Creatinine FS

Creatinine Reagent Test Kit

Intended Use

Creatinine reagent test Kit is liquid stable containing chemicals which can be used for the determination of Creatinine in Serum, Plasma or Urine on Photometric Analyzers.

Reagent Kits

Item Code	Pack Size
117119934840	R1: 4 x 60 mL, R2: 4 x 15 mL

Summary

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 con centration of creatinine in the sample.

Creatinine + Picric acid ⟶ Creatinine picrate complex

Reagent Concentration

R1:	Sodium Hydroxide	64 g/L
R2:	Picric Acid	2.05 g/L
Preservatives & Stabilizers		q.s.

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 15 – 25°C and contamination is avoided. Do not freeze the reagents and protect them from direct light!

Waste Management

Please refer to local legal requirements.

Reagent Preparation

The reagents are ready to use.

Warnings and Precautions

1. Reagent 1: Warning. May be corrosive to metals. Causes skin irritation. Causes serious eye irritation. Keep only in original container. Wash hands and face thoroughly after handling. Wear protective gloves/protective clothing/eye protection/face protection. If on skin: Wash with plenty of water/soap. If skin irritation occurs: Get medical advice/attention. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. Absorb spillage to prevent material damage.
2. Reagent 2: Warning. May be corrosive to metals. Keep only in original contai ner. Wear protective gloves/protective clothing/eye protection/face protection. Absorb spillage to prevent material damage.
3. High homogentisic acid concentrations in urine samples lead to false results.
4. In very rare cases, samples of patients with gammopat hy might give falsified results [11].
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!

Traceability

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).

Specimen

Serum, heparin plasma, urine

Stability

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; multiply the result by 50. TruLab Urine controls must be prediluted the same way as patient samples.

Discard contaminated specimens! Only freeze once!

Assay Procedure

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

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

A = (A2 – A1) sample or Calibrator

Calculation

With 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^2] [7]

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

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

Conversion factor

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

Calibrators and Controls

For the calibration of automated photometric systems, DiaSys TruCal U calibrat or is recommended. Calibrator values ha ve 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 , P and TruLab Urine controls should be assayed.
Each laboratory should establish corrective action in case of deviations in control recovery.

Compensated method

Picric acid which forms the colored complex reacts u nspecifically 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.

Performance Characteristics

Measuring range

The test has been developed to determine creatinine concentrations within a measuring range from 0.2 – 20 mg/dL (18 – 1768 µmol/L). When values exceed this ra nge samples should be diluted 1 + 1 with NaCl solution (9 g/L) and the result multiplied by 2.

Sensitivity/Limit of Detection

The lower limit of detection is 0.2 mg/dL (17.7 µmol/L).

Specificity/Interferences

No interference was observed by ascorbic acid up to 30 mg/dL, hemoglobin up to 500 mg/dL and lipemia up to 2000 mg/dL triglycerides. Bilirubin interferes starting with a bilirubin concentration of 4 mg/dL. For fur ther information on interfering substances refer to Young DS [10].

Precision (at 37°C)

Intra-assay precision n = 20	Mean [mg/dL]	SD [mg/dL]	CV [%]
Sample 1	0.56	0.01	1.30
Sample 2	1.24	0.01	0.83
Sample 3	6.73	0.06	0.93

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 (y) with a commercially available Jaffé method (x) using 68 human sera samples within a range of 0.6 – 10 mg/dL (53.0 – 884 µmol/L) gave following results:
y = 1.014 x - 0.031 mg/dL; r = 1.000

A comparison of DiaSys Creatinine compensated (y) with the enzymatic method DiaSys Creatinine PAP FS (x) using 65 human sera samples within a range of 0.5 – 4.3 mg/dL (44.2 – 380 µmol/L) gave following results:

y = 0.986 x + 0.043 mg/dL; r = 0.998

Reference Range

Serum/plasma, Ja é -method not compensated

	mg/dL	µmol/L
Adults [1]		
Women	0.6 to 1.2	44.2 - 79.5
Men	0.7 – 1.3	62 – 115
Children [2,8]		
Neonate	0.6 to 1.2	53.0 - 106.0
Infant	0.4 – 0.7	35 – 62
Child	0.5 – 1.2	44 – 106

24h urine [1]

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

Albumin/creatinine ratio (early morning urine) [12]**:**

< 30 mg/g Creatinine

Creatinine clearance [2]

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.

Limitations

Eventual Creatinine mod. Jaffe carry -over to reagents Phosphorous Inorganic (Molybdate), Iron (Ferrene), LDH -L (IFCC) and LDH -P (opt. DGKC). The actual carry-over depends on the analyzer.

Clinical Interpretation

Normal creatinine levels range from 0.6 to 1.2 mg/dL in men and 0.5 to 0.9 mg/dL in women who are 18 to 60 years old. Normal levels are roughly the same for people over 60. High serum creatinine levels in the blood indicate that the kidneys aren't functioning properly.

Literature

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Notes on Symbols and Marks

	Consult instruction for use
	Use-by date
LOT	Batch code
REF	Catalogue number
	Caution
	Manufacturer
IVD	In vitro diagnostic medical device
	Temperature limit
	Do not reuse
CONT.	The pack contains
	Recycle
	Date of manufacture

ISO 9001, ISO 13485 and ICMED 13485 Certified Company

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Revision No. : 02
Apr . 2022

IN/0019 v02