

Intended Use

Mission's Enzymatic Creatinine Reagent is for the quantitative measurement of creatinine in urine.

For Research Use Only. Site validation required for Lab Developed Test (LDT), 510K approval pending.

Summary and Principle

Creatinine measurements are used in the diagnosis and treatment of kidney diseases, in the monitoring of dialysis patients, and as an integral part of diagnostic equations to measure renal function.

Urinary creatinine is used to estimate creatinine clearance, which helps calculate the glomerular filtration rate (GFR), a key indicator of how well the kidneys are filtering waste. Low urinary creatinine can indicate kidney damage or impaired filtration.

Many urine test results (like protein, albumin, or drug levels) are expressed as a ratio to creatinine (e.g., albumin-to-creatinine ratio, ACR).

This enzymatic method for creatinine uses an enzyme cascade with a photometric end-point detection. The enzyme creatinine amidohydrolase is used to convert creatinine to creatine.

Creatine is broken down to sarcosine and urea by creatine amidinohydrolase. Further enzyme linked steps with sarcosine oxidase and peroxidase yield a colored chromogen read at 545nm.¹

Reagents

Both R1 and R2 reagents are provided in ready-to-use format. No preparation is required.

R1 Reagent contains:

Good's buffer (pH 8.1)	25 mM
Creatinase	≥ 30 kU/L
Sarcosine oxidase	≥ 10 kU/L
Ascorbate oxidase	≥ 2.5 kU/L
Catalase	≥ 350 kU/L
HTIB (3-Hydroxy 2,4,6-triiodobenzoic acid)	2.3 mM

R2 Reagent contains:

Good's buffer (pH 8.1)	25 mM
Creatininase	≥ 150 kU/L
Peroxidase	≥ 50 kU/L
4-Aminoantipyrine (4-AA)	2 mM
Potassium hexacyanoferrate	0.18 mM

Reagents Stability and Storage

After opening, both R1 and R2 reagents are stable at 2-8°C for 8 weeks if capped when not in active use. Store reagents at 2-8°C. When stored as directed, the reagents are stable until the expiration date stated on the label.

Cautions

May be harmful if inhaled or swallowed. Avoid contact with skin and eyes. In case of contact, flush area with water. Seek immediate medical attention for eyes.

Instrumentation

Mission Enzymatic Creatinine Reagent Kits are for use on Mission CA200¹ and Beckman AU680 analyzers. Refer to instrument procedure instructions in the instrument manual provided with the analyzer.

Specimen Collection and Handling

Urine is to be collected without additives. For manual dilution, dilute urine with deionized water and multiply the result by the dilution factor.

Handle all urine samples as if potentially infectious.

Quality Control

Store and handle reagents properly before and during use. Every laboratory should establish its own test requirements using controls and calibrators. Mission Diagnostics provides calibrators to meet your program needs and which conform to NLCP Guidelines²:

MD-101212 – Enzymatic Creatinine Calibrator

Specificity, Limitations, and Interferences

The Mission Enzymatic Creatinine Reagent Kit is for the detection of creatinine in urine. False positives may result from improperly stored samples and bacterial growth.

Typical Performance Characteristics

The following performance data was obtained using the Mission CA200 and Beckman AU680 analyzers. Other instruments may yield different performance data.

Linearity

The following results were obtained on Mission CA200 and Beckman AU680 analyzers using the Mission Enzymatic Creatinine Reagent Kit on samples containing 2, 6.25, 12.5, 25, 50, 100, 200, and 300 mg/dL creatinine. The table below includes mean, standard deviation (SD) and coefficient of variation (CV) for each value.

Mean (mg/dL)	SD	CV%
1.98	0.03	1.5
6.31	0.05	0.8
12.73	0.13	1.0
25.40	0.38	1.5
49.92	0.37	0.7
99.70	1.59	1.6
198.47	1.95	1.0
292.74	1.55	0.5

¹ Also known as Zybiox EC200 Analyzer



ENZYMATIC CREATININE REAGENT KIT MD-101112

Precision

Studies were performed on a Mission CA200 analyzer. The precision of the assay was evaluated following a modification of NCCLS protocol EPT-T2. The within-run precision data was obtained by running two samples in replicates of 20 on the same day. The run-to-run data was obtained from the same samples over a 20-day period.

Within-Run			Run-to-Run		
Mean (mg/dL)	SD	CV%	Mean (mg/dL)	SD	CV%
25.04	0.28	1.1	24.93	0.34	1.4
157.20	1.57	1.0	157.20	1.71	1.1

Analytical Specificity

Cross contamination studies have not been performed. Certain reagent/instrument combinations used in sequence with this assay may interfere with reagent performance and test results. The existence of, or effects of, any potential cross contamination issues are unknown.

Test Conditions

For the data presented in this insert, studies using this reagent were performed on a Mission CA200 analyzer using the parameters listed below.

Limitations

A sample with a creatinine concentration exceeding the analytical measuring range should be diluted with deionized water and reanalyzed incorporating the dilution factor in the calculation of the value.

The limit of quantification (LOQ) must be determined by each laboratory according to their SOP.

Calibration

Calibration material should be used to calibrate the procedure. The frequency of calibration using an automated system is dependent on the system and the parameters used. If control results are found to be out of range, the test may need to be re-calibrated.

Method Parameters

Analyzer Specific Settings

Method type:	Kinetic (3-pt)
Slope:	positive
Units	mg/dL
DOM wavelength	546
SUB wavelength	700
Sample volume	2
R1 volume	100
R2 volume	100
Blank rxn read (cycles)	n/a
Sample rxn read (cycles)	25 - 29

Calibration Settings

Calibration type	Linear
Reagent Blank required	No
Calibrator 1 (water)	0
Calibrator 2	200

Analytical Measuring Range (AMR)

Range: (low)	LOQ
Range: (high)	300

BIBLIOGRAPHY

1. K.Rikitake, I.Oka, M.Ando, T.Yoshimoto, & D. Tsuru; J. Biochem., 86, 1109 (1979)
2. National Laboratory Certification Program. General Laboratory Inspection Checklist / Report. OMB No. 0930-0158. November 2002.