i-STAT G Cartridge

Intended for US only

NAME

i-STAT G Cartridge – REF 03P83-26

INTENDED USE

The *i-STAT G* cartridge with the *i-STAT 1* System is intended for use in the *in vitro* quantification of glucose in arterial, venous or capillary whole blood in point of care or clinical laboratory settings.

Glucose measurements are used in the diagnosis, monitoring, and treatment of carbohydrate metabolism disorders including, but not limited to, diabetes mellitus, neonatal hypoglycemia, idiopathic hypoglycemia, and pancreatic islet cell carcinoma.

SUMMARY AND EXPLANATION / CLINICAL SIGNIFICANCE

Measured:

Glucose (Glu)

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.

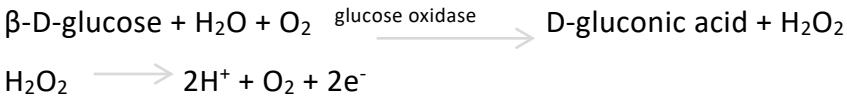
TEST PRINCIPLE

The *i-STAT 1* System uses direct (undiluted) electrochemical methods. Values obtained by direct methods may differ from those obtained by indirect (diluted) methods.[1]

Measured:

Glucose (Glu)

Glucose is measured amperometrically. Oxidation of glucose, catalyzed by the enzyme glucose oxidase, produces hydrogen peroxide (H_2O_2). The liberated hydrogen peroxide is oxidized at the electrode to produce a current 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*.[2] If results appear inconsistent with the clinical assessment, the patient sample should be retested using another cartridge.

REAGENTS

Contents

Each *i-STAT G* cartridge contains a ground electrode, and amperometric sensor for the measurement of specific analytes. It also contains a buffered aqueous calibrant solution with known concentrations of analytes and preservatives. A list of reactive ingredients relevant for the *i-STAT G* cartridge is shown below:

Sensor	Reactive Ingredient	Biological Source	Minimum Quantity
Glu	Glucose	N/A	7 mmol/L
	Glucose Oxidase	*Aspergillus niger*	0.002 IU

Warnings and Precautions

- For *in vitro* diagnostic use.
- DO NOT RE-USE - cartridges are intended for single-use only.
- Although the sample is contained within the cartridge, cartridges should be disposed of as biohazardous waste according to local, state, and national regulatory guidelines.
- The i-STAT 1 System automatically runs a comprehensive set of quality checks of instrument and cartridge performance each time a sample is tested. This internal quality system will suppress results by generating a Quality Check Code (QCC) if the instrument or cartridge does not meet certain specifications. To minimize the probability of delivering a result with medically significant error the internal specifications are very stringent. It is typical for the system to suppress a very small percentage of results in normal operation given the stringency of these specifications. If however the instrument or cartridges have been compromised, results may be persistently suppressed, and one or the other must be replaced to restore normal operating conditions. Where unavailability of results while awaiting replacement of instruments or cartridges is unacceptable, Abbott Point of Care Inc. recommends maintaining both a backup analyzer and cartridges from an alternate lot number.
- Use a puncture device that provides free-flowing blood.
- Improperly filling and/or closing the cartridges may result in Quality Check Codes and/or inability to obtain results.

For additional warnings and precautions about the *i-STAT 1 System* refer to the *i-STAT 1 System* Manual located at www.globalpointofcare.abbott.

Storage Conditions

- Refrigerated at 2-8°C (35-46°F) until expiration date.
- Room Temperature at 18-30°C (64-86°F). Cartridges may be stored at room temperature for the time frame indicated on the cartridge box.

INSTRUMENTS

The i-STAT G cartridge is intended for use with the *i-STAT 1* analyzer.

For a detailed description of the analyzer and system procedures, refer to the i-STAT 1 System Manual located at www.globalpointofcare.abbott.

SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS

Specimen Types

Arterial, venous or capillary whole blood.
Sample Volume: 65 µL

Blood Collection Options and Test Timing (time from collection to cartridge fill)

Test	Syringes	Test Timing	Evacuated Tubes	Test Timing	Capillary Tubes	Test Timing
Glucose	Without anti-coagulant	3 minutes	Without anti-coagulant	3 minutes	With balanced heparin anti-coagulant or lithium heparin anti-coagulant (tube must be filled to labeled capacity) ** †	3 minutes
	With EDTA, balanced heparin anti-coagulant or lithium heparin anti-coagulant (syringe must be filled to labeled capacity) ** • Remix thoroughly before filling cartridge.	30 minutes	With EDTA or lithium heparin anti-coagulant (tubes must be filled to labeled capacity) ** • Remix thoroughly before filling cartridge.	30 minutes		

**Fill blood collection devices to capacity. Underfilling will cause higher heparin to blood ratios which may affect results.

†Capillary whole blood specimens (e.g., obtained by fingerstick) should not be used in patients receiving intensive medical intervention/therapy because of the potential for pre-analytical collection error and specifically in patients with decreased peripheral blood flow, as it may not reflect the true physiological state. Examples include, but are not limited to, severe hypotension, shock, hyperosmolar-hyperglycemia (with or without ketosis) and severe dehydration.

PROCEDURE FOR CARTRIDGE TESTING

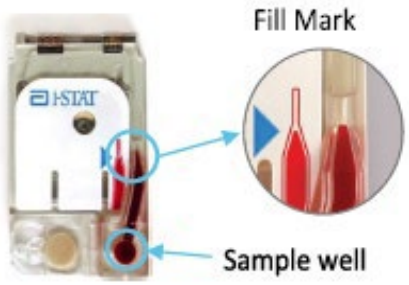
Each cartridge is sealed in a foil pouch for protection during storage--do not use if pouch has been punctured.

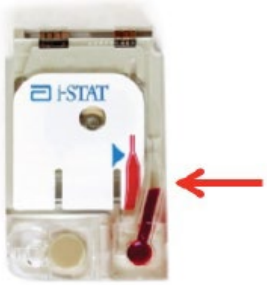
- A cartridge should not be removed from its protective pouch until it is at room temperature (18-30 °C or 64-86 °F). For best results, the cartridge and analyzer should be at room temperature.
- Since condensation on a cold cartridge may prevent proper contact with the analyzer, allow refrigerated cartridges to equilibrate at room temperature for 5 minutes for a single cartridge and 1 hour for an entire box before use.
- Use a cartridge immediately after removing it from its protective pouch. Prolonged exposure may cause a cartridge to fail a Quality Check.
- Do not return unopened, previously refrigerated cartridges to the refrigerator.
- Cartridges may be stored at room temperature for the time frame indicated on the cartridge box.

Filling and Sealing the Cartridge (after cartridge has been equilibrated and blood sample has been collected)

1. Place the cartridge on a flat surface.
2. Invert a lithium heparin blood collection tube at least 10 times. If sample was collected into a syringe, invert syringe for 5 seconds then roll the syringe between the palms (hands parallel to the ground) for 5 seconds, flip and roll for an additional 5 seconds. The blood in the hub of the syringe will not mix, therefore expelling 2 drops before filling a cartridge is recommended. Note that it may be difficult to properly mix a sample in a 1.0 mL syringe.
3. Fill the cartridge immediately. Direct the hub of syringe or tip of the transfer device (capillary tube, pipette, or dispensing tip) into the sample well of the cartridge.
4. Slowly dispense sample into the sample well until the sample reaches the fill mark indicated on the cartridge. Cartridge is properly filled when the sample reaches the 'fill to' mark and a small amount of sample is in the sample well (as displayed in the illustrations below). The sample should be continuous, no bubbles or breaks (see System Manual for details).
5. Fold the snap closure of the cartridge over the sample well.

Note: Every effort should be made to fill cartridges properly before inserting into the analyzer. The illustrations below are provided for to support proper cartridge filling using representative cartridges.

Properly filled cartridge	The sample fills the sample chamber to the fill mark indicator.  Full sample well, and no bubble appears in the sample pathway.

	
Underfilled cartridge	The sample well is sufficiently filled, but the sample does not reach the fill mark indicator.  The sample well is insufficiently filled, and the sample does not reach the fill mark indicator. 
Overfilled cartridge	The sample well is overfilled, the sample exceeds the fill mark indicator.  The sample well is overfilled, there is a bubble in the sample well.

Performing Patient Analysis

1. Press the power button to turn on the analyzer.
2. Press 2 for *i-STAT Cartridge*.
3. Follow the analyzer prompts.
4. Scan the lot number on the cartridge pouch.
5. Continue normal procedures for preparing the sample, and filling and sealing the cartridge.
6. Push the sealed cartridge into the analyzer port until it clicks into place. Wait for the test to complete.
7. Review the results.

For additional information for cartridge testing, refer to the i-STAT 1 System Manual located at www.globalpointofcare.abbott.

Analysis Time

Approximately 130–200 seconds

Quality Control

The i-STAT quality control regimen comprises four aspects, with a system design that reduces the opportunity for error, including:

1. A series of automated, on-line quality measurements that monitors the sensors, fluidics, and instrumentation each time a test is performed.
2. A series of automated, on-line procedural checks that monitors the user each time a test is performed.
3. Liquid materials are available to be used to verify the performance of a batch of cartridges when they are first received or when storage conditions are in question.
4. Traditional quality control measurements that verify the instrumentation using an independent device, which simulates the characteristics of the electrochemical sensors in a way that stresses the performance characteristics of the instrumentation.

For additional information on Quality Control, refer to the i-STAT 1 System Manual located at www.globalpointofcare.abbott.

Each laboratory should follow local, state and national regulations regarding quality control materials.

Calibration Verification

Calibration Verification is a procedure intended to verify the accuracy of results over the entire measurement range of a test. While the Calibration Verification Set contains five levels, verification of the measurement range could be accomplished using the lowest, highest and mid-levels.

For additional information on Calibration Verification, refer to the i-STAT 1 System Manual located at www.globalpointofcare.abbott.

EXPECTED VALUES

TEST	UNITS *	REPORTABLE RANGE	REFERENCE RANGE [3] (arterial)	(venous)
MEASURED				
Glu	mmol/L	1.1-38.9	3.9-5.8	
	mg/dL	20-700	70-105	
	g/L	0.20-7.00	0.70-1.05	

***** The i-STAT 1 System can be configured with the preferred units.

** Glucose reference ranges by age are provided in the table below.

Unit Conversion:

- **Glucose (Glu):** To convert mg/dL to mmol/L, multiply the mg/dL value by 0.055.

Glucose reference range by age (where applicable) [3]

AGE	Reference Range* (mg/dL)
Premature	20-60
Neonate	30-60
Newborn	
1 day	40-60
>1 day	50-80
Child	60-100
Adult	70-105

* for serum specimens

The reference ranges programmed into the analyzer and shown above are intended to be used as guides for the interpretation of results. Since reference ranges may vary with demographic factors such as age, sex, race and ethnicity it is recommended that reference ranges be determined for the population being tested.

METROLOGICAL TRACEABILITY

Glucose values assigned to *i-STAT System* controls and calibration verification materials are traceable to the U.S. National Institute of Standards and Technology (NIST) standard reference material SRM965. The *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.

Additional information regarding metrological traceability is available from Abbott Point of Care Inc.

To obtain additional information and technical support, refer to the company website at www.globalpointofcare.abbott.

PERFORMANCE CHARACTERISTICS

The typical performance of the *i-STAT G* cartridge with the *i-STAT 1 System* are shown below.

Precision

Precision data was collected in studies based on CLSI guideline EP05-A3 [4]. The precision study was conducted using five (5) levels of aqueous materials. Duplicates of each level were tested twice a day for a minimum of 20 days. The statistics for mean, standard deviation (SD) and coefficient of variation (CV) are represented below. This is representative data, results in individual laboratories may vary.

Test	Units	Fluid Levels	N	Mean	SD	CV (%)
Glu	mg/dL	CV L1	80	25.0	0.55	2.19
		CV L2	80	38.5	0.49	1.27
		CV L3	80	119.1	0.78	0.66
		CV L4	80	272.2	1.66	0.61
		CV L5	80	565.5	5.41	0.96

Whole blood precision was evaluated using arterial, venous and capillary whole blood specimens collected with lithium heparin. The repeatability analysis was conducted using the data collected across multiple point of care sites. For each sample type, samples were grouped into subintervals based on their mean values.

Test	Units	Sample Type	Sample Range	N	Mean	SD	CV (%)
Glu	mg/dL	Venous Whole Blood	20-90	38	75.0	0.32	0.43
			>90-150	67	109.6	0.39	0.35
			>150-250	32	195.8	0.73	0.37
			>250-400	15	315.0	1.17	0.37
			>400-700	12	559.0	2.01	0.36
		Arterial Whole Blood	20-90	9	82.4	0.33	0.40
			>90-150	94	125.0	0.57	0.46
			>150-250	64	182.0	0.54	0.30
			>250-700	6	357.0	0.91	0.26
		Capillary Whole blood	20-90	33	70.9	1.92	2.71
			>90-150	53	116.0	2.44	2.10
			>150-250	37	196.6	4.40	2.24
			>250-700	16	297.1	4.09	1.38

Method Comparison

Method comparison was demonstrated in a study based on CLSI guideline EP09c-ED3.[5]

Lithium heparin venous and arterial whole blood specimens collected across multiple point of care sites were evaluated using *i-STAT G* cartridges on the *i-STAT 1* analyzer against whole blood specimens tested on a comparative method. The first replicate result from the *i-STAT G* cartridge on the *i-STAT 1* analyzer was compared to the mean result from the comparative method.

Two (2) capillary specimens collected from skin punctures with balanced heparin capillary tubes from each study subject across multiple point of care sites were evaluated and analyzed in singlicate on the *i-STAT G* cartridge on the *i-STAT 1* analyzer against the comparative method.

The venous, arterial, and capillary data were pooled, and a Passing-Bablok linear regression analysis was performed using the results from the *i-STAT G* cartridge on the *i-STAT 1* analyzer versus the comparative method results. Method comparison results comparing the i-STAT Glucose test performance on the *i-STAT 1* analyzer to comparative methods for arterial, venous and capillary are shown in the table below. In the table, N is the number of specimens in the data set, and r is the correlation coefficient.

Test (units)	Comparative Method Arterial/ Venous	Capillary	N	Slope	Intercept	r	Xmin	Xmax
Glu (mg/dL)	*i-STAT CHEM8+*	epoc Blood Analysis System	571	1.00	1.85	1.00	21	682

A Passing-Bablok linear regression analysis was performed using the results of each sample from the *i-STAT G* cartridges on the *i-STAT 1* analyzer versus the comparative method results. Method comparison results for arterial, venous and capillary whole blood specimens are shown in the table, below. In the table, N is the number of specimens in the data set, and r is the correlation coefficient.

Method comparison results for arterial, venous and capillary specimens						
Test	**Sample Type**	**Comparative Method**	**N**	**Slope**	**Intercept**	**r**
Glu	Arterial	i-STAT CHEM8+	173	1.00	1.00	1.00
	Venous	i-STAT CHEM8+	164	1.00	1.50	1.00
	Capillary	epoc Blood Analysis System	234	1.00	2.00	1.00

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

Linearity

Linearity studies were performed based on guidance from CLSI EP06-Ed2 [6]. The results using lithium heparin whole blood samples demonstrated linearity across the reportable range described in the "Expected Values" section above.

LIMITATIONS OF THE PROCEDURE

The *i-STAT G* cartridge test results should be assessed in conjunction with the patient's medical history, clinical examination, and other findings. If results appear inconsistent with the clinical assessment, the patient sample should be retested using another cartridge.

Interference Testing

Interference studies were based on CLSI guideline EP07 3rd edition [7]. The substances listed were evaluated in lithium heparin whole blood for relevant tests. For those identified as an interferent, the interference is described.

Substance*	Substance Concentration (mmol/L)	(mg/dL)	Test	Interference (Yes/No)	Comment
Acetaldehyde[a]	0.045 [8]	0.2	Glu	No	
Acetaminophen	1.03 [8]	15.6	Glu	No	
Acetoacetate (Lithium Acetoacetate)	2.0	20	Glu	No	
Acetyl Cysteine (N-Acetyl-L-Cysteine)	0.92 [9,10]	15.0	Glu	No	
Ammonium[a] (Ammonium Chloride)	2.0	10.7	Glu	No	
Ascorbic Acid (L-Ascorbic Acid)	0.298	5.25	Glu	No	
β-Hydroxybutyric Acid[a]	6.0 [11]	62.46	Glu	No	
Bilirubin	0.684	40	Glu	No	
Bromide[a] (Lithium Bromide) [12, 13, 14]	2.5	21.7	Glu	No	Refer to comment below.
	37.5	325.7	Glu	Yes	Use Another Method. Refer to comment below.
Cholesterol	10.3	400	Glu	No	
Creatinine	1.326	15	Glu	No	
Dopamine (Dopamine Hydrochloride)	4.06 µmol/L	0.0621	Glu	No	
Ethanol	130	600	Glu	No	
Fluoride (Lithium Fluoride)	0.0632	0.12	Glu	No	
Formaldehyde[a]	0.133 [8]	0.399	Glu	No	
Fructose	1	18	Glu	No	
Galactose	3.33	60	Glu	No	
Gentamicin (Gentamicin Sulfate)	0.0628	3	Glu	No	
Gentisic Acid	0.0973	1.5	Glu	No	
Glucosamine[a] (Glucosamine Hydrochloride)	0.030	0.647	Glu	No	
Glutathione, reduced	3	3 mEq/L	Glu	No	
Glycolic Acid[a]	10.0 [8]	76.05	Glu	No	
Guaifenesin	0.0227	0.45	Glu	No	
Hemoglobin	10 g/L	1000	Glu	No	
Heparin (Sodium Heparin)	3.30 U/mL	330 U/dL	Glu	No	
Hydroxyurea	0.405	3.08	Glu	Yes	Increased results ≥ 0.08 mmol/L. Refer to comment below.
Ibuprofen	1.06	21.9	Glu	No	

Substance*	Substance Concentration (mmol/L)	(mg/dL)	Test	Interference (Yes/No)	Comment
Intralipid 20%	N/A	3151	Glu	No	
Isoniazid	0.438	6	Glu	Yes	The highest drug concentration under therapeutic treatment reported by CLSI EP37 is 0.146 mmol/L. Glucose measurements in patients treated with Isoniazid are expected to be elevated when Isoniazid is at ≥ 0.29 mmol/L.
Lactate (Lithium Lactate)	10	90	Glu	No	
Maltose	10.5	360	Glu	No	
Mannose[a]	1	18.02	Glu	No	
Nithiodote[a] (Sodium Thiosulfate)	16.7 [15]	264.04	Glu	No	
pH	8.0 pH units	N/A	Glu	No	
Pyruvate (Lithium Pyruvate)	0.570	5	Glu	No	
Salicylate (Lithium Salicylate)	0.207	2.86	Glu	No	
Thiocyanate (Lithium Thiocyanate)	0.898 [8,16]	5.22	Glu	No	
Triglyceride	16.94	1500	Glu	No	
Uric Acid	1.4	23.5	Glu	No	
Xylose[a]	3	45.04	Glu	No	

[a] The test concentration for this substance is not included in CLSI guideline EP37 1st edition. [17]

*The compound tested to evaluate the interfering substance is presented in parentheses.

This is representative data and results may vary from study to study due to matrix effects. Viscosity, surface tension, turbidity, ionic strength and pH are common causes of matrix effects. It is possible that interfering substances other than those tested may be encountered. The degree of interference at concentrations other than those listed might not be predictable.

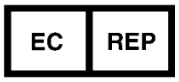
Relevant comments regarding interference of Bromide and Hydroxyurea are noted below:

- Bromide at 2.5 mmol/L is the peak plasma concentration associated with halothane anesthesia, in which bromide is released.
- Hydroxyurea is a DNA synthesis inhibitor used in the treatment of sickle cell anemia, HIV infection, and various types of cancer. The malignancies that it is used to treat include melanoma, metastatic ovarian cancer, and chronic myelogenous leukemia. It is also used in the treatment of polycythemia vera, thrombocythemia, and psoriasis. At typical doses ranging from 500 mg to 2 g/day, concentrations of hydroxyurea in a patient's blood may be sustained at approximately 0.1 to 0.5 mmol/L (100 to 500 µmol/L). Higher concentrations may be observed soon after dosing or at higher therapeutic doses.

Factors Affecting Results

Factor	Test	Effect
Allowing blood to stand (without exposure to air)	Glu	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 due to tissue utilization.[18]
pH dependence	Glu	The dependence of the i-STAT Glucose test with respect to pH is as follows: 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 unit.
PO_2 dependence	Glu	The dependence of the i-STAT Glucose with respect to ***P***O_2 is as follows: Oxygen levels of less than 20 mmHg (2.66 kPa) at 37°C may decrease results.
Hematocrit	Glu	The i-STAT Glucose test has not been evaluated at hematocrit levels <15 %PCV and >75 %PCV. No impact on performance was found at hematocrit levels within 15 - 75 %PCV.
Xylose	Glu	The i-STAT Glucose test has not been evaluated for interference at peak xylose concentrations expected to be found in patient blood following a Xylose Absorption test. No impact on i-STAT Glucose test performance was found up to 45 mg/dL of xylose. If patient undergoes a Xylose Absorption test, recommend waiting 24 hours after the procedure before collecting a specimen for testing glucose using the i-STAT Glucose test.

KEY TO SYMBOLS

Symbol	Definition/Use
	14 days room temperature storage at 18–30 °C.
	Use by or expiration date. The expiration date, expressed as YYYY-MM-DD, indicates the last day the product may be used.
	Manufacturer's lot number or batch code. The lot number or batch code appears adjacent to this symbol.
	Contains sufficient for <n> tests.
	Authorized representative in the European Community.
	Temperature limitations. The upper and lower limits for storage are adjacent to upper and lower arms.
	Catalog number, list number, or reference.
	Do not re-use.
	Manufacturer.
	Consult instructions for use or see System Manual for instructions.
	*In vitro* diagnostic medical device.
	Device for near-patient testing
	For prescription use only.

Additional Information: To obtain additional product information and technical support, refer to the company website at www.globalpointofcare.abbott.

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