

## BUN or UREA – UREA NITROGEN OR UREA

### Principle

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**Intended Use** The Alinity c Urea Nitrogen assay is used for the quantitation of urea nitrogen in human serum, plasma, or urine on the Alinity c analyzer.

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**Clinical Significance** Urea Nitrogen or Urea measurements are used in the diagnosis and treatment of certain renal and metabolic diseases.

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**Methodology** The Urea Nitrogen assay is a modification of a totally enzymatic procedure first described by Talke and Schubert. The test is performed as a kinetic assay in which the initial rate of the reaction is linear for a limited period of time. Urea in the sample is hydrolyzed by urease to ammonia and carbon dioxide. The second reaction, catalyzed by glutamate dehydrogenase (GLD) converts ammonia and  $\alpha$ -ketoglutarate to glutamate and water with the concurrent oxidation of reduced nicotinamide adenine dinucleotide (NADH) to nicotinamide adenine dinucleotide (NAD). Two moles of NADH are oxidized for each mole of urea present. The initial rate of decrease in absorbance at 340 nm is proportional to the urea concentration in the sample.

Methodology:Urease

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### **Specimen**

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**Type of Specimen**

**Specimen Type**

- Serum
- Plasma

**Collection Vessel**

Serum Tubes (with or without gel barrier)  
Collection tubes Acceptable anticoagulants are: Lithium Heparin (with or without gel barrier)  
Sodium Heparin

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## BUN or UREA – UREA NITROGEN OR UREA, *Continued*

### 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 should 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. Serum specimens from patients receiving anticoagulant or thrombolytic therapy may contain fibrin due to incomplete clot formation. For accurate results, plasma specimens should be free of platelets and other particulate matter. Ensure centrifugation is adequate to remove platelets. Specimens should be free of bubbles.
3. To ensure consistency in results, recentrifuge specimens prior to testing if they contain fibrin, red blood cells, or other particulate matter. NOTE: 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	1 year

<b>Sample</b>	<b>Dilution</b>	<b>Procedures</b>
<b>Serum/Plasma</b>		

Samples with urea nitrogen values exceeding 125 mg/dL are flagged with the code "> 125 mg/dL" and may be diluted with either the Automated or the Manual Dilution Procedure.

#### **Automated Dilution Protocol**

The system performs a 1:5 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.

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## BUN or UREA – UREA NITROGEN OR UREA, *Continued*

### Reagents

### Reagent Preparation

- Reagents are shipped on wet ice.
- Upon receipt, place reagent cartridges in an upright position for 24 hours before use to allow bubbles that may have formed to dissipate.
- If a reagent cartridge is dropped, place in an upright position for 24 hours before use to allow bubbles that may have formed to dissipate.
- 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	2 to 8°C	Until expiration date	Store in upright position
Onboard	System Temperature	25 days	
Opened	2 to 8°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.

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## BUN or UREA – UREA NITROGEN OR UREA, *Continued*

### Calibration

#### **Calibration Required**

For instructions on performing a calibration, refer to the Alinity ci-series Operations Manual, Section 5. Calibration is stable for approximately 7 days (168 hours), but is required with each change in reagent cartridge or 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.

#### **Calibrator Preparation**

This product is liquid ready-to-use. Prior to each use, mix by gentle inversion.

#### **Calibration Storage and Stability**

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

#### **Calibration Information**

1. Calibrator values may be configured using e-files accessed and imported from [www.corelaboratory.abbott](http://www.corelaboratory.abbott), or from Abbott Mail.

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## BUN or UREA – UREA NITROGEN OR UREA, *Continued*

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](#)

### Reference Range

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

Gender	Age Year Low	Age year High	Ref Low	Ref High
	0	4	0	17
	4	14	0	17
	14	19	0	21
M	19	50	0	21
F	19	50	0	19
U	19	50	0	19
M	50	250	0	26
F	50	250	0	20
U	50	250	0	20

### Analytic Range

AMR Low	AMR High	CRR Low	CRR High
3	125	3	625

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## **BUN or UREA – UREA NITROGEN OR UREA, *Continued***

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**Distributions**   Kaiser Permanente Riverside Service Area Laboratory

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