respons®910

Creatinine PAP FS*

Diagnostic reagent for quantitative in vitro determination of creatinine in serum, plasma or urine on DiaSys respons[®]910

Order Information

Cat. No. 1 1759 99 10 920 4 twin containers for 180 tests each

Method

Enzymatic colorimetric test

Principle

Creatinine is determined by the following reaction:

Creatinine + H₂O \leftarrow Creatininase \leftarrow Creatine Creatine + H₂O \leftarrow Creatinase \leftarrow Sarcosine + Urea Sarcosine + O₂ + H₂O \leftarrow Sarcosine oxidase \leftarrow Glycine + HCHO + H₂O₂ H₂O₂ + HTIB + 4-AA \leftarrow Peroxidase \leftarrow Quinone dye

The absorbance of the produced red dye at 545 nm is proportional to the creatinine concentration in the sample.

Reagents

Components and Concentrations

R1:	Goods buffer	pH 8.1	25 mmol/L
	Creatinase		≥ 30 kU/L
	Sarcosine oxidase		≥ 10 kU/L
	Ascorbate oxidase		≥ 2.5 kU/L
	Catalase		≥ 350 kU/L
	HTIB (3-Hydroxy 2,4,6	S-triiodo benzoic acid)	2.3 mmol/L
R2:	Goods buffer	pH 8.1	25 mmol/L
	Creatininase		≥ 150 kU/L
	Peroxidase		≥ 50 kU/L
	4-Aminoantipyrine (4-	4A)	2 mmol/L
	Potassium hexacyano	ferrate	0.18 mmol/L

Storage Instructions and Reagent Stability

The reagents are stable up to the end of the indicated month of expiry, if stored at 2 - 8° C, protected from light and contamination is avoided. DiaSys respons containers provide protection from light. Do not freeze the reagents!

Warnings and Precautions

- 1. Reagent 2 contains sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
- 2. High homogentisic acid concentrations in urine samples lead to false results.
- 3. In very rare cases, samples of patients with gammopathy might give falsified results [9].
- Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.
 For professional use only!

Waste Management

Please refer to local legal requirements.

Reagent Preparation

The reagents are ready to use. The bottles are placed directly into the reagent rotor.

Specimen

-					
Serum,	heparin	plasma	or	urine	

Stability [1]:		
Serum/plasn	na	
7 days	at	4 - 25°C
3 months	at	-20°C
Urine		

2 days	at	20 - 25°C
6 days	at	4 - 8°C
6 months	at	-20°C

Discard contaminated specimens. Freeze only once.

Calibrators and Controls

For calibration, the DiaSys TruCal U calibrator is recommended. The calibrator values have been made traceable to NIST (National Institute for Standardization) Standard Reference Material SRM 967 using level 1 and 2 and, therefore, to GC-IDMS (gas chromatography-isotope dilution mass spectrometry). For internal quality control DiaSys TruLab N and P or TruLab Urine controls should be assayed. Each laboratory should establish corrective action in case of deviations in control recovery.

	Cat. No.		Kit s	size
TruCal U	5 9100 99 10 063	20	х	3 mL
	5 9100 99 10 064	6	х	3 mL
TruLab N	5 9000 99 10 062	20	х	5 mL
	5 9000 99 10 061	6	х	5 mL
TruLab P	5 9050 99 10 062	20	х	5 mL
	5 9050 99 10 061	6	х	5 mL
TruLab Urine Level 1	5 9170 99 10 062	20	х	5 mL
	5 9170 99 10 061	6	х	5 mL
TruLab Urine Level 2	5 9180 99 10 062	20	х	5 mL
	5 9180 99 10 061	6	х	5 mL

Performance Characteristics

Measuring range up to 160 mg/dL creatinine in serum and 440 mg/dL in urine (in case of higher concentrations re-measure samples after manual dilution or use rerun function)		
Limit of detection** 0.1 mg/dL creatinine		
On-board stability 14 days		
Calibration stability 7 days		

Interfering substance	Interferences (serum) < 10%	Creatinine [mg/dL]
Ascorbate	up to 30 mg/dL	1.16
Hemoglobin	up to 400 mg/dL	1.55
	up to 550 mg/dL	5.08
Bilirubin, conjugated	up to 30 mg/dL	1.81
	up to 35 mg/dL	16.2
Bilirubin, unconjugated	up to 20 mg/dL	1.75
	up to 30 mg/dL	16.2
Lipemia (triglycerides)	up to 1000 mg/dL	1.66
	up to 2000 mg/dL	15.4
Creatine	up to 40 mg/dL	1.52
	up to 60 mg/dL	15.0
Proline	up to 12 mg/dL	1.10
For further information on ir	terfering substances re	fer to Young DS [8].

Precision in serum			
Within run (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	0.79	1.31	8.04
Coefficient of variation [%]	2.09	1.77	1.46
Between run (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	0.57	1.07	6.54
Coefficient of variation [%]	3.20	2.62	1.88

Method comparison in serum (n=149)		
Test x	DiaSys Creatinine PAP FS (Hitachi 917)	
Test y DiaSys Creatinine PAP FS (respons [®] 91		
Slope	1.01	
Intercept	0.033 mg/dL	
Coefficient of correlation	0.99996	

Precision in urine

Within run (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	60.0	167	261
Coefficient of variation [%]	2.77	2.40	2.18
Between run (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	36.4	164	255

Method comparison in urine (n=110)

Test x	DiaSys Creatinine PAP FS	
	(BioMajesty 6010)	
Test y	DiaSys Creatinine PAP FS (respons [®] 910)	
Slope	0.992	
Intercept	-0.171 mg/dL	
Coefficient of correlation	0.9995	

** according to NCCLS document EP17-A, vol. 24, no. 34

responsegio

Calculation of Creatinine-Clearance [mL/min/1.73 m²] [2]

mg Creatinine /100 mL Urine × mL Urine mg Creatinine / 100 mL Serum × min Urine collection time

The calculated creatinine clearance refers to the average body surface of an adult (1.73 m²).

Conversion factor

Creatinine [mg/dL] x 88.4 = Creatinine [µmol/L]

Reference Range

Serum/Plasma					
	mg/dL	µmol/L			
Adults [4]					
Women	0.51 – 0.95	45 - 84			
Men	0.67 – 1.17	59 – 104			
Children [5]					
0 – 7 days	0.6 - 1.1	53 - 97			
1 week – 1 month	n 0.3 – 0.7	27 - 62			
1 – 6 month(s)	0.2 - 0.4	18 - 35			
7 – 12 months	0.2 - 0.4	18 - 35			
1 – 18 year(s)	0.2 - 0.7	18 - 62			
1 st Morning urin	e [4]				
Women	29 – 226 mg/dL	2.55 – 20.0 mmol/L			
Men	40 – 278 mg/dL	3.54 – 24.6 mmol/L			
24h urine [2]					
Women	720 – 1510 mg/24h	6 – 13 mmol/24h			
Men	980 – 2200 mg/24h	9 – 19 mmol/24h			
Creatinine clearance [2]					

66.3 - 143 mL/min/1.73 m²

Albumin/creatinine ratio (early morning urine) [10]:

< 30 mg Albumin/g Creatinine

Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

Literature

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Manufacturer



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respons®910

Creatinine PAP FS

Application for serum, plasma or urine samples

This application was set up and evaluated by DiaSys. It is based on the standard equipment at that time and does not apply to any equipment modifications undertaken by unqualified personnel

NormitationYesThis method is usable for analysis:YesTwin reaction:NoName:CREAPShortcut:Image: CREAPReagent barcode reference:031Host reference:Image: CREAPType:End pointFirst reagent:[µL]160Blanc correctionYesSecond reagent:[µL]80Blanc correctionYesMain wavelength:[nm]546Second reagent:[µL]10001s treading time [min:sec](04:24)Last reading time [min:sec]10:00Reaction way:IncreasingLinear KineticsIncreasingSubstrate depletion: Absorbance limitIncreasingLinear KineticsSubstrate depletion: Absorbance limitSubstrate depletion: Absorbance limitEndpointStability: Largest remaining slopeProzone Limit [%]Prozone Limit [%]0Concentration technical limits-Lower0.1Concentration technical limits-Lower0.1Concentration technical limits-Lower0.1Concentration technical limits-Lower10Above normal volume [µL]4Above normal volume [µL]4Abov	Identification	
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Results	Posults		
Decimals		2	
Units		mg/dL	
Correlation fac	ctor_Offect	0.000	
Correlation fac		1.000	
Conelation la	ciol-olope	1.000	
Range			
Gender		Male	
Age			
SERUM		>=0.7<=1.2	
URINE		>=40<=278	
PLASMA		>=0.7<=1.2	
CSF			
Gender		Female	
Age			
SERUM		>=0.5<=1.0	
URINE		>=29 <=226	
PLASMA		>=0.5<=1.0	
CSF			
Contaminants			
Contaminant			
Wash with	I		
Volume [µL]	2		
Contaminant 2	2		
Wash with			
Cycle			
Volume [µL]			
Contaminant 3			
Wash with			
Cycle			
Volume [µL]			
Calibrators details			
Calibrator li	st	Concentration	
Cal. 1		0	
Cal. 2		**	
Cal. 3			
Cal. 4			
Cal. 5			
Cal. 6			
	Max delta abs.		
Cal. 1	0.003		
Cal. 2	0.010		
Cal. 3			
Cal. 4			
Cal. 5			
Cal. 6			
Drift limit [%]	0.8		
Calculations			
Model		Х	
Degree 1			
** Enter calibrator value			

** Enter calibrator value