Creatinine PAP FS*

Diagnostic reagent for quantitative in vitro determination of creatinine in serum, plasma or urine on BioMajesty JCA-BM6010/C

Order information

Cat. No.	Tests		
1 1759 99 10 963	R1	4 x	450 tests
	R2	3 x	600 tests
1 1759 99 10 962	R1	6 x	340 tests
	R2	6 x	340 tests

Method

Enzymatic colorimetric test

Principle

Creatinine is determined by the following reaction:

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

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

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

H_2O_2 + HTIB + 4-AA $\xleftarrow{\text{Peroxidase}}$ 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. 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. N-acetylcysteine (NAC), acetaminophen, metamizole and phenindione medication leads to falsely low, eltrombopag medication to falsely low or high results in patient samples.
5. 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.
6. 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 trays.

Specimen

Serum, heparin plasma or urine

Stability in serum and plasma [1]:

7 days	at	4 – 25°C
3 months	at	–20°C

Stability in urine [1]:

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

Freeze only once! Discard contaminated specimens. TruLab Urine controls must be prediluted the same way as patient samples.

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, TruLab P and 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 30 mg/dL (2800 µmol/L) creatinine (in case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function)	
Limit of detection**	0.02 mg/dL (1.59 µmol/L) creatinine
On-board stability	6 weeks
Calibration stability	6 weeks

Interferences < 10% by
Ascorbate up to 27 mg/dL
Conjugated Bilirubin up to 18 mg/dL
Unconjugated Bilirubin up to 24 mg/dL
Hemoglobin up to 500 mg/dL
Creatine up to 40 mg/dL
Lipemia (triglycerides) up to 1700 mg/dL
Proline up to 12 mg/dL
For further information on interfering substances refer to Young DS [8].

Precision (Serum/plasma)			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	0.65	1.24	7.13
Mean [µmol/L]	57.8	109	630
Coefficient of variation [%]	0.94	1.32	0.93
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	0.65	1.85	6.44
Mean [µmol/L]	57.4	164	569
Coefficient of variation [%]	1.67	1.51	1.77

Method comparison (Serum/plasma; n=100)	
Test x	Competitor Creatinine
Test y	DiaSys Creatinine PAP FS
Slope	0.993
Intercept	0.04 mg/dL (3.42 µmol/L)
Coefficient of correlation	0.999

* fluid stable

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Precision (Urine)			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	51.3	59.2	114
Mean [mmol/L]	4.54	5.24	10.1
Coefficient of variation [%]	1.29	1.42	1.36
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	50.6	60.2	115
Mean [mmol/L]	4.47	5.32	10.1
Coefficient of variation [%]	2.31	1.79	1.50

Method comparison (Urine; n=100)	
Test x	Competitor Creatinine
Test y	DiaSys Creatinine PAP FS
Slope	1.02
Intercept	0.69 mg/dL (0.061 mmol/L)
Coefficient of correlation	0.998

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

Conversion factor

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

Calculation

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).

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

Morning urine [4]

Women	29 – 226	2.55 – 20.0
Men	40 – 278	3.54 – 24.6

24h urine [2]

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

Albumin/creatinine ratio (early morning urine) [10]:
< 30 mg/g Creatinine

Creatinine clearance [2]

66.3 - 143 mL/min/1.73 m^2

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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Chemistry code 10 175

Application for serum, plasma and 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.

Analytical Conditions	
R1 volume	80
R2e volume	0
R2 volume	40
R1 diluent vol	0
R2e diluent vol	0
R2 diluent vol	0
Sample vol (S)	2
Sample vol (U)	2
Reagent 1 mix	weak
Reagent 2e mix	weak
Reagent 2 mix	weak
Reaction time	10

Sub-analy. Conditions	
Name	CREAP
Digits	2
M-wave L.	545
S-wave.L	694
Analy.mthd.	EPA
Calc.mthd.	STD
Qualit. judge	No

Analysis Test Condition Setting (M)		
Sample Type	**Serum**	**Urine**
Reac. sample vol.	2	2
Diluent method	No dil	With dil
Undil. sample vol.	0	5
Diluent volume	0	45
Diluent position	0	0

entered by user

Endpoint method	
Re.absorb (u)	9.999
Re. Absorb (d)	-9.999

Calculation Method Setting	
M-DET.P.I	0
M-DET.P.m	41
M-DET.P.n	42
S-DET.P.p	17
S-DET.P.r	18
Check D.P.I.	0
Limit value	0.003
Variance	10
Reac.type	Inc

Reaction Rate Method	
Cycle	2
Factor	2
E2 corre	Not Do
Blank (u)	9.999
Blank (d)	-9.999
Sample (u)	9.999
Sample (d)	-9.999

Standards Setting	
FV	#
BLK H	9.999
BLK L	-9.999
STD H	9.999
STD L	-9.999