DXC 600 (CR-S) CREATININE

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PURPOSE

To provide instructions for the quantitative determination of serum/plasma Creatinine on the DXC 600 and semi-quantative urine creatinine (for Urine Drug Screens) on the DXC600.

PRINCIPLE

CR-S reagent, when used in conjunction with UniCel® DxC 600/800 System(s) and SYNCHRON® Systems AQUA CAL 1 and 2, is intended for the quantitative determination of Creatinine concentration in human serum, plasma or urine.

BACKGROUND

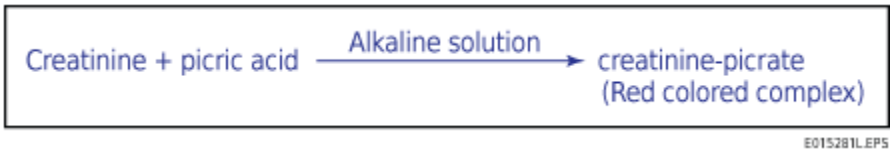
Clinical Significance

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

Methodology

CR-S reagent is used to measure the creatinine concentration by a modified rate Jaffé method. In the reaction, creatinine combines with picrate in an alkaline solution to form a creatinine-picrate complex. The SYNCHRON® System(s) automatically proportions the appropriate sample and reagent volumes into the cuvette. The ratio used is one part sample to 11 parts reagent for serum and one part sample to 73 parts reagent for urine. The System monitors the change in absorbance at 520 nanometers. This change in absorbance is directly proportional to the concentration of CR-S in the sample and is used by the System to calculate and express CR-S concentration.

Chemical Reaction



RELATED DOCUMENTS

R-PO-CH0810	Quality Control Program General Laboratory
R-PO-CH0809	Quality Control Westgard Rules Statistics
R-PR-AD0540	Specimen Rejection/Cancellation Protocol
M-F-CH0820	Chemistry Controls
M-F-CH0826	Chemistry Calibrators
M-F-CH1940	DXC 600 (AMR) Analytical Measurement Range

SPECIMEN

Type of Specimen

Biological fluid samples should be collected in the same manner routinely used for any laboratory test. Freshly drawn serum or plasma or freshly collected urine (random/timed) are the specimens of choice. Acceptable anticoagulants are listed in the PROCEDURAL NOTES section of this chemistry information sheet. Whole blood is not recommended for use as a sample.

Note: Quantitative urine creatinine is performed only at SJMC.

Specimen Storage and Stability

1. Tubes of blood are to be kept closed at all times and in a vertical position. It is recommended that the serum or plasma be physically separated from contact with cells within two hours from the time of collection.

2. Separated serum or plasma should not remain at room temperature longer than 8 hours. If assays are not completed within 8 hours, serum or plasma should be stored at +2°C to +8°C. If assays are not completed within 48 hours, or the separated sample is to be stored beyond 48 hours, samples should be frozen at minus 15°C to minus 20°C. Frozen samples should be thawed only once. Analyte deterioration may occur in samples that are repeatedly frozen and thawed.

3. For urine sample stability, see Urine Drug Screen collection information.

Sample Type	Volume	Sample Stability
Plasma/Serum/Urine	0.5mL	• Separate serum from cells within 2 hours. • Room Temp 8 hours • Refrigerated 48 hours • Frozen 3 Months • Urine recommended to be tested within 2 hours or kept refrigerated or on ice • No preservative required for urine.

Criteria for Unacceptable Specimens

See Specimen Rejection/Cancellation Protocol

Sample Volume

A filled 0.5 mL sample cup is the optimum volume. For optimum primary sample tube volumes in primary tube samples and minimum volumes, refer to the Primary Tube Sample Template for your system.

REAGENTS

Contents

Each kit contains the following items: Two CR-S Reagent Cartridges (2 x 300 tests) A40920

Also necessary: Synchron CX Antifoam REF 445967

Volume per Test	
Serum/Plasma Sample Volume	10uL
Urine	3uL
Total Reagent Volume	219uL
Cartridge Volumes	A 175uL B 44uL C --

Reactive Ingredients	
Picric Acid	8.1 mmol\L
Buffered to PH	>13.3

Also non-reactive chemicals necessary for optimal system performance

Reagent Preparation

Add 1 drop of Antifoam to reagent compartment A. Mix gently. Do not use more than the recommended volume of Antifoam.

Acceptable Reagent Performance

The acceptability of a reagent is determined by successful calibration and by ensuring that quality control results are within your facility`s acceptance criteria.

Reagent Storage and Stability

CR-S reagent, when stored unopened at room temperature, will obtain the shelf-life indicated on the cartridge label. Once opened, the reagent is stable for 15 days at +2°C to +8°C. Do not use beyond the manufacturer's expiration date. DO NOT FREEZE.

CALIBRATION

Calibrator Required

SYNCHRON® Systems AQUA CAL 1 and 2

Calibrator Preparation

No preparation is required.

Calibrator Storage and Stability

1. If unopened, the calibrators should be stored at +2°C to +8°C until the expiration date printed on the calibrator bottle. Once opened, the calibrators are stable at room temperature for 30 days.

2. Repetitive refrigeration of the aqueous calibrators may facilitate crystal formation. Once removed from refrigerated storage, these calibrators should remain at room temperature.

Calibration Information

1. The system must have a valid calibration factor in memory before control or patient samples can be run.

2. Under typical operating conditions the Creatinine assay must be calibrated every 5 days or with each new cartridge of reagent and also with certain parts replacements or maintenance procedures, as defined in the UniCel DxC 600/800 System Instructions For Use (IFU) manual.

3. This assay has within-lot calibration available. For detailed calibration instructions, refer to the UniCel DxC 600/800 Systems Instructions for Use (IFU) manual.

4. The system will automatically perform checks on the calibration and produce data at the end of calibration. In the event of a failed calibration, the data will print out with error codes and the system will alert the operator of the failure. An explanation of these error codes can be found in the UniCel DxC 600/800 Systems Instructions For Use (IFU) manual.

Traceability

For Traceability information refer to the Calibrator instructions for use.

QUALITY CONTROL

See Related Documents M-F-CH0820 Chemistry Controls

STEPS

1. If necessary, prepare reagent cartridge as described in the Reagent Preparation section of this chemistry information sheet and load the reagent onto the system.

2. After reagent load is completed, calibration may be required.

3. Program controls for analysis.

4. After loading controls onto the system, follow the protocols for system operation. To load samples manually refer to the FHS DXC Series Manual Sample Programming procedure. For detailed testing procedures, refer to the UniCel DxC 600/800 System Instructions For Use (IFU) manual.

5. After successful performance of QC, patient samples can be run.

CALCULATIONS

The system performs all calculations internally to produce the final reported result. The system will calculate the final result for sample dilutions made by the operator when the dilution factor is entered into the system during sample programming.

If calculation of creatinine clearance is desired, refer to References (4).

ANTICOAGULANT TEST RESULTS

If plasma is the sample of choice, the following anticoagulants were found to be compatible with this method based on a study of 20 healthy volunteers:

Anticoagulant	Level Tested for In Vitro Interference
Lithium Heparin	14 Units/mL
Sodium Heparin	14 Units/mL

PERFORMANCE CHARACTERISTICS

Serum/Plasma Reference Range-

Male	Female
0.70 – 1.30 mg/dL	0.50 – 1.00 mg/dL

Note: Quantitative urine creatinine is performed only at SJMC.

Analytic Range

The SYNCHRON® System(s) method for the determination of this analyte provides the following analytical ranges**:**

Sample Type	Conventional Units
Serum or Plasma	0.3 – 25.0 mg/dL
Urine	10 – 400 mg/dL

Serum/Plasma samples with concentrations exceeding the high end of the analytical range should be diluted with saline and reanalyzed. Urine samples should not be diluted.

Reporting results outside of analytical range

Lower limit of detection: serum / plasma	0.3 mg/dL	Results below 0.3, report as <0.30 mg/dL
Upper limit of detection : serum / plasma	25.00 mg/dL	Results >25.00 should be diluted to a maximum of X2, using 0.9% saline and reanalyzed. Results above 50 should be reported as >50mg/dL.
Lower limit of detection: urine	10 mg/dL	Results below 10, report as <10 mg/dL
Upper limit of detection: urine	400 mg/dL	Results above 400 should be reported as >400

NOTE: Drug screens with urine creatinine results <20 mg/ dL will have the following phrase appended: DIL1-Creatinine result is < 20 mg/dL. Negative results are inconclusive for urine with creatinine below 20.0 mg/dL.

LIMITATIONS

If urine samples are cloudy or turbid, it is recommended that they be centrifuged prior transfer to sample cups.

Interferences

1. The following substances were tested for interference with this methodology:

Substance	Source	Level Tested	Observed Effect - No Significant Interference
Bilirubin	Porcine	15.0 mg/dL	NSI
		22.5 mg/dL Index of 7	-0.5 mg/dL
Lipemia	Human	+4 (visual) Index of 9	NSI
Hemoglobin	Human	500 mg/dL Index of 10	NSI
Acetoacetate	Acetoacetic acid lithium salt	20 mg/dL	NSI
Pyruvate	Pyruvic acid	10 mg/dL	NSI
Methyl dopa	Methyl dopa HCl	5 mg/dL	NSI

Substance	Source	Level Tested	Observed Effect - No Significant Interference
Gentisic Acid	2,5-dihydroxybenzoic acid	50 mg/dL	NSI
Cephalothin	7-[2-thienylacetamido]-cephalosporanic acid sodium salt	100 mg/dL	NSI
Cefotaxime	Sodium Salt	50 mg/dL	NSI
Cefoxitin	Sodium Salt	12.5 mg/dL	NSI
		25.0 mg/dL	+0.7 mg/dL
Cephalosporin	Zinc salt	10 mg/dL	NSI

ADDITIONAL INFORMATION

For more detailed information on UniCel DxC System(s), refer to the appropriate system manual.

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DOCUMENT APPROVAL **Purpose of Document / Reason for Change:**			
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Committee Approval Date	☒ Date: 8/26/14 ☐ N/A – revision of department-specific document which is used at only one facility	**Medical Director Approval** *(Electronic Signature)*	Katie Wilkinson, MD 8/26/14