



# Creatinine FS\*

**Diagnostic reagent for quantitative in vitro determination of creatinine in serum, plasma or urine on photometric systems**

## Order Information

Cat. No.	Kit size
1 1711 99 10 021	R1 4 x 20 mL + R2 1 x 20 mL + 1 x 3 mL Standard
1 1711 99 10 026	R1 5 x 80 mL + R2 1 x 100 mL
1 1711 99 10 023	R1 1 x 800 mL + R2 1 x 200 mL
1 1711 99 10 704	R1 8 x 50 mL + R2 8 x 12.5 mL
1 1711 99 10 917	R1 8 x 60 mL + R2 8 x 15 mL
1 1711 99 10 191	R1 4 x 36 mL + R2 4 x 9 mL
1 1711 99 90 314	R1 10 x 20 mL + R2 2 x 30 mL
1 1711 99 10 950	3700 Tests on ADVIA 1650/1800
1 1700 99 10 030	6 x 3 mL Standard

## Summary [1,2]

Creatinine is a waste product excreted by the kidneys mainly by glomerular filtration. The concentration of creatinine in plasma of a healthy individual is fairly constant, independent from water intake, exercise and rate of urine production. Therefore increased plasma creatinine values always indicate decreased excretion, i.e. impaired kidney function. The creatinine clearance enables a quite good estimation of the glomerular filtration rate (GFR) which allows better detection of kidney diseases and monitoring of renal function. For this purpose creatinine is measured simultaneously in serum and urine collected over a defined time period.

## 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

<b>R1:</b> Sodium hydroxide	0.2 mol/L
<b>R2:</b> Picric acid	20 mmol/L
<b>Standard:</b>	2 mg/dL (177 µmol/L)

### Storage Instructions and Reagent Stability

The reagents and the standard are stable up to the end of the indicated month of expiry, if stored at 2 - 25 °C 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 and standard S24/25: Avoid contact with skin and eyes.
3. Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents.

## Waste Management

Please refer to local legal requirements.

## Reagent Preparation

The standard is ready to use.

## Substrate Start

The reagents are ready to use.

## Sample Start

Mix 4 parts of R1 + 1 part of R2  
(e. g. 20 mL R1 + 5 mL R2) = mono-reagent  
Stability of mono-reagent: 5 hours at 15 - 25 °C

## Materials required but not provided

NaCl solution 9 g/L  
General laboratory equipment

## Specimen

Serum, heparin plasma, urine

Stability [5]

in serum /plasma:	7 days	at	4 - 25 °C
	at least 3 months	at	-20 °C
in urine:	2 days	at	20 - 25 °C
	6 days	at	4 - 8 °C
	6 months	at	-20 °C

Dilute urine 1 + 49 with dist. water.

Discard contaminated specimens!

## Assay Procedure

**Application sheets for automated systems are available on request.**

Wavelength	Hg 492 nm, (490 - 510 nm)
Optical path	1 cm
Temperature	20 - 25 °C/37 °C
Measurement	Against reagent blank

### Substrate start

	Blank	Sample or standard
<b>Sample or standard</b>	-	50 µL
<b>Dist. Water</b>	50 µL	-
<b>Reagent 1</b>	1000 µL	1000 µL
Mix, incubate 0 - 5 min., then add:		
<b>Reagent 2</b>	250 µL	250 µL
Mix and read absorbance A1 after 60 sec, read absorbance A2 after further 120 sec.		

$\Delta A = (A_2 - A_1)$  sample or standard

### Sample start

	Blank	Sample or standard
<b>Sample or standard</b>	-	50 µL
<b>Dist. Water</b>	50 µL	-
<b>Monoreagent</b>	1000 µL	1000 µL
Mix and read absorbance A1 after 60 sec, read absorbance A2 after further 120 sec.		

$\Delta A = (A_2 - A_1)$  sample or standard

## Calculation

With standard or calibrator

### Serum/Plasma

$$\text{Creatinine [mg/dL]} = \frac{\Delta A \text{ Sample}}{\Delta A \text{ Std/Cal}} \times \text{Conc. Std/Cal [mg/dL]}$$

### Urine

$$\text{Creatinine [mg/dL]} = \frac{\Delta A \text{ Sample}}{\Delta A \text{ Std/Cal}} \times \text{Conc. Std/Cal [mg/dL]} \times 50$$

### Creatinine Clearance [mL/min/1.73 m<sup>2</sup>]

$$= \frac{\text{mg Creatinine / 100 mL Urine} \times \text{mL Urine / 24 h}}{\text{mg Creatinine / 100 mL Serum} \times 1440}$$

The calculated creatinine clearance refers to the average body surface of an adult (1.73 m<sup>2</sup>).

### Conversion factor

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

## Calibrators and Controls

For the calibration of automated photometric systems the DiaSys TruCal U calibrator is recommended. For internal quality control DiaSys TruLab N, P and TruLab Urine controls should be assayed with each batch of samples.

	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 [3,4]

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. 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.

## Performance Characteristics

### Measuring range

The test has been developed to determine creatinine concentrations within a measuring range from 0.2 – 15 mg/dL (18 – 1330 μmol/L). When values exceed this range samples should be diluted 1 + 1 with NaCl solution (9 g/L) and the result multiplied by 2.

### Specificity/Interferences

No interference was observed by ascorbic acid up to 30 mg/dL, hemoglobin up to 500 mg/dL and lipemia up to 2,000 mg/dL triglycerides. Bilirubin interferes starting with a bilirubin concentration of 4 mg/dL.

### Sensitivity/Limit of Detection

The lower limit of detection is 0.2 mg/dL.

## Precision (at 37 °C)

Intra-assay precision n = 20	Mean [mg/dL]	SD [mg/dL]	CV [%]
Sample 1	0.79	0.05	6.45
Sample 2	1.56	0.04	2.38
Sample 3	5.74	0.05	0.83

Inter-assay precision n = 20	Mean [mg/dL]	SD [mg/dL]	CV [%]
Sample 1	0.81	0.03	3.63
Sample 2	1.60	0.01	0.87
Sample 3	5.73	0.05	0.85

## Method Comparison

A comparison of DiaSys Creatinine FS (y) with a commercially available test (x) using 68 samples gave following results:  $y = 1.031x - 0.03$  mg/dL;  $r = 1.000$ .

A comparison of DiaSys Creatinine FS compensated (y) with the enzymatic method DiaSys Creatinine PAP FS (x) using 66 samples gave following results:  $y = 0.982x + 0.045$  mg/dL;  $r = 0.997$ .

## Reference Range

### Serum/plasma, Jaffé-method not compensated [1]

Women	0.6 – 1.1 mg/dL	53 – 97 μmol/L
Men	0.9 – 1.3 mg/dL	80 – 115 μmol/L

### Serum/plasma, Jaffé-method compensated [3]

Women	0.5 – 0.9 mg/dL	44 – 80 μmol/L
Men	0.7 – 1.2 mg/dL	62 – 106 μmol/L

### Urine [1]

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

### Creatinine clearance [2]

Women	95 - 160 mL/min/1.73 m <sup>2</sup>
Men	98 - 156 mL/min/1.73 m <sup>2</sup>

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

## Literature

1. Newman DJ, Price CP. Renal function and nitrogen metabolites. In: Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry. 3<sup>rd</sup> ed. Philadelphia: W.B Saunders Company; 1999. p. 1204-1270.
2. Thomas L. Clinical Laboratory Diagnostics. 1<sup>st</sup> ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 366-74.
3. 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.
4. 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.
5. 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. 1<sup>st</sup> ed Darmstadt: GIT Verlag 2001; p. 24-5,50-1.

## Manufacturer

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