

## **Creatinine PAP FS\***

Diagnostic reagent for quantitative in vitro determination of creatinine in serum, plasma or urine on DiaSys respons®920

## **Order Information**

Cat. No. 1 1759 99 10 920

4 twin containers for 180 determinations each

#### Method

Enzymatic colorimetric test

## **Principle**

Creatinine is determined by the following reaction:



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-tr	iiodo 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 hexacyanofer	rate	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**

- Reagent 2 contains sodium azide (0.95 g/L) as preservative.
   Do not swallow! Avoid contact with skin and mucous membranes.
- 2. To avoid carryover interference, please take care of efficient washing especially after use of interfering reagents. Please refer to the DiaSys respons®920 Carryover Pair Table. Carryover pairs and automated washing steps with the recommended cleaning solution can be specified in the system software. Please refer to the user manual.
- High homogentisic acid concentrations in urine samples lead to false results.
- In very rare cases, samples of patients with gammopathy might give falsified results [9].
- N-acetylcysteine (NAC), acetaminophen, metamizole and phenindione medication leads to falsely low, eltrombopag medication to falsely low or high results in patient samples.
- 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/plasma

7 days at  $4-25^{\circ}$ C 3 months at  $-20^{\circ}$ C

#### Urine

2 days at  $20 - 25^{\circ}$ C 6 days at  $4 - 8^{\circ}$ C 6 months at  $-20^{\circ}$ C

TruLab urine controls must be prediluted the same way as patient samples.

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.	ŀ	<it s<="" td=""><td>size</td></it>	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	Χ	5 mL
	5 9050 99 10 061	6	Χ	5 mL
TruLab Urine Level 1	5 9170 99 10 062	20	Χ	5 mL
	5 9170 99 10 061	6	Χ	5 mL
TruLab Urine Level 2	5 9180 99 10 062	20	Χ	5 mL
	5 9180 99 10 061	6	Х	5 mL

## **Performance Characteristics**

Measuring range in serum up to 80 mg/dL creatinine and in urine up to 700 mg/dL creatinine (in case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function).

	function).		
Limit of detection**		0.03 mg/dL creatinine	
	On-board stability	4 weeks	
	Calibration stability	4 weeks	

Interferences (serum)< 10% by
Ascorbate up to 30 mg/dL
Hemoglobin up to 500 mg/dL
Bilirubin up to 30 mg/dL
Creatine up to 30 mg/dL
Lipemia (triglycerides) up to 1000 mg/dL
Proline up to 12 mg/dL
For further information on interfering substances refer to Young S [8]

Precision in serum						
Within run (n=20)	Sample 1	Sample 2	Sample 3			
Mean [mg/dL]	1.02	1.21	7.57			
Coefficient of variation [%]	2.68	3.01	0.88			
Between run (n=20)	Sample 1	Sample 2	Sample 3			
Mean [mg/dL]	1.00	1.11	7.53			
Coefficient of variation [%]	3.21	2.59	2.63			

Method comparison in serum (n=101)					
Test x DiaSys Creatinine PAP FS (Hitachi 917)					
Test y DiaSys Creatinine PAP FS (respons®920)					
Slope 1.00					
Intercept	-0.04 mg/dL				
Coefficient of correlation 0.999					



Precision in urine			
Within run (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	67.2	149	238
Coefficient of variation [%]	2.47	2.95	3.12
Between run (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	31.3	149	238
Coefficient of variation [%]	2.90	3.24	3.33

Method comparison in urine (n=109)				
Test x DiaSys Creatinine PAP FS (BioMajesty 60				
Test y	DiaSys Creatinine PAP FS (respons®920)			
Slope	1.01			
Intercept	-0.970 mg/dL			
Coefficient of correlation	0.9999			

<sup>\*\*</sup> lowest measurable concentration which can be distinguished from zero mean + 1.645 SD (n=60) of an analyte free specimen

## Calculation of Creatinine-Clearance [mL/min/1.73 m<sup>2</sup>] [2]

mg Creatinine / 100 mL Urine × mL Urine

The calculated creatinine clearance refers to the average body surface of an adult (1.73 m<sup>2</sup>).

## Reference Range

Serum/Plasma Adults [4]	mg/dL	µmol/L
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

### First morning urine [4]

## 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<sup>2</sup>

### 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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   Thomas L. Clinical Laboratory Diagnostics. 1<sup>st</sup> ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 366-74.
- Young DS. Effects of Drugs on Clinical Laboratory Tests. 5th. ed. Volume 1 and 2. Washington, DC: The American Association for Clinical Chemistry Press, 2000.
- Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed 2007;45(9):1240-1243.
- Dati F, Metzmann E. Proteins-Laboratory testing and clinical use. 1<sup>st</sup> ed. Holzheim: DiaSys Diagnostic Systems; 2005: p. 93.

### Manufacturer



DiaSys Diagnostic Systems GmbH Alte Strasse 9 65558 Holzheim Germany

mg Creatinine / 100 mL Serum × min Urine collection time



## **Creatinine PAP FS**

## Application for serum and plasma

Test I	Details	Test Vo	lumes	Reference Ranges	
Test	: CREAP			Auto Rerun	
	: Creatinine PAP			Online Calibration	
	: mg/dL	Decimal Places	: 2	Cuvette Wash □	
Wavelength-Primary	: 546	Secondary	: 700	Total Reagents : 2	
Assay Type	: 2-Point	Curve Type	: Linear	Reagent R1 : CREAP R1	
M1 Start	: 15	M1 End	: 15	Reagent R2 : CREAP R2	
M2 Start	: 33	M2 End	: 33	]	
Sample Replicates	: 1	Standard Replicates	: 3	Consumables/Calibrators:	
Control Replicates	: 1	Control Interval	: 0	Blank /Level 0 0	
Reaction Direction	: Increasing	React. Abs. Limit	: 0.0000	Calibrator 1 *	
Prozone Limit %	: 0	Prozone Check	: Lower	]	
Linearity Limit %	: 0	Delta Abs./Min.	: 0.0000	]	
Technical Minimum	: 0.0300	Technical Maximum	: 80.0000	]	
Y = aX + b a=	: 1.0000	b=	: 0.0000	]	

Test Details		Test V	olumes	Reference Ranges
Test	: CREAP			
Sample Type	: Serum/plasma			
	Sampl	e Volumes		Sample Types
Normal	: 5.00 μL	Dilution Ratio	: 1 X	☑ Serum □ Urine
Increase	: 8.00 µL	Dilution Ratio	: 1 X	☐ CSF ☑ Plasma
Decrease	: 2.00 µL	Dilution Ratio	: 1 X	☐ Whole Blood ☐ Other
Standard Volume	: 5.00 μL			
	Reagent Volume	es and Stirrer Speed		
RGT-1 Volume	: 180 µL	R1 Stirrer Speed	: Medium	
RGT-2 Volume	: 90 µL	R2 Stirrer Speed	: High	

Test	Details	Test Volumes	Reference Ranges
Test Sample Type	: CREAP : Serum/plasma		
Reference Range Category	: DEFAULT : Male		
	Reference Rai	nge	Sample Types
	Lower Limit (mg/dL)	Upper Limit (mg/dL)	☑ Serum □ Urine □ CSF ☑ Plasma □ Whole Blood
Normal	: 0.67	1.17	□ Other
Panic	: 0.00	0.00	

<sup>\*</sup> Enter calibrator value.



# **Creatinine PAP FS**

## **Application for Urine**

Test Details		Test Volumes		Reference Ranges		
Test	: CREAP	]		Auto Rerun		
	: Creatinine PAP			Online Calibration		
	: mg/dL	Decimal Places	: 2	Cuvette Wash		
Wavelength-Primary	: 546	Secondary	: 700	Total Reagents	: 2	
Assay Type	: 2-Point	Curve Type	: Linear	Reagent R1	: CREAP R1	
M1 Start	: 15	M1 End	: 15	Reagent R2	: CREAP R2	
M2 Start	: 33	M2 End	: 33			
Sample Replicates	: 1	Standard Replicates	: 3	Consumables/Ca	librators:	
Control Replicates	: 1	Control Interval	: 0	Blank /Level 0	0	
Reaction Direction	: Increasing	React. Abs. Limit	: 0.0000	Calibrator 1	*	
Prozone Limit %	: 0	Prozone Check	: Lower			
Linearity Limit %	: 0	Delta Abs./Min.	: 0.0000			
Technical Minimum	: 0.0300	Technical Maximum	: 700.0000			
Y = aX + b $a=$	: 1.0000	b=	: 0.0000			

Test Details		Test Volumes		Reference Ranges	
Test Sample Type	: CREAP : Urine				
Sample Volumes					Sample Types
Normal	: 5.00 μL	Dilution Ratio	: 10 X		☐ Serum ☑ Urine
Increase	: 8.00 µL	Dilution Ratio	: 5 X		☐ CSF ☐ Plasma
Decrease	: 2.00 µL	Dilution Ratio	: 20 X		☐ Whole Blood ☐ Other
Standard Volume	: 5.00 µL				
	Reagent Volume				
RGT-1 Volume	: 180 μL	R1 Stirrer Speed	: Medium		
RGT-2 Volume	: 90 µL	R2 Stirrer Speed	: High		

Test Details		Test Volumes	Reference Ranges	
Test Sample Type	: CREAP : Urine			
Reference Range Category	: DEFAULT : Male			
	Reference Ra	Sample Types		
Normal Panic	Lower Limit (mg/dL) : 40 : 0.00	Upper Limit (mg/dL)  278  0.00	☐ Serum ☐ Urine ☐ CSF ☐ Plasma ☐ Whole Blood ☐ Other	

<sup>\*</sup> Enter calibrator value.