

Creatinine PAP FS*

Order Information

Cat. No.

1 1759 99 10 920

Kit size



720 (4 x 180)

Intended Use

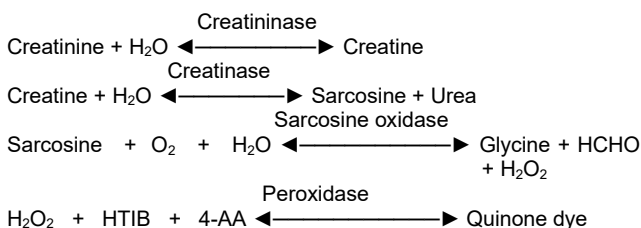
Diagnostic reagent for quantitative in vitro determination of creatinine in human serum, heparin plasma or urine on automated respons[®]910.

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 homogenistic 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. 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.
7. In case of product malfunction or altered appearance that could affect the performance, contact the manufacturer.
8. 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.
9. 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

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

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 from 0.08 mg/dL up to 230 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**	0.08 mg/dL
Limit of quantitation**	0.08 mg/dL
Onboard stability	3 weeks
Calibration stability	3 weeks

Interference by	Interferences ≤ 10% up to	Analyte concentration [mg/dL]
Ascorbic acid	30 mg/dL	1.16
Bilirubin (conjugated)	30 mg/dL	1.81
	35 mg/dL	16.2
Bilirubin (unconjugated)	20 mg/dL	1.75
	30 mg/dL	16.2
Creatine	40 mg/dL	1.52
	60 mg/dL	15.0
Hemolysis	400 mg/dL	1.55
	550 mg/dL	5.08
Lipemia (triglycerides)	1000 mg/dL	1.66
	2000 mg/dL	15.4
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]	0.791	1.31	8.04
CV [%]	2.09	1.77	1.46
Between day (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	0.570	1.07	6.54
CV [%]	3.20	2.62	1.88

Method comparison (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	0.999

Urine

Measuring range from 0.8 mg/dL up to 2300 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**	0.8 mg/dL
Limit of quantitation**	0.8 mg/dL
Onboard stability	3 weeks
Calibration stability	3 weeks

Precision			
Repeatability (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	60.0	167	261
CV [%]	2.77	2.40	2.18
Between day (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	36.4	164	255
CV [%]	4.00	3.45	5.09

Method comparison (n=110)	
Test x	DiaSys Creatinine PAP FS (BioMajesty [®] JCA-BM6010/C)
Test y	DiaSys Creatinine PAP FS (respons [®] 910)
Slope	0.992
Intercept	-0.171 mg/dL
Coefficient of correlation	0.999

*** according to CLSI document EP17-A, Vol. 24, No. 34

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

Creatinine [mg/dL] x 88.4 = Creatinine [μmol/L]
Creatinine [mg/dL] x 0.0884 = 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

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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.
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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.



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* Fluid Stable

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:	CREA PAP
Shortcut:	
Reagent barcode reference:	031
Host reference:	031

Technic	
Type:	End point
First reagent:[μ L]	160
Blank reagent	Yes
Sensitive to light	
Second reagent:[μ L]	80
Blank reagent	No
Sensitive to light	
Main wavelength:[nm]	546
Secondary wavelength:[nm]	700
Polychromatic factor:	1.0000
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 [%]	

Reagents	
Decimals	
Units	

Sample	
Diluent	DIL A (NaCl)
Hemolysis:	
Agent [μ L]	0 (no hemolysis)
Cleaner	
Sample [μ L]	0
Technical limits	
Concentration technical limits-Lower	0.08
Concentration technical limits-Upper	230.0000
SERUM	
Normal volume [μ L]	4.0
Normal dilution (factor)	1
Below normal volume [μ L]	
Below normal dilution (factor)	
Above normal volume [μ L]	4.0
Above normal dilution (factor)	6
URINE	
Normal volume [μ L]	4.0
Normal dilution (factor)	10
Below normal volume [μ L]	
Below normal dilution (factor)	
Above normal volume [μ L]	4.0
Above normal dilution (factor)	16
PLASMA	
Normal volume [μ L]	4.0
Normal dilution (factor)	1
Below normal volume [μ L]	
Below normal dilution (factor)	
Above normal volume [μ L]	4.0
Above normal dilution (factor)	6
CSF	
Normal volume [μ L]	4.0
Normal dilution (factor)	1
Below normal volume [μ L]	
Below normal dilution (factor)	
Above normal volume [μ L]	4.0
Above normal dilution (factor)	6
Whole blood	
Normal volume [μ L]	4.0
Normal dilution (factor)	1
Below normal volume [μ L]	
Below normal dilution (factor)	
Above normal volume [μ L]	4.0
Above normal dilution (factor)	6

Results	
Decimals	2
Units	mg/dL
Correlation factor-Offset	0.0000
Correlation factor-Slope	1.0000

Range	
Gender	Male
Age	
SERUM	#
URINE	#
PLASMA	#
CSF	
Whole blood	
Gender	Female
Age	
SERUM	#
URINE	#
PLASMA	#
CSF	
Whole blood	

Contaminants	
Please refer to r910 Carryover Pair Table	

Calibrators details	
Calibrator list	Concentration
Cal. 1/Blank	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 [%]	0.80

Calculations	
Model	X
Degree	1

* Enter calibrator value
Editable by user