

Creatinine Reagent

(Single Vial)
Catalog #: 43712

for use with the SDI CA480 Clinical Chemistry System

INTENDED USE

For the *in vitro* quantitative determination of Creatinine in serum, and urine on automated chemistry analyzers.

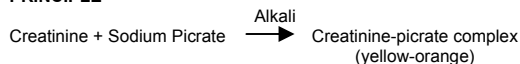
SUMMARY AND EXPLANATION¹

Creatinine measurements are used in the diagnosis and treatment of renal function, including diseases, monitoring renal dialysis, and as a calculation basis for measuring other urine analytes. Elevated Creatinine levels are found in renal diseases and insufficiency with decreased glomerular filtration (uremia or azotemia if severe); urinary tract obstruction; reduced renal blood flow including congestive heart failure, shock and dehydration; rhabdomyolysis causes high serum creatinine, which may be elevated out of proportion to BUN, or to the reduction in renal function.

METHODOLOGY

Jaffe² described a method in 1886 for the determination of creatinine involving a protein free filtrate and a reaction with picric acid in alkaline solution. Although since then several methods have been described the classic Jaffe reaction method is still the most widely used. The Jaffe reaction is subject to interferences by a number of substances, including protein and glucose.^{3,4,5} Modifications of the procedure have been developed to combat the drawbacks.⁶ The kinetic procedures⁷ have become popular because they are fast, simple and avoid interferences. This method is based on a modification of the above procedure, incorporating a surfactant and other ingredients to minimize protein and carbohydrate interferences.

PRINCIPLE



Creatinine reacts with picric acid in alkaline conditions to form a color complex which absorbs at 510 nm. The rate of formation of color is proportional to the creatinine in the sample.

REAGENT COMPOSITION

Active Ingredients	Concentration
Picric Acid	10 mM
Sodium Hydroxide	250 mM
pH 13.0 ± 0.2	

PRECAUTIONS

1. This reagent is for *in vitro* diagnostic use only.
2. Picric Acid is a strong oxidizing agent. Avoid contact with skin. WIPE ANY SPILLAGE, SINCE EVAPORATED PICRIC ACID IS EXPLOSIVE.
3. Sodium hydroxide is an alkali. Avoid ingestion and contact.

REAGENT PREPARATION

Reagent is supplied as a single vial ready to use liquid.

REAGENT STORAGE

1. Store the reagent at 2-8°C (refrigerated).
2. The reagent is stable until the expiration date when stored at 2-8°C.
3. Reagent should be protected from light when not in use.

REAGENT DETERIORATION

The reagent should not be used if:

1. The reagent is cloudy (contaminated).
2. The reagent fails to meet stated parameters of performance.
3. The initial reagent absorbance is greater than 0.330 at 500 -510nm.

SPECIMEN COLLECTION AND STORAGE⁸

1. Un-hemolyzed serum is recommended.
2. Urine should be diluted to a final concentration of approximately 34 to 64 mg/dL. A 1:100 dilution is recommended.
3. Creatinine in serum is stable for 7 days at refrigerated temperatures (2-8°C) and for several months when frozen (-20°C) and protected from evaporation and contamination.
4. Urine samples are stable for at least 7 days at 4°C.

INTERFERENCES

Studies to determine the level of interference for hemoglobin, bilirubin, and lipemia were carried out, the following results were obtained:

Hemoglobin: No significant interference from hemoglobin up to 200 mg/dL.

Bilirubin: No significant interference from bilirubin up to 10.5 mg/dL.

Lipemia: No significant interference from lipemia up to 618 mg/dL measured as triglycerides.

A number of drugs and substances may affect the accuracy of creatinine. See Young, et al.⁹

ADDITIONAL EQUIPMENT REQUIRED BUT NOT PROVIDED

1. SDI CA480 Clinical Chemistry System
2. Deionized water and related equipment, e.g.: pipettes
3. Analyzer specific consumables, e.g.: sample cups
4. Controls and Calibrator materials such as those provided by SDI Biomed.

ASSAY PROCEDURE

These instructions are to be used as a general guideline for adapting to select automated instruments. Refer to your specific instrument application instructions available upon request.

SYSTEM PARAMETERS

Temperature:	37°C
Wavelength:	510 nm
Assay Type:	Fixed Rate
Direction:	Increase
Sample/ Rgt. Ratio:	1: 10
e.g. Sample Vol.	0.1 mL (100mL)
Reagent Vol.	1.0 mL
First Read Time:	60 Sec
Delay Time:	120 Sec
Last Read Time:	180 Sec

PROCEDURE NOTES

The reagent and sample volumes may be altered proportionally to accommodate various instrument requirements.

Calculations: (A = Absorbance)

$$\frac{A_{\text{patient}}}{A_{\text{standard}}} \times \text{Concentration of standard} = \text{Creatinine (mg/dL)}$$

Example:	
A patient	= 0.01
A (standard)	= 0.05
Concentration of standard	= 5 mg/dL.

$$\frac{0.01}{0.05} \times 5 = 1.0 \text{ mg/dL Creatinine}$$

LIMITATIONS

Samples with values exceeding 20 mg/dL should be diluted 1:1 with saline and re-run. The final answer should be multiplied by two.

CALIBRATION

Use an aqueous Creatinine standard or an appropriate serum calibrator.

QUALITY CONTROL

The integrity of the reagent should be monitored by use of a two level control with known Creatinine values.

EXPECTED VALUE¹⁰

Serum:	0.60 – 1.40 mg/dl
Urine:	0.80 – 2.00 g/day

It is highly recommended that each laboratory establish its own reference range.

PERFORMANCE

Linearity:

When run as recommended the assay is linear to 20 mg/dL

Method Comparison:

Studies performed between this procedure and a similar methodology yielded the following results:

	<u>Serum</u>	<u>Urine</u>
Number of samples pairs:	45	44
Range of samples:	0.2–24.6 (mg/dL)	17-355 (mg/dL)
Correlation Coefficient:	0.999	0.9952
Slope:	1.02	1.04
Intercept:	-0.00 (mg/dL)	-0.30 (mg/dL)

Precision:

<u>Within Run</u>	<u>Level 1</u>	<u>Level 2</u>
Mean (mg/dL)	1.62	4.81
S.D.(mg/dL)	0.05	0.10
C.V. (%)	3.2	2.1

Run to Run

Mean (mg/dL)	1.62	4.81
S.D.(mg/dL)	0.07	0.12
C.V. (%)	4.6	2.4

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Manufactured for:



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