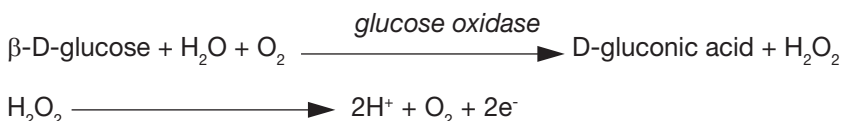




GLUCOSE/GLU

Glucose is measured amperometrically. Oxidation of glucose, catalyzed by the enzyme glucose oxidase, produces hydrogen peroxide (H₂O₂). The liberated hydrogen peroxide is oxidized at the electrode to produce a current which is proportional to the sample glucose concentration.



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 glucose, as part of the i-STAT System, is intended for use in the *in vitro* quantification of glucose 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 glucose, a list of reactive ingredients is indicated below:

Reactive Ingredient	Biological Source
Glucose	N/A
Glucose Oxidase	<i>Aspergillus niger</i>

Metrological Traceability

The i-STAT System test for glucose measures glucose amount-of-substance concentration in the plasma fraction of arterial, venous, or capillary whole blood (dimension mmol L⁻¹) for *in vitro* diagnostic use. Glucose 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 SRM965. 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
Glucose/Glu (fasting)	mg/dL	20 – 700	70 – 105
	mmol/L	1.1 – 38.9	3.9 – 5.8
	g/L	0.20 – 7.00	0.70 – 1.05

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

To convert a result from mg/dL to mmol/L, multiply the mg/dL value by 0.055.

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

Glucose is a primary energy source for the body and the only source of nutrients for brain tissue. Measurements for determination of blood glucose levels are important in the diagnosis and treatment of patients suffering from diabetes and hypoglycemia. Some causes for increased values of glucose include diabetes mellitus, pancreatitis, endocrine disorders (e.g. Cushing's syndrome), drugs (e.g. steroids, thyrotoxicosis), chronic renal failure, stress, or I.V. glucose infusion. Some causes of decreased values of glucose include insulinoma, adrenocortical insufficiency, hypopituitarism, massive liver disease, ethanol ingestion, reactive hypoglycemia, and glycogen storage disease.

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 at 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	41.8	0.68	1.6
Level 3	289	2.4	0.8

Method Comparison (mg/dL)

	Beckman Coulter LX20	Bayer 860	Dade Dimension RxL-Xpand
n	35	40	32
Sxx	2.21	4.71	0.98
Syy	0.69	0.96	0.59
Slope	1.03	0.99	1.01
Int't	-3.39	-1.67	-0.85
Sy.x	0.91	0.70	1.57
Xmin	45	58	48
Xmax	297	167	257
r	0.999	0.993	0.998

Cartridge Comparison

The performance characteristics of the sensors are equivalent in all cartridge configurations. System difference analysis was performed on 34 patient samples using the i-STAT CHEM8+ and i-STAT CG8+ cartridges. In the 65–249 mg/dL range, the average difference was 0.80.

Factors Affecting Results*

Glucose values will decrease in whole blood samples over time. Venous blood glucose is as much as 7 mg/dL less than capillary blood glucose as a result of tissue utilization.⁶

Interferent	Effect
Bromide	37.5mmol/L (300mg/dL) bromide will decrease glucose results by 30 mg/dL.
pH	Values below 7.4 at 37°C decrease results by approximately 0.9 mg/dL (0.05 mmol/L) per 0.1 pH units. Values above 7.4 at 37°C increase results by approximately 0.8 mg/dL (0.04 mmol/L) per 0.1 pH units.
Hydroxyurea (Droxia®, Hydrea®)	Hydroxyurea may cause significant errors in the measurement of glucose with the i-STAT System. Use an alternative method to measure glucose when patients have been administered hydroxyurea. See note (1) below for typical uses of this drug and note (2) below for details of the interference.
Thiocyanate	Thiocyanate can cause falsely low glucose results on the i-STAT System. Preliminary studies indicated that 24 mmol/L (140 mg/dL) thiocyanate decreased glucose results from 85.6 to 65.8 mg/dL (4.75 to 3.65 mmol/L), approximately 23%. Thiocyanate is a degradation product of nitroprusside treatment and also a product of thiosulphate treatment of cyanide poisoning.
PO ₂	Oxygen levels of less than 20 mmHg (2.66 kPa) at 37°C may decrease results.

* It is possible that other interfering substance 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.

Notes:

- 1) Hydroxyurea is a DNA synthesis inhibitor used in the treatment of various forms of cancer, sickle cell anemia, and HIV infection. This drug is used to treat malignancies including melanoma, metastatic ovarian cancer, and chronic myelogenous leukemia. It is also used in the treatment of polycythemia vera, thrombocytopenia, and psoriasis. At typical doses ranging from 500 mg to 2 g/day, concentrations of hydroxyurea in patients' blood may be sustained at approximately 100 to 500 $\mu\text{mol/L}$. Higher concentrations may be observed soon after dosing or at higher therapeutic doses.
- 2) For every 100 $\mu\text{mol/L}$ hydroxyurea in the whole blood sample, glucose will be increased by approximately 8 mg/dL (0.44 mmol/L), up to a whole blood hydroxyurea concentration of at least 921 $\mu\text{mol/L}$ (maximum concentration tested). The magnitude of the bias is independent of the glucose level over a range of at least 75 mg/dL (4.2 mmol/L) to 645 mg/dL (35.8 mmol/L).

Ascorbic acid up to 0.63 mmol/L (11 mg/dL), uric acid up to 12 mg/dL, lactate up to 20 mmol/L (182 mg/dL), β -hydroxybutyrate up to 20 mmol/L (208 mg/dL), acetoacetate up to 10 mmol/L (100 mg/dL), acetaminophen up to 1.32 mmol/L (20 mg/dL), maltose up to 13.3 mmol/L (480 mg/dL) and hematocrit levels between 15–75 %PCV were tested and found not to interfere with glucose results.

References

1. D.S. Young, *Effects of Drugs on Clinical Laboratory Tests*, 3rd ed. (Washington, DC: American Association of Clinical Chemistry, 1990).
2. P.C. Painter, J.Y. Cope, J.L. Smith, "Reference Ranges, Table 41-20" in *Tietz Textbook of Clinical Chemistry—Second Edition*, C.A. Burtis and E.R. Ashwood, eds. (Philadelphia: W.B. Saunders Company, 1994).
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.
6. D.S. Young and E.W. Bermes, "Influence of Site Collection on Blood Gases and pH," in *Tietz Textbook of Clinical Chemistry—Second Edition*, C.A. Burtis and E.R. Ashwood, eds. (Philadelphia:W.B. Saunders Company, 1994).

i-STAT is a registered trademark of Abbott Laboratories, East Windsor, NJ USA. Vacutainer is a registered trademark of Becton Dickinson and Company, Franklin Lakes, NJ USA. LX20 is a registered trademark of Beckman Coulter Incorporated, Fullerton, CA USA. The Bayer 860 analyzer is manufactured by Bayer Diagnostics, Tarrytown, NY USA. Dimension RxL-Xpand is a registered trademark of Dade Behring Inc., Deerfield, IL USA.



Abbott Point of Care Inc.
Abbott Park, IL 60064 • USA



Emergo Europe
P.O. Box 18510
2502 EM The Hague
The Netherlands
Tel: (31)70 345 8570
Fax: (31)70 346 7299



©2008 Abbott Point of Care Inc.. All rights reserved. Printed in USA.