Creatinin

Jafee Colorimetric Kinetic. Liquid

Product information

24CREA01-UN	**Meditest Creatinin**	**4x40 mL 2x20 mL**
24CREA01-AU	**Meditest Creatinin**	**4x40 mL 2x20 mL**
24CREA01-AB	**Meditest Creatinin**	**4x40 mL 2x20 mL**
24CREA01-ER	**Meditest Creatinin**	**4x40 mL 2x20 mL**

Purpose

In vitro assay for the quantitative determination of creatin in human serum, plasma and urine.

Summary

Creatinine is the result of the breakdown of creatinine, the component of muscles; It can be converted into ATP, which is a high energy source for cells. Creatinine production depends on the modification of muscle mass and varies very little, and levels are usually very constant. It is excreted by the kidneys. In progressive renal failure, urea, creatinine and uric acid are retained in the blood. A high creatinine level may be indicative of kidney failure1,4,5. Clinical diagnosis should not be based on a single test result, but clinical and other laboratory data should be integrated.

Test principle

The test is based on the reaction of creatinine with sodium picrate as described by Jaffé. Creatinine reacts with alkaline picrate to form a red complex. The time interval chosen for the measurements avoids interference from other serum components. The intensity of the resulting color is proportional to the creatinine concentration in the sample[1].

Creatinine + picric acid $\xrightarrow{\text{Alkaline pH}}$ yellow-orange complex

Reagents - working solutions

R 1	Picric acid	<17.5 mmol/L
R 2	Sodium hydroxide	>0.29 mol/L

Precautions warnings

It is intended for in vitro diagnostic use by healthcare professionals. Follow the normal precautions necessary in handling all laboratory reagents.
Infectious or microbial waste:
Warning: handle waste as potentially biohazardous. Dispose of waste according to accepted laboratory instructions and procedures.
Environmental hazards: Follow all relevant local disposal regulations to determine that it has been disposed of safely. If requested, a safety data sheet can be provided to professional users.

Inhibit foam formation in all reagents and sample types (sample, calibrator and control).

If there is any damage on the
package, do not use it Read the user manual carefully before use, do not use the expired assay kit Do not mix different lot reagents.

All samples should be considered epidemic material, please dispose of them in accordance with the laboratory working standard of infectious diseases.
Take the necessary protective measures to prevent users from becoming infected during operation.

Use of reagents

Ready to use.

Storage and stability

All components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8ºC, protected from light and contamination is avoided during their use.
Do not use reagents after the expiration date. Signs of reactive decay: Presence of particles and turbidity- empty absorbance (A) at 492 nm >1.80.

Sample collection and preparation

Serum or heparinized plasma[1].
Creatinine stability: 24 hours at 2-8ºC
Urine (24 hours): Dilute the sample with 1/50 distilled water and mix. Multiply the results by 50 (dilution factor);
Stability of creatinine: 7 days at 2-8ºC.

Required Materials (not included in the kit)

1. Cat# 24BIO01-DC Meditest Diachem Calibrator
2. Cat# 24BIO01-DQ Meditest Diacheck Control L1
3. Cat# 24BIO02-DQ Meditest Diacheck Control L2
4. General laboratory equipment
5. Distilled or deionized water

Working Procedure

If you are using a spectrophotometer to perform this test, work with the following procedure. Ask your representative for the application data for fully automatic devices.

1.Test Conditions:
Wavelength: . 492 nm
Cuvette: . . . . . 1 cm light path
Temperature: . 37^{0C}/15-250C 2.Set the appliance to zero with distilled water.
3.Place the pipettes in a cuvette.

	Blank	Standard	Sample
WR (mL)	1,0	1,0	1,0
Standard(Note 1,2) (µL)	--	100	--
Sample (µL)	--	--	100

4.Mix, incubate for 1 minute.
5. Read the absorbance (A1) 30 seconds after sample addition and 90 seconds after (A2).
6. ΔA= A2 – A1.

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Calculation

$$\frac{\Delta A \text{ Sample} - \Delta A \text{Blank}}{\Delta A \text{ Standard} - \Delta A \text{Blank}} \times 2 \text{ (Standard conc.)} = \text{mg/dL}$$

Conversion factor: mg/dL x 88.4 = µmol/L

Expected values

Serum or plasma:		
Male	0.7 - 1.4 mg/dL	⍰ 61.8 – 123.7 µmol/L
Woman	0.6 - 1.1 mg/dL	⍰ 53.0 – 97.2 µmol/L
Urine: 15-25 mg/Kg/24 h		
Male	10 - 20 mg/Kg/24 h	
Woman	8 – 18 mg/Kg/24 h	

These values are for orientation purposes; Each laboratory should establish its own reference range

Limitations

Hemoglobin (1 g/L),
Bilirubin (55 mg/dL),
Interfere1. Lipids are immiscible < 4 g/L.
A list of drugs and other substances involved in the determination of creatinine has been reported by Young et al.2,3.

Performance characteristics

Measuring range: 0.000-35 mg/dL
If the results obtained are greater than the linearity limit, dilute the sample by 1/2 with 9 g/L NaCl and multiply the result by 2s.

Precision

	Intra-assay (n=20)		Inter-assay (n=20)	
Mean (mg/dL)	0,92	3,43	0,96	3,50
SD	0,03	0,07	0,04	0,09
CV (%)	2,76	1,90	3,97	2,51

Sensitivity: 1 mg/dL = 0.0407 ΔAbs/min
Accuracy: Results obtained using Meditest reagents (y) showed no systematic differences when compared to other commercial reagents (x). The results obtained using 50 samples are as follows:
Correlation coefficient $(r)^2$: 0.99584
Regression equation y= 0.953x – 0.075

The results of the performance characteristics depend on the analyzer used.

References

1. Murray R.L. Creatinine. Kaplan A et al. Clin Chem The C.V. Mosby Co. St Louis. Toronto. Princeton 1984; 1261-1266 and 418.
2. Young DS. Effects of drugs on Clinical Lab. Tests, 4th ed AACC Press, 1995.
3. Young DS. Effects of disease on Clinical Lab. Tests, 4th ed AACC 2001.
4. Burtis A et al. Tietz Textbook of Clinical Chemistry, 3rd ed AACC 1999.
5. Tietz N W et al. Clinical Guide to Laboratory Tests, 3rd ed AACC 1995.

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