Creatinine FS*

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

Order Information

Cat. No. 1 1711 99 10 962
R1: 6 x 315 tests
R2: 6 x 315 tests

Method

Kinetic test without deproteinization according to the Jaffé method

Principle

Creatinine forms a colored orange-red complex in an alkaline picrate solution. The difference in absorbance at fixed times during conversion is proportional to the concentration of creatinine in the sample.

Creatinine + Picric acid ⟶ Creatinine picrate complex

Reagents

Components and Concentrations

R1:	Sodium hydroxide	0.2 mol/L
R2:	Picric acid	20 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 – 25 °C, protected from light and contamination is avoided. Do not freeze the reagents!

Warnings and Precautions

1. Reagent 1 is irritating. R36/38: Irritating to eyes and skin. S2: Keep out of the reach of children. S26: In case of contact with eyes rinse immediately with plenty of water and seek medical advice. S37/39: Wear suitable gloves and eye/face protection.
2. Reagents S24/25: Avoid contact with skin and eyes.
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.
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.

Waste Management

Please refer to local legal requirements.

Reagent Preparation

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

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

Only freeze once! Discard contaminated specimens.

Calibrators and Controls

For calibration 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

Compensated method [2-4]

Picric acid which forms the coloured complex reacts unspecifically with interfering serum components, so-called pseudo-creatinines. This leads to falsely elevated creatinine values in serum and plasma samples especially in the low measuring range. To compensate these interferences the calibrator value for the compensated method indicated in the value sheet of TruCal U has to be used for calculation. Additionally 0.3 mg/dL (27 µmol/L) has to be subtracted from the calculated creatinine value.
When using the compensated method, calibration with the calibrator TruCal U is explicitly recommended. The method is applicable only for serum and plasma samples.
The compensated method is traceable to GC-IDMS and can, therefore, be used for estimation of the glomerular filtration rate using the MDRD formula as mentioned below.

Performance Characteristics

Measuring range up to 14 mg/dL (1270 µmol/L) creatinine (in case of higher concentrations re-measure samples after manual dilution or use the rerun function)	
Limit of detection**	0.1 mg/dL (9 µmol/L) creatinine
On-board stability	8 days
Calibration stability	1 day

Interferences < 10% by
Ascorbate up to 30 mg/dL
Hemoglobin up to 600 mg/dL
Conjugated bilirubin up to 3 mg/dL
Unconjugated bilirubin up to 1.5 mg/dL
Lipemia (triglycerides) up to 1800 mg/dL
For further information on interfering substances refer to Young DS [10].

Precision (Serum/plasma)			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	0.66	1.52	4.70
Mean [µmol/L]	58.3	134	415
Coefficient of variation [%]	1.49	1.26	0.70
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	0.64	1.50	4.65
Mean [µmol/L]	56.7	133	411
Coefficient of variation [%]	3.07	2.05	0.94

Method comparison (Serum/plasma; n=98)	
Test x	DiaSys Creatinine FS
Test y	Competitor Creatinine
Slope	1.03
Intercept	0.029 mg/dL (2.55 µmol/L)
Coefficient of correlation	0.9998

BioMajesty

Precision (Urine)			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	27.8	58.3	107
Mean [mmol/L]	2.46	5.15	9.50
Coefficient of variation [%]	1.03	0.63	0.67
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	35.4	60.5	122
Mean [mmol/L]	3.13	5.35	10.8
Coefficient of variation [%]	2.74	2.13	1.81

Method comparison (Urine; n=99)	
Test x	DiaSys Creatinine FS
Test y	Competitor Creatinine
Slope	0.957
Intercept	0.113 mg/dL (0.010 mmol/L)
Coefficient of correlation	1.00

** 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 of Creatinine Clearance [mL/min/1.73 m^2] [5]

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

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

Estimated **Glomerular Filtration Rate** [mL/min/1.73 m^2] according to MDRD (modification of diet in renal disease) using creatinine values obtained by a standardized method [4].

For serum creatinine (sCr) (mg/dL):

GFR = 175 x $sCr^{-1.154}$ x $age^{-0.203}$ x 1.212 (if Afro-American)
x 0.742 (if female)

For serum creatinine (sCr) (µmol/L):

GFR = 30849 x $sCr^{-1.154}$ x $age^{-0.203}$ x 1.212 (if Afro-American)
x 0.742 (if female)

Reference Range

Serum/plasma, Jaffé method not compensated

	mg/dL	µmol/L
Adults [6]		
Women	0.6 – 1.1	53 – 97
Men	0.9 – 1.3	80 – 115
Children [7,8]		
Neonate	0.5 – 1.2	44 - 106
Infant	0.4 – 0.7	35 - 62
Child	0.5 – 1.2	44 - 106

Serum/plasma, Jaffé method compensated

	mg/dL	µmol/L
Adults [2]		
Women	0.5 – 0.9	44 - 80
Men	0.7 – 1.2	62 - 106
Children [9]		
Neonate	0.24 – 1.04	21 – 92
Infant	0.17 – 0.42	15 – 37
Child	0.24 – 0.87	21 - 77

Urine [6]

Women	11 – 20 mg/kg/24h	97 – 177 µmol/kg/24h
Men	14 – 26 mg/kg/24h	124 – 230 µmol/kg/24h

Creatinine clearance [7]

Women	95 - 160 mL/min/1.73 m^2
Men	98 - 156 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

1. Guder WG, Zawta B. Recommendations of the Working group on Preanalytical Quality of the German Society for Clinical Chemistry and the German Society for Laboratory Medicine: The Quality of Diagnostic Samples. 1st ed Darmstadt: GIT Verlag 2001; p. 24-5,50-1
2. Mazzachi BC, Peake MJ, Ehrhardt V. Reference Range and Method Comparison Studies for Enzymatic and Jaffé Creatine Assays in Plasma and Serum and Early Morning Urine. Clin. Lab. 2000; 46: 53-55.
3. Swanson AF, Swartzentruber M, Nolen PA et al. Multicenter Evaluation of the Boehringer Mannheim Compensated, Rate-Blanked Creatinine/Jaffe Application on BM/Hitachi Systems. Advances in Clinical Diagnostics. 1993. Boehringer Mannheim Corporation.
4. Levey AS, Coresh J, Greene T, Marsh J et al: Expressing the Modification of Diet in Renal Disease Study Equation for Estimating Glomerular Filtration Rate with Standardized Serum Creatinine Values. Clin Chem 2007; 53 (4): 766-72.
5. Junge W, Wilke B, Halabi A, Klein G. 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
6. Newman DJ, Price CP. Renal function and nitrogen metabolites. In: Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry. 3rd ed. Philadelphia: W.B Saunders Company; 1999. p. 1204-1270.
7. Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 366-74.
8. Soldin SJ, Brugnara C, Wong EC, eds. Pediatric Reference Intervals. 6th ed. AACC Press, 2007: p. 77-78
9. Schlebusch H, Liappis N, Klein G. Ultrasensitive CRP and Creatinine: Reference intervals from infancy to childhood. Clin Chem Lab Med. 2001; 39 Special supplement pp S1-S448; May 2001. PO-T042
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.

Manufacturer

IVD CE

DiaSys Diagnostic Systems GmbH
Alte Strasse 9 65558 Holzheim Germany

BioMajesty

Creatinine FS

Chemistry code 10 171

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	20
R1 diluent vol	0
R2e diluent vol	0
R2 diluent vol	0
Sample vol (S)	5
Sample vol (U)	5
Reagent 1 mix	weak
Reagent 2e mix	weak
Reagent 2 mix	weak
Reaction time	10

Sub-analy. Conditions	
Name	CREA
Digits	2
M-wave L.	505
S-wave.L	571
Analy.mthd.	RRA
Calc.mthd.	STD
Qualit. judge	No

Analysis Test Condition Setting (M)		
Sample Type	**Serum**	**Urine**
Reac. sample vol.	5	5
Diluent method	No dil	With dil
Undil. sample vol.	0	2
Diluent volume	0	98
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	21
M-DET.P.m	24
M-DET.P.n	32
S-DET.P.p	0
S-DET.P.r	0
Check D.P.I.	21
Limit value	0.003
Variance	10
Reac.type	Inc

Reaction Rate Method	
Cycle	2
Factor	2
E2 corre	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