{CK}} \text{Creatine} + \text{ATP}$$

$$\text{ATP} + \text{Glucose} \xrightarrow{\text{HK}} \text{ADP} + \text{Glucose-6-phosphate (G-6-P)}$$

$$\text{G-6-P} + \text{NADP}^+ \xrightarrow{\text{G-6-P-DH}} \text{6-PG} + \text{NADPH} + \text{H}^+$$

PERFORMANCE CHARACTERISTICS

LINEARITY

The test has been developed to determine CK activities which correspond to a maximal ΔA/min of 0.25 at 340 nm and 334 nm or 0.14 at 365 nm.

If these values are exceeded, the sample should be diluted 1+9 with NaCl solution (9 g/L sodium chloride in dist. water) and results multiplied by 10.

PRECISION (at 37 °C)

Intra-assay, n = 20	Mean [U/L]	SD [U/L]	CV [%]
Sample 1	159	3.18	2.00
Sample 2	220	1.54	0.70
Sample 3	508	3.69	0.73

Inter-assay, n = 20	Mean [U/L]	SD [U/L]	CV [%]
Sample 1	157	1.63	1.04
Sample 2	228	2.31	1.01
Sample 3	507	4.09	0.81

METHOD COMPARISON

A comparison of the Dialab CK-NAC (y) with the IFCC reference reagent (x) using 51 samples gave following results:
y = 0.997 x + 0.249 U/L; r = 0.999.
A comparison between Dialab CK-NAC (y) and a commercially available test (x) using 51 samples gave following results:
y = 1.031 x + 0.059 U/L; r = 1.000.

QUALITY CONTROL

All control sera with CK-NAC values determined by this method can be used. We recommend:

REF	Cont.		
D98481	12 x 5 ml	**DIACON N**	Assayed Control Serum Normal
D98482	12 x 5 ml	**DIACON P**	Assayed Control Serum Abnormal

CALIBRATION

The use of a CK-NAC Calibrator is optional. We recommend:

REF	Cont.		
D98485	1 x 3 ml	**DIACAL AUTO**	Assayed Multi Calibration Serum

AUTOMATION

Special adaptations for automated analyzers can be made on request.

WARNINGS AND PRECAUTIONS

1. Reagent 2 is toxic: T
   R61: May cause harm to the unborn child.
   S53: Avoid exposure – obtain special instructions before use.
   S28: After contact with skin, wash immediately with plenty of water.
   S29: Do not empty into drains.
   S36/37: Wear suitable protective clothing and gloves.
   S45: In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible)
2. The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
3. Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents.

WASTE MANAGEMENT

Please refer to local legal requirements.

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IVD

DIALAB Produktion und Vertrieb von chemisch – technischen Produkten und Laborinstrumenten Gesellschaft m.b.H.
A – 2351 Wiener Neudorf, Austria
IZ-NÖ Süd, Hondastrasse, Objekt M55
Phone: ++43 (0) 2236 660910-0
Fax: ++43 (0) 2236 660910-30 e-mail: office@dialab.at