Point of Care Testing (POCT) Using the i-STAT Analyzer System

Atrium Health Wake Forest Baptist	**DOCUMENT TYPE:** Procedure	**ORIGIN DATE** 10/02/2019
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APPLICABLE LABORATORY(S):

☒ North Carolina Baptist Hospital (NCBH)
☐ Lexington Medical Center (LMC)
☐ Davie Medical Center (DMC)
☐ Wilkes Medical Center (WMC)
☐ High Point Medical Center (HPMC)
☐ Westchester (CT Imaging Clinic)
☐ Clemmons

PURPOSE

The Clinical Laboratory at Atrium Health Wake Forest Baptist (AHWFB) Medical Center is responsible for oversight of explicitly identified non-waived laboratory testing performed in clinical areas by non-lab personnel. Specific testing sites have been identified and included under the CLIA certificate of the AHWFB Medical Center Clinical Laboratories for a highly complex lab. Testing policies and procedures must meet all regulatory guidelines established by CLIA, College of American Pathologists (CAP), and other accrediting agencies, as applicable.

The purpose of this procedure is to provide guidelines to ensure that all testing is performed according to established protocols and per manufacturer's recommendations, and that each employee follows the same quality control and patient testing procedures. Each specific user site must have approval from the AHWFB Point of Care Committee to perform this testing.

The i-STAT System is a non-waived (waived for some cartridges/circumstances) testing device that performs critical care blood analysis at the point of care. At AHWFB, the i-STAT test system is used by laboratory and non-laboratory personnel to provide critical lab service at or near the patient. Results are electronically posted to the patient's electronic health record. This document serves to define the procedures and guidelines for point of care testing using the i-STAT system. The i-STAT System Manual should also be used as a resource for information not specifically covered in this document, such as, use of the i-STAT test system and information about specific i-STAT tests (test principles, clinical significance, and interpretation of results).

All testing personnel must complete assigned training modules and demonstrate successful i-STAT testing under the direction and supervision of an authorized staff member. Only staff members who have been trained and completed required competency assessment for this particular procedure may perform this testing. Competency is assessed annually and at 6 months the first year. Current regulatory standards will be followed. Any user that fails to meet the competency requirements will need to be re-educated on use of the system. The Clinical Laboratory POCT Office and user site managers maintain training and competency records.

All i-STAT testing should have a documented physician order or be performed following a documented protocol. Staff should not perform testing on themselves, co-workers, or visitors. Results can be traced back to the device, location, and user.

SCOPE

This document establishes procedures and guidelines for assuring quality of Point of Care Testing (POCT) results obtained from the i-STAT analyzer. Non-Waived POCT sites covered by the Clinical Laboratory CLIA certificate shall adhere to processes outlined in this document.

Responsible Department/Party/Parties:

i. Procedure Owner: Clinical Laboratory Point of Care Testing Compliance Manager
ii. Procedure: Non-Waived POCT sites covered by the Clinical Laboratory CLIA certificate shall adhere to processes outlined in this document.
iii. Supervision: The Medical Director and/or laboratory director, as indicated on covering CLIA certificate for Point of Care Testing, shall supervise the person(s) performing activities outlined in this document.
iv. Implementation: Each applicable POCT site manager is responsible for ensuring compliance with processes stated in this document.

DEFINITIONS

A. **Procedure:** A process or method for accomplishing a specific task or objective.
B. **WFBH Lab System:** Wake Forest Baptist Lab System is a health system that includes Wake Forest Baptist Medical Center and all affiliated organizations including Wake Forest University Health Sciences (WFUHS), North Carolina Baptist Hospital (NCBH), Lexington Medical Center (LMC), Davie Medical Center (DMC), Wilkes Medical Center (WMC), High Point Medical Center (HPMC), Lab at Westchester and Lab at Clemmons.
C. **Point of Care Testing (POCT):** Tests designed to be used at or near the site where the patient is located, do not require permanent dedicated space, and are performed outside the physical facilities of the clinical laboratory.
D. **Non-Waived Tests:** Tests of moderate or high complexity as designated by the FDA.
E. **Waived Tests:** Tests of low complexity as designated by the FDA; tests that are simple and have low risk for erroneous results.
F. **Clinical Laboratory Improvement Amendments (CLIA):** United States federal regulatory standards that apply to all laboratory testing performed on humans.
G. **College of American Pathologists (CAP):** Accrediting agency for the AHWFBMC Clinical Laboratory. Point of Care sites included on the CLIA certificate of the Clinical Laboratory are accountable to standards set forth by CAP.
H. **The Joint Commission (TJC):** Accrediting agency whose standards pertaining to laboratory testing apply to some locations within the AHWFB network.
I. **Quality Control (QC):** A process to ensure the test system is performing as expected.
    - **External QC** - External liquid material or substance with known value(s) for the test(s) being performed.
    - **Internal QC** - An internal check within the test system to validate the test system is working properly.
J. **Quality Assurance (QA):** A system for ensuring a desired level of quality. The POCT program incorporates activities to monitor the quality of processes and the test system.
K. **Quality Improvement (QI):** Activities implemented to improve the quality of processes.

L. **Proficiency Testing (PT):** Unknown samples sent to a lab/test site by a Centers for Medicare and Medicaid Services (CMS)-approved PT program.
M. **Technical Limits/Reportable Range/Analytical Measurement Range (AMR):** The range at which the analyzer has been verified to obtain accurate results. Each method-specific analyte has a specific reportable range.
N. **Normal (Reference) Range:** The range of values for the average patient population.
O. **Upload/Download/Docking of device/analyzer:** Refers to the action of connecting the test devices to the AHWFB network to allow transmit of patient results and QC results to the device data manager.
P. **ADT (Admit/Discharge/Transfer):** Refers to visit-specific demographics for a patient.
Q. **CSN (Contact Serial Number):** Refers to Electronic Health Record encounter—related to account number.
R. **AC:** Part of the CSN that is stored in Wake One; included in the linear barcode on the patient armband (AC is NOT included in the document label CSN barcode).
S. **Electronic Health Record (EHR):** Digital version of a patient's paper medical chart (currently, referenced as Wake One).
T. **Erroneous:** Containing error, mistaken, incorrect, wrong.
U. **Analyzer/Device:** For the purposes of this document, refers to the i-STAT analyzer.
V. **Calibration Verification:** Assaying materials of known concentration in the same manner as patient samples to validate the instrument or test system's calibration throughout the reportable range.
W. **Linearity:** Achieved when measured results are directly proportional to the concentration of the analyte in the test sample, within a given range.

REAGENTS/MEDIA

SUPPLIES/MATERIALS

1. **I-STAT Test Cartridges/Inventory:** A single-use disposable cartridge contains micro-fabricated sensors, a calibrant solution, fluidics system, and a waste chamber. Sensors for a variety of tests are available. Refer to the iSTAT System Manual for details.
    a. **Storage: The main inventory of cartridges** will be stored in the Clinical Laboratory POCT Office.
        i. Cartridges should be stored at 2° to 8°C (35° to 46°F) and are good through the expiration date printed on the package.
        ii. Do not allow cartridges to freeze. Cartridges should NOT be stored next to the refrigerator wall. Freezing could occur.
        iii. Follow manufacturer labeling for room temperature storage and expiration dating (18° to 30°C or 64° to 86°F).
            - Color change temperature indicators will be used to monitor upper level temperature to ensure the environment does not exceed 86°F.
            - In environments where low temperatures are of concern, a minimum/maximum temperature monitoring system will be used to monitor room temperature.
        iv. Cartridges should not be returned to the refrigerator once they have been at room temperature, and should not be exposed to temperatures above 30°C (86°F).
        v. Each cartridge should be marked to indicate the appropriate cartridge-specific room temperature expiration date. The staff member that

removes cartridges from the refrigerator is responsible for marking the room temperature expiration date.

vi. Cartridges should remain in SEALED pouches until time of use.

vii. Do not use after the labeled expiration date or erroneous results may be given.

viii. Cartridges should be allowed to sit at room temperature without any quick heating. Example: DO NOT hold close to the body or put on a warm object for quick heating. Follow manufacturer instructions.

b. **Storage: Testing site inventory** will be obtained by testing site personnel from the Clinical Laboratory POCT Office.

i. The cartridges in the testing sites should be stored at room temperature and kept away from extreme heat and cold.

ii. Do not store on computers, above lights or any other warm surface.

iii. If cartridges are noted as having been exposed to an unacceptable temperature, the cartridges should be removed from patient use and the POCT office should be notified for further action.

iv. If a user site stores refrigerated cartridges, the refrigerator temperature must be monitored and be maintained 2° to 8°C.

v. Refrigerator temperature logs and ambient temperature/humidity logs are reviewed by the POCT office each month.

EQUIPMENT

The i-STAT System consists of the following primary components:

1. **i-STAT Analyzer:** Analyzers are the handheld i-STAT Portable Clinical Analyzers. AHWFB utilizes the i-STAT 1 (300 series). When a sample-filled cartridge is inserted into an analyzer for analysis, the analyzer automatically controls all functions of the testing cycle, including fluid movement within the cartridge, calibration, and continuous quality monitoring. All analyzers that pass the Electronic Simulator test are considered equivalent.

a. Battery Change/Charge -
i-STAT 1 analyzers can operate using (2) 9-volt lithium batteries or a rechargeable battery. Refer to the i-STAT System Manual for additional instructions. When performing testing, confirm adequate battery voltage prior to testing (a flashing battery icon or low battery message will indicate low battery voltage). If battery voltage is low, testing may cease in the middle of a patient test. **NOTE:** Alkaline batteries should not be used in the i-STAT analyzers. Use only 9V lithium batteries or i-STAT 1 specific rechargeable batteries.

- Follow appropriate AHWFB battery disposal policies.

b. Extreme temperature usage -
When using the i-STAT analyzer in an area with extreme temperatures, it may be required to insulate the analyzer between testing samples to keep the analyzer's internal temperature stable. If the analyzer gets too hot or too cold, an error code will occur. Storing the analyzer in an insulated cooler may resolve temperature error codes.

c. When the i-STAT system is used in a sterile environment, such as an OR suite, the analyzer and all supporting equipment should be disinfected prior to and after use in the OR suite/sterile area.

i. **The i-STAT analyzer and related equipment should never come in contact with a patient.**

ii. **<u>The analyzer must be disinfected between each patient use.</u>**

2. **i-STAT Data Management System:** Used to monitor patient results and quality control data.
    a. Operator ID Usage Information
        i. Upon satisfactory completion of training for the i-STAT system, each user will be given a user identification number/Employee ID (EID) code which is entered into the Database to allow access to testing. This EID barcode is to be scanned/entered each time that the i-STAT system is used and is the equivalent of an electronic signature.
        ii. Each EID code is assigned exclusively for each testing staff member (operator). They should not be shared with anyone else or posted for general access of staff members. This code allows tracing of testing personnel. Sharing ID codes or using someone else's code is prohibited.

SAMPLE REQUIREMENTS

1. **Required Blood Volume:**
    a. 17-95 µL depending on cartridge type (see i-STAT System Manual for specific details)
2. **Suitable Specimens:**
    a. Only Fresh whole blood may be used for i-STAT testing.
    b. Different i-STAT tests require different sample collection techniques and collection devices. Refer to the i-STAT System Manual (Test specific 'Cartridge and Test Information Sheet') or the attached cartridge specific IFU for details not included in this document.
    c. Certain samples may be collected in a capillary tube or a plastic syringe without anticoagulant.
        - **Test within 3 minutes of collection.**
    d. Certain samples may be collected in a lithium heparinized capillary tube, plastic blood gas syringe, or blood collection tube. Refer to the i-STAT System Manual or cartridge specific IFU for specific details regarding timing of testing specimens.
        - **Capillary samples should be tested within 3 minutes, regardless of whether sample is heparinized.**
    e. Lactate, ACT, and PTINR samples should be tested immediately after collection with no delay.
        - There are additional considerations when testing lactate, ACT, or PTINR test cartridges. Refer to the i-STAT System Manual test specific 'Cartridge and Test Information Sheet' or cartridge specific IFU for additional details.
    f. Refer to the i-STAT system Manual or cartridge specific IFU for a listing of test-specific acceptable anticoagulants for use with the i-STAT.
    g. Sample collection containers must be filled to capacity.

SPECIMEN COLLECTION

1. **Safety/Precautions:**
    a. Gloves should be worn while collecting or analyzing any patient sample.

- Gloves should be worn while performing any function on the i-STAT, including cleaning/ disinfecting, performing quality control (QC), carrying/handling and downloading the analyzer.

b. Safety Shield (Face or Stand Alone Shield) – should be available in each test site.
c. AHWFB-approved safety re-sheathable needles should be used to collect samples.
d. All sharps should be discarded in AHWFB-approved biohazard sharps containers.
e. Appropriate waste containers should be available for disposal of used cartridges or other blood/sample contaminated non-sharp equipment. Follow appropriate AHWFB policies and procedures.
f. Germicidal wipes, fresh 10% bleach, or AHWFB-approved disinfectant should be used to decontaminate analyzer between each patient use or when visibly soiled.
    - DO NOT ATTEMPT TO CLEAN INSIDE THE CARTRIDGE PORT. This may damage the probes.
    - Return internally contaminated analyzers to the POCT Office.

2. **Capillary Testing –** the following supplies will be needed:
    a. Warming pad, if applicable
    b. Alcohol pad
    c. Skin puncture lancet - only auto-disabling, single-use capillary stick devices
    d. Capillary tubes and caps
        - **NOTE: If ionized calcium is to be tested, a balanced heparin capillary tube should be used.**
    e. Gauze
    f. Bandage
3. **Venipuncture Testing for Venous specimens –** the following supplies will be needed:
    a. Venipuncture collection equipment: Refer to the AHWFB Intranet. Go to - Department of Pathology (Internal)-OnLine Resources-Laboratory-Phlebotomy-General Phlebotomy Procedures
    b. Appropriate collection tube or plain syringe, as indicated in the test specific information listed in the i-STAT System Manual or cartridge specific Instructions For Use (IFU) - see Attachments
    c. NOTE: If ionized calcium is to be tested, a balanced heparin blood collection tube should be used or appropriate tube, as referenced in the i-STAT System Manual or cartridge specific IFU.
    d. Disposable transfer device, if applicable
4. **Arterial Testing –** the following supplies will be needed:
    a. Plastic syringe with no anticoagulant or an AHWFB-approved pre-heparinized blood gas syringe/blood gas collection kit
    b. Cap for syringe
    c. Refer to site-specific blood gas collection policies/procedures for specific details.
    d. NOTE: If ionized calcium is to be tested, a balanced heparin syringe should be used.

    ****NOTE: *Complications Associated with Arterial Puncture Education Module*** (see attachments) should be reviewed by all staff that perform arterial testing.
5. **Patient Preparation:**
    a. There are no specific patient preparation procedures prior to collecting samples for i-STAT testing. However, if samples are collected from an artery, appropriate

testing for collateral circulation (Allen's testing) should be performed, prior to arterial puncture. Follow site-specific procedures.

6. Follow site-specific and AHWFB sample collection policies and procedures. If no site-specific policy/procedure exists, refer to the section below and Clinical Laboratory-Department of Pathology sample collection procedures (Intranet-Department of Pathology Handbook).

a. Prior to collecting any sample for i-STAT testing, the patient's identity should be verified by the AHWFB identification bracelet.

i. Use (2) identifiers.

ii. Verification of patient identification by staff may be completed using the patient's full name and date of birth, and comparing that information to the document label on the paper or electronic chart.

iii. Medical record number may also be utilized, if necessary, as a patient identifier.

iv. The patient or patient's family should be utilized in the patient identification process, when appropriate. Follow all AHWFB policies and procedures regarding sample identification.

b. If the i-STAT testing is performed away from the patient's bedside, the blood sample should be labeled in the presence of the patient. Label with a patient identification sticker, which should, at a minimum, include the patient name and medical record number.

c. Ensure correct patient identity throughout entire test process.

d. To ensure quality blood gas results and to avoid contamination by air, place an airtight cap on the end of the syringe immediately after collection. Excess air in the sample should be expelled prior to mixing the sample and prior to capping the sample.

e. NEEDLES SHOULD NOT BE RECAPPED!

f. When using blood gas syringes with liquid heparin, extreme care should be taken to avoid sample dilution/contamination from the liquid heparin.

g. **ACT Samples:** Follow all current manufacturer recommendations.

i. ACT testing is used to monitor patients receiving heparin for treatment and certain medical procedures.

ii. Only venous or arterial samples should be used for ACT testing.

iii. Must be collected in a plastic syringe WITHOUT anti-coagulant and tested IMMEDIATELY after collection.

iv. A metal needle should not be used during cartridge fill.

v. If sample testing is delayed, results will be adversely affected.

vi. i-STAT analyzers are programmed to read kaolin ACT's in the pre-warm mode and Celite ACT's in the non-warm mode.

vii. The i-STAT analyzer should not be moved or subjected to any vibration during sample testing. Results may be adversely affected. Keep the analyzer flat and free of movement.

h. **PTINR Samples:** Follow all current manufacturer recommendations.

i. Only capillary or venous samples should be used for PTINR testing.

ii. When disinfecting finger stick skin puncture sites, swabs or solutions containing substances other than isopropanol (e.g. chlorhexidine gluconate) are not recommended.

- The i-STAT PTINR test may report a false prolongation of the prothrombin time (PT) and an elevation of the INR on samples contaminated with chlorhexidine gluconate.

iii. The first drop of blood from a capillary sample should be used.
- I-STAT recommends filling cartridge directly from skin puncture.
- Capillary tubes are NOT recommended for PTINR testing.

iv. If a collection container is used for a venous sample, the sample must be collected in a plastic syringe without anti-coagulant and tested IMMEDIATELY after collection.
- Devices used to transfer sample to cartridge must be plastic.
- Metal needles should not be used when filling an i-STAT cartridge.

v. If sample testing is delayed, results will be adversely affected.

vi. The i-STAT analyzer should not be moved or subjected to any vibration during sample testing or results may be adversely affected. Keep the analyzer flat and free of movement.

i. **Ionized calcium:** Follow all current manufacturer recommendations.
   i. For ionized calcium, use balanced or low volume heparin sample collection containers (syringes, capillary tubes, or blood collection tubes).
   ii. Balanced heparin or 10 IU/mL lithium heparin is recommended.
   iii. Collection containers should be filled to correct sample fill capacity to avoid binding of ionized calcium by heparin.
   iv. Incomplete filling/under filling of the sample collection container causes higher heparin to blood ratio, which will falsely decrease ionized calcium results and may affect other results.

j. In-Dwelling Line:
   i. Back flush line with sufficient amount of blood to remove intravenous solution, heparin, or medications that may contaminate the sample. Recommendation: five to six times the volume of the catheter, connectors, and needle.
   ii. **ACT Coagulation cartridges:** If blood must be drawn from an indwelling line, possible heparin contamination and specimen dilution should be considered.
      - The line should be flushed with 5mL of saline and the first 5mL of blood or six dead space volumes of the catheter should be discarded.
      - **Accurate results depend on an adequate back flush to eliminate the possibility of sample contamination with IV fluids**.
      - Caution should be taken when collecting from lines which have had fluids that could adhere to the sides of the tubing. These lines may be difficult to adequately back flush.

k. **Arterial Specimens:**
   i. Avoid or immediately remove any air drawn into the syringe to maintain anaerobic conditions.
   ii. Samples should be capped immediately after collection to avoid air contamination.

iii. Mix blood and anticoagulant by rolling syringe between palms for at least 15 seconds.
iv. Roll syringe 5 seconds in one direction.
v. Then roll 5 seconds in the other direction.
vi. Then invert for 5 seconds.
vii. ENSURE ADEQUATE SAMPLE MIXING.

l. **Venous Specimens:** Follow current manufacturer recommendations.
i. As appropriate per manufacturer's instructions, if cartridge cannot be filled immediately, collect the sample in a heparinized evacuated blood collection tube. A syringe containing balanced heparin may also be used.
ii. Fill collection containers to capacity.
iii. Mix blood and anticoagulant by rolling tube/syringe between palms for at least 15 seconds.
- Roll syringe/tube 5 seconds in one direction.
- Then roll 5 seconds in the other direction.
- Then invert for 5 seconds.

iv. ENSURE ADEQUATE SAMPLE MIXING.

m. **Capillary specimens (finger and heel stick):**
i. **For NON-PTINR samples, *wipe away the first drop of blood*,** which contains excess tissue fluid and can increase potassium results and dilute other test results.
ii. Avoid drawing air into capillary tubes and cap immediately after collection.
iii. Mix blood and anticoagulant by rolling capillary tube between palms for at least 15 seconds.
iv. Test samples immediately to avoid clotting (especially in neonates).
v. ALL SAMPLES SHOULD BE WELL MIXED IMMEDIATELY PRIOR TO ANALYSIS TO ENSURE ACCURATE RESULTS.

SAMPLE LABELING

1. Unless the specimen is analyzed immediately after collection at the patient's side/bedside and then discarded, the specimen should be labeled in the presence of the patient with the following information:
   - Full Patient name and at least one of the following:
     - Medical Record Number or Date of Birth
   - **Specimen Identification entered into the analyzer**
     - Patient samples are identified in the i-STAT by the patient's Wake One Contact Serial Number (CSN). As applicable, this information should be taken directly from the patient armband on the patient.
2. Any i-STAT result that has a valid CSN entered in the handheld analyzer will be automatically ordered, billed, and resulted to the permanent electronic health record (EHR). It is crucial that sample identification be entered correctly into the i-STAT handheld analyzer at the time of sample testing.
   a. If the CSN is not available at the time of i-STAT sample analysis, alternate means of sample identification should be used. See below:
      i. Use the i-STAT generic ID. Current version contains 11 Zeros and an alpha character at the END—for example 00000000000A,

00000000000B, 00000000000C Z-Number. This is a temporary ID#, specifically used for i-STAT testing.

ii. Enter the number into the i-STAT as the patient ID number.
iii. Log the ID used on the patient flow sheet and i-STAT Resolution Requisition.
iv. Be sure that the ID used is noted on the patient care flow sheet maintained in the user site.
v. During your SAME-DAY shift, do NOT use the same generic ID for multiple patient samples.
vi. Do NOT use the same generic ID for a multiple-patient transport.
vii. Send the properly completed i-STAT RESOLUTION REQUISITION to the POCT Office as soon as correct patient identity is available.
    - A copy of the results should be attached to the resolution requisition.
    - It is very important to complete an i-STAT Resolution Requisition and send to the POCT Office - otherwise, the i-STAT results do not get posted to the patient's electronic health record.
viii. NOTE: Use the correct CSN for subsequent samples as soon as one is available. The admission CSN must be used for inpatient samples.

b. Sample identification during sterile procedures -

If the armband is not accessible during a sterile procedure, adhere to the following process:

i. Print extra patient armband that matches the armband that is on the patient.
ii. If the patient has been admitted, the inpatient admission armband must be used.
iii. The extra armband must be verified against the armband that is on the patient, including:
    - Full patient name
    - Date of birth
    - Medical record number
    - CSN
iv. Verification of the second armband should be documented on the time-out form during time-out procedures.
v. This extra armband can be used to scan patient ID into the i-STAT analyzer (**only during sterile procedures)**.
vi. Once the case is completed, the extra armband should be destroyed.

c. Sample Misidentification –

i. Immediately correct the results in the electronic health record, using Enter/Edit functionality. **Notify physicians of all affected patients.**
    - The i-STAT analyzer must be downloaded to allow results to be editable in the electronic health record.
    - An i-STAT Resolution Requisition should be completed and sent to the POCT Office immediately. E-mail resolution to LabPOC_Testing_DL@wakehealth.edu.
ii. Refer to ***Tips and Tricks: Procedure to Correct i-STAT Results in WakeOne*** for specific details.
    - POCT website –under Resources-Resource Links – Internal Resources

https://intranet.wakehealth.edu/Departments/Pathology/POCT/Resources/Resource-Links.htm

iii. An RL6 report should be submitted and the RL6 report number provided to the POCT Office.
iv. It is the responsibility of testing personnel to return i-STAT Resolution Requisitions, as necessary.
v. If there are instances when results cannot easily be traced to the correct patient, it will be the responsibility of the point of care contact person in each user site to work with the Clinical Laboratory POCT office to resolve such issues.

SPECIMEN ACCEPTABILITY AND REJECTION CRITERIA

Do not perform sample analysis if any of the following circumstances apply:

1. Do not test CSF, pleural, peritoneal, urine, or any other body fluid that is not whole blood.
2. Do not ice samples prior to test analysis.
3. Do not use samples from improperly filled tubes. Tubes/syringes/collection containers must be filled to capacity to ensure correct blood to anticoagulant ratio.
4. Do not use samples with evidence of clotting.
5. Do not use specimens collected in containers with inappropriate anticoagulant for the test being performed.
6. Do not use partially filled sample collection containers.
7. Do not use samples if air bubbles are present in the sample syringe for pH, pCO2, pO2, and ionized calcium testing.
8. Do not use samples for pH, pCO2, pO2, and ionized calcium testing that are not capped immediately after collection.
9. Do not use an incompletely filled heparinized collection container for the measurement of ionized calcium.
10. Do not use samples collected from a line which can NOT be adequately cleared to remove contaminating fluids.
11. Do not use samples that are not adequately mixed or allow the filled cartridge to sit for any period of time before testing.

CALIBRATION – N/A

- i-STAT cartridges are calibrated by the manufacturer. Calibration is 'controlled' by software upgrades issued by the manufacturer. Other on-site calibration options are not available.
- Calibration is also automatically performed as part of the test cycle on each cartridge. Operator intervention is not necessary.

QUALITY CONTROL

I. <u>Quality Control Materials</u>

1. **Internal Electronic Simulator**
2. **External Electronic Simulator**
3. **Liquid Quality Controls**—performed by the Clinical Laboratory and the test site. ***<u>Note:</u>** Refer to the appropriate package insert and i-STAT System Manual for additional handling information and details.

a. i-STAT Liquid Tri-Controls – Used to verify the blood gas, hematocrit chemistry, and electrolyte sensor performance.

- **i.** Store at 2° to 8°C (35° to 46°F) through package expiration date.
- **ii.** Controls may be stored at room temperature (18° to 30°C or 64° to 86°F) for up to five days.
- **iii.** Do not use after expiration date on the box and ampules.
- **iv.** Protect fingers with gauze or tissue when opening vial.
- **v.** If oxygen is being tested, QC material should equilibrate to room temperature for 4 hours prior to use. Test samples IMMEDIATELY after opening.

b. ACT Liquid Controls – Used to validate performance of i-STAT ACT test cartridges.

- **i.** CAUTION: Handle using standard precautions. This product contains human plasma.
- **ii.** Store at 2° to 8°C through package expiration date.
- **iii.** Equilibrate at room temperature for 45 minutes prior to use.
- **iv.** Refer to package insert or i-STAT System Manual for additional reconstitution information. Carefully follow timing instructions.

c. PTINR liquid Controls – Used to validate performance of PTINR test cartridges.

- **i.** CAUTION: Handle using standard precautions. This product contains human plasma.
- **ii.** Store 2° to 8°C through package expiration date.
- **iii.** Equilibrate at room temperature for 45 minutes prior to use.
- **iv.** Refer to package insert or i-STAT System Manual for additional reconstitution information. Carefully follow timing instructions.

d. Other Controls – As i-STAT develops more cartridges, a need may exist for additional quality control materials. Details will be included as an appendix at the end of this document or the QC specific package insert or the i-STAT System Manual may be referenced for details.

II. Procedures Performed by the User Site

1. Analyzer Verification

a. Internal Electronic Simulator (Daily Quality Control)

i. To verify performance, each i-STAT analyzer will automatically perform an internal electronic simulation every 8 hours of use for each different cartridge type. The internal electronic simulation is activated when a filled test cartridge is inserted into the analyzer. The automatic electronic simulator option is activated/programmed by the POCT Office, via the i-STAT data management system, when an analyzer is placed into service.

ii. The simulator is a circuit in the analyzer, when enabled, verifies the electrical measurement of the analyzer and performs the same functions as the external electronic simulator.

iii. If 8 hours have elapsed since the last electronic simulator test, the analyzer will automatically perform the internal test before the sample is analyzed. 15-20 seconds will be added to the test cycle.

iv. If the simulator test fails, the FAIL result will be displayed on the analyzer screen, and the sample will not be analyzed.

v. Action for failed electronic simulator:

- Repeat the electronic simulation test by inserting another test cartridge or run the external electronic simulator QC device.
- Analyzers are programmed with “QC Lockout”. Results will not be given to the user, unless the QC/simulator check is acceptable.
- The i-STAT System Manual should be consulted for assistance.
- If the analyzer does not pass the external electronic simulator testing, contact the Clinical Laboratory POCT office for assistance.

vi. Action for passing electronic simulator:

- If the internal electronic simulator passes, patient testing continues and gives results in the standard way.
- When the internal simulator is run, the PASS message will not be displayed on the analyzer screen. The QC record will appear in the analyzer’s memory and will be transmitted to the i-STAT data manager when the analyzer is downloaded.

b. External Electronic Simulator (As Needed, Quality Control)

i. Test the external electronic simulator in the following circumstances:

- If the internal QC check fails
- If the analyzer is dropped
- If analyzer performance is in question
- If a quality check code indicates that the simulator should be tested

ii. Store at room temperature and protect contact pads from contamination by placing the simulator in its protective case.

iii. **Note:** Do not remove the simulator while “Simulator Locked” is displayed on the analyzer screen. Damage may occur to the analyzer. It is safe to remove the simulator when the ‘Simulator Locked’ message disappears from the display screen.

iv. Action for failed electronic simulator:

- Repeat the procedure with a different external electronic simulator or contact the Clinical Laboratory POCT office.
- If FAIL is displayed with the second electronic simulator, do not use the analyzer for patient testing.
- Return the analyzer to the POCT office.
- **Use another analyzer for patient testing.**

v. Action for passing electronic simulator:

- If PASS is displayed, the analyzer may be used for patient **testing.**

2. QC Documentation

Both the internal and external simulator test results are stored as distinct QC records in the analyzer and will be downloaded into the i-STAT data management system when patient data is transmitted. QC data is reviewed by the POCT Office staff. Follow-up action is taken as necessary for QC failures.

3. Cartridge Supply Check (Performed by test sites)

a. Room Temperature Cartridges are stored with each device in each user site.
b. Inventory should be performed periodically using the form, “i-STAT Supply Inventory”.

c. When checking the i-STAT inventory, the cartridges' expiration dates should also be checked.
d. Prior to patient use, verify that cartridges are within manufacturer and/or room temperature expiration dating.
e. Follow manufacturer instructions for room temperature storage.
f. NEVER use expired cartridges for patient or quality control testing.
g. The expiration date of each cartridge should be stamped or written on the outside of the cartridge pouch.
h. Always use the oldest date first to avoid loss of cartridges due to expiration.
i. Return any expired cartridges to the POCT Office.
j. If the room temperature exceeds 30°C (86°F) for any period of time, quarantine the cartridges and notify the POCT Office. DO NOT USE the cartridges.
k. If a user site needs more test cartridges, they may be picked up from the POCT Office.
l. DO NOT allow supplies to get critically low.

4. Verification of Cartridge Storage Conditions

a. Refrigerated Cartridges - Stored in the POCT Office (Performed by POCT Clinical Laboratory staff)

i. Periodically and prior to user site release, verify that the cartridges stored in the refrigerator are within the expiration date printed on the boxes.
ii. Pull any expired cartridges from patient issue stock. These cartridges should be labeled as "Do Not Use for Patient Testing".
iii. Daily, verify that the refrigerator does not exceed the limits of 2 to 8°C (35 to 46°F).
iv. Document temperature review in the appropriate temperature/humidity monitoring database.
v. Action: If the temperature of the cartridge storage refrigerator is within the range of 2 to 8°C,
- Dispense cartridges, as required.

vi. Action: If the temperature is outside of 2 to 8°C,
- Quarantine the cartridges in the storage refrigerator.
- DO NOT USE the cartridges from the out-of-control refrigerator for patient testing.
- I-STAT Tech Support may be contacted for assistance and liquid quality control checks may be performed to verify cartridge performance.
- Record the temperature failure in the appropriate temperature /humidity monitoring database, along with any action taken to resolve the problem.

b. Refrigerated Cartridges - Stored in user site refrigerators (Performed by user site testing personnel)

i. Prior to patient use, verify that the cartridges stored in the refrigerator are all within the expiration date printed on the boxes
ii. Deliver any expired cartridges to the POCT Office.
iii. Daily, verify that the refrigerator did not exceed the limits of 2 to 8°C (35 to 46°F).
iv. Action: If the temperature of the cartridge storage refrigerator is within the range of 2 to 8°C,
- Use the cartridges as required.

v. **Action:** If the temperature is outside of 2 to 8°C,
   - Quarantine the cartridges in the storage refrigerator.
   - DO NOT USE the cartridges from the out-of-control refrigerator
   - Notify the POCT Office immediately with any corrective actions taken to resolve the problem.
   - POCT Office staff will document any temperature failures and/or corrective actions in the appropriate temperature/ humidity monitoring database as necessary.

5. **Cartridge Release (Refer to Appendix C: i-STAT Cartridge Sign Out Procedure)**
   a. Do not take cartridges from the refrigerator that are labeled with, "Do Not Use".
   b. Complete i-STAT cartridge sign out logs located in the POCT Office Supply area.
   c. All cartridges should be marked with the appropriate room temperature expiration dating when taken from refrigerator.

III. Liquid Quality Control

Liquid Quality Control (LQC) is used to verify the integrity of the test cartridges. Appropriate liquid controls should be used to test all analytes. Refer to the i-STAT System Manual for the most current list of available liquid controls.

1. **New Cartridge Shipments:** LQC checks verify the acceptable integrity of the I-STAT cartridges when they are received from the manufacturer. LQC should be tested on each lot number of each cartridge type received. The Clinical Laboratory POCT staff will perform quality control checks on each new shipment of I-STAT cartridges that are received.
   a. The quality control checks will be performed, prior to release of cartridges to the user sites. If a particular shipment of cartridges fails to pass the quality control check, they will not be released for patient use.
   b. In addition, i-STAT cartridges are shipped refrigerated with a temperature indicator to monitor temperature during transit. The record of receipt is checked and documented.
      - Complete the 'i-STAT Cartridge Receipt Form' (see attachments).
        i. Refer to ***i-STAT Cartridge Receipt Process*** (linked procedure).
      - If all windows are white or if only the "A/1" or "B/1" windows have changed color, then transit temperatures were satisfactory.
      - If any or all of the "C/3 or D/4" windows have changed color:
        i. Quarantine the suspect cartons.
        ii. POCT Office staff will immediately contact I-STAT Tech Support for assistance.
        iii. DO NOT USE the cartridges from the suspect cartons.
        iv. Record the out of control event on the 'i-STAT Cartridge Receipt Form' – see attachments.
2. **Questionable Cartridge or Analyzer Performance:** If cartridge or analyzer performance is in doubt, then LQC checks may also be performed.
3. **Monthly:** Each month test sites will perform LQC checks.
4. **General Information for Testing Liquid Quality Control:**
   The analyzer should be programmed to test quality control. Refer to i-STAT System Manual for instructions.
   a. Use appropriate liquid controls that test all parameters on the test cartridges.
   b. Follow manufacturer recommendations regarding QC performance and handling.
   c. Refer to the i-STAT System Manual for additional information.

d. Random cartridges should be selected for quality control performance.
e. QC ampules for non-pO2 cartridges may be used once they have reached room temperature (approximately 30 minutes).
f. For best results, ampules, cartridges, and analyzers should be at room temperature.
g. QC material for pO2 should equilibrate to room temperature for 4 hours prior to use.
h. For blood gas and electrolyte QC, immediately before use, shake the ampule vigorously for 5 to 10 seconds to equilibrate the liquid and gas phases.
i. To shake, hold the ampule at the top and bottom with forefinger and thumb to minimize increasing the temperature of the solution.
j. If necessary, tap the tip of the ampule to send solution back into the bottom section of the ampule.
k. Protect fingers with gauze, tissue or glove to snap off the tip of the ampule neck.
l. Aspirate the liquid QC material into a pipette, capillary or syringe. Aspirate from the bottom of the ampule. Do not contaminate the sample with air.
m. Immediately transfer the solution into a cartridge.
n. Immediately snap the closure on the cartridge sample well and insert it into an analyzer.
o. It is important not to expose the solution to room air since this will alter the results.
p. Compare the results obtained against the package insert values. Use the expected values published in the package inserts to verify the integrity of the cartridges.
q. Check that the lot number of the control ampule matches the lot # on the package insert. The software version (CLEW) listed on the QC range insert should also match the version that is installed in the I-STAT analyzer.
r. Results should be transmitted to the i-STAT data management system.
    - **i. Action: If all results are within the expected ranges,**
        - Use the cartridges as needed.
    - **ii. Action: If any results are outside the published expected ranges:**
        - Enter Comment Code 5 in the handheld analyzer.
        - Repeat the QC check and if the failure continues:
            - DO NOT USE cartridges from the suspect lot
            - Quarantine the suspect lot.
            - Notify the POCT Office immediately.
            - Document action taken to resolve the problem.

NOTE: The analyzer will not lock-out patient testing if liquid QC values are not within acceptable limits.

s. Staff Must ensure liquid QC values are within acceptable range or “PASS”
    - **i. <u>If QC fails – Patient testing should STOP!!</u>**
    - **ii.** The testing staff member should begin troubleshooting procedures.
    - **iii. <u>NEVER report patient results on a failed quality control event.</u>**

IV. <u>Quality Assurance Review-Performed by the POCT Office or Designee</u>

1. Check the I-STAT data management system for any results that did not get sent to the electronic health record. Results should be evaluated for the following circumstances:
    a. The results should be evaluated for proper identification.

- The results are checked to determine if ID modification is necessary, i.e. generic ID number, or patient misidentification.

b. Star-Out results (*******) are evaluated for necessary reporting and will be documented on the "Star-Out Log" on our Non-waived checklist.
c. Evaluate results flagged with comment code 0.

2. Electronic simulator results are reviewed, using the i-STAT data management system.
    a. When an electronic simulator is noted as 'FAILED', the electronic simulator results are evaluated to confirm appropriate action was taken.
3. Cartridge usage and error rate is monitored.
4. Quality check codes are reviewed.
    a. Quality check codes are monitored, via the i-STAT data management system, to check for trends in cartridge or analyzer performance.
    b. If there are recurrent and unexplained quality check codes, I-STAT Technical Support may be contacted for resolution of the problem.
5. **Quality Assurance (QA) reports are monitored for results that are outside of pre-defined limits (out of instrument range or critical values).**
    a. Results that report as "Out of Instrument Range" are also reviewed for validity.
    b. Any result that could be inaccurate, invalid, or indicate poor operator technique is investigated accordingly and appropriate action taken, as necessary.
    c. When problems are noted, communication is sent immediately to user sites in the form of memos/e-mail documentation for user review.
    d. As necessary, quality assurance (QA) reports are sent to user site supervisors or managers for follow-up of problematic issues.
6. **Proficiency Testing (PT) and Bi-annual Patient Comparison:**

a. Non-waived Point of Care i-STAT Testing, which is not considered our primary test method and is also covered by the same CLIA certificate as the Clinical Laboratory (CLIA ID 34D0664386), does not subscribe to a proficiency testing program. However, this i-STAT testing does participate in bi-annual comparison testing with the main laboratory and blood gas lab to verify performance of the i-STAT test method.
b. Sites not included on CLIA ID 34D0664386 must participate in a CMS-approved proficiency testing program. Users should follow instructions provided with the survey samples. Current accrediting and regulatory standards are followed. The proficiency samples are rotated among different users. There is no communication between the Clinical Laboratory and POCT sites regarding specific result values until after the proficiency provider submission deadline. If proficiency survey sample results fail, the problem is investigated and resolved as necessary, including re-training and evaluating instrument performance and survey sample handling. Follow-up and corrective actions are documented. Samples will be handled as follows:
    i. <u>All PT samples in the kit should be tested on the SAME DAY</u>.
    ii. <u>One staff member should test ALL samples that come in the survey kit</u> (referenced as PT event).
    iii. Testing of PT events should be rotated among testing personnel each calendar year, if possible.
    iv. A goal, but NOT a requirement, is to follow this rule: At least one PT event -- per year -- per staff member when possible. Managers will keep track of personnel testing PT to make sure that one person is not always performing the PT.
    v. <u>One analyzer</u> should be used to test <u>ALL samples</u> that come in a survey kit (referenced as PT event).
    vi. A PT event should be handled the same as a patient sample, so analyzer selection should be based on patient sample workflow. The analyzer used for

proficiency testing is not assigned. The analyzer used is at the discretion of the testing staff member when this is the workflow for patient samples.

7. **Bi-annual Calibration Verification:**
   a. Calibration verification is the process of assaying reference standards or calibration materials in the same manner as patient samples to confirm that the calibration of the analyzer has remained stable throughout the laboratory's reportable range for patient test results.
   b. I-STAT Calibration Verification:
   Performed on the i-STAT analytes, with the exception of coagulation tests, each 6 months, using a manufacturer approved calibration verification kit. The kit consists of 5 levels of test material that is tested in singlet.
      - There are no calibration verification procedures for coagulation-based tests.

   c. Manufacturer instructions are followed. Results should match insert values. Follow-up and corrective action is taken, as needed.

CORRECTIVE ACTION

1. **Action for failed Internal Electronic Simulator (Daily Quality Control):**
   a. Repeat the electronic simulation test by inserting another test cartridge or run the external electronic simulator QC device.
   b. Analyzers are programmed with "QC Lockout". Results will not be given to the user, unless the QC/simulator check is acceptable.
   c. The i-STAT System Manual should be consulted for assistance.
   d. If the analyzer does not pass the external electronic simulator testing, contact the Clinical Laboratory POCT office for assistance.
2. **Action for failed External Electronic Simulator (As Needed, Quality Control):**
   a. Repeat the procedure with a different external electronic simulator or contact the Clinical Laboratory POCT office.
   b. If FAIL is displayed with the second electronic simulator, do not use the analyzer for patient testing.
   c. Return the analyzer to the POCT office.
   d. Use another analyzer for patient testing.
3. **Action for failed Liquid Quality Control or Calibration Materials:**
   a. Enter Comment Code 5 in the handheld analyzer.
   b. Repeat the QC check and if the failure continues:
      i. DO NOT USE cartridges from the suspect lot
      ii. Quarantine the suspect lot.
      iii. If performed by a user site, notify the POCT Office immediately.
      iv. Document action taken to resolve the problem.
      v. If problem does not resolve, do NOT perform patient testing using this analyzer or lot number of cartridges.
4. To troubleshoot error codes on the analyzer, refer to the i-STAT Technical Bulletin "Analyzer Coded Messages".
5. The i-STAT ceramic cartridge may be used to correct certain error codes. Refer to i-STAT Technical Bulletin, "Analyzer Coded Messages", for specific details.
6. For technical assistance with the i-STAT system:
   a. Contact the designated super user/site preceptor,
   b. Call the POCT Office at extension 3-4136, 3-0377, or 6-7248, or
   c. Call i-STAT technical service at 1-800-366-8020 after hours, weekends or holidays.

PROCEDURE GUIDELINES

1. A documented order or protocol, submitted by an authorized provider, should exist for any patient i-STAT testing.
2. The order/protocol should be traceable to the patient health record.
3. **Cartridge Preparation for use:** All cartridges should equilibrate to room temperature prior to use. Individual cartridges may be used after standing at room temperature for 5 minutes. A box of 24/25 cartridges should stand at room temperature for one hour before use.
    a. Ensure cartridges have not been exposed to unacceptable room temperature (>86F°), prior to patient use.
4. **Sample testing procedure:**
    a. Gloves should be worn during entire sample collection and testing process.
    b. Face shield protection should be available in each test site and used as appropriate.
    c. Analyzer should be programmed, PRIOR TO COLLECTING blood sample. This is extremely important when testing coagulation cartridges (PT/INR, ACT).
    CAUTION: Laser Radiation—do not stare into beam when scanning information (Class 2 product - Laser Diode 650nm Maximum Output 1.0mW).
        i. Select the desired cartridge and confirm the cartridge is not expired. Check the expiration date.
        ii. Turn on the analyzer.
        iii. Select '2-i-STAT Cartridge'.
        iv. Scan or manually enter operator ID.
            - To scan ID, hold 'Scan' and scan barcode reader over bar-coded operator ID.
            - Confirm that information scanned by the analyzer is correct.
                - **Notify the POCT Office if erroneous ID scanning occurs.**
            - If operator ID is manually entered, the ID must be entered twice to ensure accurate entry.
            - Testing personnel should not share ID numbers.
        v. Scan or manually enter the patient ID.
            - To scan ID, hold 'Scan' and scan barcode reader over bar-coded patient armband.
            - Confirm that correct information is canned by the analyzer.
                - **Notify the POCT Office if erroneous ID scanning occurs.**
            - If the patient ID is entered manually, the ID must be entered twice to ensure accurate entry.
            - **Accurate patient ID should be confirmed throughout entire testing process. As applicable, the ID entered into the i-STAT analyzer should come directly from the patient armband.**
        vi. Scan the cartridge barcode information. IMPORTANT NOTE: You must use the cartridge from the pouch barcode that was scanned into the analyzer. This barcode contains important calibration information that is needed for an accurate testing process. If you cannot use the cartridge of the pouch that was scanned, you must start over from the beginning with the testing process.
        vii. Information scanned into the i-STAT 1 analyzer will stay in the analyzer for 15 minutes, then the analyzer turns off.
        viii. Collect the blood sample – refer to **Specimen Collection** section above.
            - ***Remove residual air bubbles in the end of the collection container and cap the sample immediately after collection to avoid air contamination and erroneous results.***

ix. Open the pouch. Remove the cartridge from the pouch and use immediately.
x. Place the cartridge on the pouch or other absorbent material.
    - **Avoid touching the contact pads or exerting pressure over the calibrant pack in the center of the cartridge.**
xi. Samples should be properly mixed immediately prior to testing.
    - If a sample is not properly mixed, results may not be accurate.
    - Hematocrit results are adversely affected by improperly mixed samples.
        - ***If the sample is not adequately mixed or the filled cartridge sits for any period of time, inaccurate hematocrit results may be obtained***.
xii. As applicable, carefully squirt out a few drops of sample to confirm no sample clotting, to remove any residual air in the end of the syringe/capillary, and to facilitate smooth movement of the syringe plunger.
    - **Do not test samples that have or have had evidence of clotting.**
xiii. Fill the test cartridge.
    - Direct the syringe, dispensing tip, capillary tube, or finger to the sample well of the test cartridge.
    - Dispense the sample until it reaches the fill mark on the cartridge.
    - **Do not use force to fill the i-STAT cartridge. The cartridge should fill easily by capillary action. If resistance is encountered, stop the fill process and check for a clot in the sample. If force is used while filling the i-STAT cartridge, blood splatter may occur.**
    - Leave a small blood dome at the sample fill well.
    - After the cartridge is properly filled, carefully close the cover over the sample well until it snaps into place.
        - Do not lean over cartridge while snapping cover – shield with gauze or use eye protection as necessary in case of splash back.
    - **Do not press over the sample well**. Inspect the cartridge to be sure any visible blood has been wiped off. **Do not allow blood to seep into the analyzer.**
xiv. As applicable, recap the sample so integrity is maintained in case of needed repeat testing (not applicable for coagulation tests).
    - DO NOT re-cap needles.
xv. Insert the cartridge into the cartridge door until it clicks into place.
    - 'Cartridge locked' will display on the analyzer screen.
    - ***DO NOT try to remove a cartridge when 'cartridge locked' is displayed. Damage to the analyzer may occur.***
xvi. Do not move the analyzer during the testing process.
xvii. For analyzers programmed with Operator Test Select, an additional screen will appear. The user should numerically select the desired tests to be performed and press the 'right arrow' soft keypad to move forward to the next screen.
    - NOTE: When testing blood gas cartridges, TCO2 must be selected for display of HCO3 results.
    - NOTE: For cardiopulmonary bypass patient samples, select CPB hematocrit correction, as necessary. Refer to i-STAT System Manual or cartridge specific IFU for detailed information regarding the CPB hematocrit correction.
xviii. Enter additional parameters (**if required**):

- Patient temperature can be entered as degrees Centigrade or Fahrenheit. Use the '.' key for a decimal point.
- The patient temperature only requires entry if a temperature corrected blood gas is desired. Care should be taken in entering the temperature. The temperature corrected results are reported in the patient's electronic health record (EHR).
  - ***If an incorrect entry is entered for the patient temperature, the testing staff member must correct the results in the EHR (Wake One) and notify appropriate patient care providers.***
- FIO2 can be entered as the number of liters or as a percentage of the oxygen a patient is receiving.
- Choose the number corresponding to the sample type used when prompted at the Sample Type field. Press ENT.

xix. Depending on the test performed, after 2 minutes, results will be displayed on the i-STAT analyzer.

xx. Results should be evaluated for good sample quality, abnormal and critical values, and suppressed results.
- Use Comment Codes, as appropriate. Comment codes better 'automate' result hold or posting to the patient record—MUST be entered at the time of testing for affect.
- **COMMENT CODES --- FOR ISTAT**
  - **0 translates to --- Procedure Error**
    - Results flagged with comment code 0 will NOT post to the patient electronic healthcare record.
    - This code should be used when the staff member does not believe the result and feels an error was made in testing.
  - **5 translates to --- Recheck/confirm**
    - Results flagged with comment code 5 will post to the patient electronic healthcare record but the patient will not be billed for testing.
  - **6 translates to --- To notify Provider**
  - **123 translates to --- Lab Confirmation to Follow**
    - Results flagged with comment code 123 will post to the patient electronic healthcare record but the patient will not be billed for testing.

xxi. Document results and report to the appropriate personnel, according to user site specific guidelines.

xxii. Results may be printed. See **Reporting Results** section below for procedure.

xxiii. Remove the test cartridge at any time after the 'cartridge locked' prompt disappears.

xxiv. Discard the used cartridge in a container designated for biohazard materials.

xxv. Once a cartridge is removed, the analyzer is ready to accept another cartridge.

xxvi. Download results to the electronic health record as soon as possible.

DILUTION OR CONCENTRATION (IF APPLICABLE) – N/A

CALCULATIONS (IF APPLICABLE)

1. The i-STAT analyzer contains a microprocessor that performs all calculations required for reporting results. Refer to the i-STAT System Manual or cartridge specific IFU for calculated parameters.
2. Creatinine test results will include an estimated glomerular filtration rate (eGFR) when reported to the electronic health record. The i-STAT analyzer does not report the eGFR. It will be automatically calculated when the creatinine value is entered into the electronic health record.
    a. eGFR values will be calculated and resulted using the CKD-EPI Creatinine Equation (2021) for all patients >=18 years or <=80 years of age.
    b. $eGFR_{cr} = 142 \times \min(S_{cr}/\kappa, 1)^{\alpha} \times \max(S_{cr}/\kappa, 1)^{-1.200} \times 0.9938^{Age} \times 1.012$ [if female]
    where:
    S_{cr} = standardized serum creatinine in mg/dL
    κ = 0.7 (females) or 0.9 (males)
    α = -0.241 (female) or -0.302 (male)
    $\min(S_{cr}/\kappa, 1)$ is the minimum of S_{cr}/κ or 1.0
    $\max(S_{cr}/\kappa, 1)$ is the maximum of S_{cr}/κ or 1.0
    Age (years)

INTERPRETATION OF RESULTS

1. Suppressed Results:
There are three conditions under which the i-STAT System will **not** display results:

- **Out of Instrument Range**
    - Results outside the System's reportable ranges are flagged with **"<" or ">"**, indicating that the result is below the lower limit or above the upper limit of the reportable range, respectively.
    - If a result is dependent upon another result that is outside of the reportable range of the analyzer, the results will be suppressed and display as **<>**.
    - Refer to **Appendix B: Reference Ranges and Reportable Ranges**.
    - **Action:**
        - If contamination is a possibility, recollect and retest on another cartridge.
        - Otherwise, consider sending specimens to the Clinical Laboratory as outlined in **Downtime** section below.
        - Submit patient credit requests or use analyzer comment codes, as necessary.
- **QC failed parameters (*** or Star-Outs)**
    - Individual parameter results, which are not reportable based on internal QC rejection. Only the parameter noted with the flag (*******) is affected. Other reported results are not affected by the QC rejection (*******).
    - **Note:** Star-Out results will be sent to the electronic health record if comment code 0 is not entered into the analyzer at the time of testing. These ******* results will report as "Instrument Error" in the electronic health record.
    - **Action:**
        - If comment code 0 is used so all results on the test cartridge are held from the patient record, repeat using a new cartridge and blood sample. A new blood sample must be obtained if testing ACT, PT/INR, or CG4 (lactate).
        - If a parameter still results as *******, consider that an interfering substance may be present, or there may be a cartridge problem that needs to be investigated.

        - A specimen may be sent to the Clinical Laboratory as outlined in **Downtime** section below.
        - The results that are not suppressed can be used and should be reported in the usual manner.
        - Submit patient credit requests, as necessary.
- I**nstrument/Cartridge problem (Quality Check Code)**
    - Results will not be reported if a test cycle has a problem with the sample, calibrant solution, sensors, mechanical or electrical functions of the analyzer.
    - **Action:**
        - Take the action displayed with the message that identifies the problem.
        - Refer to the i-STAT System Manual - Technical Bulletin - "Analyzer Coded messages" for assistance. The current Technical Bulletin is placed in the i-STAT binder at each site biannually when the software is updated.

2. Unexpected results:

- Any result that is obtained and is unexpected or not consistent with patient presentation should be tested by an alternate method.
- If contamination is suspected, repeat testing with a freshly collected specimen.
    - Submit patient credit requests or use analyzer comment codes, as necessary.
- If analyzer/test system performance is in question, try using a different lot number/box of cartridges and a different analyzer.
- When unexplained discrepant results are noted, the POCT Office should be notified immediately

RESULTS REPORTING

1. **Reference and Reportable Ranges**:
    - **Reference ranges (Normal ranges) -**
        - Test results that fall outside of these ranges exceed the normal value range for a normal population.
        - These results should be handled according to user site specific guidelines or physician orders.
    - **Values Outside the Analyzer Reportable Range -**
        - Values outside the reportable range of the i-STAT system have not been documented as being accurate.
        - Such values should be evaluated for accuracy. Consider repeat testing via an alternate method with a freshly drawn specimen.
        - Refer to **Appendix B: Reference Ranges and Reportable Ranges**.
2. **Critical Values**:
        - Critical results are test results that fall outside high and low critical limits which define the boundaries of life-threatening values for a test.
        - Critical results represent an emergency condition and should be reported immediately to the patient's attending physician, nurse, or mid-level provider. Follow AHWFB policy regarding critical value notification and documentation.
        - The analyzer will flag potential critical values with bold black arrows.
        - Documentation of notification should be noted in the patient record and include:
            - Notifying individual's name/signature
            - Critical result
            - Date

        - Time
        - Name of the person that is notified of the critical value
        - The author's name should be legible and authenticated. Documentation pertaining to the person that is notified of the critical value should be identifiable for future questions. At a minimum, last name and credentials should be documented. It is preferred that the full name of the provider be documented.
    - Results that are verbally reported need to be confirmed by verbal reading back of results.
    - ***Unexpected critical values should be followed-up with appropriate repeat testing by an alternate methodology.***

3. i-STAT PT/INR Reflex Testing:

- INR values equal to or greater than 4.0, as reported by i-STAT, should have a reflex venous PT/INR ordered and sent to the Clinical Laboratory for confirmatory testing. Comment code 123, "Lab Confirmation to Follow", should be entered into the i-STAT handheld device at the time of testing.

4. **Reporting results:** Results should be reported to the clinical provider in a timely manner.
    a. Transmitting results to the Electronic Health Record -
        i. i-STAT 1 Analyzers should be downloaded after each patient test.
        ii. Test results obtained during procedural cases should be downloaded immediately following completion of the procedure.
        iii. Place analyzer in the downloader.
        iv. 'Waiting to Send' and then 'Communication in Progress' will display on the analyzer screen.
        v. All unsent results will automatically transmit.
        vi. Do not move analyzer until message disappears.
        vii. If the analyzer display indicates that there are unsent results:
            1. Check all plug connections and repeat the download process.
            2. If unsuccessful after 3 attempts, contact the Help Desk for assistance.
            3. i-STAT handheld analyzers should be downloaded at an alternate site until issue is resolved.
    b. **Printing results** - Some i-STAT sites are supplied with portable printers. Refer to the i-STAT System Manual for additional information.
        i. Turn the printer on.
        ii. To print the displayed test record:
            1. Align the infrared windows on the analyzer and printer.
            2. Press the PRT key on the analyzer.
            3. **NOTE:** Results printed on thermal paper will fade with time and are not acceptable as a permanent chartable record.
        iii. Do not move the analyzer while results are printing.
        iv. Write the patient's name on the result tape, if applicable.
    c. **Creatinine results and estimated glomerular filtration rate (GFR) Calculation -**
        i. Creatinine test results will include an estimated glomerular filtration rate (eGFR) when reported to the electronic health record. Refer to **Calculations** section above for additional information.

INTERFERING SUBSTANCES/TEST METHOD LIMITATIONS

1. i-STAT hemoglobin and hematocrit results may be affected by improper sample mixing, total protein values, and other factors. Refer to the i-STAT System Manual or cartridge specific IFU for detailed information.
    - **<u>NOTE</u>: Extreme caution should be exercised if using i-STAT hemoglobin and hematocrit results for transfusion decisions.**
2. Drawing a specimen from an arm with an IV may give erroneous results.
3. Stasis (tourniquet left on longer than two minutes before venipuncture) may adversely affect results.
4. Extra muscle activity (fist pumping) may adversely affect results.
5. Icing sample before filling cartridge may adversely affect results.
6. Time delays before filling cartridge may adversely affect results.
7. Using the first drop of a capillary blood sample for NON-PTINR testing can give erroneous results.
8. Exposing the sample to air when measuring pH, pCO2 or pO2 can give erroneous results.
9. ACT and PTINR results may be adversely affected by using a metal needle to fill the test cartridge or moving the analyzer during sample testing. The analyzer should be level with display facing up during testing.
10. PTINR results may be adversely affected if the first drop of blood is NOT used.
11. Hemolysis, caused by alcohol left over puncture site, a traumatic draw, or forceful flow of blood through a needle, can affect the quality of results.
    a. Hemolysis is defined as the destruction of red blood cells, caused by disruption of the cell membrane, and resulting in the release of hemoglobin in the sample.
    b. Hemolysis will falsely elevate potassium results.
    c. i-STAT tests whole blood. Hemolysis can NOT be determined when testing via i-STAT.
    d. To determine the presence of hemolysis, the sample must be spun in a centrifuge and the plasma/serum layer observed for pink to red color.
    e. The intensity of red color is proportional to the amount of hemolysis that is present in the sample.
    f. DO NOT report/treat high potassium results until verified via an alternate method.
12. Refer to the cartridge and test information sheets in the i-STAT System Manual or cartridge specific IFUs (see attachments) for a detailed listing of interfering substances. Any time questionable results are obtained on the i-STAT, interfering substances should be considered.
    - **<u>Most common interferences:</u>**
        - Propofol, Thiopental Sodium and Hydroxyurea can cause interference with the i-STAT test system. Results from patients receiving these drugs should be evaluated with caution. See the i-STAT System Manual - Cartridge and Test Information section or cartridge specific IFU for details.
        - Increased patient lactate may interfere with certain i-STAT results.
        - Hemodilution of the plasma by more than 20%, associated with priming cardiopulmonary bypass pumps, plasma volume expansion or other fluid administration therapies using certain solutions, may cause clinically significant errors in sodium, chloride, ionized calcium and pH results.

DOWNTIME

1. When an i-STAT analyzer is inoperable and an additional analyzer is not available at the site where testing is being performed, consider the following options:
    a. Specimens for ACT, blood gas, whole blood electrolytes, ionized calcium and hematocrit analysis should be collected and submitted to the Blood Gas Lab.
        i. Samples for ACT tests must be tested immediately after collection, so these samples should be hand-delivered to the Clinical Laboratory, as appropriate.
    b. PTINR samples may be collected by venous sample collection and sent to the Clinical Laboratory for testing. Samples may be delivered or sent via the pneumatic tube system.
    c. Other Chemistry/Hematology testing may be sent to the Clinical Laboratory via the pneumatic tube system or via courier.
2. The POCT Office has extra analyzers that can be used for testing – notify the POCT office (M-F 8-5) to switch out analyzer if necessary.
3. After hours, weekends, and holidays call Abbott Tech Support at 1-800-366-8020 for assistance.

LITERATURE REFERENCES:

College of American Pathologists (CAP) Lab Accreditation Program. Lab General, All Common, and Point of Care Testing checklists, CAP, 325 Waukegan Rd, Northfield, Illinois 60093-2750. Revised June 2022.

i-STAT System Manual, i-STAT Corporation, 303 College Road East, Princeton, NJ 08540Art # 714446-00P. Updated May 2022.

National Kidney Disease Education Program web site
https://www.niddk.nih.gov/health-information/community-health-outreach/information-clearinghouses/nkdep

https://www.kidney.org/apps/professionals/egfr-calculator

RELATED PROCEDURES/POLICIES AND ATTACHMENTS/LINKED DOCUMENTS IN NAVEX/POLICY TECH AND/OR TITLE 21:

Appendix A: Critical Results
Appendix B: Reference Ranges and Reportable Ranges
Appendix C: i-STAT Cartridge Sign-out Procedure

Monthly i-STAT Supply Inventory Form
Complications Associated with Arterial Puncture Education Module
Complications Associated with Arterial Puncture – Training Documentation
i-STAT Ambient Room Temperature Log
i-STAT Cartridge Sign Out Log
i-STAT Resolution Request
i-STAT EG7 Cartridge IFU
i-STAT CG4 Cartridge IFU
i-STAT ACT-Celite Cartridge IFU
i-STAT ACT-Kaolin Cartridge IFU

i-STAT PTINR Cartridge IFU
i-STAT Creatinine Cartridge IFU

Temperature and Humidity Monitoring for Reagents, Equipment and Environments in Clinical Areas
Point of Care Waived and Non-Waived Testing
Responsibilities of Testing Sites and the Clinical Laboratory for POC Testing
Competency Assessment for Non-Waived Testing
QC Range Verification
Non-Waived POCT Quality Management Policy and Quality Control/Quality Assurance Procedures
Handling of POCT Analyzers when Removed from Service or Returned to Manufacturer for Repair
Proficiency Testing
Managing Inventory for Expired Reagents, Point of Care
i-STAT Cartridge Receipt Process
i-STAT New Analyzer Receipt Process

REVISION DATES: REVIEW CHANGE SUMMARY AS REPRESENTED IN TITLE 21.

Appendix A

Critical Results:

Critical results are test results that fall outside high and low critical limits, which define the boundaries of life-threatening values for a test. Critical results represent an emergency condition and should be reported immediately to the patient's attending physician, nurse, or mid-level provider. Documentation of notification should be noted in the patient record. Documentation should include: notifying individual's initials/signature, the result, date, time, and the name of the person that is notified of the critical value. The author's name should be legible and authenticated. Documentation pertaining to the person that is notified of the critical value should be identifiable for future questions. At a minimum, last name and credentials should be documented. It is preferred that the full name of the provider be documented. Critical values should be properly evaluated with the patient's clinical symptoms and followed-up as necessary with laboratory confirmation. Any unexpected result should be repeated on the i-STAT or sent to the laboratory for confirmation.

****Critical value limits are defined by the Clinical Laboratory and, in conjunction with, the Medical Directors for i-STAT user sites.

Analyte	Adult	Pediatric	Neonate (Patient in NICU)	Comments
Sodium mEq/L or mmol/L	<120 >160	<120 >160	<120 >150	
Potassium mEq/L or mmol/L	<3.0 >6.0	<3.0 >6.0	<3.0 >6.0	Unexpected results >6.0 should be verified by the laboratory. Hemolysis falsely elevates results. For potassium results to be considered critical, they should also fail the normal range defined for the patient's age.
Total CO2 mEq/L or mmol/L	<10 >40	<10 >40	<10 >40	
Ionized Calcium mmol/L	<0.75 >1.40	<0.75 >1.40	<0.80 >1.40	
pH	<7.2 >7.6	<7.15 >7.6	<7.20 >7.45	
pCO2 mm/Hg	<25 >60	<30 >80	<35 >80	
pO2 mm/Hg	<50 >200	<30 >200	<30 >200	<30/50 ARTERIAL; >200 All Sample Types (does not apply to OR/ECMO circuit arterial samples)
Hemoglobin g/dl	<=6 >=20	<=6 >=20	<=6 >=20	
Hematocrit %PCV	<=18 >=60	<=18 >=60	<=18 >=60	
PT/INR	>= 5 or value not calculated	>= 5 or value not calculated	>= 5 or value not calculated	INR values equal to or greater than 4.0, as reported by i-STAT will have a reflex venous PT/INR ordered and sent to the Clinical Laboratory for confirmatory testing.

Appendix B
Reference Ranges and Reportable Ranges:

Reference (normal) range means the range of test values expected from 95% of fasting individuals presumed to be healthy. Our reference ranges come from the normal ranges established by the Clinical Laboratory at Atrium Health Wake Forest Baptist Medical Center and from the i-STAT System Manual (manufacturer IFU). Literature based references used by the Clinical Laboratory include Tietz Fundamentals of Clinical Chemistry and Molecular Diagnostics, Henry's Clinical Diagnosis Management by Laboratory Methods, 23rd Edition (Adults), and Nathan and Oski's Hematology of Infancy and Childhood, Sixth Edition (Pediatrics).

Reportable range means the range of test values over which i-STAT results have been shown to be valid.

The following table contains the Reference Ranges and Reportable Ranges applicable to the i-STAT. Reference the i-STAT System Manual for information not listed in this document.

ANALYTE	UNIT	REFERENCE RANGE	REPORTABLE RANGE
SODIUM	mEq/L or mmol/L	18y 135-146	100-180
		2y 136-143	
		0d 133-142	
Potassium	mEq/L or mmol/L	18y 3.5-5.3	2.0-9.0
		9y 3.5-5.5	
		5y 3.5-5.0	
		1y 3.5-5.5	
		3m 4.0-6.5	
		1m 4.5-7.5	
		7d 4.5-7.0	
		0d 3.8-6.2	
PT/INR	INR	0.9-1.2 (venous and capillary whole blood) **--** recommended by i-STAT. WFBMC normal range may differ	0.9-6.0
ACT (Activated Clotting Time) **(Kaolin Activated)**	Seconds	Kaolin activated - Prewarm Non-heparinized 74-137	50-1000
ACT (ACTIVATED CLOTTING TIME) **(Celite Activated)**	Seconds	Celite activated - NON-Warm Non-Heparinized 84-139	50-1000
CREATININE	mg/dL	18y 0.5-1.5	0.2-20.0
		10y 0.5-1.0	
		4y 0.4-0.9	
		1y 0.3-0.8	

ANALYTE	UNIT	REFERENCE RANGE	REPORTABLE RANGE
		3m 0.3-0.7	
		1m 0.3-0.9	
		14d 0.4-1.1	
		7d 0.3-1.2	
		0d 0.5-1.5	
Ionized Calcium	mmol/L	1.00-1.30	0.25-2.50
pH		Arterial 7.350-7.450 Venous 7.310-7.410 Capillary None Defined	7.00-7.70 (Cath Lab: CG4,EG7) 6.50-7.70 (RT/All other sites WFBMC: EG7)
pCO2	mm/Hg	Arterial 35-45 Venous 41-51 Capillary None Defined	15-120
pO2	mm/Hg	Arterial 80-100 Venous None Defined Capillary None Defined	15-400
HEMATOCRIT – MALE (K3EDTA)	%PCV	18y 41.5-50.4	15-72
		12y 37-49	
		6y 35-45	
		2y 34-40	
		6m 33-39	
		3m 29-41	
		1m 28-42	
		2w 31-55	
		1w 39-63	
		3d 42-66	
		1d 45-67	
		0d 42-60	
Hematocrit - FEMALE (K3EDTA)	%PCV	18y 35.9-44.6	
		12y 36-46	
		6y 35-45	
		2y 34-40	
		6m 33-39	
		3m - 0d same as male	

ANALYTE	UNIT	REFERENCE RANGE	REPORTABLE RANGE
HCO3	mmol/L	Arterial 22-26 Venous 23-28 Capillary None Defined	1-85
TCO2	mEq/L or mmol/L	23-30	10-50
BE	mmol/L	Arterial (-2) - (+3) Venous (-2) - (+3) Capillary None Defined	(-30)-(+30)
SO2 **(O2 SATURATION)**	%	>95 Arterial	0-100
HEMOGLOBIN - MALE	g/dL	18y 14.0-17.5	5.1-25.5
		12y 13-16	
		6y 11.5-16.5	
		2y 11.5-13.5	
		6m 10.5-13.5	
		3m 9.5-13.5	
		1m 9-14	
		2w 10-18	
		1w 12.5-20.5	
		3d 13.5-21.5	
		1d 14.5-22.5	
		0d 13.5-19.5	
Hemoglobin - FEMALE	g/dL	18y 12.3-15.3	
		12y 12-16	
		6y-0d same as male	
Lactate	mmol/L	Arterial: 0.36-1.25 Venous: 0.90-1.70	0.5-18.0

Abbott Manufacturer IFU: PTINR, ACT-Celite, ACT-Kaolin, pH, pCO2, [HCO3], [BE], Lactate

Clinical Laboratory/Literature based:

- Chemistry - Sodium, Potassium, Creatinine, [TCO2]
- Hematology – [Hemoglobin], Hematocrit
- Critical Care Lab – Ionized Calcium, pO2, [SO2]

***[ ] = Calculated value

Appendix C
i-STAT Cartridge Sign Out Procedure:

1) Purpose

The Clinical Laboratory POCT Office maintains i-STAT supplies for specifically identified Point of Care Testing (POCT) I-STAT user sites. The POCT Office receives the cartridges from the manufacturer and performs Quality Control (QC) checks, prior to release for patient use. Each user site is responsible for obtaining I-STAT cartridges and supplies from the POCT Office. This procedure serves as a guide for POCT staff and I-STAT user sites, regarding appropriate means of issuing and obtaining I-STAT supplies.

2) Procedure

Each user site should designate someone to maintain adequate I-STAT supplies. When a user site needs supplies, they can be obtained from the POCT Office.

- **CARTRIDGES CANNOT BE SENT THROUGH THE PNEUMATIC TUBE!**

A. Cartridge Sign Out and Handling

a. The oldest expiration dated cartridges should be issued first.
b. The cartridges are kept refrigerated, per manufacturer's instructions, in the Clinical Laboratory.
c. The cartridges should be at room temperature prior to patient use. An individual cartridge is ready to use after sitting at room temperature for 5 minutes. A full box of 24/25 cartridges should sit at room temperature for 1 hour prior to patient use.
d. Once cartridges are removed from the refrigerator, an appropriate room temperature expiration date should be noted on each individual cartridge.
    - ❖ **NOTE**: Room temperature expiration dating should never exceed manufacturer refrigerated expiration dating.
        - Creatinine cartridges—14 DAY room temperature expiration date
        - PT/INR—14 DAY room temperature expiration date
        - ACT-Celite—14 DAY room temperature expiration date
        - ACT-Kaolin—14 DAY room temperature expiration date
        - CG4—2 Month room temperature expiration date
        - EG7—2 Month room temperature expiration date
        - Other cartridges—Refer to i-STAT System Manual
e. Each box of cartridges that is removed from the refrigerator should have the following information:
    - Receipt date
    - Date/time out of the refrigerator
    - Room temperature expiration date
    - Initials of issuing staff member
f. Do not issue/sign out cartridges that are marked "NEW LOT NUMBER or DO NOT USE".
g. When cartridges are issued or signed out by user sites, they should be logged in the i-STAT Cartridge Sign Out book maintained in the POCT Office. There is a sheet for each cartridge type and each user site. The following information should be documented on the sign out log sheet.
    - Date
    - User site
    - Cartridge type
    - Lot number

- Box number(s) of cartridges issued
- Quantity Issued
- Room temperature expiration date or refrigerated expiration date, if cartridges will be stored refrigerated at the user site
- How cartridges are issued--room temperature or refrigerated
- Name of person issuing/signing out the cartridges

h. User sites without refrigerators should only take the amount of cartridges that will be used before the room temperature expiration date.

i. It is the responsibility of the testing personnel to ensure an adequate supply of I-STAT cartridges are maintained.

j. Testing site personnel are responsible for cartridge pick-up from the POCT Office.

k. **User Site Refrigerated Cartridge Sign Out:**
Specifically identified sites may stock I-STAT cartridges in site-specific refrigerators.
    - If a site stocks refrigerated cartridges, the refrigerator temperature must be monitored and review/ corrective actions documented.
    - The refrigerator must be maintained within i-STAT's current recommended temperature range. Refer to cartridge packaging for correct refrigerated storage temperature range.
    - The cartridges should be taken directly from the POCT Office refrigerator to the user site refrigerator, so the cartridges do not warm to room temperature.

l. **Cartridges close to expiration:**
User sites may come to the POCT Office and swap cartridges that are close to expiration.
    - POCT Office staff should be notified so the cartridges can be given to a site that will use them prior to the expiration date.

B. <u>Other I-STAT Supplies</u>

The POCT Office also issues the following supplies for the I-STAT system:

a. Thermal printer paper for the I-STAT printers

C. <u>Replacement Analyzers/Printers</u>

a. i-STAT sites should deliver faulty analyzers or printers to the POCT Office.

b. As appropriate, POCT Office staff may issue a replacement device. The serial number (located on the back of the device) should be documented.

c. Extra devices are located in the Clinical Laboratory POCT Office.

d. The POCT Office will document the following:
    - ❖ Label the faulty device with "DO NOT USE".
    - ❖ Note the user site that returned the device.
    - ❖ Leave the faulty device in the POCT Office.
    - ❖ Leave a note documenting the replacement device serial number that was issued to the user site.

e. As necessary, POCT staff should refer to the linked procedure ***Handling of POCT Analyzers when Removed from Service or Returned to Manufacturer for Repair.***