


Creatinine PAP FS*

Order Information

Cat. No.

1 1759 99 10 920

Kit size

 720 (4 x 180)

Intended Use

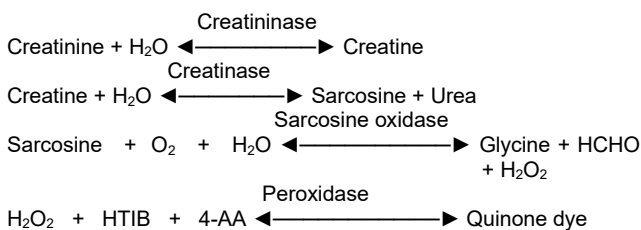
Diagnostic reagent for quantitative in vitro determination of creatinine in human serum, heparin plasma or urine on automated respons[®]920.

Summary

Creatinine, a molecule produced by muscle cells, is a byproduct of creatine metabolism and is excreted in urine [1]. Since healthy kidneys consistently filter creatinine through the glomeruli, its blood concentration serves as a marker of kidney function [2]. Creatinine determination is used to evaluate kidney function and detect general kidney damage but is not intended for early-stage detection. Elevated plasma or serum levels indicate impaired kidney function, although age, gender, and muscle mass can influence results [1]. The glomerular filtration rate (GFR) is a more accurate kidney function measure, with a reduced GFR indicating decreased filtration ability [3]. Calculating creatinine clearance, based on plasma, serum, and a 24-hour urine sample, provides a direct kidney filtration assessment, but complex handling may lead to errors [1]. The currently recommended strategy for GFR estimation is based on specific formulas using plasma or serum creatinine values. The latest KDIGO guideline recommends the use of the 2021 CKD-EPI or EKFC formula [4]. This approach is used to screen, diagnose, and classify kidney disease and monitor patients with kidney damage [1,3,4]. Chronic kidney disease (CKD) is one of the most common causes of impaired kidney function. As outlined in the KDIGO guideline CKD is diagnosed when the estimated GFR remains below 60 mL/min/1.73 m² for over three months [4].

Method

Enzymatic, colorimetric test in which creatinine is converted by the use of several enzymes (creatininase, creatinase, and sarcosine oxidase) to produce hydrogen peroxide. In a final reaction in the presence of 4-aminophenazone, the enzyme peroxidase catalyzes the hydrogen peroxide and generates a red quinone dye. The amount of produced red dye measured by the change of absorption at 545 nm is proportional to the amount of creatinine present in the sample. [5, 6]



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

Reagents

Components and Concentrations

R1:	Good's 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:	Good's 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 and Stability

Reagents are stable up to the date of expiry indicated on the kit, if stored at 2 – 8°C and contamination is avoided. Do not freeze and protect from light.

The open-vial stability of the reagent is 9 months until expiry date.

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. The reagents contain material of biological origin. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practice.
3. High homogentisic acid concentrations in urine samples lead to false results.
4. In very rare cases, samples of patients with gammopathy might give falsified results [7].
5. N-acetylcysteine (NAC), acetaminophen, metamizole and phenindione medication leads to falsely low, eltrombopag medication to falsely low or high results in patient samples.
6. 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.
7. In case of product malfunction or altered appearance that could affect the performance, contact the manufacturer.
8. Any serious incident related to the product must be reported to the manufacturer and the competent authority of the Member State where the user and/or patient is located.
9. Please refer to the safety data sheets (SDS) 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.
10. For professional use only.

Waste Management

Refer to local legal requirements for chemical disposal regulations as stated in the relevant SDS to determine the safe disposal.

Warning: Handle waste as potentially biohazardous material. Dispose of waste according to accepted laboratory instructions and procedures.

Reagent Preparation

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

Materials Required

General laboratory equipment

Specimen

Human serum, heparin plasma or urine

Only use suitable tubes or collection containers for specimen collection and preparation.

When using primary tubes, follow the manufacturer's instructions.

Stability in serum/plasma [8]:

7 days	at	4 – 25°C
3 months	at	-20°C

Stability in urine [8]:

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

Dilute TruLab Urine controls 1 + 9 with dist. water and multiply results by 10.

Only freeze once. Discard contaminated specimens.

Calibrators and Controls

DiaSys TruCal U is recommended for calibration. Calibrator values have been made traceable to the 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). Use DiaSys TruLab N and P or TruLab Urine Level 1 and Level 2 for internal quality control. All target values of the controls are traceable to DiaSys reagent/calibrator system. Quality control must be performed after calibration. Control intervals and limits have to be adapted to the individual requirements of each laboratory. Results must be within the defined ranges. Follow the relevant legal requirements and guidelines. 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

Serum/Plasma

Measuring range up to 80 mg/dL, linearity is given within ± 5%. In case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function.	
Limit of detection**	0.03 mg/dL
Onboard stability	4 weeks
Calibration stability	4 weeks

Interference by	Interferences ≤ 10% up to	Analyte concentration [mg/dL]
Ascorbic acid	30 mg/dL	1.16
Bilirubin (conjugated)	20 mg/dL	1.10
Bilirubin (unconjugated)	30 mg/dL	1.11
Creatine	30 mg/dL	1.08
Hemolysis	500 mg/dL	5.49
Lipemia (triglycerides)	1000 mg/dL	1.01
Proline	12 mg/dL	1.10

For further information on interfering substances, refer to the literature [10-12].

Precision			
Repeatability (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	1.02	1.21	7.57
CV [%]	2.68	3.01	0.885
Between day (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	1.00	1.11	7.53
CV [%]	3.21	2.59	2.63

Method comparison (n=101)	
Test x	DiaSys Creatinine PAP FS (Hitachi 917)
Test y	DiaSys Creatinine PAP FS (respons [®] 920)
Slope	1.00
Intercept	-0.040 mg/dL
Coefficient of correlation	0.999

Urine

Measuring range up to 800 mg/dL, linearity is given within ± 5%. In case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function.	
Limit of detection**	0.3 mg/dL
Onboard stability	4 weeks
Calibration stability	4 weeks

Precision			
Repeatability (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	67.2	149	238
CV [%]	2.47	2.95	3.12
Between day (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	31.3	149	238
CV [%]	2.90	3.24	3.33

Method comparison (n=109)	
Test x	DiaSys Creatinine PAP FS (BioMajesty [®] JCA-BM6010/C)
Test y	DiaSys Creatinine PAP FS (respons [®] 920)
Slope	1.01
Intercept	-0.970 mg/dL
Coefficient of correlation	0.999

** lowest measurable concentration which can be distinguished from zero; mean + 3 SD (n = 20) of an analyte free specimen.

Calculation

Creatinine Clearance [mL/min/1.73 m²] [9]

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

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

Conversion Factor

$$\text{Creatinine [mg/dL]} \times 88.4 = \text{Creatinine [}\mu\text{mol/L]}$$

$$\text{Creatinine [mg/dL]} \times 0.0884 = \text{Creatinine [mmol/L]}$$

Reference Range

Serum/Plasma

	mg/dL	μmol/L
Adults [13]		
Women	0.51 – 0.95	45 – 84
Men	0.67 – 1.17	59 – 104

Children [14]

0 – 21 days	0.26 – 1.01	22 – 90
2 months – < 3 years	0.15 – 0.39	11 – 34
3 – < 7 years	0.24 – 0.48	21 – 42
7 – < 11 years	0.32 – 0.64	28 – 57
11 – < 15 years	0.42 – 0.81	37 – 72

Urine

1st Morning urine [13]

Women	29 – 226 mg/dL	2.55 – 20.0 mmol/L
Men	40 – 278 mg/dL	3.54 – 24.6 mmol/L

24h urine [9]

Women	720 – 1510 mg/24h	6 – 13 mmol/24h
Men	980 – 2200 mg/24h	9 – 19 mmol/24h

Albumin/creatinine ratio (early morning urine) [15]:

< 30 mg/g Creatinine

Creatinine clearance [9]

66.3 – 143 mL/min/1.73 m²

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

Literature

1. Thomas L. Clinical Laboratory Diagnostics [Internet]. Prof. Lothar Thomas; 2024 [cited 2024 November 05]. https://www.clinical-laboratory-diagnostics.com/k12.html#_idTextAnchor4288 and https://www.clinical-laboratory-diagnostics.com/k12.html#_idTextAnchor4328.
2. Liu Y, Xu G. Trueness investigation of routine creatinine assays on nine homogeneous systems in Beijing demonstrates an encouraging outcome that meets clinical requirements. *Chinese Medical Journal*. 2010;123(17):p 2364-2369
3. Boss K, Stolpe S, Müller A, Friebus-Kardash J, et al. Effect of Difference in Serum Creatinine between Jaffe and Enzymatic Methods in Outpatient Kidney Transplant Recipients. *Journal of Clinical Medicine*. 2024;13(20):6066.
4. Kidney Disease: Improving Global Outcomes (KDIGO) CKD Work Group. KDIGO 2024 Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease. *Kidney Int*. 2024;105(4S): S117–S314.
5. P Fossati, L Prencipe, G Berti, Enzymic creatinine assay: a new colorimetric method based on hydrogen peroxide measurement., *Clinical Chemistry*, Volume 29, Issue 8, 1 August 1983, Pages 1494–1496.
6. Lamb E, Newman DJ, Price CP. Kidney Function Tests. In: Burtis CA, Ashwood ER, Bruns DE editors. *Tietz Textbook of Clinical Chemistry and Molecular Diagnostics*. 4th ed. Elsevier Saunders, St. Louis, Mo., ©2006 p. 799-800.
7. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. *ClinChemLabMed* 2007;45(9):1240-1243.
8. Guder WG, da Fonseca-Wollheim F, Heil W, et al. The Quality of Diagnostic Samples, *Deutsche Vereinte Gesellschaft für Klinische Chemie und Laboratoriumsmedizin*. 3rd ed; 2010. page 42-3 and 66-7.
9. Junge W, Wilke B, Halabi A, et al. Determination of reference intervals for serum creatinine, creatinine excretion and creatinine clearance with an enzymatic and a modified Jaffé method. *Clin Chim Acta*. 2004;344:137-148.
10. 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.
11. Young DS. *Effects on Clinical Laboratory Tests - Drugs Disease, Herbs & Natural Products*, <https://clinfx.wiley.com/aaccweb/aacc/>, accessed in June 2021. Published by AACC Press and John Wiley and Sons, Inc.
12. Sonntag O, Scholer A. Drug interference in clinical chemistry: recommendation of drugs and their concentrations to be used in drug interference studies. *Ann Clin Biochem*. 2001 Jul;38:376-85.
13. Mazzachi BC, Peake M, Erhardt V. Reference range and method comparison for enzymatic and Jaffé Creatinine assays in plasma and serum and early morning urine. *Clin Lab*. 2000;46:53-5.
14. Ceriotti F, Boyd JC, Klein G, et al. Reference intervals for serum creatinine concentrations: assessment of available data for global application. *Clinical chemistry*. 2008;54(3):559-566.
15. Dati F, Metzmann E. *Proteins-Laboratory testing and clinical use*. 1st ed. Holzheim: DiaSys Diagnostic Systems; 2005: p. 93.

Additions and/or changes in the document are highlighted in grey. Deletions are communicated via customer info by stating the edition no. of the package insert/instruction for use.



DiaSys Diagnostic Systems GmbH
 Alte Strasse 9 65558 Holzheim
 Germany
www.diasys-diagnostics.com

* Fluid Stable

Creatinine PAP FS

Application for serum and plasma

Test Details		Test Volumes		Reference Ranges	
Test	: CREAP			Auto Rerun	<input type="checkbox"/>
	: Creatinine PAP			Online Calibration	<input type="checkbox"/>
	: mg/dL	Decimal Places	: 2	Cuvette Wash	<input type="checkbox"/>
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			

* Enter calibrator value.

Test Details		Test Volumes		Reference Ranges	
Test	: CREAP				
Sample Type	: Serum/plasma				
Sample Volumes				Sample Types	
Normal	: 5.00 μ L	Dilution Ratio	: 1 X		
Increase	: 8.00 μ L	Dilution Ratio	: 1 X		
Decrease	: 2.00 μ L	Dilution Ratio	: 1 X		
Standard Volume	: 5.00 μ L				
Reagent Volumes and Stirrer Speed					
RGT-1 Volume	: 180 μ L	R1 Stirrer Speed	: Medium		
RGT-2 Volume	: 90 μ L	R2 Stirrer Speed	: High		

Test Details		Test Volumes		Reference Ranges	
Test	: CREAP				
Sample Type	: Serum/plasma				
Reference Range	: DEFAULT				
Category	: Male				
Reference Range				Sample Types	
	Lower Limit		Upper Limit		
	(mg/dL)		(mg/dL)		
Normal	: #		: #		
Panic	: #		: #		

