# i-STAT G Cartridge

Intended for use with the i-STAT Alinity Instrument


## NAME

i-STAT G Cartridge – REF 03P83-25

## INTENDED USE

The i-STAT G cartridge with the i-STAT Alinity System is intended for use in the *in vitro* quantification of glucose in arterial, venous, or capillary whole blood.

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 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 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 $H_2O_2$ is oxidized at the electrode to produce a current proportional to the sample glucose concentration.

$$\beta\text{-D-glucose} + H_2O + O_2 \xrightarrow{\textit{glucose oxidase}} \text{D-gluconic acid} + H_2O_2$$

$$H_2O_2 \longrightarrow 2H^+ + O_2 + 2e^-$$

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 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. A list of reactive ingredients 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.
- Cartridges are intended for single-use only. Do not reuse.
- Refer to the i-STAT Alinity System Operations Manual for all warnings and precautions.

### Storage Conditions

- Refrigeration at 2–8 ºC (35–46 ºF) until expiration date.
- Room Temperature at 18–30 ºC (64–86 ºF). Refer to the cartridge box for room temperature storage requirements.

## INSTRUMENTS

The i-STAT G cartridge is intended for use with the i-STAT Alinity Instrument (Model No. AN-500).

## 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)

**As higher heparin-to-blood ratios may affect results, fill blood collection tubes and syringes to capacity, following manufacturers' instructions.**

| | G Sample Collection |
|---|---|
| Syringe | **Without anticoagulant**<br>• Mix sample immediately before filling cartridge.<br>• Fill cartridge within 3 minutes of sample collection.<br><br>**With balanced heparin anticoagulant**<br>• Mix sample immediately before filling cartridge.<br>• Fill cartridge within 30 minutes of sample collection. |
| Evacuated Tube | **Without anticoagulant**<br>• Mix sample immediately before filling cartridge.<br>• Fill cartridge within 3 minutes of sample collection.<br><br>**With lithium heparin anticoagulant**<br>• Mix sample immediately before filling cartridge.<br>• Fill cartridge within 30 minutes of sample collection. |
| Capillary Tube | **With balanced heparin anticoagulant**<br>• Mix sample immediately before filling cartridge. |

| G Sample Collection | |
|---|---|
| | • Fill cartridge within 3 minutes of sample collection.<br><br>**With lithium heparin anticoagulant**<br>- If labeled for measurement of electrolytes.<br>• Mix sample immediately before filling cartridge.<br>• Fill cartridge within 3 minutes of sample collection. |
| Fill cartridge directly from skin puncture | While a sample can be transferred directly from a skin puncture to a cartridge, a capillary tube is preferred. |

## PROCEDURE FOR CARTRIDGE TESTING

Preparation for Use:

1. Individual cartridges may be used after standing five minutes at room temperature. An entire box of cartridges should stand at room temperature for one hour.
2. All cartridges should be used immediately after opening pouch.
3. If the pouch has been punctured, the cartridge should not be used.
4. Do not return cartridges to the refrigerator after bringing them to room temperature.

### How to Perform Patient Testing

1. From the Home screen, touch "**Perform Patient Test**". This initiates the patient testing pathway.
2. To begin, follow instructions on the screen to "**Scan or Enter OPERATOR ID**"
3. Follow instructions on the screen to "**Scan or Enter PATIENT ID**"
4. Continue to follow prompts on the screen to proceed with patient testing. "**Scan (CARTRIDGE POUCH) Barcode**", Scanning is required. Information cannot be entered manually.
5. The screen for selecting sample type will display if more than one sample type is applicable; select sample type if applicable.
6. Follow instructions on the screen to "**Close and Insert Filled Cartridge**". The action buttons at the bottom of the screen allow forward, backward and pause functionality.
7. Once the cartridge is inserted, **"Contacting Cartridge"** will display followed by the countdown bar. The following alerts are also displayed: **"Cartridge locked in instrument. Do not attempt to remove the Cartridge"** and **"Testing - Instrument Must Remain Level"**.
8. When the test is complete, the test results are displayed.

#### Analysis Time

Approximately 130–200 seconds.

#### Quality Control

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

**1.** The i-STAT Alinity System automatically runs a comprehensive set of quality checks of analyzer and cartridge performance each time a sample is tested. This internal quality system will suppress results if the analyzer or cartridge does not meet certain internal specifications.

**2.** Aqueous-based control solutions are available for verifying the integrity of newly received cartridges.

**3.** In addition, the instrument performs internal electronic checks and calibration during each test cycle, and the Electronic Simulator test provides an independent check on the ability of the instrument to take accurate and sensitive measurements of voltage, current and resistance from the cartridge. The instrument will pass or fail this electronic test depending on whether or not it measures these signals within limits specified in the instrument software.

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

**Calibration Verification**

Standardization is the process by which a manufacturer establishes "true" values for representative samples. A multi-point calibration is derived for each sensor by this standardization process. These calibration curves are stable over many lots.

A one-point calibration is performed each time a cartridge requiring calibration is used. During the first part of the testing cycle, the calibrant solution is automatically released from its foil pack and is positioned over the sensors. The signals produced by the sensors' responses to the calibrant solution are measured. This one-point calibration adjusts the offset of the stored calibration curve. Next, the instrument automatically moves the sample over the sensors and the signals produced by the sensors' responses to the sample are measured. While coefficients are used rather than graphic calibration curves, the calculation of the result is equivalent to reading the sample's concentration from an adjusted calibration curve.

## EXPECTED VALUES

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

***** The i-STAT System can be configured with the preferred units. (See "Unit Conversion" below.)

Unit Conversion

- **Glucose (Glu):** To convert 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.

i-STAT Alinity does not have default reference ranges programmed into the instrument. The reference ranges 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, gender and heritage, it is recommended that reference ranges be determined for the population being tested.

## METROLOGICAL TRACEABILITY

The measured analytes in the i-STAT G cartridge are traceable to the following reference materials or methods. 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.

**Glucose (Glu)**

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 System controls and calibration verification materials are traceable to the U.S. National Institute of Standards and Technology (NIST) standard reference material SRM965.

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

## PERFORMANCE CHARACTERISTICS

The performance data summarized below was collected at Abbott Point of Care. Representative cartridges were used to collect the data.

**Precision***

A multiday precision study was performed with aqueous calibration verification materials in representative cartridges. Duplicates of each aqueous fluid were tested twice a day for 20 days.

| Test | Units | Aqueous Cal Ver | n | Mean | SD (Standard Deviation) | CV (%) [Coefficient of Variation (%)] |
|---|---|---|---|---|---|---|
| Glu | mg/dL | Very Low Abnormal | 80 | 26.9 | 0.42 | 1.6 |
| | | Low Abnormal | 80 | 41.0 | 0.34 | 0.8 |
| | | High Abnormal | 80 | 125.0 | 0.32 | 0.3 |
| | | Very High Abnormal | 80 | 286.7 | 0.77 | 0.3 |
| | | Highest Abnormal | 80 | 600.6 | 3.47 | 0.6 |

*Note: Representative data, individual laboratories may vary from these data.

**Method Comparison**

Method comparison was demonstrated in a study comparing the i-STAT Alinity to the i-STAT 1 Wireless (i-STAT 1W) using representative cartridges. The studies were based on CLSI guideline EP9-A3. [4] Whole blood samples anticoagulated with lithium heparin were evaluated. Samples were analyzed in duplicate on both systems. A weighted Deming regression analysis was performed using the first replicate result from the i-STAT Alinity versus the mean of the duplicates from the i-STAT 1W.

In the method comparison table, n is the number of specimens, and r is the correlation coefficient.

| Test | Units | | Comparative Method i-STAT 1W |
|---|---|---|---|
| Glu | mg/dL | n | 188 |
| | | Slope | 1.00 |
| | | r | 1.000 |
| | | intercept | 1.17 |
| | | $X_{min}$ | 24 |
| | | $X_{max}$ | 671 |

## FACTORS AFFECTING RESULTS

The following substances were evaluated in plasma for the Glucose analyte at the test concentrations recommended in CLSI guideline EP7-A2 [5] unless otherwise noted. For those identified as an interferant the interference is described.

| Substance | Test Concentration (mmol/L) | Analyte | Interference (Yes/No) | Comment |
|---|---|---|---|---|
| Acetaldehyde | 0.045 [6] | Glu | No | |
| Acetaminophen | 1.32 | Glu | Yes | Increased results |
| Acetaminophen (therapeutic) | 0.132 [6] | Glu | No | |
| Acetoacetate | 2.0 | Glu | No | |
| Acetylcysteine | 10.2 | Glu | Yes | Decreased results. |
| Acetylcysteine (therapeutic) | 0.3 [7 8] | Glu | No | |
| Ascorbate | 0.34 | Glu | No | |
| Bromide | 37.5 | Glu | Yes | Decreased results. Use another method. |
| Bromide (therapeutic) | 2.5 [9 10 11] | Glu | Yes | Decreased results |
| β-Hydroxybutyrate | 6.0 [12] | Glu | No | |
| Dopamine | 0.006 | Glu | No | |
| Formaldehyde | 0.133 [6] | Glu | No | |
| Hydroxyurea | 0.92 | Glu | Yes | Increased results. Use another method. |
| Lactate | 6.6 | Glu | No | |
| Maltose | 13.3 | Glu | No | |
| Nithiodote (Sodium thiosulfate) | 16.7 [13] | Glu | Yes | Decreased results |
| Pyruvate | 0.31 | Glu | No | |
| Salicylate | 4.34 | Glu | No | |
| Thiocyanate | 6.9 | Glu | Yes | Decreased results |
| Thiocyanate (therapeutic) | 0.5 [6] | Glu | No | |
| Uric Acid | 1.4 | Glu | No | |

The degree of interference at concentrations other than those reported above might not be predictable. It is possible that interfering substances other than those tested may be encountered.

Relevant comments regarding interference of Acetaminophen, Acetylcysteine, Bromide, Hydroxyurea, and Nithiodote are noted below:

- Acetaminophen has been shown to interfere with glucose results in the i-STAT G cartridge, at a concentration prescribed by the CLSI guideline, 1.32 mmol/L, which represents a toxic concentration of acetaminophen. Acetaminophen at 0.132 mmol/L, which represents the upper end of the therapeutic concentration, has been shown not to significantly interfere with i-STAT glucose results for i-STAT G cartridge.
- Acetylcysteine has been tested at two levels: the CLSI recommended level and a concentration of 0.30 mmol/L. The latter is 3 times the peak plasma therapeutic concentration associated with treatment to reverse acetaminophen poisoning. APOC has not identified a therapeutic condition that would lead to levels consistent with the CLSI recommended level. Acetylcysteine at a concentration of 10.2 mmol/L decreased i-STAT glucose results, while acetylcysteine at a concentration of 0.3 mmol/L did not significantly interfere with i-STAT glucose results.
- Bromide has been tested at two levels: the CLSI recommended level and a therapeutic plasma concentration level of 2.5 mmol/L. The latter is the peak plasma concentration associated with

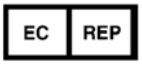
halothane anesthesia, in which bromide is released. APOC has not identified a therapeutic condition that would lead to levels consistent with the CLSI recommended level. Bromide tested at concentrations of 2.5 and 37.5 mmol/L decreased i-STAT glucose results.

- 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, thrombocythemia, 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 µmol/L. Higher concentrations may be observed soon after dosing or at higher therapeutic doses.
- Nithiodote (sodium thiosulfate) is indicated for the treatment of acute cyanide poisoning. The journal article titled "Falsely increased chloride and missed anion gap elevation during treatment with sodium thiosulfate" indicated that sodium thiosulfate could be used in the treatment of calciphylaxis indicating that "the highest concentration likely to be seen in plasma [is] after infusion of a 12.5 g dose of sodium thiosulfate pentahydrate. Assuming that the 12.5 g dose of sodium thiosulfate pentahydrate is distributed in a typical blood volume of 5 L with a hematocrit of 40%, the peak sodium thiosulfate plasma concentration expected is 16.7 mmol/L." [13]

**OTHER FACTORS AFFECTING RESULTS**

| Factor | Analyte | Effect |
|---|---|---|
| Allowing blood to stand | 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 as a result of tissue utilization. [14] |
| pH dependence | Glu | The dependence of the i-STAT glucose 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 units. |
| ***P***$O_2$ 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. |

## KEY TO SYMBOLS

| Symbol | Definition/Use |
|---|---|
|  | 14 days room temperature storage at 18–30 $^{0}$C. |
|  | Use by or expiration date.<br>The expiration date, expressed as YYYY-MM-DD, indicates the last day the product may be used. |
|  | Manufacturer's lot number or batch code.<br>The lot number or batch code appears adjacent to this symbol. |
|  | Sufficient for <n> tests. |
|  | Authorized representative for Regulatory Affairs in the European Community. |
|  | Temperature limitations.<br>The upper and lower limits for storage are adjacent to upper and lower arms. |
|  | Catalog number, list number, or reference. |
|  | Do not reuse. |
|  | Manufacturer. |
|  | Consult instructions for use or see System Manual for instructions. |
|  | *In vitro* diagnostic medical device. |
|  | Compliance to the European directive on *in vitro* diagnostic devices (98/79/EC) |
|  | For prescription use only. |

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

## References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