respons®910

Creatinine FS*

Diagnostic reagent for quantitative in vitro determination of creatinine in serum or plasma on DiaSys respons®910

Order Information

Cat. No. 1 1711 99 10 920
4 twin containers for 200 tests each
Cat. No. 1 1711 99 10 921
4 twin containers for 50 tests each

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. DiaSys respons containers provide protection from light. 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 rotor.

Specimen

Serum or heparin plasma

Stability [1]:

7 days	at	4 - 25 °C
at least 3 months	at	-20 °C

Discard contaminated specimens. Freeze only once.

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 and P 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

Compensated method [2-4]

Picric acid which forms the colored 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.
For use of the compensated method calibration with the calibrator TruCal U is strictly 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 15 mg/dL creatinine (in case of higher concentrations re-measure samples after manual dilution or use rerun function)	
Limit of detection**	0.1 mg/dL creatinine
On-board stability	3 weeks
Calibration stability	1 week

Interfering substance	**Interferences < 10%**	**Creatinine [mg/dL]**
Ascorbate	up to 30 mg/dL	2.01
Hemoglobin	up to 550 mg/dL	1.67
	up to 550 mg/dL	4.82
Bilirubin, conjugated	up to 6 mg/dL	1.47
	up to 6 mg/dL	5.48
Bilirubin, unconjugated	up to 7 mg/dL	1.47
	up to 7 mg/dL	5.58
Lipemia (triglycerides)	up to 2000 mg/dL	1.07
	up to 2000 mg/dL	5.94
For further information on interfering substances refer to Young DS [10].		

Precision			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	0,49	1,31	6,45
Coefficient of variation [%]	2,29	1,86	1,19
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	0,81	1,34	5,45
Coefficient of variation [%]	3,33	2,20	1,98

Method comparison (n=118)	
Test x	DiaSys Creatinine FS (Hitachi 911)
Test y	DiaSys Creatinine FS (respons®910)
Slope	1.03
Intercept	-0.001 mg/dL
Coefficient of correlation	0.999

** according to NCCLS document EP17-A, vol. 24, no. 34

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

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

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

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

For serum creatinine (sCr) (µmol/L):

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

Conversion factor:

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

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	45 - 105
Infant	0.4 - 0.7	35 - 62
Child	0.5 - 1.2	45 - 105

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

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

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Manufacturer

IVD CE

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Application for serum and plasma 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
Name:	CREA
Shortcut:	
Reagent barcode reference:	032
Host reference:	

Technic	
Type:	Linear Kinetic
First reagent:[µL]	160
Blanc correction	Yes
Second reagent:[µL]	40
Blanc correction	Yes
Main wavelength:[nm]	508
Secondary wavelength:[nm]	570
Polychromatic factor:	1.000
1 st reading time [min:sec]	5:48
Last reading time [min:sec]	7:36
Reaction way:	Increasing
Linear Kinetics Substrate deplation: absorbance limit	0.22
Linearity: Maximum deviation [%]	100
Fixed Time Kinetics Substrate deplation: absorbance limit	
Endpoint Stability: largest remaining slope	
Prozone Limit [%]	

Sample	
Diluent	NaCl
Concentration technical limits-Lower	0.1
Concentration technical limits-Upper	15
SERUM	
Normal volume [µL]	12
Normal dilution (factor)	1
Below normal volume [µL]	24
Below normal dilution (factor)	1
Above normal volume [µL]	2
Above normal dilution (factor)	1
URIN	
Normal volume [µL]	12
Normal dilution (factor)	1
Below normal volume [µL]	24
Below normal dilution (factor)	1
Above normal volume [µL]	2
Above normal dilution (factor)	1
PLASMA	
Normal volume [µL]	12
Normal dilution (factor)	1
Below normal volume [µL]	24
Below normal dilution (factor)	1
Above normal volume [µL]	2
Above normal dilution (factor)	1
CSF	
Normal volume [µL]	12
Normal dilution (factor)	1
Below normal volume[µL]	24
Below normal dilution (factor)	1
Above normal volume [µL]	2
Above normal dilution (factor)	1

Results	
Decimals	2
Units	mg/dL
Correlation factor-Offset	0.000
Correlation factor-Slope	1.000

Range	
Genre	Male
Age	
SERUM	>=0.9 <=1.3
URINE	
PLASMA	>=0.9 <=1.3
CSF	
Genre	Female
Age	
SERUM	>=0.6 <=1.1
URINE	
PLASMA	>=0.6 <=1.1
CSF	

Contaminants	
Contaminant 1	
Wash with	
Cycle	
Volume [µL]	
Contaminant 2	
Wash with	
Cycle	
Volume [µL]	

Calibrators details	
Calibrator list	**Concentration**
Cal. 1	0
Cal. 2	*
Cal. 3	*
Cal. 4	*
Cal. 5	*
Cal. 6	*
	Max delta abs.
Cal. 1	0.015
Cal. 2	0.004
Cal. 3	
Cal. 4	
Cal. 5	
Cal. 6	
Drift limit [%]	0.8
Calculations	
Model	X degree
Degree	1

* Enter calibrator value