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Abbott iSTAT-1: Glucose (Whole Blood)

PURPOSE

The iSTAT 1 analyzer is intended for use in approved Point of Care locations. With the iSTAT 1 System, the FDA has categorized the Glucose Cartridge as a Non-Waived Complex Test when testing is performed using arterial, venous, and capillary whole blood samples.

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. 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.

PRINCIPLE

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

TESTING PERSONNEL

A. Qualified and licensed Registered Nurses.

EQUIPMENT AND MATERIALS

- iSTAT 1 Analyzer by Abbott
- iSTAT Glucose "G" Cartridge (cat# 03P83-25 by Abbott)
- Disposable transfer device (e.g., syringes, pipets)
- iSTAT dispensing tips (cat# 06F24-20 or 06F24-30 by Abbott)
- Lithium heparin evacuated collection tube or syringe
- Plain syringe (no preservative)
- Combo Blood Collection Tubes for capillary blood samples (cat# CT 095 by RNA Medical)
- Supplies for collecting a blood sample: cotton balls, alcohol preps, approved auto-disabling single-use lancing device
- Quality Assurance Materials
  - Electronic Simulator
  - iSTAT Level 1 and Level 3 Control Solutions (cat# 06F12-01 and 06F14-01, respectively, by Abbott)
  - Calibration Verification (cat# 06F15-01 by Abbott)
- Data Management System
  - iSTAT 1 Downloader/Recharger
  - iSTAT DE
  - InfoHQ
- Approved cleaning solutions and materials (e.g., mild non-abrasive cleaner, detergent, soap and water, alcohol, Clorox Healthcare Hydrogen Peroxide cleaner disinfectant wipes, PDI Bleach wipes)
- 9-volt lithium batteries or rechargeable batteries (cat# 06F23-55 by Abbott)
- Kimwipe tissues or gauze
- iSTAT 1 System Manual

GENERAL SAFETY INSTRUCTIONS

A. Only trained health care professionals may operate iSTAT 1 Analyzer. Operators must have received comprehensive instruction in the operation, quality control, and care of the iSTAT 1 Analyzer.

GLUCOSE CARTRIDGES STORAGE AND HANDLING

A. **iSTAT Glucose "G" Cartridge**
   1. **Receipt and Storage of Glucose Cartridges:**
      a. **Check Temperature Monitor** (Performed by POCT Services)
         i. New cartridges are shipped with a temperature monitor card.
         ii. Glucose cartridges are shipped refrigerated with a four-window indicator to monitor temperature during transit.
         iii. If **all windows are WHITE** or if only the **A or B windows are BLUE** or the **1 or 2 windows are RED**, then transit temperatures were **Satisfactory** and the cartridges can be used.
         iv. If a temperature strip reading is **Acceptable, run QC Level 1 and 3** and record the results on the i-STAT 1 Liquid QC Glucose Log, **indicating the new shipment information**. Also, document if the temperature monitor card was acceptable.
         v. Forward materials to refrigerator if there are no issues with the temperature.
         vi. If the **C or D windows are BLUE** or the **3 or 4 windows are RED**:
            - Quarantine the suspect materials
            - Do not use cartridges

- Record the lot number
- Contact POCT Services and **do NOT use that shipment/lot of cartridges for patient testing**

i. If **new shipment/lot of cartridges fails 3 times** either Internal/External Electronic Simulator or Liquid Quality Control, contact POCT Services. **Do NOT use that shipment/lot of cartridges for patient testing**. Document all actions taken on the i-STAT 1 Liquid QC Glucose log.

b. **Glucose Cartridge Storage**

i. **Refrigerated storage**: (Performed by POCT Services)

- Store cartridges at **2°C -8°C (35°F -46°F). Do not FREEZE.**
- Refrigerated cartridges may be used until date shown on cartridge box and pack.
- Prior to using a cartridge, cartridges must be removed form refrigerated storage and kept at room temperature for:
  - **Individual Cartridge**: Must be at room temperature for **at least 5 minutes** before using it.
  - **Box of Cartridges**: Must be at room temperature for **at least 1 hour** before using the cartridges.
- It is required that refrigerated storage be equipped with a 24-hour temperature monitor, and that the temperature record be reviewed each day.
- Verify that the cartridges and control materials are stored in the refrigerator are within the expiration date printed on the boxes. If the temperature at which the cartridges are stored is in doubt, do not use them for patient testing and notify POCT.

***NOTE**: This is especially important if freezing conditions are suspected at the back of the refrigerator.*

ii. **Room Temperature Storage**:

NOTE: POCT Services issue cartridges to locations where they are stored at room temperature.

- When removing a cartridge box from refrigerated storage, glucose cartridges may be stored at Room Temperature **(18°C-30°C or 64°F -86°F) for 14 days or until the expiration date on the label if it occurs first**. Mark the margins of individual pouches with the 14-day expiration date on the designated line or use the expiration date on the label if it occurs first. Do NOT write on the center of the pouch as this may result in breakage of the calibrator solution bubble in the center of the cartridge.
- Discard any cartridges after the expiration date.
- Cartridges should not be returned to the refrigerator once they have been at room temperature.
- Cartridges should not be exposed to temperature above 30°C (86°F) or used beyond the expiration date.

i. Verify that cartridges stored at Room temperature are within the expiration date and that the cartridges have been out of the refrigerator less than the time frame indicated on the cartridge box. If the temperature at which the cartridges are stored is in doubt, do not use them for patient testing and notify POCT.

2. **Handling Instructions**:
    a. Glucose cartridges are sealed in individual pouches and packaged 25 to a box.
    b. Glucose cartridges should remain in pouches until time of use. **Once pouch is opened, cartridge is only good for 5 minutes.**
    c. If the pouch has been punctured, the cartridge should not be used.
    d. Do not contaminate the contact pads as the analyzer may not be able to make proper contact with the cartridge.
    e. Do not squeeze the foil pack. Handle it only by the edges to prevent accidental release of calibrant from its sealed pouch.
    f. Do not block the air vent as the sample will not flow to the fill mark and the calibrant solution will not flow to the sensors.
    g. Cartridges should be disposed of as biohazardous waste.
    h. Refer to package insert for more information regarding the glucose cartridge.
    ***NOTE**: To avoid contaminating the analyzer do not use a cartridge on which blood or any other fluid has spilled. Avoid filling cartridges on surfaces that may cause the cartridge to pick up fibers, fluid or debris that may lodge in the analyzer.*

CALIBRATION

The iSTAT analyzer automatically calibrates each cartridge before the sample is assayed.

CALIBRATION VERIFICATION AND SOFTWARE UPDATES

Initial Calibration Verification is performed as part of method verification by POCT personnel. Thereafter, the iSTAT analyzers are calibrated on a semi-annual basis using the CLEW software update provided by the manufacturer.

METHOD COMPARISON

Patient samples (PCOM) are compared against the reference instrument on a regular interval (e.g., every 6 months). POCT will perform the method comparison study. The result(s) must fall within the set allowable total error. Method comparison analysis may also be useful for troubleshooting when patient results are questionable.

NEW, REPLACEMENT AND REPAIRED i-STAT ANALYZERS

Linearity solutions (Levels 1, 3 and 5) and QC (Levels 1 and 3) are performed on new, replacement, and repaired iSTAT analyzers. New and repaired iSTAT analyzers must pass calibration verification, QC testing, and a method comparison test. Results are considered acceptable if the QC and calibration verification results fall within the manufacturer's ranges and the method comparison result(s) fall within the set allowable total error.

QUALITY CONTROL

The quality control procedure for the i-STAT System includes:

A. **Automatic Quality Check**
    1. A series of automatic checks are performed during each test cycle.
    2. If the analyzer detects a problem during power on, a Quality Check message will be displayed indicating the cause and corrective action that must be taken before testing can begin.

3. A Quality Check message will also be displayed, and testing halted if the analyzer detects a problem during the test cycle.
4. The quality checks detect improper environmental conditions, handheld function, cartridge filling, cartridge function, and sensor function.
5. If a Quality check failure persists after taking the recommended action, contact POCT services.
6. See the iSTAT 1 System Manual for the General Quality Check Codes or notify the Super User, POCT Services or the vendor's Technical Support for troubleshooting.

B. **Electronic Simulator Check**
1. An independent check of the handheld's ability to take accurate and a precise reading from the sensors is performed automatically every 24 hours when cartridges are being tested.
2. The Electronic Simulator, External and Internal, is a quality control device for the analyzer's cartridge signal-reading function.
3. Both the **Internal and External Electronic Simulator** sends signals that simulate those of a cartridge to the handheld are signal detection system. The signals are below and above the measurement ranges of the tests and the acceptance limits are tighter than those for liquid control samples. Therefore, the simulator test is more sensitive to an out-of-specification condition than liquid control samples.
4. Both the internal and external simulator results are stored in the handheld's memory and can be transmitted to the Central Data Station.

5. **Internal Electronic Simulator**
   a. The internal simulator check is triggered by the insertion of a cartridge once every 24 hours when the analyzer is used continuously.
   b. The internal test will automatically be performed when a cartridge is inserted before the sample is tested, adding about 20 seconds to the testing cycle.
   c. If the check passes, the cartridge test cycle continues. If it fails, the analyzer displays, "ELECTRONIC SIMULATOR FAIL," testing is blocked, and the External Electronic Simulator must be performed. (See next steps)

6. **External Electronic Simulator**
   a. The external Electronic Simulator is a stable electronic device, which is inserted into the cartridge port. The test cycle for the external Electronic Simulator is about 60 seconds.
   b. An external Electronic Simulator is used:
      i. To verify an internal Electronic Simulator failure
      ii. To verify performance if the analyzer is dropped or damaged
      iii. To check the i-STAT's **Thermal Probe** every 6 months. NOTE: This is captured in InfoHQ as part of external EQC.
      iv. Troubleshooting or as needed.
   c. **Storage:** Store the external Electronic Simulator at Room Temperature (18 - 30^{0}C). Protect the contact pads from contamination by replacing the plastic cap each time and store in its protective case.

      NOTE: *The "Cartridge Locked" or "Simulator Locked" prompt is always displayed when a cartridge or Electronic Simulator is inserted into the analyzer. Any attempt to remove a cartridge or Electronic Simulator before this prompt is removed from the screen may cause damage to the analyzer.*

   d. **Stability:** The i-STAT External Electronic Simulator has no expiration date and can be used unless dropped or damaged.

e. **Frequency:** The External Electronic Simulator Test must be performed when the Internal Electronic Simulator fails (the analyzer will display "ELECTRONIC SIMULATOR FAIL") and after the analyzer is dropped or damaged.

f. **Cleaning the Simulator**: cover the connector area with the blue rubber boot. This will minimize the possibility of any cleaning fluid getting into the simulator housing, thus contaminating the internal circuitry. Clean the simulator with a gauze pad moistened with any of the cleaning agents approved for the analyzer (e.g., alcohol wipe). Rinse the simulator using another gauze pad moistened with water and dry.

NOTE: *Do not immerse the simulator in any fluid, at any time. If the connector itself is contaminated, contact POCT Services.*

7. **Performing the External Electronic Simulator Check:**
   a. Press On / Off key
   b. Press the Menu key
   c. Select 3 – Quality Tests
   d. Select 4 – Simulator
   e. Scan or enter Operator ID
   f. Scan or enter Simulator ID
   g. Insert Simulator; avoid touching the contact pads
   h. Wait until PASS or FAIL is displayed, then Press Menu and wait for message
   i. "Remove Cartridge".
   j. One of two messages will display:
      - PASS – continue to use analyzer
      - FAIL – troubleshoot and document corrective actions taken on the iSTAT Daily QC Log

      NOTE: Removing the simulator or any cartridge before the "Remove Cartridge" message displays will result in damaging the analyzer.

1. **Corrective action if Internal Electronic Simulator Fails or Out of Range**:
   a. If "**FAIL**" is displayed on the analyzer screen, **reinsert** the cartridge.
   b. If "**FAIL**" is displayed a second time, use **External Electronic Simulator** to verify if the failures are being caused by the iSTAT analyzer and not by a faulty cartridge. **DO NOT PERFORM PATIENT TESTING.**
   c. If "**PASS**" is displayed with the External Electronic Simulator, use the analyzer.
   d. If "FAIL" is displayed a second time with the External Electronic Simulator, contact POCT Services. **THE iSTAT WILL LOCK AND PATIENT TESTING CANNOT BE PERFORMED.**

e. Failures will be recorded in InfoHQ as flagged results to be reviewed.

NOTE*: If the check fails, "**FAIL**" and a failure code are displayed. A cartridge test cannot be performed until the handheld passes the simulator check. If there is a delay between the time the cartridge is inserted and the time the display is read, use a fresh cartridge and sample or the external simulator rather than re-inserting the original cartridge.*

C. **i-STAT Liquid Quality Control – Level 1 and Level 3**

1. Aqueous assayed control fluids to verify the integrity of newly received cartridges.
2. Each level of control is packaged in a box of 10 ampules. Control solutions are contained in 1.7 mL glass ampules.
3. The control solutions do not contain human serum or serum products but do contain buffers and preservatives.
4. **New shipments and new lots of liquid controls**: (performed by POCT Services)
   a. New control materials are shipped with a temperature monitor card.
   b. **Check Temperature Monitor**:
      i. iSTAT control materials are shipped refrigerated with a four-window indicator to monitor temperature during transit.

ii. If **all windows are WHITE** or if only the **A or B windows are BLUE** or the **1 or 2 windows are RED**, then transit temperatures were **Satisfactory** and the controls can be used.

iii. Fill out the record of receipt and attach temperature reading on the designated log.

iv. If a temperature strip reading is **Acceptable, run QC Level 1 and 3 with Glucose cartridge from each shipment/lot upon receipt**.

v. Forward materials to refrigerator if there are no issues with the temperature.

vi. If the **C or D windows are BLUE** or the **3 or 4 windows are RED**:

- Quarantine the suspect materials
- Do not use control materials
- Record the lot number
- Contact POCT Services

vii. If **new shipment/lot of QC fails 3 times** with glucose cartridges, contact POCT Coordinator or supervisor.

5. **Storage**: Store controls at 2 to 8 °C until the printed expiration date on the box and ampule labels. Once vials are opened, they must be used immediately. Do NOT return controls to the refrigerator once they have been brought to room temperature. Do NOT use controls if they are cloudy or discolored.
6. **Control Testing Frequency**: Level 1 and Level 3 must be performed
   a. Monthly - Quality control testing is rotated among the locations according to the iSTAT Glucose QC Testing Schedule (e.g., assignment is based on a 3-month rotation) to ensure proper cartridge storage.
   b. Whenever **new shipments and new lots** of control materials or glucose cartridges are received.

   NOTES:
   When the temperature at which the cartridges are stored is in doubt, do not use them and notify POCT Services.
   New lots are tested with current/old lots.
7. Acceptable ranges for liquid quality controls are specific to i-STAT software version, CLEW standard, cartridge type, and cartridge lot numbers are available online at Abbott Website **https://www.abbottpointofcare.com/support/value-assignment-sheets.** However, the iSTAT analyzers are configured to automatically display if the liquid QC passes or fails. NOTE: If the liquid QC fails, the iSTAT will automatically lock out patient testing.

D. **Thermal Probe Check**

1. Two thermal probes in the handheld maintain the cartridges at the correct temperature during the testing cycle. The thermal probe check is performed EVERY SIX MONTHS by POCT Services.

E. **Liquid Quality Control Procedure**

i. **Prepare the Cartridge**

1. Prior to using a cartridge, it must be removed from refrigerated storage and kept at room temperature in its protective pouch for **at least 5 minutes**.
2. Removing a cartridge from the Protective Pouch:
   a. Tear open cartridge pouch at notch.
   b. Remove cartridge from pouch. Always hold by sides.
   c. Place on level surface.
   ***NOTE**: DO NOT remove cartridge until you reach the appropriate step in the patient or control testing process.*

ii. **Quality Checks**

1. Quality checks are automatically performed during each test. If a quality check fails, the handheld stops the test and shows a cause and action to be followed.

2. If a Quality check failure persists after taking the recommended action, contact POCT services.

iii. **Perform a Control Test** – upon receipt of each shipment or new lot, monthly, as needed

1. **Materials**:
   a. iSTAT 1 analyzer
   b. Glucose cartridge
   c. iSTAT Level 1 and Level 3 Controls
   d. Disposable transfer device (e.g., plain syringe, disposable pipet)
   e. Value Assignment Sheet – available at www.abbottpointofcare.com if needed
   f. Gauze or Ampule breaker
   g. Container for broken glass disposal
2. **Prior to testing**
   a. Allow iSTAT Liquid Controls and Glucose cartridge to reach temperature before beginning the test.
   b. **Liquid QC** – remove from refrigerated storage for **at least 30 minutes**.
   c. **Glucose cartridge** - remove from refrigerated storage **at least 5 minutes**.
3. **Test Liquid Quality Control**

   i **Prepare the iSTAT Analyzer**

   NOTE: It is Best Practices to perform steps i – vii without stopping so that the user then has 15 minutes to perform the test.

   i. Press "ON/OFF" button to turn ON iSTAT analyzer.
   ii. Press "Menu" to change screen to Administration Menu.
   iii. Press "3" for the Quality Tests Menu.
   iv. Press "1" for Control.
   v. Scan or Enter the "Operator ID". **DO NOT SHARE** your barcode ID with anyone. Sharing barcode ID is prohibited.
   vi. Then scan "Control Lot Number".
   vii. Scan the "barcoded cartridge lot number".

   ii **Prepare to Test**

   i. Find a stable surface to perform the test.
   ii. Remove cartridge from pouch. Only touch the cartridge by its side to avoid damage or contamination.
   iii. Put on disposable gloves.

   iii **Prepare the Control Sample**

   i. Shake the ampule. Hold the ampule between index finger and thumb. Shake vigorously for 10 seconds.
   ii. Tap the top of the ampule to ensure all fluid flows to the bottom of the ampule.
   iii. Break the ampule. Hold top of ampule with gauze or ampule breaker. Snap top off.
   iv. Fill an empty syringe (no preservatives) halfway with liquid control. (A clean disposable pipet may be used instead of a syringe)
      - Tilt opened ampule so fluid flows close to opening.
      - Position syringe tip into the fluid.
      - Slowly pull back on syringe plunger to draw control into syringe until it is about half full.
   iv. Expel air from the syringe (or pipet).
      - Place a gauze pad on the counter.
      - Press the syringe plunger until you see 3 drops of control empty from the syringe.
   v. Look for any air bubbles in the control fluid.
      - If you see any air bubbles in the control, then discard this syringe and

control and repeat the test using a new control ampule, new cartridge, and new syringe.

iv **Fill the cartridge**

i. Fill the cartridge with control to the fill mark.
   a. Place tip of the syringe over cartridge sample well.
   b. Press plunger so that control enters the cartridge until it reaches the fill mark.
   c. Confirm that there is control fluid in sample well. If you do not see control in sample well, continue to press plunger to deliver more control fluid. Do not wipe off excess sample from the cartridge.
   ***NOTE**: Grossly over or under filling cartridge may cause an error code requiring you to repeat the test.*

v **Seal the Cartridge**
   i. Touching only the plastic tab and sides of cartridge, fold snap closure over the sample well. **Do not press directly over the sample well.**
   ii. Press the tab until it clicks into place. Slightly lift finger or thumb and ensure that the cartridge is closed before completely.

vi **Insert Cartridge**
   i. Push the sealed cartridge into the cartridge port until it clicks into place
      - To avoid permanent damage to the iSTAT analyzer, **do not remove cartridge until the testing process is complete.**
      - Wait about 2 to 3 minutes for the test to complete.

vii **Complete Testing Process**
   i. Pull out cartridge from iSTAT analyzer.
   ii. Turn off analyzer by pressing the ON/OFF button for one second.
   iii. Discard broken ampule in a container that is safe for broken glass.
   iv. Discard remaining test materials in biohazard container.

viii **Repeat the steps with each liquid QC level (1 and 3).**

iv. **Review Quality Control Results**

1. Target values and ranges are found on the Value Assignment Sheet (VAS) posted on the APOC website at **www.abbottpointofcare.com**. Select the correct cartridge, lot number and CLEW software version for the appropriate target values. Current values are also posted at the POCT website. Control test results are shown in numerical values.
2. If **ALL** results are within the acceptable ranges (indicated by PASS), you can use the cartridges for patient testing. If any failures, follow the corrective actions below.
3. Results are recorded in InfoHQ for POCT administrators viewing as well.
4. **Corrective Actions if Liquid QC is Out of Range (FAIL)**:
   a. Before repeating with a new ampule of control, review the following.
      i. Ensure that the correct QC level was run.
      ii. Ensure that the acceptance range is for the appropriate cartridge lot number.
      iii. Ensure that the CLEW software is the same as the CLEW version on the iSTAT analyzer. Press "Menu" and select "Analyzer Status" to view iSTAT software version and CLEW standard.
      iv. Contact POCT Services for acceptance range if the analyzer CLEW standard and/or Cartridge lot number is not found.
   b. Repeat the control with a new ampule. Bring the ampule at room temperature for 30 minutes prior to testing. If the repeat Liquid Quality Control fails multiple times, contact your designated POCT super user or POCT Services.
   c. Do not use iSTAT analyzer for patient testing when QC fails. Consider sending samples to

the Clinical Laboratory for Glucose testing.

d. If iSTAT analyzer is broken or out of service, a backup instrument may be retrieved from the Clinical Lab or POCT Services.
e. POCT will work with Biomed to arrange for the analyzer to be fixed. POCT will then verify the performance of the fixed analyzers that are returned and must have the Clinical Laboratory Director's approval for reimplementation for patient testing of such analyzers.
f. When the repaired iSTAT analyzer has been shipped back to POCT department, the POCT designee will evaluate (QC check, PCOMs check, etc.) the repaired iSTAT analyzer. The Clinical Laboratory Director or designee will review the results and sign-off if the loaner is approved for patient testing.

SPECIMEN / SAMPLE COLLECTION AND HANDLING

A. Universal Precautions should be observed through all phases of the testing procedure.
B. The specimen used to fill a cartridge must be collected and handled properly to ensure that the results represent the patient's current status. Whole blood specimens should be kept in anaerobic conditions (i.e., capped) and analyzed within 30 minutes of collection (fingerstick collections should be immediately tested). If not tested immediately, remix and discard 2 drops of blood before filling cartridge.
C. **Plain Syringe:** Collect a minimum of 0.5 mL whole blood into a plain syringe and test within 3 minutes.
D. **Lithium heparin syringes or evacuated tubes** are the anticoagulants of choice. Fill tube to capacity. Test within 30 minutes.
E. **Fingerstick**: Use a puncture device that provides free-flowing blood. Allow alcohol to dry over puncture site before collecting sample. Inadequate blood flow may produce erroneous results. Avoid vigorous massaging or "milking." To avoid tissue fluid contamination, wipe away the first drop of blood as it may contain excess tissue fluid, which can affect result. *Use a Combo blood collection tube* to transfer the fingerstick blood collected to the cartridge. Test within 3 minutes.
F. **Minimum specimen volume:** 65 µL
G. **Criteria for Specimen Rejection – Redraw the patient if**:
    1. Any evidence of clotting
    2. Incorrect anticoagulant
    3. Specimens with insufficient quantity
    4. Incorrectly drawn specimens
    5. Incorrectly handled specimens prior to sampling
H. **Precautions: Potential Sources of Error in Patient Results**
    1. Cartridge stored incorrectly.
    2. Improper sample collection and/or sample handling
    3. Any deviations will cause inaccurate results.
    4. Use of expired cartridges.
    5. See the **LIMITATIONS AND INTERFERENCES** section for additional information regarding factors that can affect results. If interfering substances is an issue, do not perform this test. Rather, send the sample to the Clinical Laboratory for blood plasma glucose testing.

PATIENT TESTING PROCEDURE

A. Venous, arterial, and capillary whole blood samples collected in a syringe or evacuated tubes with lithium are acceptable for Glucose testing.
B. Unless immediately analyzing and the patient is the only one in the patient room and the testing is being performed in that same room, label all collected samples with **AT LEAST 2 PATIENT**

IDENTIFIERS (Full Name and Medical Record Number, CSN or Date of Birth) in the presence of the patient.

***NOTE**: Correct sample collection and handling are important for accurate results.*

C. **Prepare the Cartridge**

1. Press "ON/OFF" button to turn ON iSTAT analyzer.
2. Press "2" for iSTAT Cartridge.
3. Scan or Enter your "Operator ID". **DO NOT SHARE** your barcode ID with anyone. **Sharing barcode ID is prohibited.**
4. Scan or Enter the "Patient ID" or CSN number. NOTE: You have 2 minutes to enter the patient ID before the iSTAT times out.

A. After scanning the patient ID barcode:	B. Actions to take:
Demographics display on the screen	1. Verify that the demographics displayed on the screen is correct. 2. If so, then select 2 to continue. 3. If not, then select 1 to reenter. 
Demographics do not display on the screen	1. Verify the scanned CSN is correct, checking it against the patient label or patient wristband. 2. If not correct, select 1 to reenter the number. 3. If it is correct, then select 2 to continue. NOTE: Delay in posting or blocking of result may occur. 

D. **Prepare to Test**

1. Find a level, stable surface to perform the test. A level surface includes running the iSTAT analyzer in the downloader/recharger.
2. Remove the cartridge from its pouch and place on a flat surface. Only touch the cartridge by its side to avoid damage or contamination.
3. Scan the lot number on the cartridge pouch. NOTE: You have 2 minutes to scan in the cartridge barcode before the iSTAT times out. Once the cartridge barcode is scanned in, you have 15 minutes to load the sample before the iSTAT times out. You may press any button to reset for another 15 mins. Be sure the iSTAT remains on a level, stable surface.
4. Put on disposable gloves.

E. **Prepare the Blood**

1. For syringe (no needle) collections:
   a. Expel air from the syringe tip.
   b. Place enough gauze pads on the counter to absorb a few drops of blood.
   c. Hold syringe over gauze without touching it.
   d. Press syringe plunger until you see 3 drops of blood empty from the syringe onto the gauze.
   e. Look for any air bubbles in the blood sample. Remove any air bubbles.
2. For heparinized collections, gently mix the blood, inverting the tube 2 to 3 times. Use a dispensing tip to fill the cartridge.
3. For blood collected by fingerstick (capillary), immediately transfer blood to the cartridge using a Combo blood collection tube. See Combo Blood Collection Tubes package insert for instructions.

F. **Fill the Cartridge**

1. For syringes:
   a. Dispense blood, slowly and steadily filling the cartridge with sample to the fill mark.
   b. Place the tip of the syringe over the cartridge sample well.
   c. Press plunger so that sample enters cartridge until it reaches the fill mark.
   d. Confirm that there is sample in the sample well. If you do not see sample in the sample well, continue to press the plunger to deliver more sample. Do not wipe off excess from the cartridge.
2. Fingersticks: See Combo Blood Collection Tubes package insert for additional information. Ensure that there are no air bubbles present.
   a. Remove one capillary tube and one plunger. Do not touch the tip furthest from the red band.
   b. Insert the plunger in the end with the red band. Use the plunger to reposition the porous plug to the 65 µL fill mark as in Figure 1. The porous plug will stop the blood at the fill mark at which it is positioned. NOTE: For best results, fill a little past the fill mark.

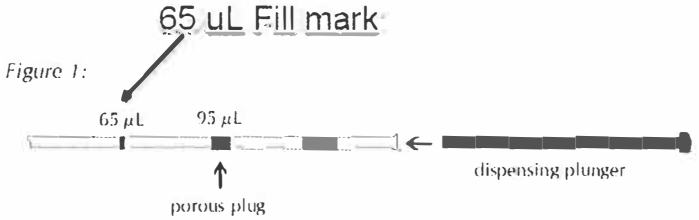

Figure 1:

   c. Hold the capillary tube so the tip furthest from the red band is pointed toward the puncture stie and so gravity can aid the flow of blood into the capillary tube.
   d. Touch the tip to the blood drop and allow the blood to fill to the porous plug.
   e. Introduce the sample to the cartridge by depressing the plunger until the entire sample is dispensed.
   f. Discard the capillary tube and plunger as biohazardous waste.
3. Using a dispensing tip with evacuated heparinized tubes:
   a. Remove the plug from the barrel of the dispensing tip.
   b. Immediately insert the tube into the barrel. With the cap pointing away, press the tube into the barrel until needle pierces the stopper.
   c. With the cap pointing up and away, remove the cap.
   d. Align dispensing tip with the sample well on the i-STAT cartridge and apply firm pressure to the end of the blood collection tube to dispense blood.
   e. If the blood collection tube will not be discarded, hold the tube upright and away, gently removing the dispensing tip.

NOTES:
If the rec cap or red plug is missing, dispensing tip may be contaminated and must be discarded immediately into a biohazardous Sharps container. User standard precautions. The needle inside of the barrel is sharp and can puncture the skin. Do not use the same dispensing tip on a different evacuated tube of blood. Do not put the red plug or red cap back on.
Grossly over or under filling cartridge may cause an error code requiring you to repeat the test.

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

Analyte	Syringes	Test Timing	Evacuated Tubes	Test Timing	Capillary Tubes	Test Timing
Glucose	Without anticoagulant	3 minutes	Without anticoagulant	3 minutes	With balanced heparin anticoagulant or lithium heparin if labeled for the measurement of electrolytes	3 minutes
	With balanced heparin anticoagulant or lithium heparin anticoagulant (syringe must be filled per manufacturer's recommendation) • Remix thoroughly before filling cartridge.	30 minutes	With lithium heparin anticoagulant (tubes must be filled per manufacturer's recommendation) • Remix thoroughly before filling cartridge,	30 minutes		

G. **Seal the Cartridge**
1. Touching only the plastic tab and the sides of the cartridge, fold the snap closure over the sample well. **Do not press directly over the sample well**.
2. Press the tab until it clicks into place. Slightly lift finger or thumb and ensure cartridge is closed before completely removing the finger or thumb from the closure.

H. **Insert the Cartridge**
1. Push the sealed cartridge into the iSTAT analyzer port until it clicks into place.
   a. To avoid permanent damage to the iSTAT analyzer, **DO NOT remove cartridge until testing process is complete**.
   b. Wait about 2 to 3 minutes for the test to complete.

NOTE: Prior to transmission of result, if the user decides to cancel the run, he/she may enter "99" (press the "9" key twice in succession). The result will not transmit to the EMR.

I. **Review Patient Results**
1. The iSTAT analyzer shows the test results by test name, the numerical values, and units with the results.
   ***NOTE**: If iSTAT analyzer turns OFF before review of results is complete, press ON/OFF button to turn it ON, and then press "**1**" for Last Result.*
2. After reviewing results, remove the cartridge. Discard gloves, tube, transfer device and cartridge in biohazard waste container.

J. **Flagged Results**
1. A Quality Check message will be reported instead of results if the handheld detects a problem with the sample, calibrant solution, sensors, or mechanical or electrical functions of the handheld during the test cycle.
   Remedial Action: Take the action displayed with the message that identifies the problem. Refer to the Analyzer Coded Messages Technical Bulletin in the iSTAT 1 System Manual. If a

Quality check failure persists after taking the recommended action, contact POCT services.

2. If stars (***) are displayed instead of a result, it means that a test **failed** internal quality checks.
   Remedial Action: All reported results are accurate as long as the sample integrity is not in question. Remix tube of blood and repeat test using a fresh cartridge. **If result is not displayed again, draw a fresh blood sample and repeat test.** If result is still not displayed, contact POCT Services.
3. Results outside the System's Reportable Range are flagged with a "<" is shown in front of the lowest reportable value when the result is lower than this value. ">"is shown in front of the highest reportable value when the result is higher than this value.
   Remedial Action: Follow corrective actions in accordance with the department's IDA page. NOTE: Send a specimen to the Clinical Laboratory for confirmation when glucose is >600 mg/dL.

TEST RANGES

Reportable Range: 25 – 600 mg/dL
(Ranges are for patients ≥ 1 year old)

Fasting:

Normal	70-99 mg/dL
Impaired Fasting Glucose (Pre-diabetes)	100-125 mg/dL
Diabetes	≥ 126 mg/dL

Random:

Normal	70-199 mg/dL
Impaired Glucose Tolerance	140-199 mg/dL
Diabetes	≥ 200 mg/dL

Critical Values:

Glucose	< 50 or > 500 mg/dL

RESULTING AND REPORTING

1. Results can be reported only if QC requirements are met, and no operational flags or instrument malfunctions have occurred.
2. Results are displayed numerically with reporting units.
3. Patient results are automatically posted in the patient's electronic medical record when using the wireless analyzers. If using the wired analyzer, the results will transmit when the iSTAT analyzer is docked on the iSTAT downloader.
4. During Electronic Medical Record (EMR) or Sunquest downtime, results will not appear in the EMR. Users may use the downtime results form temporarily until the system(s) are back in service and results populate in the EMR.
5. Critical and abnormal results: Follow corrective actions in accordance with the provider's orders or IDA page. NOTE: Send a specimen to the Clinical Laboratory for confirmation when glucose is >600 mg/dL.

RECORD KEEPING

1. All records for QC Testing, Patient Testing, Orientation & Training, Competency Testing, Meter Validation, Patient Comparisons, Maintenance, and Testing Issues will be kept on file in the Clinical Laboratory for at least three years.
2. Patient results are documented in the patient's electronic medical record.

3. Data management is maintained through the InfoHQ system in POCT Services.

LIMITATIONS AND INTERFERENCES

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. Interference studies were based on CLSI guideline EP7-A2. Test concentrations used were as per the CLSI guideline unless otherwise indicated.

When added to a plasma pool the following substances (at the concentrations indicated) were found to interfere with the i-STAT glucose assay:

Substance	Test Concentration (mmol/L)	Interference
Acetaminophen	1.32	Increased i-STAT Glucose results. See Note 1 Below.
Acetylcysteine	10.2	Decreased i-STAT Glucose results. See Note 2 below.
Bromide	37.5	Use another method. See Note 3 below.
Bromide *(therapeutic)*	2.5 [7,8,9]	Decreased i-STAT Glucose results. See Note 3 below.
Hydroxyurea	0.92	Increased i-STAT Glucose results. Use another method.
Thiocyanate	6.9	Decreased i-STAT Glucose results.
Nithiodote (sodium thiosulfate)	16.7[14]	Decreased i-STAT Glucose results. See Note 7 below.

The following substances are known not to significantly interfere with the i-STAT glucose assay at the stated test concentrations:

Substance	Test Concentration (mmol/L)
Acetaldehyde	0.045 [10]
Acetaminophen *(therapeutic)*	0.132 [10]
Acetoacetate	2.0
Acetylcysteine *(therapeutic)*	0.3 [11,12]
Ascorbate	0.34
Dopamine	0.006
Formaldehyde	0.133 10
β–Hydroxybutyrate	6.0 13
Lactate	6.6
Maltose	13.3
Pyruvate	0.31
Salicylate	4.34
Thiocyanate (therapeutic)	0.515
Uric Acid	1.4

Refer to the package insert for additional information regarding the limitations and interferences.

ALTERNATIVE TEST METHODS

1. Blood plasma glucose testing is performed in the Clinical Laboratory.
2. If interfering substances is an issue, do not perform this test. Rather, send the sample to the Clinical Laboratory for blood plasma glucose testing.

3. Refer to your location's IDA page for appropriate documentation and actions indicated. POCT glucose testing may not be performed by the patient or by using the patient's own glucose monitoring device in the hospital setting at SFGH.
4. Alternate site (such as arm or leg) capillary testing is unacceptable in a hospital setting. Due to the potential for less vascular circulation in alternate sites, a 30-minute lag time may occur in detecting hypoglycemia from alternate site capillary samples.

MAINTENANCE AND CARE

CAUTION: Exercise universal safety precautions at all times when handling the analyzer, cartridges, and peripherals to prevent exposure to blood-borne pathogens.

1. Daily Maintenance
   - Clean surfaces with gauze moistened with deionized water or mild non-abrasive cleaner (Clorox Healthcare Hydrogen Peroxide cleaner disinfectant wipes are acceptable). Wipe the infrared window with a Kimwipe tissue. NOTE: When dealing with patients in isolation (e.g., *Clostridium difficile* or Norovirus infections), use PDI Bleach Wipes.
   - Always follow the hospital policy for wet contact time.
   - Check Analyzer Status (Menu\Analyzer Status). Are there any error messages, alerts, or quality check codes to investigate? If so, please refer to the i-STAT 1 System Manual.
   - Battery Status. The user will be warned when the batteries are running low (displays as "low battery" message). Note: Wait until any test in progress is completed and turn off the analyzer before replacing the battery or the most recent set of results may be lost. Stored results will not be lost when replacing the batteries.
   - Temp Trak and/or Apogee temperature monitoring systems are used for temperature monitoring in lieu of manual logs.
2. Every 6 months
   - POCT Services will perform the Software Update
     NOTE: The iSTAT 1 will start displaying warnings 20 days prior to when the software updated is due.
   - POCT Services will verify that the thermal probe check.
3. As needed, loading docks and battery charging:
   - Perform External Electronic Simulator Test if the internal electronic simulator fails or if the analyzer is dropped. Results are recorded in the InfoHQ System.
   - If the analyzer is placed on a wet surface or if any liquid is spilled onto it, dry the analyzer immediately. If liquid enters the following compartments, the analyzer may be damaged: the electronics compartment, the battery compartment, or the cartridge port.
   - Most iSTAT analyzers have a rechargeable battery pack that is recharged when connected to the base unit docking station. However, two 9V lithium batteries may be used instead of rechargeable batteries. iSTAT analyzers that use rechargeable batteries should be stored on the docking stations when not in use to maintain the charge.
   - Wired iSTAT analyzers must be docked in order to transmit data to and from the patient's electronic medical record.

- To replace the battery: refer to the operator's manual.

TROUBLESHOOTING

When the analyzer detects a potential or real problem before the test cycle is initiated or at any time during the test cycle, a Quality Check Code number, the type of problem and the next step to be taken will be displayed. Please refer to the Troubleshooting the Analyzer section in the iSTAT 1 System Manual. If a problem persists, notify the Super User or POCT Services. Outside of business hours, call Technical Support (1-800-366-8020). NOTE: Do not contact Biomedical Services for iSTAT analyzer problems.
You may contact POCT Service Team to attain an iSTAT replacement. During off hours, a meter replacement may be attained from the Clinical Laboratory.

STAFF EDUCATION, ORIENTATION & TRAINING, COMPETENCY, & BARCODE IDs

1. Each operator using the i-STAT 1 meter at ZSFG becomes approved to perform this POCT through completion of **Orientation & Training and Competency Testing**, which includes successful demonstration of skills and knowledge. This Competency Testing is required upon initial training and before technical duties are performed, six months after initial competency, and annually thereafter.
2. Once approved to test, the new operator will be issued a barcode ID with their unique identifiers embedded within the barcode. Those renewing their annual Competency will not require a new barcode ID; rather, their current barcode ID will be updated by POCT Services.
3. If an operator's barcode ID is active (is working), it signifies the operator has completed all prerequisites for patient testing and is currently approved to perform this POCT.
4. If an operator's barcode ID is not active (not working), it signifies the lack of approval for performing this POCT and the need to renew their Competency test.
5. If an employee loses or damages their barcode ID, they may request a new barcode ID from the POCT Services.
6. Barcode IDs are to be secured to the employee's hospital or university ID badge.
7. **Barcode IDs are to be treated like secure passwords and thus the sharing of barcode IDs is not allowed.**
8. All activity occurring under an employee's barcode ID is the responsibility of that employee.
9. It is the responsibility of the unit Nurse Manager to prevent use by unauthorized staff.
10. Students are not trained, nor approved, to perform this POCT test at ZSFG. Their educational experience may be gained only when an employee with an active barcode ID is with them at the patient's bedside supervising and taking full responsibility for the experience, results, documentation, and follow-up actions.

REFERENCES

1. i-STAT 1 System Manual, 3/7/2013
2. i-STAT 1 User Guide Rev. 4/23/2018
3. i-STAT Software Upgrade Technical Bulletins
4. G Cartridge IFU Rev. 2/20/2020

DISTRIBUTION

1. ZSFG – POCT Policies and Procedures Manual

REVISION HISTORY

Revision Date	Description:	Director Signoff on:
3/1/2022	Initial version	3/1/2022