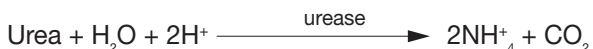




BUN/UREA

Urea is hydrolyzed to ammonium ions in a reaction catalyzed by the enzyme urease.



The ammonium ions are measured potentiometrically by an ion-selective electrode. In the calculation of results for urea, concentration is related to potential through the Nernst Equation.

See below for information on factors affecting results. Certain substances, such as drugs, may affect analyte levels *in vivo*.¹

If results appear inconsistent with the clinical assessment, the patient sample should be retested using another cartridge.

Intended Use

The test for blood urea nitrogen (BUN/urea), as part of the i-STAT System, is intended for use in the *in vitro* quantification of BUN/urea in arterial, venous, or capillary whole blood.

Contents

Each i-STAT cartridge contains one reference electrode (when potentiometric sensors are included in the cartridge configuration), sensors for the measurement of specific analytes, and a buffered aqueous calibrant solution that contains known concentrations of analytes and preservatives. For cartridges that contain a sensor for the measurement of urea nitrogen, a list of reactive ingredients is indicated below:

Reactive Ingredient	Biological Source
Urea	N/A
Urease	<i>Canavalia ensiformis</i>

Metrological Traceability

The i-STAT System test for blood urea nitrogen/urea measures blood urea nitrogen/urea amount-of-substance concentration in the plasma fraction of arterial, venous, or capillary whole blood (dimension mmol L⁻¹) for *in vitro* diagnostic use. BUN/urea values assigned to i-STAT's controls and calibration verification materials are traceable to the U.S. National Institute of Standards and Technology (NIST) standard reference material SRM909. i-STAT System controls and calibration verification materials are validated for use only with the i-STAT System and assigned values may not be commutable with other methods. Further information regarding metrological traceability is available from Abbott Point of Care Inc..

Expected Values

Test/Abbreviation	Units*	Reportable Range	Reference Range ²
Urea Nitrogen/BUN	mg/dL	3 – 140	8 – 26
Urea	mmol/L	1 – 50	2.9 – 9.4
Urea	mg/dL	6 – 300	17 – 56
Urea	g/L	0.06 – 3.00	0.17 – 0.56

*The i-STAT System can be configured with the preferred units.

To convert a BUN result in mg/dL to a urea result in mmol/L, multiply the BUN result by 0.357. To convert a urea result in mmol/L to a urea result in mg/dL, multiply the mmol/L result by 6. To convert a urea result in mg/dL to a urea result in g/L, divide the mg/dL result by 100.

The i-STAT reference ranges for whole blood listed above are similar to reference ranges derived from serum or plasma measurements with standard laboratory methods.

The reference range programmed into the analyzer and shown above is intended to be used as a guide for the interpretation of results. Since reference ranges may vary with demographic factors such as age, gender and heritage, it is recommended that reference ranges be determined for the population being tested.

Clinical Significance

An abnormally high level of urea nitrogen in the blood is an indication of kidney function impairment or failure. Some other causes of increased values for urea nitrogen include prerenal azotemia (e.g. shock), postrenal azotemia, GI bleeding and a high protein diet. Some causes of decreased values for urea nitrogen include pregnancy, severe liver insufficiency, overhydration and malnutrition.

Performance Characteristics

The typical performance data summarized below was collected in health care facilities by health care professionals trained in the use of the i-STAT System and comparative methods.

Precision data were collected in multiple sites as follows: Duplicates of each control fluid were tested in the morning and in the afternoon on five days for a total of 20 replicates. The averaged statistics are presented below.

Method comparison data were collected using CLSI guideline EP9-A³. Venous blood samples were collected in lithium heparin Vacutainer[®] tubes and analyzed in duplicate on the i-STAT System. A portion of the specimen was centrifuged and the separated plasma was analyzed in duplicate on comparative methods within 20 minutes of collection.

Deming regression analysis⁴ was performed on the first replicate of each sample. In the method comparison table, n is the number of specimens in the data set, Sxx and Syy refer to estimates of imprecision based on the duplicates of the comparative and the i-STAT methods respectively, Sy.x is the standard error of the estimate, and r is the correlation coefficient.*

Method comparisons will vary from site to site due to differences in sample handling, comparative method calibration and other site specific variables.

Interference studies were based on CLSI guideline EP7.⁵

*The usual warning relating to the use of regression analysis is summarized here as a reminder: For any analyte, "if the data is collected over a narrow range, the estimate of the regression parameters are relatively imprecise and may be biased. Therefore, predictions made from these estimates may be invalid".³ The correlation coefficient, r, can be used as a guide to assess the adequacy of the comparative method range in overcoming this problem. As a guide, the range of data can be considered adequate if $r > 0.975$.

Precision Data (mg/dL)

Aqueous Control	Mean	SD	%CV
Level 1	52.8	0.76	1.4
Level 3	5.5	0.45	8.2

Method Comparison (mg/dL)

	Beckman Coulter LX20	Dade Dimension RxL-Xpand	Beckman Coulter CX9
n	39	32	26
Sxx	0.36	0.48	0.39
Syy	0.67	0.34	0.60
Slope	1.03	1.05	1.00
Int't	1.39	-0.28	-0.38
Sy.x	0.99	0.31	0.85
Xmin	5	5	7
Xmax	70	38	66
r	0.997	0.998	0.997

Cartridge Comparison

The performance characteristics of the sensors are equivalent in all cartridge configurations. System difference analysis was performed on 40 patient samples using the i-STAT 6+ and i-STAT EC8+ cartridges. In the 25–60 mg/dL range the average difference was -1.13. In the 60–140 mg/dL range the average difference was -0.77.

Factors Affecting Results*

Endogenous ammonium ions will not affect results.

Interferent

Effect

Thiocyanate

Thiocyanate can cause falsely decreased BUN/urea results on the i-STAT System. Preliminary studies indicated that 140 mg/dL (24 mmol/L) thiocyanate decreased BUN/urea results from 11.8 to 9.3 mg/dL (4.2 to 3.3 mmol/L), approximately 21%. Thiocyanate is a degradation product of nitroprusside treatment and also a product of thiosulphate treatment of cyanide poisoning.

*It is possible that other interfering substances may be encountered. These results are representative and your results may differ somewhat due to test-to-test variation. The degree of interference at concentrations other than those listed might not be predictable.

References

1. D.S. Young, *Effects of Drugs on Clinical Laboratory Tests*, 3rd ed. (Washington, DC: American Association of Clinical Chemistry, 1990).
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3. CLSI. *Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline*. CLSI document EP9-A [ISBN 1-56238-283-7]. CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 1995.
4. P.J. Cornbleet and N. Gochman, "Incorrect Least-Squares Regression Coefficients in Method-Comparison Analysis," *Clinical Chemistry* 25:3, 432 (1979).
5. CLSI. *Interference Testing in Clinical Chemistry; Proposed Guideline*. CLSI document EP7-P [ISBN 1-56238-020-6]. CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 1986.

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