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:

$$\text{Creatinine} + H_2O \xleftrightarrow{\text{Creatininase}} \text{Creatine}$$

$$\text{Creatine} + H_2O \xleftrightarrow{\text{Creatinase}} \text{Sarcosine} + \text{Urea}$$

$$\text{Sarcosine} + O_2 + H_2O \xleftrightarrow{\text{Sarcosine oxidase}} \text{Glycine} + HCHO + H_2O_2$$

$$H_2O_2 + \text{HTIB} + \text{4-AA} \xleftrightarrow{\text{Peroxidase}} \text{Quinone dye}$$

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-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-AA)		2 mmol/L
	Potassium hexacyanoferrate		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].
4. 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.
5. 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/plasma		
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 size
TruCal U	5 9100 99 10 063	20 x 3 mL
	5 9100 99 10 064	6 x 3 mL
TruLab N	5 9000 99 10 062	20 x 5 mL
	5 9000 99 10 061	6 x 5 mL
TruLab P	5 9050 99 10 062	20 x 5 mL
	5 9050 99 10 061	6 x 5 mL
TruLab Urine Level 1	5 9170 99 10 062	20 x 5 mL
	5 9170 99 10 061	6 x 5 mL
TruLab Urine Level 2	5 9180 99 10 062	20 x 5 mL
	5 9180 99 10 061	6 x 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 interfering substances refer 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®910)
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
Coefficient of variation [%]	4.00	3.45	5.09

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

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

$$= \frac{\text{mg Creatinine / 100 mL Urine} \times \text{mL Urine}}{\text{mg Creatinine / 100 mL Serum} \times \text{min Urine collection time}}$$

The calculated creatinine clearance refers to the average body surface of an adult (1.73 m^2).

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	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

1st Morning urine [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 m^2

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

IVD CE

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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

Identification	
This method is usable for analysis:	Yes
Twin reaction:	No
Name:	CREAP
Shortcut:	
Reagent barcode reference:	031
Host reference:	

Technic	
Type:	End point
First reagent:[µL]	160
Blanc correction	Yes
Second reagent:[µL]	80
Blanc correction	Yes
Main wavelength:[nm]	546
Secondary wavelength:[nm]	700
Polychromatic factor:	1.000
1 st reading time [min:sec]	(04:24)
Last reading time [min:sec]	10:00
Reaction way:	Increasing
Linear Kinetics Substrate depletion: Absorbance limit	
Linearity: Maximum deviation [%]	
Fixed Time Kinetics Substrate depletion: Absorbance limit	
Endpoint Stability: Largest remaining slope	
Prozone Limit [%]	

Sample	
Diluent	DIL A (NaCl)
Hemolysis:	
Agent [µL]	0 (no hemolysis)
Sample [µL]	0
Concentration technical limits-Lower	0.1
Concentration technical limits-Upper	160 (440)*
SERUM	
Normal volume [µL]	4
Normal dilution (factor)	1
Below normal volume [µL]	8
Below normal dilution (factor)	1
Above normal volume [µL]	4
Above normal dilution (factor)	6
URIN	
Normal volume [µL]	4
Normal dilution (factor)	10
Below normal volume [µL]	8
Below normal dilution (factor)	10
Above normal volume [µL]	4
Above normal dilution (factor)	16
PLASMA	
Normal volume [µL]	4
Normal dilution (factor)	1
Below normal volume [µL]	8
Below normal dilution (factor)	1
Above normal volume [µL]	4
Above normal dilution (factor)	6
CSF	
Normal volume [µL]	4
Normal dilution (factor)	1
Below normal volume[µL]	8
Below normal dilution (factor)	1
Above normal volume [µL]	4
Above normal dilution (factor)	6

()* Upper technical limit for urine measurements

Results	
Decimals	2
Units	mg/dL
Correlation factor-Offset	0.000
Correlation factor-Slope	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 1	
Wash with	
Cycle	
Volume [µL]	
Contaminant 2	
Wash with	
Cycle	
Volume [µL]	
Contaminant 3	
Wash with	
Cycle	
Volume [µL]	

Calibrators details	
Calibrator list	**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	X
Degree	1

** Enter calibrator value