CR-S - CREATININE

Intended Use

The Alinity c Creatinine assay is used for the quantitative determination of creatinine in human serum, plasma, or urine on the Alinity c analyzer.

Clinical Significance

Creatinine is eliminated from blood by glomerular filtration. Reduced renal function results in an increased serum creatinine concentration. Measurement of serum creatinine is used to diagnose and monitor acute and chronic renal disease, estimate glomerular filtration rate (GFR), or assess the status of renal dialysis patients.

Methodology

At an alkaline pH, creatinine in the sample reacts with picrate to form a creatinine-picrate complex. The rate of increase in absorbance at 500 nm due to the formation of this complex is directly proportional to the concentration of creatinine in the sample. Methodology: Kinetic Alkaline Picrate

Specimen

Type of Specimen

Specimen Type	Collection Vessel
• Serum • Plasma	Serum Tubes (with or without gel barrier) Collection tubes Acceptable anticoagulants are: Lithium Heparin (with or without gel barrier) Sodium Heparin EDTA

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Specimen Storage and Stability

1. Tubes of blood are kept closed at all times 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. For accurate results, serum and plasma specimens should be free of fibrin, red blood cells, and other particulate matter. Ensure centrifugation is adequate to remove platelets.
3. If fibrin, red blood cells, or other particulate matter are observed, mix by low speed vortex or by inverting 10 times prior to recentrifugation.

Specimen Type	Temperature	Maximum Storage Time
Serum/ Plasma	20 to 25 °C	7 days
	2 to 8°C	7 days
	-20°C	3 months

Sample Dilution Procedures

Serum/Plasma

Samples with creatinine value exceeding 37.00 mg/dl are flagged with the code "> 37.00 mg/dL" and may be diluted with either the Automated Dilution Protocol or the Manual Dilution Procedure.

Automated Dilution Protocol

Serum/Plasma

If using an automated dilution protocol, the system performs a dilution of the sample and automatically calculates the concentration by multiplying the result by the dilution factor.

Manual Dilution Procedure

Dilute the sample with saline (0.85% to 0.90% NaCl). The operator must enter the dilution factor in the Specimen or Control tab of the Create Order screen. The system will use this dilution factor to automatically calculate the concentration of the sample and report the result.

Reagents

Reagent Handling

- Upon receipt, place reagent cartridges in an upright position for 8 hours before use to allow bubbles that may have formed to dissipate. If a reagent cartridge is dropped, place in an upright position for 1 hour before use to allow bubbles that may have formed to dissipate.

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- Reagents are susceptible to the formation of foam and bubbles. Bubbles may interfere with the detection of the reagent level in the cartridge and cause insufficient reagent aspiration that may adversely affect results.

Reagent Storage and Stability

	Storage Temperature	Maximum Storage Time	Additional Storage Instructions
Unopened	15 to 30°C	Until expiration date	Store in upright position
Onboard	System Temperature	5 days	
Opened	15 to 30°C	Until expiration date	Store in upright position. Do not reuse original reagent caps or replacement caps due to the risk of contamination and the potential to compromise reagent performance.

Calibration

Calibration Required

For instructions on performing a calibration, refer to the Alinity ci-series Operations Manual.

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Calibration is stable for approximately 5 days (120 hours), but is required with each change in reagent lot. Verify calibration with at least 2 levels of controls according to the established quality control requirements for your laboratory. If control results fall outside acceptable ranges, recalibration may be necessary. This assay may require recalibration after maintenance to critical parts or subsystems or after service procedures have been performed.

Calibration Preparation

Calibration material is the 08P6001 Alinity c Multiconstituent Calibrator Kit. This product is liquid ready-to-use. Prior to each use, mix by gentle inversion.

Calibration Storage and Stability

	Calibrator Storage	Stability Once OPEN
MC Cal (CAL 1 and CAL 2)	Unopened: 2 to 8 (until expiration date)	2 to 8 °C: 7 days 15 to 30 °C: 24 hours Onboard: 5 days

Calibration Information

1. Calibrator values may be configured using e-files accessed and imported from www.corelaboratory.abbott, or from Abbott Mail.
2. Verify that the correct calibrator values have been entered into the calibration file.
3. Calibration is performed by running a water blank and Alinity c Multiconstituent Calibrator Kit. Water for the blank is provided by the instrument.
4. For information on configuring calibrator data, refer to the Alinity ci-series Operations Manual, Section 2.

Quality Control

See Policy Chemistry Quality Control Policy

Sample Processing

See Policy RIV-PPP-1199

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Test unit=mg/dL for all ages and both sexes

Reference Range

Sex	Age Day Low	Age Day High	Age Year Low	Age Year High	Ref Low	Ref High
	0	15			0.42	1.05
	15			1	0.31	0.53
			1	4	0.39	0.55
			4	7	0.44	0.65
			7	12	0.52	0.69
			12	15	0.57	0.8
M			15	17	0.65	1.04
M			17	19	0.69	1.1
M			19	250	0.72	1.25
F			15	17	0.59	0.86
F			17	19	0.6	0.88
F			19	250	0.57	1.11
U			15	17	0.65	0.86
U			17	19	0.69	0.88
U			19	250	0.72	1.11

Analytic Range

AMR Low	AMR High	CRR Low	CRR High
0.20	37	0.20	37

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