**CHEM.DIMENSION.ASSAY.16.0 CREATININE BY DIMENSION**

**INTENDED USE**

The CRE2 method used on the Dimension® clinical chemistry system is an *in vitro* diagnostic test intended for the quantitative determination of creatinine in serum, plasma and urine.

**PRINCIPLE**

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 510 nm due to the formation of this chromophore is directly proportional to the creatinine concentration in the sample and is measured using a bichromatic (510, 600 nm) rate technique. Bilirubin is oxidized by potassium ferricyanide4 to prevent interference.

**DOCUMENT OWNER**

Manager, St. Vincent Jennings Hospital Laboratory

**RELATED DOCUMENTS**

CHEM.DIMENSION.1.0 *Operation of the Siemens Dimension RxL MAX, Xpand and EXL Clinical Chemistry*

*Systems*

CHEM.DIMENSION.2.0 *Dimension Calibration Procedure*

**SPECIMEN**

A. Patient Preparation: None.

B. Sample Size:

1. Primary tube: Compare the tube to the filling gauge supplied with the Dimension.

2. SSC or Dimension sample cup: 20 µL plus 50 µL dead space volume.

C. Specimen Type:

1. Serum: SST® and Corvac® collection tubes do not affect the CRE2 method.

2. Plasma:

a. Lithium heparin is the preferred anticoagulant.

b. Sodium fluoride and EDTA do not interfere with the CRE2 method at concentrations normally found in blood collection tubes.

3. Urine:

a. Collected without a preservative.

b. 24-hour specimens should be stored at 2 – 8⁰ C

D. Specimen Preparation:

1. Complete clot formation should be allowed to take place before centrifugation to obtain

serum samples.

2. Serum or plasma samples should be separated from the red cells within 2 hours of collection.

3. Specimens should be free of particulate matter.

E. Storage and Stability for Separated Specimens:

1. 1 day at 20 – 25 ⁰C

2. Refrigerated at 2 – 8 ⁰C

a. Serum or plasma: 7 days

b. Urine: 4 days

3. For longer storage, specimens may be frozen up to 3 months at -20 ⁰C or colder.

**REAGENTS**

A. CRE2 Flex® reagent cartridge, Cat. No. DF33B

1. Preparation: All reagents are liquid and ready to use.

2. Storage and Stability:

a. Unopened reagent cartridges are stable until the date given on the packaging

when stored at 2 – 8 ⁰C.

b. On board stability:

1) Sealed cartridge wells are stable for 30 days.

2) Open well stability is 5 days.

**EQUIPMENT**

Siemens Dimension® RxL MAX®, Xpand® or EXL™Clinical Chemistry System

**CALIBRATION**

A. Calibration Material: CHEM I Calibrator, Cat. No. DC18C

1. Three levels: typical calibrator levels are 0, 11, and 22 mg/dL; see the package

insert for exact values for the lot in use.

2. See the package insert for preparation, storage and stability.

B. Calibration Frequency:

1. For each new lot of Flex® reagent cartridges.

2. Every 3 months for any one lot of reagent cartridges.

3. After major maintenance or service if indicated by quality control results.

4. When indicated by unacceptable QC data.

C. Procedure: See CHEM.DIMENSION.2.0 *Dimension Calibration Procedure*

**QUALITY CONTROL**

A minimum of two levels of controls spanning the medical decision range are to be run once every 24 hours of assay use. See QC procedure, HBL.GEN.7.0 for specific details.

**PROCEDURE**

Sampling, reagent delivery, mixing and processing are automatically performed by the Dimension® System. For details of this processing, refer to the Dimension® Operator’s Guide.

**RESULTS**

A. The instrument automatically calculates and prints the concentration of creatinine in mg/dL using the calculation scheme outlined in your Dimension® Operator’s Guide.

B. Results of the test should always be interpreted in conjunction with the patient’s medical history, clinical presentation and other findings.

**REPORTING RESULTS**

A. Expected values:

1. Serum or plasma (mg/dl):

Female Male

0 Days 0.70 – 1.20 0 Days 0.70 – 1.20

8 Days 0.30 – 0.80 8 Days 0.30 – 0.80

29 Days 0.20 – 0.50 29 Days 0.20 – 0.50

1 Y 0.20 – 0.80 1 Y 0.20 – 0.80

10 Y 0.50- 1.10 10 Y 0.50 – 1.10

17 Y 0.60 – 1.30 17 Y 0.70 – 1.40

2. Urine: 30.0 – 125.0 mg/dl

B. Critical values: Not applicable.

C. Sunquest Computer Entry

1. Manual Entry

Function: MEM

Worksheet: Site specific

Test Code: CREAT (serum/plasma) or UCRR (urine)

1. Online Entry

Function: OEM

Device: Site specific

Test Code: CREAT (serum/plasma) or UCRR (urine)

D. QLS Computer Entry

1. Enter: 3, 3, 1
2. Worksheet: Enter worksheet from QLS label.
3. Accession number: Enter JI number.

E. If the HIS or LIS system is down, see the appropriate Laboratory Computer Downtime Policy.

**PROCEDURE NOTES**

A. Expected Turnaround Time (TAT):

Nursing units are to be notified if the turnaround time is unable to be met per current MACL network turnaround time standards.

B. Backup method: When testing cannot be performed, the testing site’s backup policy should be followed.

**LIMITATIONS**

A. AMR:

1. Serum or plasma: 0.15 – 20.0 mg/dL

a. Patient serum or plasma samples with CRE2 levels that exceed 20.0 mg/dL will autodilute. If a valid result cannot be obtained a manual dilution should be made.

b. If a manual dilution is required, the specimen should be handled as follows:

1) Make an appropriate dilution with reagent grade water to obtain results within the assay range.

2) Enter the dilution factor into the instrument when programming the sample.

3) Reassay. The resulting readout will be corrected for the dilution.

c. Serum or plasma specimens with CRE2 levels greater than 40.0 mg/dL should be reported as >40.0 mg/dL.

2. Urine: 5.00 – 400.0 mg/dl

a. Patient urine samples with CRE2 levels that exceed 400.0 mg/dL will **not** autodilute. If a valid result is not obtained a manual dilution must be made.

b. If a manual dilution is required, the specimen should be handled as follows:

1) Make a dilution with 1 part urine and 1 parts Reagent Grade Water.

2) Enter a dilution factor of 2 into the instrument when programming the sample.

3) Reassay. The resulting readout will be corrected for the dilution.

c. Urine Specimens with CRE2 levels greater than 800.0 mg/dL should be reported as >800.0 mg/dL.

B. Interfering Substances:

1. The CRE2 method was evaluated for interference from hemolysis, icterus and lipemia according to CLSI/EP07-A2. Bias exceeding 10% is considered “interference”.

a. Hemoglobin (hemolysate) at 500 mg/dL did **not** interfere with a CRE2 result of 1.5 mg/dL.

b. Bilirubin (unconjugated): Bilirubin at 10 mg/dL did **not** interfere with a CRE2 result of 1.5 mg/dL.

c. Lipemia (Intralipid): Lipemia at 1000 mg/dL did **not** interfere with a CRE2 result of 1.5 mg/dL.

2. Other substances: The CRE2 package insert contains a list of common drugs and other substances that do not interfere.

**CLINICAL SIGNIFICANCE**

Measurement of serum creatinine levels has been advocated as a useful index of renal function, primarily of glomerular filtration, owing to the constancy of formation and excretion. Serum creatinine determinations have been found to be significantly more reliable than urea nitrogen determinations largely because of the relative independence from dietary protein, degree of patient hydration and protein metabolism. Serum creatinine values vary less than 10% per day in normal subjects. However, serum creatinine has the least usefulness in detecting mild impairments in GFR. Values often are not above the upper limit of normal until one half to two thirds of function is lost. If better sensitivity is required, a creatinine or inulin clearance test is recommended. Most experts advocate the establishment of a baseline GFR with a creatinine clearance test, and then the serum creatinine can be used to establish changes in GFR.

**REFERENCES**

A. Siemens Dimension® Clinical Chemistry System CRE2 Flex® reagent cartridge package insert US , Siemens Healthcare Diagnostics, Inc., Newark, DE, 02/27/2014.

B. Anderson, S. C. & Cockayne, S. (1993). *Clinical Chemistry Concepts and Applications*. Philadelphia, PA: W. Saunders Company.