UnityPoint Health Pekin
Department of Pathology
Pekin, IL 61554

Effective Date: 02/18/19
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Urine Creatinine

Siemens Dimension® Rxl®Max
UCREA

I. PRINCIPLE

The creatinine (CRE2) method uses a modified kinetic Jaffe technique. In the presence of a strong base such as NaOH, picrate reacts with creatinine to form a red chromophore. The rate of increasing absorbance at 510nm due to the formation of this chromophore is directly proportional to the creatinine concentration in the sample and is measured using a bichromatic rate technique. Bilirubin is oxidized by potassium ferricyanide to prevent interference.

II. CLINICAL SIGNIFICANCE

Creatinine measurements are used in the diagnosis and treatment of certain renal disease, in monitoring renal dialysis, and as a calculation basis for measuring other urine analytes.

Creatinine is also used in the Protein Creatinine Ratio (UTPCRR) and the microalbumin Creatinine Ratio (MACRA).

III. SPECIMEN

A. Collection of urine specimens should be done using recommended procedure with no special patient preparation.
B. Urine specimens which are turbid must be centrifuged prior to testing. Specimens should be free of particulate matter
C. Urine creatinine specimens require no preservatives.
D. Specimens should be stored at 2-8°C and analyzed within 4 days.

IV. REAGENT

A. Siemens CRE2 Flex® reagent cartridge, Cat No DF33B
B. Reagent 1- Wells 1-3 liquid Lithium Picrate at 125 nM.
C. Reagent 2- Wells 4-6 liquid NaOH at 2000nM and K3Fe(CN)6 at 2.7 nM.
D. Reagents are liquid and ready to use. Store at 2-8^{0}C
E. Unopened individual cartridges are good until expiration date on carton.
F. Sealed cartridges wells on the analyzer are good for 30 days.

V. INSTRUMENTATION/EQUIPMENT

A. Siemens Dimension® Rxl® Max analyzer

VI. CALIBRATION

A. CHEM I Calibrator, Cat No. DC18C
B. Three calibration levels at 0.00 mg/dL, 1.00 mg/dL, and 22.00 mg/dL.
C. Calibration frequency is every 90 days for one lot number and a new calibration is required for each new lot number of reagent flex, after major maintenance or service, if

indicated by quality control results, as indicated by quality control procedure, and when required by CAP regulations.

VII. QUALITY CONTROL

A. Quality Control is performed daily using the Bio-Rad Liquichek Urine Chemistry control consisting of two levels of control.
B. All QC procedures must be followed if results are outside the acceptable limits.

VIII. PROCEDURE:

A. Urine specimen is tested straight and untreated.
B. Identify specimen with two forms of information. Specimen should have a Sunquest generated barcode label with the patient information.
C. Specimen should be centrifuged before testing if cloudy or turbid.
D. Place patient barcoded tube onto analyzer and start by pressing "RUN"
E. If the result exceeds the linear range of the analyzer, a manual dilution must be performed with CLR water. The recommended manual dilution factor is 1:2 See the AMR chart.

IX. REPORTING RESULTS

A. Analytical Measurement Range (AMR) is 13 –400 mg/dL
B. Clinical Reportable Range (CRR) is 13 – 800 mg/dL
C. Results less than 13.00 mg/dL will show "below assay range" on the printout and should be reported as "less than 13.00 mg/dL
D. Results greater than 400mg/dL will show "above assay range" on the printout and should be diluted.
E. Normal ranges are not established for random specimens.

X. PROCEDURAL NOTES/PROBLEM-SOLVING TIPS

A. The analyzer reporting system contains flags and messages for user information. See the Dimension® RxL Max® Operator's Guide for information on these messages. Address the messages before reporting patient results.

XI. REFERENCES

A. Siemens Healthcare Diagnostics, Inc. CRE2 Method Insert Sheet, 12/2016
B. Dade Behring Inc. Dimension® RxL Max® Operator's Guide 06/2008

POLICY CREATION :	***Date***
Author: ***Suzanne Behle, MT (ASCP)***	***02/18/2019***
Medical Director: ***Lori Racsa, DO***	***02/18/2019***

MEDICAL DIRECTOR		
DATE	NAME	SIGNATURE
SECTION MEDICAL DIRECTOR		

REVISION HISTORY (began tracking 2011)			
Rev	Description of Change	Author	Effective Date

Reviewed by

Lead	**Date**	**Coordinator/ Manager**	**Date**	**Medical Director**	**Date**