Shared health
Soins communs
Manitoba

Document History:

Title: i-STAT 1 System SOP		Site(s):	Shared Health Diagnostic Services – All
Document #:	**100-10-02**	**Version #:**	**05**
Section:	**General Operations**	**Subsection:**	**General**

Approved by: *(Approval on File)*	N. Landry, A. Hartel	**Date:**	14 December 2023
Approved by: *(Approval on File)*	Dr. L. Thorlacius	**Effective Date:**	11 January 2024

#	Details of Revisions:	Approval:	Date:
1	New Document; combined all i-STAT documents into one complete SOP and archived the following documents: 110-10-04, F110-10-04B, F110-10-04C, F110-10-04D, F110-10-04E, F110-10-04F, F110-10-04G, F110-10-04H, F110-10-04I, JA110-10-04, 140-170-02, F140-170-02	L Thorlacius A Sokoro C McMahon	27 April 2020
2	Added required levels of cal/ver and liquid QC material to Supplies List 6.3.1 (p.6). Added sample rejection time of 40 minutes for Chem8+ and cTnI (p.7). Printout for e-simulator daily results optional (p.10). Corrected ordering code for Whole Blood Chemistry; added ordering and worksheet code for INR (p.12). Updated criteria and process for sending PT/INR samples to lab for confirmatory testing (ps. 13/14). Added instructions for phoning and recording critical results in Delphic (p.16). Added name of log sheet to record monthly PT/INR QC testing; corrected the volume of $CaCl_2$ added pipetted in PT/INR QC preparation steps (p.22). Added space for Cartridge expiry date to Incoming QC Log; renamed log sheet to include monthly PT/INR reporting (p.32). Removed column for Cal/Ver results from Semi-Annual QC Log (p.34).	C McMahon L Thorlacius	1 June 2020
3	Added interference of high levels of $\boldsymbol{P}O_2$ on $\boldsymbol{P}CO_2$ as per Abbott Bulletin dated Sept 2020 (p.18).Corrected preparation of PT/INR controls for Integrity Testing (p.22). Added number dates to Electronic Simulator Log (p.29).	L Thorlacius C McMahon	28 Sep 2020
4	Updated list of who to send completed validations to (p.5). Added approved tests and samples types for each cartridge; added instruction to use Ceramic Conditioning Cartridge when certain errors occur (p.6). Added instruction to draw discard tube before collecting from a line (p.7). Added gel tubes may be used for chemistries and TnI collections when needed (p.8). Removed cartridges not validated from Panel (p.9). Added instructions for suppressed results with Blood Gases chemistry cartridges (p12). Clarification of reportable range for INR: standardized to >4 requires confirmatory testing across all sites; added instructions for No clot or **** error for PT/INR (p.13). Added reporting chart for results outside the Reportable Range; updated criteria for sending PT/INR sample to reference lab (p.15). Updated Reportable Range for INR (p.17). Updated critical results table; added capillary samples critical results; added reference ranges and critical results for umbilical cord samples (p.18/19). Added comment regarding blood gases in lipemic samples (p.20). Changed Appendix 4 i-STAT Calibration verifiers and QC Log entry to a fillable form (p.33).	A Hartel H Klassen Vakili	4 Jan 2023 17 Jan 2023
5	Removed G3+ and CG4+ Blue (discontinued Effective June 30, 2023). Updated specimen requirements for skin puncture samples collected in balanced heparin capillary tubes. Corrected the Lactate critical results in section 14. Corrected	H Klassen Vakili N Landry	24 Nov 2023

reporting less than for base excess to L-30, addition of capillary pO2 reference range and capillary and mixed gas reference ranges for neonates. Critical value for umbilical cord blood pH has been updated. Clarified the requirements for on-going validation of new/replacement instruments, and to whom the data should be sent. Appendix 9 has been split into a job aid and specimen requirements page. Additional formatting changes and converted final document format to fillable PDF to facilitate ease of use.

Table of Contents

1.0 PURPOSE:

1.1. To provide instruction for use of the i-STAT 1 analyzer.
1.2. Non-Shared Health sites may use this SOP if they have a Memorandum of Understanding (MOU) with Shared Health. The MOU will clarify the responsibilities of both the external organization and Shared Health.

2.0 GENERAL INFORMATION:

2.1. The i-STAT analyzer may be utilized as a main analyzer in low volume sites and in POCT settings or as a back-up analyzer in certain circumstances.
2.2. Use of the analyzer will vary from site to site depending on the site test menu or service agreement in place.
2.3. External Proficiency Testing (EPT) must be done for each analyte being tested for on the i-STAT analyzer; if no EPT is available then a suitable alternative must be used as advised by the applicable provincial discipline team. See Section 20.0 for details.
2.4. All operators must be provided with a unique Operator ID number; ID must not be shared.
2.5. All staff utilizing the i-STAT analyzer must have initial training and annual competency assessment.
2.6. All staff utilizing the i-STAT must be re-certified annually.
2.7. For additional information on operation or troubleshooting of the i-STAT analyzer, refer to the vendor operations manual.

3.0 SYSTEM OVERVIEW:

3.1. The i-STAT system incorporates comprehensive components needed to perform blood analysis at the point of care level.
3.2. The system consists of the following components:
  3.2.1. Analyzer into which a sample-filled cartridge is inserted for analysis; the analyzer automatically controls all functions of the testing cycle including fluid movement within the cartridge, calibration and continuous monitoring.
  3.2.2. Cartridges which are single use and disposable and contain micro-fabricated sensors, a calibrant solution, fluidics system and waste chamber. Cartridges available at each site will depend on the site test menu and the intended use of the analyzer at the site.

4.0 SAFETY PRECAUTIONS:

4.1. As per Routine Practices (Standard Precautions).
4.2. Mandatory use of gloves and safety glasses.
4.3. Cartridges should be disposed of as biohazard waste, not in general waste.

5.0 ESSENTIAL FUNCTIONS:

5.1. Regional Functions

5.1.1. Coordinate ordering of cartridges, providing sites with cartridges that match their test menu.
5.1.2. Ensuring that QC on new lots of cartridges are performed by receiving site and documented according to requirements.
5.1.3. Keep track of loaner i-STAT and provide it to sites as needed.
5.1.4. Coordinate software updates (CLEW).
5.1.5. Ensure each site subscribes to the appropriate external proficiency testing programs.
5.1.6. Assign operator ID numbers for new issuers in their region.
5.1.7. Arrange for training of new operators and ensure that current operators are re-certified annually.
5.1.8. Ensure customization changes are made to meters and that this is password protected.
5.1.9. Ensure new or replacement analyzers are validated.

5.2. Site Functions

5.2.1. Keep track of inventory of i-STAT cartridges and initiate regional order process when more are needed.

5.2.2. Conduct quality checks of new lots of cartridges as they are received and document according to requirements.

5.2.3. Ensure external proficiency testing is done and reported.

5.3. Operator Functions

5.3.1. Run electronic simulator when necessary.

5.3.2. Perform patient testing.

5.3.3. Be re-certified annually.

5.4. Operator ID Numbers

5.4.1. Operator ID numbers should be unique and 6 or 7 digits long. Do not replicate previously used ID numbers.

5.4.2. For Shared Health sites, the first number indicates the region:

Region	Operator ID
Prairie Mountain Health RHA	1xxxxx 2xxxxx 9xxxxx
Northern RHA	3xxxxx
Southern Health-Santé Sud RHA	4xxxxx 8xxxxx
Winnipeg RHA (Churchill only)	5xxxxx
Interlake-Eastern RHA	6xxxxx 7xxxxx
Winnipeg RHA	0xxxxx

5.5. Training

5.5.1. Training of new operators will be provided by a previously trained technologist, and this will be coordinated within each region.

5.6. Validations of New or Replacement Analyzers (On-going Validations)

These requirements are to validate that new or replacement analyzers are functioning as expected.

5.6.1. For sites using Chem8, CG4+, EC8+, Crea, G, cTnI cartridges:

Integrity Testing must be performed on all new or replacement analyzers as well as on each analyzer when it is moved or transported from one site to another.

- See Section 19.0 for instructions on performing integrity testing with liquid controls.

Results must be within the acceptable ranges provided by the manufacturer prior to using the analyzers to report patient results.

5.6.2. For sites using PT/INR cartridges:

- Follow the procedure described in document 140-170-09 (i-STAT POCT INR Mini Verification Protocol).

5.6.3. Results of calibration verification and liquid controls should be reported to, as applicable to either:

- For Blood gases, Chemistry and cTnI:
  - **Shared Health labs:** Shared Health Point-of-Care Biochemist
  - **Non-Shared Health Diagnostics Sites**: Regional POCT Specialist
  - In the event that either of the above are not available, send validation data to the Shared Health Technical Director for Biochemistry

- For PT/INR:
  - Shared Health Hematology Technical Director prior to patient testing.

5.7 Annual Competency Assessment

5.7.1. Shared Health Diagnostics staff

- Annual Competency Assessment for the i-STAT Analyzer System must be assigned and successfully completed.

5.7.2. Non-Shared Health Diagnostics staff

- Annual competency assessment of all operators must occur annually, as per MOU agreement for POCT with Shared Health.

6.0 SUPPLIES AND STORAGE REQUIREMENTS:

6.1. Cartridges

6.1.1. General Information

- Note – Not all listed cartridges are available for testing at every site; refer to individual test menus, and request extended menus if necessary
- Sealed in individual pouches or portion packs.
- Individual pouches must be warmed to room temperature (between 18 °C and 30 °C) for 5 minutes prior to testing, entire boxes must be warmed for one (1) hour prior to use.
- **DO NOT** allow cartridges to freeze.
- **DO NOT** return cartridges to the fridge once they have been at room temperature.
- **DO NOT** use cartridge if pouch has been punctured.
- **DO NOT** use after the labeled expiration date.

6.1.2. Storage

- Store main supply of cartridges at fridge temperature (between 2 °C and 8 °C).

6.1.3. Room temperature storage

- Between 18 °C and 30 °C is acceptable but will shorten expiry dating:
  - Chem8+/EC8+/Creatinine cartridges = 14 days
  - CG4+ cartridge = 2 months
  - PT/INR cartridge = 14 days
  - cTnI cartridge = 14 days
- Shortened expiry date must be written on the package when taken out of the fridge.

6.1.4. Approved Tests and Sample Types Reported from Cartridges

- CG4+ cartridges = used for all sample types including capillary; report all results
- Chem8+ cartridges = used for venous and arterial samples only; report all results except

Ionized Calcium unless on approved Test Menu for the site
- EC8+ cartridges = used for all sample types including capillary; do not report blood gases, including TCO2
- Crea cartridge = used for all samples in combination with EC8+ cartridge
- PT/INR Cartridge = used for venous and capillary blood

6.2. Ceramic Conditioning Cartridge (CCC)

6.2.1. Store at room temperature (between 18 °C and 30 °C).

6.2.2. Use to condition the pins of the analyzer when given error codes related to poor contact between the analyzer and the cartridge (e.g. Codes 20,23,27,41,49,50,87, and 126).

6.2.3. CCC consists of an aluminum base that supports a white ceramic strip. The ceramic cartridge may be used 50 times before the strip is worn and needs to be rotated or up to 200 times before the strip must be replaced.

6.2.4. See Appendix 14: i-STAT System – Ceramic Conditioning Code for instructions on using the CCC and replacing the ceramic strip.

6.2.5. See Appendix 15: i-STAT Ceramic Conditioning Cartridge (CCC) Usage Log to track rotation and replacement of strip.

6.3. Calibration Verifiers and Liquid Controls

6.3.1. General Information

6.3.1.1. PT Quality Controls levels 1 and 2 are used for monthly PT/INR quality testing; there are no Calibration Verifiers for PT/INR.

6.3.1.2. i-STAT Aqueous Calibration Verifiers (levels 1-5) and Quality Control (levels 1 and 3) materials are used for blood gas and general chemistry quality testing.

6.3.1.3. cTnI Calibration Verifiers (levels 1-3) and Quality Control (levels 1 and 3) materials are used for Troponin I quality testing.

6.3.1.4. All products are stored at fridge temperature (between 2 °C and 8 °C); do not allow to freeze.

6.3.1.5. **DO NOT** use after expiration date on the box and ampules.

6.3.2. PT Quality Control Levels 1 and 2 must be reconstituted with provided $CaCl_2$ fluid and allowed to stand at room temperature (18-30°C) for a minimum of 45 minutes prior to use.

6.3.3. TnI calibration verifiers and controls must not be left at room temperature. Once opened, controls are stable in the fridge for 30 days. cTnI controls do not need to be warmed prior to use.

6.3.4. All other calibration verifiers and controls must come to room temperature (between 18 °C and 30 °C) prior to use. Minimum room temperature equilibration:
- PT/INR Controls – 45 minutes
- Chemistry and Blood Gas Testing other than pO2 – 30 minutes
- pO2 testing – 4 hours

6.3.5. Room temperature storage (between 18 °C and 30 °C) is acceptable but will shorten expiry dating:
- PT/INR Controls – 4 hours
- i-STAT Aqueous Calibration Verifiers and Controls – 5 days
- cTnI Calibration Verifiers and Controls – None; do not leave at room temperature

6.3.6. Shortened expiry date must be written on the vials/box when taken out of the fridge.

6.4. Electronic Simulator

6.4.1. Store at room temperature (between 18 °C and 30 °C).
6.4.2. Protect contact pads from contamination by replacing the plastic cap and placing the electronic simulator in its protective case after use.

7.0 SPECIMEN REQUIREMENTS:

7.1. General Information

7.1.1. Specimen requisition must be completed as outlined in Specimen Acceptance Policy (10-50-03).
7.1.2. Specimen must be collected and labeled as outlined in Phlebotomy Manual (100-10-79).
7.1.3. Do not expose sample to air.
7.1.4. Avoid drawing air and forming air bubbles in the blood gas syringe.
7.1.5. Completely full tubes and syringes to capacity for correct heparin-to-blood ratio, incomplete filling can cause erroneous results.
7.1.6. Non-Shared Health Diagnostics staff collecting samples from a line must expel air or fluid from the line by drawing blood into a discard tube or syringe prior to sample collection.
7.1.7. Mix blood and anticoagulant by inverting tube gently at least 10 times immediately following collection (do not mix PT/INR sample as this could activate clotting process).
7.1.8. **DO NOT** put samples on ice following collection.
7.1.9. **DO NOT** use clotted samples.
7.1.10. Run samples cartridges that are Health Canada approved for the specific sample type only.
7.1.11. Testing must be performed within 10 minutes of collection for CG4+ cartridges, or if analyzing for TCO_2 or ionized Calcium. If performing testing on a Chem8+/EC8+/CREA cartridge and not analyzing for TCO_2 or ionized Calcium, testing must be performed within 30 minutes of collection.
7.1.12. Samples tested outside of these time limits must be resulted with the following comment:
"Results may be inaccurate due to delayed analysis"

- If testing is not performed within 20 minutes of collection for blood gases or ionized Calcium, or within 40 minutes for all other chemistry tests, sample must be rejected.

7.1.13. Precautions:
7.2.1. Avoid the following circumstances:
- Drawing a specimen from an arm with an IV.
- While avoiding the use of a tourniquet during phlebotomy if recommended, samples that are collected after elastic tourniquet application for ≤1 minute are also acceptable.
- Extra muscle activity (fist pumping).
- Hemolysis (alcohol left on puncture site; traumatic draw).
- Exposing the sample to air when measuring blood gases (pH, PCO_2, PO_2 and TCO_2).

7.2.2. Criteria for Specimen Rejection:
- Evidence of clotting.
- Specimens collected in incorrect tubes.
- Syringe for blood gases with air bubbles in sample.
- Incompletely filled evacuated tubes.
- Excessive delay in analysis (see points 7.1.10, 7.3.4, 10.5)
- Other types of samples such as urine, CSF, and pleural fluid.
- Specimen does not meet requirements of Specimen Acceptance Policy (10-50-03).

7.1.14. PT/INR
<u>Skin puncture (Capillary samples)</u>
- Use the first drop of blood.
- Test specimen immediately.

Venipuncture

- Fresh whole blood collected into a plastic syringe.
  - Dispense sample directly from syringe.
- Fresh whole blood collected in a clear top non-additive tube.

Dispense sample with a plastic transfer device.

7.2. Blood Gases, Electrolytes, Chemistries

7.2.1. Skin puncture (Capillary samples)

- **Do not use Chem8+ cartridges for capillary collections.**
- Fresh whole blood collected in a plain, no-gel lithium heparin microtainer for chemistries or balanced heparin capillary tube for electrolytes and blood gases.
- The first drop of blood will contain excess tissue fluid and must be wiped away.
- Avoid strong repetitive pressure (“milking “) as it may cause hemolysis or tissue fluid contamination of the sample.
- **Samples collected in capillary tubes with balanced heparin anticoagulant must be tested within 3 minutes of collection.**

7.2.2. Venipuncture

- Fresh whole blood collected in an evacuated collection tube with lithium heparin anticoagulant, no gel; fill collection tube to capacity. Gel tubes may be used for chemistry testing but are not acceptable for blood gases.
- A balanced heparin blood gas syringe may be used for venous collections.

7.2.3. Arterial puncture

- **Collection of arterial samples is not performed by medical laboratory technologists or laboratory assistants**.
- Collected using plain syringe, syringe using the least amount of liquid heparin to prevent clotting (10 U heparin/mL of blood), or heparinized blood gas syringe; filled to the recommended capacity.
- Samples collected in plain syringe with no anticoagulant must be tested immediately at bedside.
- Blood gas syringe should be used when testing for ionized calcium.

7.2.4. Cord Blood

- Samples are collected by delivery room staff (physician, respiratory therapist, nurse, or physician assistant) and are sent to the lab. **Lab staff does not collect cord blood.**
- Sample must be tested within 10 minutes following collection from umbilical cord; clamped cord can be stored at room temperature for up to one hour if clamping was not delayed.
- **If cord clamping is delayed, cord blood gas results may be affected.**
  - Samples should be collected from unclamped cord as soon as possible as birth and should be tested immediately
- Syringes not containing the minimum volume (1.0-1.5 mL) or containing numerous air bubbles should be rejected.
- Samples must be properly labeled as venous or arterial in order for correct reference intervals to be applied.
- Samples greater than 20 minutes old must be rejected, samples between 10-20 minutes old must have the following comment added:
  “Results may be inaccurate due to delayed analysis”

7.3. Troponin I/cTnI

7.3.1. Skin puncture

- Not recommended; do not use capillary samples.

7.3.2. Venipuncture

- Fresh heparinized whole blood or plasma samples collected in syringes or evacuated tubes containing lithium heparin with or without gel.
- Collection tubes must be filled; failure to completely fill tubes may cause falsely elevated results, especially if plasma is used.
- Mix blood and anticoagulant by inverting tube gently at least 10 times.
- If sample will not be analyzed within 30 minutes of collection, samples should be centrifuged and plasma must be used for analysis.
  - Plasma samples are stable for 24 hours at 2 °C to 8 °C and for 12 months at -20 °C (freeze only once).
- A plain syringe or plain collection tube and disposable transfer device can be used if the sample is tested within one minute of patient draw.

8.0 CARTRIDGE PANEL CONFIGURATIONS AND BLOOD VOLUME: (shading denotes calculated value)

Cartridge	Vol. (µL)	pH	PCO_2	PO_2	Na	K	Cl	iCa	Glu	BUN	Creat	Lact	Hct	TCO_2	PT/INR	cTnI	HCO_3	TCO_2	SO_2	BE	**Anion Gap**	Hb
CHEM8+	95				•	•	•	•	•	•	•		•	•							•	•
CG4+	95	•	•	•								•					•	•	•	•		
EC8+	65	•	•		•	•	•		•	•			•				•	•		•	•	•
G	65								•													
Crea	65										•											
PT/INR	20														•							
cTnI	17															•						

NOTE: Only cartridges validated and approved for your site's testing menu may be used for testing.

OPERATOR FUNCTIONS

9.0 DAILY QUALITY CONTROL:

9.1. Verify the performance of each i-STAT System using the external Electronic Simulator every 24 hours of use.
9.2. All Analyzers will lock and not report results if the Electronic Simulator has not been run in the last 24 hours; running the Electronic Simulator will unlock the analyzer.

<table>
<tr><th colspan="3">Electronic Simulator</th></tr>
<tr><td>Step 1</td><td colspan="2">Turn on i-STAT</td></tr>
<tr><td>Step 2</td><td colspan="2">Press Menu</td></tr>
<tr><td>Step 3</td><td colspan="2">Press 3, Quality Test</td></tr>
<tr><td>Step 4</td><td colspan="2">Press 4, Simulator</td></tr>
<tr><td>Step 5</td><td colspan="2">Scan or enter unique operator ID, repeat if prompted</td></tr>
<tr><td>Step 6</td><td colspan="2">Scan Simulator ID (found on simulator box or on the sticker on the front of the simulator)</td></tr>
<tr><td>Step 7</td><td colspan="2">Insert Simulator</td></tr>
<tr><td>Step 8</td><td colspan="2">Document results on log sheet; sites may retain a copy of the instrument printout if desired.</td></tr>
<tr><td>If,</td><td colspan="2">Then,</td></tr>
<tr><td>PASS is displayed on the screen</td><td colspan="2">Remove the Electronic Simulator after the LCK or Simulator Locked message disappears from the display screen; use the analyzer as required.</td></tr>
<tr><td rowspan="3">FAIL is displayed on the screen
(analyzer will lock and not report results if the electronic simulator has failed)</td><td colspan="2">Clean Electronic Simulator by gently wiping electrodes with a lint-free cloth or tissue; repeat procedure.</td></tr>
<tr><td>If,</td><td>Then,</td></tr>
<tr><td>PASS is displayed</td><td>Document results on log sheet; use the analyzer.</td></tr>
<tr><td></td><td>FAIL is displayed</td><td>Document results on log sheet; call Abbott Tech Support 1-800-387-8378 (prompt 1 then 3).</td></tr>
</table>

10.0 PROCEDURE FOR ANALYSIS:

10.1. All cartridges must be at room temperature.
10.1.1. Individual cartridges can be removed from fridge for 5 minutes prior to testing; an entire box should stand at room temperature for 1 hour before cartridges are used.
10.2. DO NOT open cartridge pouches before scanning the barcode.
10.3. DO NOT pre-load cartridges.
10.4. Re-mix specimen before loading the next cartridge.
10.5. Run multiple cartridges in this order (as applicable): **PT/INR → CG4+ → Chem8 → cTnI**
10.5.1. For pH, blood gases, TCO2 and ionized calcium, test within 10 minutes of collection.
10.6 For capillary samples, run in this order (as applicable): **PT/INR → CG4+ → EC8+ → Creat**
10.7. Approximate testing times:

- PT/INR testing – 2-10 minutes
- Blood Gas (CG4+) – 2 minutes
- Chemistry (Chem8+/EC8+) – 2 minutes
- Troponin I/cTnI – 10 minutes

Specimen Analysis	
Step 1	Use universal precautions when handling samples.
Step 2	Place analyzer on a flat surface or leave on downloader/recharger cradle; DO NOT MOVE until analysis is complete.
Step 3	Press ⏻ (on/off) to turn on analyzer.
Step 4	Press 2 for i-STAT Cartridge on the Test Menu.
Step 5	Scan or enter Unique Operator ID; repeat if prompted; Enter the Patient ID.
Step 6	Scan or enter cartridge lot number from the cartridge pouch.
Step 7	Remove cartridge from pouch, handling it by its edges; avoid touching the contact pads or exerting pressure over the centre of the cartridge.
If Using Finger Poke method for PT/INR • Clean and prepare finger; prick with lancet; Gently squeeze the finger, developing a hanging drop of blood; ***DO NOT wipe away the first drop.*** • Perform the test with the first drop of blood by touching the drop of blood against the bottom of the sample well; once in contact with the sample well, the blood will be drawn into the cartridge; apply blood until it reaches the fill mark indicated on the cartridge. • Avoid "milking" as it may cause hemolysis or tissue fluid contamination of the specimen.	
Step 8	For PT/INR collected by venipuncture, following sample collection use a plastic disposable pipette to dispense sample into bottom of cartridge well immediately; once in contact with the well, blood will be drawn into the cartridge. For Blood Gas, Chemistry and Troponin cartridges, mix the sample well (8 figure 8 motions); draw up sample into dispensing device (pipette,syringe with blunt needle) **discard the first 1-2 drops of blood**, direct the dispensing device tip or capillary tube into the sample well and dispense sample until it reaches the fill mark on the cartridge; well will be about half full.
Step 9	Holding the cartridge by its edges, close the cover over the sample well until it snaps into place. DO NOT press over the sample well. DO NOT touch metal contact pads.
Step 10	Insert the cartridge into the cartridge port: • Hold the analyzer in place with one hand. • Handling the cartridge by its edges, gently guide the sealed cartridge into the handheld port until it clicks into place.
Step 11	Enter additional parameters on the Chart page, if required. • Choose the number corresponding to the type of sample used when prompted at the Sample Type field.
Step 12	The "*Time to Results*" countdown bar will be displayed; once time has elapsed results can be viewed on the display.
Step 13	To print results, place on downloader/recharger and press Print or point the analyzer at the printer and press Print. If device turns off before printing, turn it on and press 1 (last results); print. **DO NOT report**: TCO_2 (from Chem8+) or Ionized Calcium, unless tested within 10 minutes **DO NOT USE**: Creatinine for eGFR calculation **DO NOT perform OGTT** (oral glucose tolerance testing) using i-STAT (whole blood). I-STAT can be used for pre-screening.
Step 14	Remove cartridge after "Cartridge Locked" message disappears; the analyzer is ready for the next test immediately.
Step 15	Attach analyzer printout to requisition/report; sign and date; enter results into laboratory electronic information system, if applicable. Photocopy requisition with attached report. Save copy as per retention guidelines.

11.0 RESULTS:

11.1. Ordering and Reporting Results in the Delphic LIS:

11.1.1. Do not use any codes other than those listed below.
11.1.2. Use of proper order codes ensures correct reference ranges will be reported with each sample.
11.1.3. There should not be any variation between sites with respect to the use of these codes.
11.1.4. All tests that are run on a cartridge must be resulted (exception see point 7.1.10). If the test is not run but there is a slot for results in Delphic, it may be deleted from the order (i.e. Lactate or *p*O2 on the EC8+ cartridge).

Sample Source / Test Name		Test Code	Worksheet
Arterial Blood Gas		AGAS	AVGAS
Venous Blood Gas		VGAS	AVGAS
Capillary Blood Gas		CGAS	CMGAS
Mixed Blood Gas (mixed arterial/venous from a line)		MGAS	CMGAS
Umbilical Arterial Blood Gas		UAGS	UGAS
Umbilical Venous Blood Gas		UVGS	UGAS
Whole Blood Chemistry		CHW	CHWB or CHEMWB
Troponin I		TIWB	TIWB
PT/INR	Shared Health Laboratory Staff	IINR	COAG (request appears on COAGLIST and IINR worksheets as well)
	Non-Shared Health Lab Staff	IINR & POCT	Note: Users must not combine lab performed and non-lab performed tests on a single registration as the code will apply to all tests under a single request ID.

11.2. Calculations

11.2.1. The i-STAT analyzer contains a microprocessor that performs all calculations required for reporting results.

11.3. Displayed Results

11.3.1. Results are displayed numerically with their units.
- PT/INR is reported as an International Normalized Ratio (INR).
- Electrolyte and chemistry results are also depicted as bar graphs with reference ranges marked under the graphs.

11.4. Suppressed Results

11.4.1. Conditions under which the i-STAT will not display results:

<table>
<tr><th>If,</th><th>Then,</th></tr>
<tr><td>Results outside the System's reportable ranges are flagged with a "<" or ">", indicating that the result is below the lower limit or above the upper limit of the reportable range respectively. (See the table of Reportable Ranges.) The "< >" flag indicates that the results for this test were dependent on the result of a test flagged as either > or <.</td><td>Send specimen(s) to laboratory for analysis, if necessary.

For Blood Gases / Chemistry:
<table>
<tr><th>If,</th><th>Then,</th></tr>
<tr><td>Measured results are outside the reportable range</td><td>See Section 11.5 for reporting of greater than or less than values.</td></tr>
<tr><td>Calculated results are suppressed</td><td>In Delphic open appropriate worksheet. Enter / (forward slash) in front of pH result (for blood gases only) then type</td></tr>
</table></td></tr>
</table>

<table>
<tr><td></td><td>
<table>
<tr><td></td><td>*&DEL in any calculated result box that cannot be reported.</td></tr>
</table>

For PT/INR:
<table>
<tr><th>If,</th><th>Then,</th></tr>
<tr><td>I-STAT PT/INR result is <0.9</td><td>Enter L0.9; no confirmatory testing required.</td></tr>
<tr><td>i-STAT PT/INR result is >8.0</td><td>Enter G8.0. Confirmatory venous testing is required at a reference site. Enter comment &INRP</td></tr>
</table>
</td></tr>
<tr><td>Cartridge results which are not reportable based on internal QC rejection criteria are flagged with *** and a code.

For full code lists and possible troubleshooting see technical bulletins and product updates link: https://www.pointofcare.abbott/us/en/offerings/support/i-stat/technical-bulletins-product-updates
Find the Technical Bulletins link and go to Analyzer coded messages.
NOTE: Account and login are required to access technical bulletins. See Appendix 17 for quality check error codes.</td><td>For codes 20,23,27,41,49,50, 87 and 126:

These codes can sometimes be corrected by conditioning the pins in the analyzer using the ceramic conditioning cartridge (CCC) using the following steps:
1. Run an Electronic Simulator.
2. Run the CCC cycle two times, initiate CCC the same as you would the electronic simulator (disregard the Simulator Failure Code – this is expected).
3. Update the CCC Usage Log.
4. Analyze the specimen again using a fresh sample and another cartridge. If specimen integrity is not in question, the results that are not suppressed should be reported in the usual manner. If result is suppressed again, send specimen to the reference lab.</td></tr>
<tr><td>For PT/INR, if the results state “No clot detected” or “****” error occurs</td><td>• Repeat patient sample to confirm lack of result
• Free text the following “No result can be obtained from the i-STAT. Concurrent sample is sent to reference lab with result pending”. In IICM comment field.
• Notify physician that sample is being sent out as no result was obtained.
• Send venous sample to reference lab for analyzer analysis.
• Cancel IINR test</td></tr>
</table>

See Appendix 16 for more guidance on troubleshooting analyzer flags.

Reporting Blood Gas / Chemistry / Troponin Results Outside the Reportable Range:

ANALYTE	REPORTABLE RANGE	ENTER IN DELPHIC	
		REPORTING LESS THAN	REPORTING GREATER THAN
Sodium	100 – 180	L100	G180
Potassium	2.0 – 9.0	L2.0	G9.0
Chloride	65 – 140	L65	G140
UREA	1 – 50	L1	G50
Glucose	1.1 – 38.9	L1.1	G38.9
Creatinine	18 – 1768	L18	G1768
pH	6.50 – 8.20	L6.50	G8.20
PCO_2	5 – 130	L5	G130
pO_2	5 – 800	L5	G800
TCO_2	5 – 50	L5	G50
Lactate	0.30 – 20.0	L0.30	G20.0
HCO_3	1 – 85	L1	G85
BE	(-30) – (+30)	L-30	G30
Troponin I/cTnI	0.00 – 35.00		G35

11.5. Troubleshooting Quality Check Error Messages

11.6.1. The i-STAT performs numerous quality checks upon start-up and with every cartridge run.

11.6.2. If any quality checks fail, the i-STAT will halt testing and display a:

- Cause message describing the reason for failed quality check.
- Action message describing the next step to be taken to resolve the issue.
- Cause or Quality Check Code number.
- Refer to Appendix 17 – i-STAT Analyzer Coded Messages and the user manual for code explanation and troubleshooting steps.

NOTE – Not all recovery steps are valid in each scenario.

11.6.3. If the problem cannot be resolved using the manual, contact Abbott Technical Support and provide the Quality Check Code number for assistance.

11.6. Criteria for Sending Sample to Reference Lab for Confirmation of PT/INR Result

11.7.1. When PT/INR result exceeds 4, a sodium citrate sample must be drawn and sent to a reference laboratory.

11.7.2. If the sample cannot be sent soon after collection, freeze a plasma aliquot and send the next day on ice.

11.7.3. If PT/INR result is higher than 4, the site can provide the ordering physician with a preliminary report stating the PT/INR result, as well as indicating a sample has been sent to a reference laboratory.

- Document INR result in the IINR test slot as provided by the i-STAT.
- For LIS sites insert coded comment &INRP (***Attention: Preliminary report. Sample is referred for confirmation. Final report to follow***) in IICM comment area.
- If the result is a critical value, add a comment to indicate notification of critical to the ordering physician.
- For other sites ensure patient report has comment attached "***Attention: Preliminary report. Sample is referred for confirmation. Final report to follow***."
- Sending laboratory will register referred sample into Delphic, test code **PT**, with a copy to ordering physician and referral site.

11.7. Process to Send PT/INR Sample to Reference Lab for Confirmation Result Using LIS

11.8.1. Ensure positive patient identification between requisition and sample.

11.8.2. Register test code **PT** (orders PT/INR).

- Note: Do **NOT** register INR for conformation testing (PT) at a sending site until after the IINR result has been entered or the IINR result will not fax appropriately.
- Register sample for confirmatory testing with a new Delphic LIS number, not under the POC LIS number.

11.8.3. For all samples referred for PT confirmation:

- Enter laboratory code (site specific) in COPYTO box to ensure referring site will receive a final copy of report.

11.8.4. Using Delphic LIS Test Referral:

- Click on **Test Referral**
- Click on **Batch**
- Scan/type in registration number
- Click **Search**
- Check (√) batch name that requires dispatch
- Click **Batch** and the LIS will provide a batch name

11.8.5. Using Delphic LIS:

- Go to **DISPATCH**
- Click on **Internal**
- Check (√) batch name that requires dispatch
- Click **Dispatch**
- Printer will show up on screen
- Print off sheet to send with samples

11.8.6. Send sample as per proper protocol to site's reference lab for testing.

11.8.7. Reference site must acknowledge receipt of sample to have sample appear on their work list and to review WLU for testing sample.

12.0 REPORTS:

12.1. Sites which have Delphic must enter their results in Delphic.

12.2. Sites not using Delphic must have an appropriate reporting system in place.

12.3. To print multiple results at once, press menu key, press 2 for Data Review, Press 7 for List, press the numbered key for the test record(s), when all desired tests are selected, press Print key.

12.4. Print-outs from the i-STAT are on thermal paper, and as such may fade with time, therefore result reports must be either photocopies or recorded another way.

12.5. Both the physician/chart and the laboratory should retain a copy of the results as per SOP 100-10-05 Lab Records and Materials Retention Policy.

12.6. Reports generated by laboratory must include:

- Patient demographics (name, DOB, Gender, Unique Identification Number).
- Test results, units and reference values.
- Unique Operator ID.
- Time and date test performed.
- Clear indication that testing was done on the i-STAT.

12.7. For sites where a test is not routinely performed on the i-STAT (back-up for a down analyzer or short term use where a technologist is not available) it is critical to state on the report:

"Test performed by alternate method (i-STAT) results may differ from main laboratory analyzer".

13.0 REFERENCE RANGES AND REPORTABLE RANGES:

13.1. Reference ranges may differ from those used for the same test at a site when it is run on different instrumentation.

13.2. When reporting i-STAT results, use i-STAT reference ranges.

- Reference range means the range of test values expected from 95% of fasting individuals presumed to be healthy.
- Reportable range means the range of test values throughout which the measurement systems results have been shown to be valid.

13.3. **The i-STAT only displays adult reference ranges; reference values in pediatric patients may differ.**

ANALYTE	UNIT	ADULT AND CHILDREN REFERENCE RANGES		NEONATE	REPORTABLE RANGE
		(arterial)	(venous & capillary & mixed)	(Capillary & mixed)	
Sodium	mmol/L	138 – 146	138 - 146	138 - 146	100 – 180
Potassium	mmol/L	3.5 – 4.9	3.5 - 4.9	3.5 - 4.9	2.0 – 9.0
Chloride	mmol/L	98 – 109	98 – 109	98 – 109	65 – 140
UREA	mmol/L	2.9 – 9.4	2.9 – 9.4	2.9 – 9.4	1 – 50
Glucose	mmol/L	3.9 – 5.8	3.9 – 5.8	3.9 – 5.8	1.1 – 38.9
Creatinine	µmol/L	53 - 115	53 - 115	53 - 115	18 – 1768
Ionized Calcium	mmol/L	1.12 – 1.32	1.12 – 1.32	N/A	0.25 – 2.50
pH		7.35 – 7.45	7.31 – 7.41	7.29 - 7.40	6.50 – 8.20
PCO_2	mmHg	35 – 45	41 – 51	35 - 50	5 – 130
pO_2	mmHg	80 – 105	35-45 (Capillary and mixed only)	40 - 70	5 – 800
Measured TCO_2 (on the CHEM8+ cartridge only)	mmol/L (mEq/L)	23-27	24-29	21 - 29	5 – 50
Lactate	mmol/L	0.36 –1.25	0.90 - 1.70	0.90 - 1.70	0.30 – 20.0
HCO_3*	mmol/L (mEq/L)	22 – 26	23 - 28	18 - 28	1.0 – 85.0
Calculated TCO_2* (on all cartridges but CHEM8+)	mmol/L (mEq/L)	23 – 27	24 - 29	21 - 29	5 – 50
BE*	mmol/L (mEq/L)	(-2) – (+3)	(-2) – (+3)	(-5) - (+5)	(-30) – (+30)
Anion Gap*	mmol/L (mEq/L)	10 – 20	10 – 20	10 – 20	(-10) – (+99)
sO_2*	%	95 – 98	N/A	70 - 90	0 – 100
Troponin I/cTnI (see chart next page)	µg/L	N/A	0.00 – 0.08***	N/A	0.00 – 35.00##

ANALYTE	UNIT	ADULT AND CHILDREN REFERENCE RANGES		NEONATE	REPORTABLE RANGE
		(arterial)	(venous & capillary & mixed)	(Capillary & mixed)	
INR	N/A	0.9 – 1.1	0.9 – 1.1	NA	0.9 – 8 >4 requires confirmatory venous testing at reference site.

*Calculated values. ##Performance characteristics not established for cTnI values above 35.00 µg/L.
***Represents the 0-99% range of results.

This chart can be provided to physicians to aid interpretation of TnI. Some sites have placed this information directly on the lab report as a sticker. For further information please see "Manitoba Troponin Guideline".	i-STAT TnI µg/L	Interpretation
	<0.08	No myocardial necrosis, if > 6 - 9 hrs after onset of symptoms.
	0.08 *to* 0.10	Possible myocardial injury, in the context of suspected ACS, repeat after two (2) hours (must be > 6 hrs after onset of symptoms)
	>0.10	NSTEMI when seen in the context of suspected ACS

13.4. Umbilical Cord Blood Gases Reference Ranges:

ANALYTE	UNIT	UMBILICAL CORD REFERENCE RANGES	
		(arterial)	(venous)
pH	–	7.23 - 7.33	7.31 - 7.40
PCO_2	mmHg	41 - 57	32 - 44
pO_2	mmHg	12 - 24	–
TCO_2	mmol/L (mEq/L)	22 - 32	21 - 29
Base Excess	mmol/L (mEq/L)	(-6) – (-2)	(-6) – (-2)
HCO_3	mmol/L (mEq/L)	20 - 25	18 - 23
sO_2*	%	7 - 32	–

14.0 CRITICAL RESULTS:

14.1. Critical results are test results that fall outside high and low critical limits that define the boundaries of life-threatening values for a test.
14.2. Critical results represent an emergency condition and must be reported immediately to the patient's attending physician or nurse with documentation of the date/time and the person (first and last name) who took the results.

14.3. Phoning / Reporting Critical Results in Delphic:

14.3.1. Immediate notification is required when any results of tests exceed established critical values.
14.3.2. Documentation of critical results is done in the **TELE** format for biochemistry results and in the **IICM** comment box for PT/INR results.

14.3.3. Enter the phoned comment using **&CVP** (Critical/alert values called to) followed by free text of the person notified (first and last name), test result, date and time of call in "_". Use **&RB** to indicate results were read back.

CRITICAL RESULTS BY ANALYTE

ANALYTE (units)	ADULT		CHILDREN		NEONATES**	
	low	high	low	high	low	high
Sodium (mmol/L)	120	158	121	156	121	156
Potassium (mmol/L)	2.8	6.2	2.8	6.4	2.8	6.5
Chloride (mmol/L)	75	126	77	121	77	121
TCO_2 (mmol/L) (Arterial, Venous, Mixed Venous, and Capillary)	11	40	11	39	–	–
Ionized Calcium (mmol/L)	0.78	1.58	0.74	1.57	–	–
pH (Arterial, Venous, Mixed Venous and Capillary)	7.21	7.59	7.21	7.59	7.21	7.59
$\boldsymbol{P}CO_2$ (mmHg) (Arterial, Venous, Mixed Venous and Capillary)	19	67	21	66	–	–
$\boldsymbol{P}O_2$ (mmHg) (Arterial only)	43	–	45	124	37	124
Urea (mmol/L)	–	37	–	20	–	20
Glucose (mmol/L)	2.6	27	2.6	25	1.8	18
Lactate (mmol/L) (Arterial, Venous, Mixed Venous and Capillary)	–	5	–	5	–	5
Creatinine (µmol/L)	–	654	–	336	–	–
Troponin I	>0.10 µg/L‡					
INR (venous/capillary)	≥5.0					
Umbilical Cord pH (Arterial and Venous)	<7.0					

**Values may differ in premature infants

‡Critical TnI values should be called with the exception of patients in critical care areas (including Emergency)

15.0 RECHARGING:

15.1. Each site will have a downloader/recharger; it is recommended that the analyzer be left on the recharger when not in use.
15.2. Docking the i-STAT on this will recharge the batteries.
15.3. Each unit also comes with lithium 9V batteries that should be stored on site for use in the event of a power outage.
15.4. Refer to vendor manual for additional information / instructions.

16.0 INTERFERENCES:

16.1. An interferent is a substance which, if present at significant levels in the blood specimen being analyzed, will produce an error in the result of the analyte being measured.
16.2. **Lipemic samples:** There is no documented evidence for interferences from lipemia.

ANALYTE	INTERFERENT	INTERFERENT CONCENTRATION	EFFECT ON ANALYTE RESULT
Sodium	β-hydroxybutyrate Lactate Bromide	16 mmol/L 20 mmol/L 37.5 mmol/L	Decrease (↓) Na by 5 mmol/L Decrease (↓) Na by 5 mmol/L Increase (↑) Na by 5 mmol/L
Chloride	β-hydroxybutyrate Bromide Lactate Salicylate Thiocyanate	16 mmol/L 12.5 mmol/L 11 mmol/L 4 mmol/L 24 mmol/L	Increase (↑) Cl by 3 mmol/L Increase (↑) Cl by 30 mmol/L Increase (↑) Cl by 3.5 mmol/L Increase (↑) Cl by 5 mmol/L May cause falsely elevated chloride results, or to be suppressed (***)
Ionized Calcium	Magnesium β-hydroxybutyrate Lactate Salicylate	1.0 mmol/L above normal 20 mmol/L 20 mmol/L 4.34 mmol/L	Increase (↑) iCa by 0.04 mmol/L Decrease (↓) iCa by 0.1 mmol/L Decrease (↓) iCa by 0.05 mmol/L Decrease (↓) iCa by 0.1 mmol/L
Glucose	Bromide pH Oxygen Hydroxyurea Thiocyanate	37.5 mmol/L Per 0.1 pH units below 7.4 @ 37 °C Per 0.1 pH units above 7.4 @ 37 °C PO_2 less than 20 mmHg @ 37 °C 100 μmol/L 24 mmol/L	Decrease (↓) glucose by 1.7 mmol/L Decrease (↓) glucose by 0.05 mmol/L Increase (↑) glucose by 0.04 mmol/L May decrease (↓) glucose Increase (↑) glucose 0.44 mmol/L Decrease (↓) glucose by approx. 23%
Urea	Thiocyanate	24 mmol/L	Decrease (↓) urea by approx. 21%
Lactate	Bromide Cysteine Hydroxyurea Glycolic Acid	25 mmol/L 6.4 mmol/L 100 μmol/L 10 mmol/L	Decrease (↓) lactate by 40% Decrease (↓) lactate by 11% Increase (↑) lactate 0.16 mmol/L Increase (↑) lactate by approx. 1.96 mmol/L from an initial Lactate concentration of 1.45 mmol/L

ANALYTE	INTERFERENT	INTERFERENT CONCENTRATION	EFFECT ON ANALYTE RESULT
Creatinine	Acetaminophen	For every 1 mmol/L acetaminophen	Increase (↑) creatinine by 22 µmol/L
	Ascorbate	0.227 mmol/L	Increase (↑) creatinine by 62 µmol/L
	Bromide	12.5 mmol/L (100 mg/dL)	Increase (↑) creatinine by 71 µmol/L from an initial Creatinine concentration of 88 µmol/L
<177 µmol/L			
	PCO_2	Above 40 mmHg	Increase (↑) creatinine by 6.9% per 10 mmHg ***P***CO_2
		Below 40 mmHg	Decrease (↓) creatinine by 6.9% per 10 mmHg ***P***CO_2
>177 µmol/L			
	PCO_2	Above 40 mmHg	Decrease (↓) creatinine by 3.7% per 10 mmHg ***P***CO_2
		Below 40 mmHg	Increase (↑) creatinine by 3.7% per 10 mmHg ***P***CO_2
	Hydroxyurea	100 µmol/L	Increase (↑) 164 µmol/L
	Creatine	5 mg/dL creatine	Increase (↑) creatinine by 18 µmol/L
	N-acetylcysteine	16.6 mmol/L	Increase (↑) creatinine by 35 µmol/L
PCO_2	Propofol (Diprovan® Diprovan is a registered trademark of the AstraZeneca group of companies)		For patients administered propofol or thiopental sodium, i-STAT recommends the use of CG4+, CG8+, EG6+, and EG7+ cartridges, which are free from clinically significant interference at all relevant therapeutic doses. i-STAT does not recommend the use of EC8+ cartridges for patients receiving propofol or thiopental sodium.
	Thiopental Sodium		
	PO_2	> 100 mmHg above normal range	In patient samples where the ***P***O_2 is > 100 mmHg above the normal range (80-105 mmHg) an increase in ***P***CO_2 of approximately 1.5 mmHg may be observed fir every 100 mmHg increase in ***P***O_2.
Troponin I	Grossly hemolyzed samples can cause a decreased alkaline phosphatase activity, resulting in decreased detection of cTnI, increased assay backgrounds, and/or quality check codes. Failure to completely fill tubes may cause falsely elevated results, especially when plasma is used[4]. Partially clotted samples can result in elevated cTnI results above the reference range, as well as quality check code errors. To prevent this from occurring, upon drawing the whole blood sample into a heparinized collection tube, the sample should be inverted gently at least 10 times to ensure even dissolution of the heparin anticoagulant.		
PT/INR	Presence of exogenously added heparin, citrate, oxalate or EDTA from blood collection devices will interfere with test results. Poor technique in sample collection may compromise the results. Ensure correct order of draw. Glass syringes or tubes may prematurely activate coagulation, resulting in accelerated clotting times and lower PT/INR's; venous samples must be collected into plastic syringes or tubes. PT/INR results may be affected by commonly administered drugs. Abbott has not characterized the i-STAT PT/INR with patients that have lupus anticoagulant antibodies; if the presence of lupus anticoagulant bodies is known or suspected, consider using a prothrombin time laboratory assay using a reagent that is known to be insensitive to lupus anticoagulant antibodies or an alternate laboratory method. Cubicin® (daptomycin for injection) has been found to cause a concentration-dependent false prolongation of PT and elevation of PT/INR when using i-STAT PT/INR test; it is recommended that for patients being treated with this antibiotic, an alternate method should be used to evaluate PT/INR.		

SITE FUNCTIONS

17.0 VERIFICATION OF CARTRIDGE STORAGE CONDITIONS: (must be done at each site)

17.1. Refrigerated cartridges (document on i-STAT QC Log)

17.1.1. Verify that the cartridges stored in the refrigerator are all within the expiration date printed on the boxes; if not, DO NOT USE and initiate ordering replacements.
17.1.2. Verify that the refrigerator did not exceed the limits of 2 °C to 8 °C.
17.1.3. Refer to Appendix 2 – i-STAT Expiration Date & Storage Conditions Log – Refrigerated.

Refrigerated Cartridge Temperature Verification	
If,	***Then,***
Temperature of cartridge storage refrigerator is within range of 2 °C to 8 °C	Use cartridges as required.
Temperature of cartridge storage refrigerator is outside the range of 2 °C to 8 °C	Quarantine the cartridges in the storage fridge. Notify supervisor/designate immediately. **DO NOT USE** the cartridges from this fridge. Document all actions in the QC log.

17.2. Room Temperature Cartridges (document on i-STAT QC Log)

17.2.1. Verify that all boxes of cartridges at room temperature have been out of the refrigerator less than two weeks (exception: CG4+, which is <2 months).
17.2.2. Verify that room temperature has not exceeded 30 °C.
17.2.3. Refer to Appendix 3 – i-STAT Expiration Date & Storage Conditions Log – Room Temperature.

Room Temperature Cartridge Verification	
If,	***Then,***
Measured room temperature has been continuously below 30 °C	Use cartridges as required.
Measured room temperature has exceeded 30 °C for any period of time	Quarantine the cartridges. Notify supervisor/designate immediately. **DO NOT USE** the cartridges. Document all actions in the QC log.

18.0 PROCEDURE FOR SHIPMENTS OF CARTRIDGES

18.1. For new shipments of cartridges from the vendor (must be done at receiving site), check the Temperature Monitor and perform integrity testing with QC materials.

18.1.1. Temperature Monitor

- i-STAT cartridges are shipped refrigerated with a four-window indicator used to monitor temperature during transit.
- Fill out the record of receipt and forward materials to the refrigerator.

Temperature Monitor – New Shipments of Cartridges	
If,	***Then,***
All windows are white or if only the A or B windows are blue or the 1 or 2 windows are red	Record result on QC log. Transit temperatures were satisfactory and the cartridges can be used.
The C or D windows are blue, or the 3 or 4 windows are red	Quarantine the suspect cartons. Notify supervisor/designate immediately. **DO NOT USE** cartridges from the suspect carton. Document all actions in the QC log. Notify Abbott and request replacement.

18.2 For shipments of cartridges coming from another site within the province of Manitoba (Shared Health and non-Shared Health), perform integrity testing with QC materials to verify that the cartridges perform as intended.

19.0 INTEGRITY TESTING:

19.1. Performed using liquid quality control materials listed in section 6.3.

19.2. Integrity testing is required on each new lot and each new shipment of cartridges and for instrument validation following calibration verification (see section 21.0).

19.3. Integrity testing must also be performed monthly for PT/INR.

19.4. Compare results to the Value Assessment Sheets (VAS), available on the Abbott POC website: https://www.pointofcare.abbott/int/en/offerings/support/istat/value-assignment-sheets

19.5. Check that the lot number on the control ampule matches the lot number on the VAS and that the software version listed on the VAS matches the software installed in the analyzer. The VAS displays target values and ranges expected when materials and equipment are performing properly.

19.6. Each region must have a system for maintaining documentation and verifying that sites are performing required QC.

19.7. Always remember to analyze the control material in the Control pathway and the calibration verification material in the Cal Ver pathway under the Quality Tests option of the i-STAT 1 Analyzer Administration Menu.

Quality Control	
Step 1	Power On
Step 2	Menu → 3-Quality Tests → 2-Quality Control
Step 3	Enter required information on screen
Step 4	Follow pre-analytical directions below for individual QC material types
Step 6	Run cartridge as usual; repeat above steps for all levels

If,	*Then,*
All results ***PASS***	Document QC results. Use cartridges as needed.
Any results are outside the published expected ranges	**DO NOT USE** cartridges from the suspect lot. Quarantine the suspect lot. Notify supervisor/designate immediately. Record QC results/failure and actions on i-STAT QC log.

19.8. For blood gases/chemistry cartridges, use i-STAT Aqueous Level 1 and Level 3 controls:

Integrity Testing – Blood Gas / Chemistry Cartridges	
Step 1	Prior to testing cartridges that measure ***P***O2, ampules should stand at room temperature a minimum of 4 hours before use. When testing other cartridges (e.g. Chem8+), ampoules may be used once the fluid has reached room temperature, approximately 30 minutes for individual ampoules. For best results, ampules, cartridges, and analyzers should be at the same temperature. When using cartridges that contain sensors for measuring ionized calcium, pH, ***P***CO_2, or ***P***O_2 (CG4+, Chem8+ where applicable), a separate ampule must be used for each cartridge being tested; if these sensors are not present (Chem8+) the contents of one ampule may be used to fill more than one cartridge as long as the cartridges are filled and inserted into an analyzer within 10 minutes of opening the ampule.
Step 2	Immediately before use, shake the ampoule vigorously for 5 to 10 seconds to equilibrate the liquid and gas phases. To shake, hold the ampule at the tip and bottom with forefinger and thumb to minimize increasing the temperature of the solution. If necessary, tap the tip of the ampule to send solution back into the bottom section of the ampule. Protect fingers with gauze, tissue, or glove, or use an ampule breaker to snap off the tip of the ampule at the scored neck.
Step 3	Using a plain capillary tube or plain syringe, immediately transfer the solution from the ampule into a cartridge. Seal the cartridge and insert it into an analyzer. It is important not to expose the solution to room air since this will alter the results. • When using a capillary tube, fill from the bottom of the ampule. Avoid drawing solution from the surface by covering the far end of the tube as it is inserted into the ampule. Once the open end of the tube rests at the bottom of the ampule, uncover the other end to allow filling by capillary action. • When using a syringe (1cc or 3cc syringes with 16 to 20 gauge blunt needles are recommended), slowly draw approximately 1 mL of solution from the bottom of the ampule. If air is trapped between the leading edge of the solution and the plunger, do not invert the syringe to expel it; this will not affect solution near the tip of the syringe. If air bubbles are continually drawn into the syringe, or if a bubble is trapped near the tip of the syringe, discard the ampule and syringe and use a fresh ampule and syringe. Expel one or two drops from the syringe before filling the cartridge. • When using a disposable transfer pipette, slowly draw approximately 1 mL of solution from the bottom of the ampule, avoiding the formation of air bubbles. If air bubbles are continually drawn into the pipette, discard the ampule and pipette and use fresh ones. Expel one drop from the pipette before filling the cartridge.
Step 4	Compare results to the Value Assessment Sheets (VAS). If all results are within expected ranges, use the cartridges as needed.

19.9. For cTnI cartridges, analyze using i-STAT Level 1 and Level 3 cTnI Controls

Integrity Testing – cTnI Cartridges	
Step 1	Remove controls from fridge; controls do not need to sit at room temperature before testing.
Step 2	Thoroughly mix by gently swirling the bottle. Avoid foaming of the sample.
Step 3	Dispense sample directly from the bottle into the i-STAT cTnI cartridge and seal the cartridge. Return vials to fridge immediately after use, can be stored at 2-8 ºC for 30 days after opening.
Step 4	Insert cartridge into i-STAT analyzer.
Step 5	Compare results to the Value Assessment Sheets (VAS). If all results are within expected ranges, use the cartridges as needed.

19.10. For PT/INR, analyze Level 1 and 2 PT/INR Controls

19.10.1. To be performed monthly, and with every new lot and/or shipment of cartridges.

Integrity Testing – PT/INR Cartridges	
Step 1	All vials containing lyophilized plasma and $CaCL_2$ reconstituting fluid to stand at room temperature (18 °C to 30 °C) for 45 minutes. • Reconstitute only one level of control at a time. • Control solutions must be used immediately (<30 seconds) after completing the reconstitution and mixing steps.
Step 2	After 45 minutes, remove cap and stopper from one of the lyophilized plasma control vials and from one vial of the $CaCL_2$ reconstituting fluid.
Step 3	Pour the entire contents of the calcium chloride vial into the lyophilized human plasma control vial. Place the stopper back in the reconstituted control vial, sealing the vial appropriately so that the contents do not leak or spill out.
Step 4	Allow vial to sit at room temperature for one (1) minute.
Step 5	Mix contents of vial by swirling gently for one (1) minute; then invert slowly for 30 seconds **Note**: to minimize foaming, avoid vigorous mixing. Visually inspect control vial to ensure that the sample is fully reconstituted. If **NOT**, discard and start over with a fresh vial.
Step 6	Using a plastic transfer pipette, immediately transfer the solution from the vial into the PT/INR cartridge.
Step 7	Immediately seal the cartridge and insert it into the analyzer.
Step 8	Document results on i-STAT Calibration verifiers and QC Log entry (Appendix 4).

19.11. Thermal Probe Verification

19.11.1. Thermal probe verification is required for PT/INR testing and must be performed on each analyzer every 6 months.

<table>
<tr><th colspan="2">Thermal Probe Verification</th></tr>
<tr><td>Step 1</td><td>If the analyzer and the electronic simulator have been stored separately in areas where the ambient temperature differs by more than 3 °C, allow the simulator and analyzer to stand in the same place, out of drafts for 30 minutes before inserting the simulator into the analyzer.
Handle the simulator as little as possible to maintain its thermal uniformity and stability.</td></tr>
<tr><td>Step 2</td><td>Insert the simulator into the analyzer.</td></tr>
<tr><td>Step 3</td><td>When results are displayed, the difference between the thermal probes can be viewed on the analyzer’s screen.
• Portable Clinical Analyzer – while holding down the DIS key press the 1 key.
• I-STAT 1 Analyzer – press the period key.</td></tr>
<tr><td>Step 4</td><td>Interpret the thermal probe check value:

<table>
<tr><td>Acceptable</td><td>A value equal to or less than 0.1 (≤0.1)</td></tr>
<tr><td>Not Acceptable</td><td>A FAIL message with a “t” Quality Check code or a value greater than 0.1 (>0.1).
Repeat the procedure to confirm results.
Contact Technical Support if the repeat test fails / thermal check value is greater than 0.1 (>1.0).</td></tr>
<tr><td>Repeat the procedure if “--.—“ is displayed</td><td>Take care to handle the simulator as little as possible; it may help to partially insert the simulator into the analyzer and let it stand for 15 minutes before inserting it all the way.</td></tr>
</table></td></tr>
<tr><td>Step 5</td><td>Record results on Semi Annual Quality Control Log (Appendix 6).</td></tr>
</table>

20.0 EXTERNAL PROFICIENCY TESTING (EPT):

20.1. Each site should subscribe to an external proficiency testing program for all analytes being tested at the site; programs can be ordered through the College of American Pathologists. https://www.cap.org/.
20.2. Samples must be tested according to instructions included with each kit, and treated the same as all patient samples.
20.3. Each region/program must have a system for maintaining documentation and verifying that sites are performing required Quality Control.
20.4. Programs subscribed to should include (where applicable):

- Chemistry and blood gases – College of American Pathologists (CAP) AQ4
- Troponin I/cTnI – College of American Pathologists (CAP) PCARM
- PT/INR – College of American Pathologists (CAP) WP-3

21.0 CALIBRATION:

21.1. Routine Calibration

21.1.1. For cartridges, calibration is automatically performed as part of the test cycle on each cartridge type; operator intervention is not necessary.

21.2. Calibration Verification (for all tests except PT/INR)

21.2.1. Calibration verification must be performed on all new or replacement analyzers, and after each CLEW update, with i-STAT Calibration Verification sets, which are designed to verify the calibration of each assay through the reportable range.

21.2.2. Five (5) levels of verification solution (3 for cTnI) are run and compared to the Value Assignment Sheet available on the i-STAT website: https://www.pointofcare.abbott/int/en/offerings/support/istat/value-assignment-sheets, (also available from Technical Support 1-800-387-8378 option 1).

21.2.3. Cal/Ver samples are handled using the same pre-analytical techniques as quality control materials.

Calibration / Verification	
Step 1	Power On
Step 2	Menu → 3-Quality Tests → 3-Cal/Ver
Step 3	Enter required information on screen
Step 4	Shake ampule vigorously for 5 to 10 seconds then snap tip off at neck, using gauze to protect hands
Step 5	Immediately transfer solution to cartridge
Step 6	Run cartridge as usual; repeat above steps for all 3-5 levels
Step 7	Confirm results by running 2 levels of QC

REGIONAL FUNCTIONS

22.0 UPDATING SOFTWARE – CLEW:

22.1. The i-STAT system does not require lot-specific calibration information, however Abbott re-issues standardization values periodically to maintain long term consistency of results over a range of lot numbers; this is equivalent to adjusting calibration on a traditional analyzer.

22.2. New CLEW (software) re-establishes the standardization and incorporates refinements to the internal quality monitoring system.

22.3. These software updates occur every 6 months.

22.4. Application software (JAMS) will also be updated periodically to enable new features or allow the analyzer to recognize new cartridges; these updates will typically occur at the same time as the CLEW updates.

22.5. Document CLEW updates on Semi-Annual QC Control Log (Appendix 6).

22.6. After doing CLEW updates perform daily QC with the e-simulator to ensure analyzer is functioning correctly.

22.7. If site is using PT/INR cartridges, run both levels of PT Quality Control after e-simulator.

22.8. For all other cartridges, perform Calibration Verification (See 21.2) after the e-simulator, post-CLEW update.

23.0 CUSTOMIZATION:

23.1. Customizations (SI units, exceptions, requirements) must be entered into each i-STAT analyzer prior to being used for patient testing.
- 23.1.1. If an i-STAT is sent for repair, customizations will need to be re-entered prior to sample testing.
- 23.1.2. If a different unit is received, customizations will need to be entered prior to sample testing.
- 23.1.3. For detailed information refer to the i-STAT technical manual and the i-STAT Analyzer Customization Worksheets for customization settings.
- 23.1.4. For each new or replacement i-STAT, Calibration Verification should be performed and units verified prior to reporting results.
- 23.1.5. All customizations must be made through the Administration Menu.

23.2. See Appendix 10: i-STAT System – Customizations for a complete list of required customizations.

24.0 CLINICAL SIGNIFICANCE:

Analyte	Some Causes of Increased Values	Some Causes of Decreased Values
Sodium	Dehydration Diabetes insipidus Salt poisoning Skin losses Hyperaldosteronism CNS disorders	Dilutional hyponatremia (cirrhosis) Depletional hyponatremia Syndrome of inappropriate ADH
Potassium	Renal glomerular disease Adrenocortical insufficiency Diabetic Ketoacidosis (DKA) Sepsis *In vitro* hemolysis	Renal tubular disease Hyperaldosteronism Treatment of DKA Hyperinsulinism Metabolic alkalosis Diuretic therapy
Chloride	Prolonged diarrhea Renal tubular disease Hyperparathyroidism Dehydration	Prolonged vomiting Burns Salt-losing renal disease Over hydration Thiazide therapy
Ionized Calcium	Dehydration Hyperparathyroidism Malignancies Immobilization Thiazide diuretics Vitamin D intoxication	Hypoparathyroidism Early neonatal hypocalcemia Chronic renal disease Pancreatitis Massive blood transfusions Severe malnutrition
Urea	Impaired renal function Prerenal azotemia (e.g. shock) Postrenal azotemia GI bleeding High protein diet	Pregnancy Severe liver insufficiency Overhydration Malnutrition
Glucose	Diabetes mellitus Pancreatitis Endocrine disorders (e.g. Cushing's syndrome) Drugs (e.g. steroids, thyrotoxicosis) Chronic renal failure Stress IV glucose infusion	Insulinoma Adrenocortical insufficiency Hypopituitarism/Massive liver disease Ethanol ingestion/Reactive hypoglycemia Glycogen storage disease
Creatinine	Impaired renal function High muscle mass	Low muscle mass
Lactate	Hypoxia (shock, hypovolumia, left ventricular failure); sepsis; diabetes mellitus, neoplasia, liver disease; drug or toxins (ethanol, methanol, salicylates); glycolic acid as a product of ethylene glycol metabolism; strenuous exercise. Samples drawn with a tourniquet may elevate the lactate result.	
pH	Respiratory alkalosis Metabolic alkalosis	Respiratory acidosis Metabolic acidosis

Analyte	Some Causes of Increased Values	Some Causes of Decreased Values
***P*CO$_2$**	Acute Respiratory Acidosis: • Depression of respiratory center • Suppressed neuromuscular system • Pulmonary disorders • Inadequate mechanical ventilation Chronic respiratory acidosis • Decreased alveolar ventilation • Hypoventilation Compensation in metabolic alkalosis	Respiratory alkalosis: • Increased stimulation of respirator center • Hypermetabolic states • Mechanical hyperventilation Compensation in metabolic acidosis
***P*O$_2$**	Breathing oxygen-enriched air	Carbon-monoxide exposure Pulmonary disorders Myocardial infarction Congestive heart failure
HCO$_3$	Primary metabolic alkalosis Primary respiratory acidosis	Primary metabolic acidosis Primary respiratory alkalosis
cTnI	Myocardial Infarction Coronary vasospasm Cardiac contusion/trauma Rhythm disturbance (SVT, AF) Chemotherapy (ex. Adriamycin) Myocarditis/pericarditis Infiltrative diseases (ex. Amyloidosis, sarcoidosis, hemochromatosis, connective tissue disease) Congestive heart failure Heart transplantation Cardiac procedures (PTCA, DC cardioversion) Intracranial hemorrhage/stroke Pulmonary embolism Pulmonary hypertension Chronic renal insufficiency Sepsis, Strenuous exercise, certain drug ingestions	Rare antibodies to troponin or its circulating complexes

25.0 PRINCIPLES OF MEASUREMENT:

Analyte	Principles of Measurement
Sodium, Potassium, Chloride, Ionized Calcium,	Measured by ion-selective electrode potentiometry. Concentrations are calculated from the measured potential through the Nernst equation
pH, and *P*CO_2	Measured by direct potentiometry. Concentrations are calculated from the measured potential through the Nernst equation.
Urea	Is first hydrolyzed to ammonium ions in a reaction catalyzed by the enzyme urease. The ammonium ions are measured by an ion-selective electrode and the concentration is calculated from the measured potential through the Nernst equation.
Glucose	Is measured amperometrically. Oxidation of glucose, catalyzed by the enzyme glucose oxidase, produces hydrogen peroxide. The liberated hydrogen peroxide is oxidized at an electrode to produce an electric current which is proportional to the glucose concentration.
Creatinine	Is hydrolyzed to creatine in a reaction catalyzed by the enzyme creatinine amidohydrolase. Creatine is then hydrolyzed to sarcosine in a reaction catalyzed by the enzyme creatine amidinohydrolase. The oxidation of sarcosine, catalyzed by the enzyme sarcosine oxidase, produces hydrogen peroxide. The liberated hydrogen peroxide is oxidized at the platinum electrode to produce a current which is proportional to the creatinine concentration.
Lactate	Is measured amperometrically. The enzyme lactate oxidase, immobilized in the lactate biosensor, selectively converts lactate to pyruvate and hydrogen peroxide. The liberated hydrogen peroxide is oxidized at the platinum electrode to produce a current which is proportional to the sample concentration.
***P*O_2**	Is measured amperometrically. The oxygen sensor is similar to a conventional Clark electrode. Oxygen permeates through a gas permeable membrane from the blood sample into an internal electrolyte solution where it is reduced at the cathode. The oxygen reduction current is proportional to the dissolved oxygen concentration
TCO_2	The measured TCO_2 (CHEM 8 cartridge) is calibrated to the International Federation of Clinical Chemistry (IFCC) TCO_2 reference method with an algorithm based on the Henderson-Hasselbalch equation, which used pH, PCO_2, ionic strength (Na) measurement. The calculated TCO_2 (excluding CHEM 8 cartridge) provided by the i-STAT system is determined from the measured and reported values of pH and PCO_2 according to a simplified and standardized form of the Henderson-Hasselbalch equation: $TCO_2 = HCO_3 + 0.03\ PCO_2$ Results from both methods are equivalent.
Troponin I/cTnI	Is determined amperometrically using a two-site ELISA method. Antibodies specific for human cardiac troponin I (cTnI) are located on an electrochemical sensor fabricated on a silicon chip. Also deposited in another location on the sensor silicon chip is an antibody/alkaline phosphatase enzyme conjugate specific to a separate portion of the cTnI molecule. The whole blood or plasma sample is brought into contact with the sensors allowing the enzyme conjugate to dissolve into the sample. The cTnI within the sample becomes labeled with alkaline phosphatase and is captured onto the surface of the electrochemical sensor during an incubation period of approximately seven minutes. The sample, as well as excess enzyme conjugate, is washed off the sensors. Within the wash fluid is a substrate for the alkaline phosphatase enzyme. The enzyme bound to the antibody/antigen/antibody sandwich cleaves the substrate releasing an electrochemically detectable product. The electrochemical (amperometric) sensor measures this enzyme product which is proportional to the concentration of cTnI within the sample
PT/INR	Coagulation is initiated by mixing the sample with tissue thromoboplastin. The endpoint is indicated by the conversion of a thrombin substrate other than fibrinogen. An electrochemical sensor is used to detect this conversion. The added thrombin substrated is H-D-phenylalanyl-pipecolyl-arginine-p-amino-p methoxydiphenylamine. Thrombin cleaves the amide bond at the carboxy terminus of the arginine residue. The product of the thrombin-substrate reaction is the electrochemically inert tripeptide Phenylalanyl-Popecolyl-Arginine and electroactive compound $NH_3^+ - C_6H_4 - NH - C_6H_4 - OCH_3$. A formation of the electroactive compound is detected amperometrically and the time of detection is measured. ISI of 1.05 and a typical Mean Normal Plasma PT time of 12.0 seconds is used to calculate the INR.

26.0 REFERENCES:

26.1. Statland, B.E., Clinical Decision Levels for Lab Tests. Medical Economics Books, 1987
26.2. Tietz, N.W., Tietz Textbook of Clinical Chemistry, third edition, Ed. C.A. Burtis, E.R. Ashwood, W.B. Saunders Company, Philadelphia, 1999. Table 50 – 20, Appendix
26.3. Kost, Gerald J., Using critical limits to improve patient outcome. Medical Laboratory Observer. March 1993; 25(3): 22–27
26.4. Urgent Recall Notice, Abbott Point of Care, March 2012
26.5. SOGC Clinical Practice Guideline. Fetal Health Surveillance: Antepartum and Intrapartum Consensus Guideline. No. 197, September 2007
26.6. i-STAT technical Bulletin, Analyzer Coded Messages (Art: 714260-00W), Abbott Point of Care Inc. 28-Mar-2017
26.7. i-STAT 1 System Manual, Abbott Point of Care Inc. 23 Apr 2018
26.8. Abbott i-STAT Technical Bulletin, Analyzer Coded Messages, Abbott Point of Care Inc. 25 April 2018
26.9. Fetal Health Surveillance Consensus Committee, No: 197b-Fetal Health Surveillance" Intrapartum Consensus Guideline. Journal of Obstetrics and Gynecology Canada,2018;40(4) e298-e322.
26.10. Abbott i-STAT Technical Bulletin, Important Product Information, Factors Affecting Results, September 2020

APPENDICES (all appendices should be printed off and used as required)

Appendix 1 – i-STAT Electronic Simulator Log
Appendix 2 – i-STAT Expiration Date & Storage Conditions Log – Refrigerated
Appendix 3 – i-STAT Expiration Date & Storage Conditions Log – Room Temperature
Appendix 4 – i-STAT Calibration verifiers and QC Log entry
Appendix 5 – i-STAT QC Action Log
Appendix 6 – i-STAT System Semi Annual Quality Control Log
Appendix 7 – i-STAT Operator Recertification Log
Appendix 8 – i-STAT Patient Log
Appendix 9A – i-STAT System Specimen Requirements
Appendix 9B – i-STAT System Job Aid
Appendix 10 – i-STAT System – Customizations
Appendix 11 – i-STAT CLEW Updates Job Aid
Appendix 12 – i-STAT System Printer
Appendix 13 – i-STAT System Printer Power
Appendix 14 – i-STAT System – Ceramic Conditioning Cartridge
Appendix 15 – i-STAT Ceramic Conditioning Cartridge (CCC) Usage Log
Appendix 16 – i-STAT Troubleshooting & Test Flags Job Aid
Appendix 17 – i-STAT Analyzer Coded Messages

Appendix 1: *i-STAT Electronic Simulator Log*

i-STAT Serial #: _____ **Month:** _____ **Year:** _____

Simulator Serial #: _____ **Site/Location:** _____

Date	Time	Result Pass/Fail	**Only to be completed in event of simulator fail			Operator
			**Failure Code or Letter	**Action taken	**Rpt Result Pass/Fail	
1		P / F			P / F	
2		P / F			P / F	
3		P / F			P / F	
4		P / F			P / F	
5		P / F			P / F	
6		P / F			P / F	
7		P / F			P / F	
8		P / F			P / F	
9		P / F			P / F	
10		P / F			P / F	
11		P / F			P / F	
12		P / F			P / F	
13		P / F			P / F	
14		P / F			P / F	
15		P / F			P / F	
16		P / F			P / F	
17		P / F			P / F	
18		P / F			P / F	
19		P / F			P / F	
20		P / F			P / F	
21		P / F			P / F	
22		P / F			P / F	
23		P / F			P / F	
24		P / F			P / F	
25		P / F			P / F	
26		P / F			P / F	
27		P / F			P / F	
28		P / F			P / F	
29		P / F			P / F	
30		P / F			P / F	
31		P / F			P / F	

Reviewed by: _____ **Date:** _____

Appendix 2*: i-STAT Expiration Date and Storage Conditions Log - Refrigerated*

Site/Location: _____ Acceptable Refrigerator Temperature Range: +2°C to +8°C i-STAT Serial #: _____

Date	Location	Cartridge Type	Cartridge Lot #	Manufacturer Expiry Date	Quantity Number of boxes	Shipping Box Temp Indicator A = acceptable U = unacceptable	Comments / Action taken	Initials

Reviewed by:_____ Date: _____

Appendix 3*: i-STAT Cartridge Expiration Date and Storage Conditions Log - Room Temperature*

Site/Location: _____ Acceptable Room Temperature Range: +18°C to +30°C i-STAT Serial #: _____

Date	Location	Cartridge Type	Cartridge Lot #	Manufacturer Expiry Date	Quantity/ Number of boxes	Shipping Box Temp Indicator A = acceptable U = unacceptable	Comments / Action taken	Initials

Reviewed by:_____ Date: _____

CLEAR FORM

Appendix 4: *i-STAT Calibration Verifiers and QC Log entry*

Site: ***Date:*** Click or tap to enter a date ***Serial #:***

To obtain Abbott Point of Care Value Assignment sheets: ***https://www.abbottpointofcare.com/support/value-assignment-sheets***

Cartridge Type: Select type **Lot No:** **Expiry Date:** Click or tap to enter a date **Rec'd Date:** Click or tap to enter a date

No of Boxes Rec'd: **Temp Strip Indicator:** **Clew:**

Control Name: Select Control **Lot No:** **Level:** Select Level **QC Expiry Date:** Click or tap to enter a date

TEST									
Mean									
Range									
Results									
Initials Performed by					Date		Comments:		

Control Name: Select Control **Lot No:** **Level:** Select Level **QC Expiry Date:** Click or tap to enter a date

TEST									
Mean									
Range									
Results									
Initials Performed by					Date		Comments:		

Control Name: Select Control **Lot No:** **Level:** Select Level **QC Expiry Date:** Click or tap to enter a date

TEST									
Mean									
Range									
Results									
Initials Performed by:					Date		Comments:		

Reviewed by: _____ Date Reviewed: _____

Appendix 5: *i-STAT QC Action Log*

Site/Location: _____ i-STAT Serial #: _____

Date	Cartridge Type	Cartridge Lot No.	Date Rec'd	Quantity	Test(s) Out of Range	Corrective Actions	Initials

Reviewed by:_____ Date:_____

Appendix 6: *i-STAT System – Semi Annual Quality Control Log Sheet*

Site/Location: _____ i-STAT Serial #: _____

Date	Scheduled Software Update	Software Update Performed	Electronic Simulator Check Performed	Thermal Probe Check Performed	INR QC Performed	Operator ID	Comments

Reviewed by: _____ Date: _____

Appendix 7: *i-STAT Operator Recertification Log*

Site/Location: _____ **Year: _____**

Requirement for Recertification: **1.** Staff must run a minimum 20 tests in a year ***OR***
2. Run electronic simulator and two cartridges

Staff Name	How Recertification Requirements Met (Indicate 1 or 2)	Date Recertified	Staff Signature	Supervisor Signature	Recertification Next Due

Reviewed by: _____ **Date: _____**

Appendix 8: *i-STAT Patient Log*

Site/Location: _____ **i-STAT Serial #: _____**

***Note: non-reportable Chem 8+ tests – TCO2; Ionized Calcium (unless applicable); do not use for eGFR calculation; do not use for oral glucose tolerance test**

Date / Time	Patient Name *(first and last)*	Patient ID (PHIN)	Chem 8+** *Calculated Tests								CG4+ *Calculated Tests								cTnI	PT/INR	Staff Initials
			Sodium	Potassium	Chloride	Glucose	Urea	Creatinine	Anion Gap*	Ionized Calcium	pH	PCO2	pO2	TCO2*	HCO3*	sO2*	Base excess*	Lactate	Troponin I	PT/INR	

Reviewed by: _____ **Date: _____**

Appendix 9A: *i-STAT System Specimen Requirements*

CHEM8+ cartridge

Sample Type	Instructions
Capillary	**DO NOT USE**
Venous, Arterial	Use Dark Green Li-Heparin tube (no gel)* or balanced heparin blood gas syringe Invert 8-10 times in a figure-eight motion to mix before testing

Analytes reported	Test Timing
Ionized Calcium, Total CO_2	Within 10 minutes after collection. Maintain anaerobic conditions until testing.
Sodium, Potassium, Chloride, Glucose, Urea, Creatinine, Hematocrit, Hemoglobin	Within 30 minutes after collection.

CG4+, CREA, EC8+, and G cartridges

Sample	Instructions
Capillary	Collect sample using a balanced heparin capillary tube
Venous, Arterial	Use Dark Green Li-Heparin tube (no gel) or balanced heparin blood gas syringe Invert 8-10 times in a figure-eight motion to mix before testing

Analytes reported	Test Timing
Lactate	**Immediately after collection.** Any delay can falsely elevate results.
pH, pCO_2, pO_2, Total CO_2, HCO_3, Base Excess, sO_2	**Capillary: within 3 minutes after collection** Venous/Arterial: Within 10 minutes after collection. Maintain anaerobic conditions until testing.
Sodium, Potassium, Chloride, Glucose, Urea, Creatinine, Hematocrit, Hemoglobin	**Capillary: Within 3 minutes after collection** Venous/Arterial: Within 30 minutes after collection.

PT/INR Cartridge

Sample Type	Instructions
Capillary	Direct skin puncture to cartridge application Use **first drop** of blood (do not wipe away)
Venous	Use non-additive tube (no additives, no anticoagulant, no gel) or plain plastic syringe Do **not** mix sample prior to testing

Test Timing
Immediately after collection. Any delay can cause sample to clot before testing.

Troponin I cartridge

Sample Type	Instructions
Capillary	**DO NOT USE**
Venous, Arterial	Use Dark Green Li-Heparin tube (no gel)* or balanced heparin blood gas syringe Invert 8-10 times in a figure-eight motion to mix before testing

Analytes reported	Test Timing
Troponin I	Within 30 minutes after collection.

***Light Green Li-Heparin tubes with gel may be used for CHEM8+ and cTnI cartridges, only if necessary**

Appendix 9B: *i-STAT System Job Aid*

Run multiple cartridges in the following order, as applicable: **PT/INR→ CG4+/EC8+→ CHEM8/CREA/G→ cTnI**

STEP 1

EQUILIBRATE CARTRIDGE

Allow sealed pouch to come to room temperature for at least 5 minutes before use.
DO NOT OPEN POUCH BEFORE SCANNING THE BARCODE.

STEP 2

PREPARE THE ANALYZER FOR TESTING

Press the power button to turn on the i-STAT.
Scan or manually enter your operator ID. Repeat if prompted.
Enter the patient ID.

Scan the lot number on the cartridge pouch.

Place the analyzer on a clean flat surface.
DO NOT MOVE THE i-STAT UNTIL ANALYSIS IS COMPLETE.

STEP 3

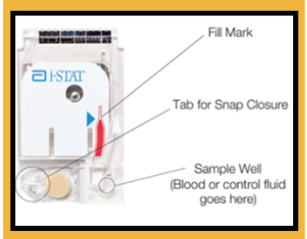
PREPARE THE SAMPLE AND CARTRIDGE

Remove the cartridge from the pouch, touching only the sides. Place on a clean surface.

Samples collected **without anticoagulant must be tested immediately**, without mixing.

Samples collected in tubes with anticoagulant must be mixed well. Invert 8-10 times.

Briskly roll blood gas syringes back and forth for 5 seconds before testing.



STEP 4

FILL CARTRIDGE

Using a plastic transfer pipette or blunt-tipped syringe dispense blood into the cartridge up to the fill mark as indicated. Some blood should be left in sample well.

Fold the snap closure over the sample well until it clicks into place.

DO NOT PRESS DIRECTLY OVER THE SAMPLE WELL.

STEP 5

RUN THE TEST

Push the filled cartridge into the analyzer port until the cartridge clicks into place.

The analyzer will display a 'Time to Results' bar.

When the results are shown, and 'Cartridge Locked' message disappears, the cartridge may be removed and discarded in an appropriate biohazard waste container.

Print and review results. The next cartridge may be tested immediately.

PRINTING RESULTS

Place the i-STAT on the downloader/recharger base, making sure to align the infrared window of the i-STAT to the printer, and press PRINT.

If the device turns off before printing, turn it back on and press 1, then press PRINT

Appendix 10: *i-STAT System – Customizations*

Customization Action	Explanation
CLEWS and JAMS Analyzer Status; verify CLEWS and JAMS are current software	**Current software** Analyzer will not run if software is expired
Date and Time Set Clock; enter password; verify date; arrow to toggle to time; Enter to complete change	**Correct time**
Auto-transmit Customization; Change; enter password; Analyzer; Auto-transmit; Disabled	Auto-transmit disabled to stop the i-STAT from looking for software (LIS) to send results to
Operator ID Customization; Change; enter password; ID entry; Operator ID; Minimum Length; 6 Repeat for Maximum Length	**Operator ID – Min. 6; Max. 6** Each operator is assigned a unique 6 digit ID
Patient ID Customization; Change; enter password; ID entry; Patient ID; Minimum Length: 0; Maximum Length: 9; ID Recall; DISABLED	**Patient ID** PHIN entry preferred; however, site can select other identifier if it works better with other site systems. Set minimum and maximum length based on the identifier type selected
Cartridge Information / Cartridge Barcode Customization; Change; enter password; Pt tests; 2, 3 and 4 are required to run bar-coded cartridges Cartridge Information ; required Cartridge Barcode; required Cartridge Lot Number; required	**REQUIRED** Initiates Pt info request prior to running test
External Simulator Customization; Change; enter password; QC tests; Simulator; External Simulator; Interval; 24; Lock out	**Enabled – 24 hours** i-STAT will request electronic simulator every 24 hours; operators will be locked out and testing cannot proceed until e-simulator is run
Internal Simulator Customization; Change; enter password; QC tests; Simulator; Int Simulator; Disabled	**Disabled** i-STAT is being checked daily with external simulator so internal simulator has been disabled
Urea Customization; Change; enter password; Results; Units & Ranges; Urea; Enabled; Urea, mmol/L	**Urea selected – change to SI** Reports results in mmol/L
Glucose Customization; Change; enter password; Results; Units & Ranges; Glucose; Enabled; mmol/L	**Glucose selected – change to SI** Reports results in mmol/L
sO_2 Customization; Change; enter password; Results; Units & Ranges; sO2; Enabled; %	**sO_2 - change to %**
Hb, Hct, ACT, CKMB, BNP, iCa (menu dependent) Customization; Change; enter password; Results; Units & Ranges; DISABLED; Repeat	**DISABLED** i-STAT will not report hemoglobin, hematocrit, ACT, PT, CKMB, BNP, iCa
Creatinine Customization; Change; enter password; Results; Units & Ranges; Crea; Enabled; µmol/L	**Creatinine – change to SI** Reports results in µmol/L
Troponin I Customization; Change; enter password; Results; Units & Ranges; cTnI; Enabled; µg/L	**Troponin I – change to SI** Reports results in µg/L
Password – change to ###### Customization; Change; Password	**Password Protected** Prevents accidental changes to configurations; password should be recorded and kept in a secure location

Appendix 11: *i-STAT System –CLEW Updates Job Aid*

****After doing CLEW update, perform calibration/verification to ensure analyzer is functioning properly****

First handheld i-STAT must be updated using JammLite method:

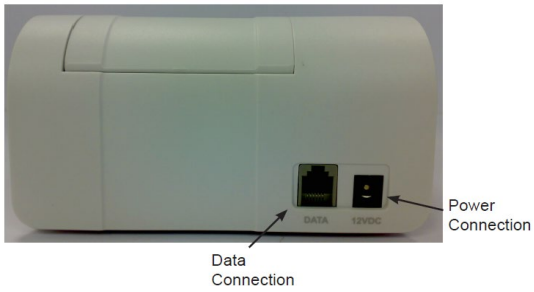
Step	Action
1	Go to: http://pointofcare.abbott/int/en/offerings/support/i-stat/istat-system Click on Support and login to see access to i-STAT System Software update information
2	Navigate to i-STAT 1 Software Update Note: File is not MAC compatible; Microsoft Windows 7 or 10 and Internet Explorer web browser is recommended
3	Ensure the i-STAT 1 Serial Downloader/Recharger (home base) is plugged in to the computer using either the USB cable or 9-pin null modem serial cable provided with the i-STAT. Connect the power supply for the Serial Downloader.
4	Download Software Update "SUxxxxxx.EXE" and save to the Desktop. Navigate to saved file location, double cliock on software file, click RUN. If command windows opens prompting for overwrite, answer "Yes" to all promtps.
5	In JammLite utility, select i-STAT 300 Analyzer under Instrument dropdown; select correct COM port for connection to Serial Downloader; check that the Application and CLEW listings match those in Product Update. Click the Update button.
6	Follow onscreen instructions: ensure analyzer is removed from Downloader; turn analyzer off and place on the Downloader to begin update.
7	Do not move the handheld until the success screen is displayed.
8	If installation is successful, an on-screen message will appear "The application update was successful." Run the Electronic Simulator in the Handheld to verify software was updated correctly and analyzer is functioning properly.
9	If installation is not successful, or if Electronic Simulator fails, ➢ Contact Abbott Technical Support for Customer at 1-609-454-9000 ➢ Support is available 24 hours, 7 days a week

After uploading the first i-STAT analyzer, additional analyzer updates may be done following the Analyzer-to-Analyzer Process:

Step	Action
1	Ensure the updated analyzer (Sending Analyzer) and the analyzer to be updated (Receiving Analyzer) are both available
2	Power off the Receiving analyzer
3	Place Sending and Receiving analyzers on a flat surface with infrared windows aligned, approximately 1 foot apart
4	Turn on the Sending analyzer ➢ Press **Menu** ➢ Select **7 - Utility**
5	Enter password if needed when prompted, or press ENT and continue
6	In the Utility Menu ➢ Press 1 - Send Software ➢ Press JAMSxxx/Axx *(note; numbers have been replaced with x's and will change with each software update)* Ensure the Receiving analyzer's power is **off**
7	When the Sending analyzers displays "**Waiting to Send"** ➢ Keep the infrared windows aligned in both analyzers ➢ Without lifting either analyzer off the flat surface, slide the Receiving analyzer towards the Sending analyzer until the Sending analyzer displays "**Sending"**
8	When the update is in progress, the Sending analyzer will display Sending along with a bar indicating that the software is being sent ➢ The Receiving analyzer will have 1's and 0's streaming across the screen signifying it is receiving the software ➢ Do not move the analyzers until the Sending analyzer goes back to the Utility menu and displays **Last Send Successful**
9	The update is complete
10	Check that the Receiving i-STAT analyzer has been properly updated ➢ If the screen has gone blank press the **On/Off** key to activate display ➢ Press the **Menu** key, select **Analyzer Status** ➢ Check the numbers adjacent to Version and CLEW to make sure they match the current software update ➢ Run the Electronic Simulator in the Handheld to verify software was updated correctly and analyzer is functioning properly.
11	If there are other analyzers to update, repeat the above steps
12	If update was not successful ➢ Contact Abbott Technical Support for Customer at 1-609-454-9000 ➢ Support is available 24 hours, 7 days a week

Appendix 12: *i-STAT System – Printer*

The i-STAT printer is used to print results from all models of the i-STAT Analyzer



Components: i-STAT printer, AC adapter, power cord, rechargeable battery, one roll of printer paper. Other items can be ordered from Abbott Customer Service as required.

Orderable Item	Abbott List Number
i-STAT printer	04P74-01
i-STAT combo power supply	04P74-02
Rechargeable battery for the i-STAT printer	04P74-03
Portable printer paper (6 rolls per box)	**06F17-11**
i-STAT printer kit	04P74-04

Status indicator will illuminate to indicate the print status:

Ready: Green ●
Out of Paper: Orange ●
Error: Red ●

Replacing Paper

Step	Action	
1	Open the paper compartment lid by pulling the release lever; remove any remaining paper	
2	Reel off a few centimeters of paper from the new roll, with the leading edge of the paper feeding forward from the bottom of the roll	
3	Site the new paper roll in the compartment such that the leading edge is resting outside of the compartment on the printer casing	
4	Close the lid until it snaps into place	
Should the paper become creased or misaligned, simply reload the paper as described above, ensuring that the paper has a clean, straight edge When removing a printout from the paper, pull the printout toward the front of the printer and tear from one side to the other across the serated edge		

Appendix 13: *i-STAT System – Printer Power*

There are three options for powering the i-STAT printer:

1. Using the AC adapter and power cord only
2. Using the rechargeable battery only
3. Using the rechargeable battery with the AC adapter and power cord.

The printer can be turned on and off by pressing the **Power** button. When the printer is on, the **POWER** indicator will be illuminated:

Power OK: Green ●
Battery Low: Orange ●
Battery Empty: Red ●

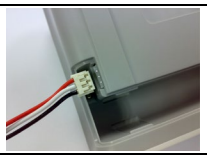
If the printer is inactive for >60 seconds, it will automatically enter the power-saving mode. When in the power-saving mode, the POWER indicator will change from a solid colour light to pulsed illumination.

The printer's rechargeable battery needs to be recharged when the POWER indicator turns orange. If the battery becomes exhausted, the POWER indicator will turn red and printing will be disabled.

The printer's battery can be recharged using the supplied AC power adapter. The socket for the AC power adapter is located on the rear of the printer. **Note:** Charging only occurs when the printer is switched off or in the power-saving mode. A full charge takes approximately three hours.

Symptoms indicating that the rechargeable battery requires replacement:

1. A steady orange or red POWER indicator light on the printer, even after charging it for the recommended three hours.
2. Loss of battery capacity, indicated by a shorter interval between charges.

Step	Action – To Install or Replace Rechargeable Battery	
1	Disconnect the printer from the AC adapter	
2	Turn the i-STAT printer upside down and place on a flat surface; remove the batter door by sliding it off while pressing on the grooved section; set the door aside	
3	If replacing an existing rechargeable batter in the printer, disconnect the existing battery by gently pulling up on the red/while/black wires until the connector releases from the three metal pins. Once the batter is disconnected, remove it completely from the battery compartment	
4	Remove the new rechargeable battery from its packaging; with the thumb and index finger of one hand, grasp the connector at the end of the red/white/black battery wires	
5	Assure proper connect alignment as shown:	
6	Slide the connector onto the three metal connector pins	
7	Once the wires are connected, place the battery portion of the pack into the rectangular compartment; make sure the wires are not under the battery or projecting out of the opening. Correct positioning is shown:	
8	Slide the battery door back onto the compartment until it closes and locks into place	
9	Turn the printer over, plug it back into the AC power adapter and charge the new batter in the printer for a minimum of three hours before use	
Note: if the rechargeable battery is removed or becomes exhausted, it is still possible to print at reduced speed using the AC power adapter		

Cautions:

- Use only a rechargeable battery pack purchased from Abbott; battery packs not recommended, or purchased from Abbott may be susceptible to overheating and could lead to a potential fire or burn hazard
- Use only power adaptor and power supply provided with the i-STAT printer kit
- Do not operator the printer without paper
- Do not allow power supply to become a trip hazard
- Do not disturb the handheld or printer until printing is complete as this will interrupt the printout; if printing is interrupted realign the printer and handheld. If significant time has elapsed, some results may be missing from the printout; reprint the results
- If printed results appear inconsistent with a patient's clinical assessment, verify that the printed results match the data in the handheld. If the results do not match, the patient sample should be retested using another cartridge. If they do not match, reprint the results. If the reprint still does not match the handheld data, the printer requires service and the printed results must not be used
- Skin irritation, including caustic burns/injury, may occur following exposure to a leaking battery. Always wear gloves when handling a leaking battery, and do not permit a leaking battery to contact skin. Should skin exposure to a leaking battery occur, follow the first aid measure outlined in the MSDS sheet for the Novacell nickel metal hydride battery

Printer Troubleshooting: *(refer to vendor manual for complete list of troubleshooting activities)*

Printer Symptom	Recommendations
Printer is not printing. The POWER indicator light is green/orange and the STATUS indicator light is green.	• Check that the results are displayed on the handheld, or that results have been selected from **List** under **Data Review.** • If printing directly from the handheld, check that the distance between the analyzer and printer is not too short or too long. • Perform printer self-test to ensure that printer is functioning. o Turn the printer off. o While pressing the Paper Feed button, press down on the Power button until the printout begins, and then let go of both buttons. o Ensure that the resulting printout is clear & complete
Printer is feeding paper, but nothing is printed.	Check that the paper is feeding from under the roll.
Printer is not printing and POWER indicator is red.	Battery needs to be recharged.
Printer POWER indicator does not illuminate when printer is turned on.	Battery needs to be recharged.
Printer is not printing and STATUS indicator is orange.	Printer is out of paper.
Printer is not printing and STATUS indicator is red.	Print head temperature is out of range. Printing will be inhibited until print head temperature returns to normal level.

Cleaning the Printer

- Clean the external casing of the i-STAT printer with a gauze pad moistened with any of the following approved cleaning agents:
  - 10% bleach solution
  - Isopropyl alcohol (IPA)
  - PDI Super Sani-Cloth (solution of IPA, n-Alkyl dimethyl ethylbenzyl-and benzyl-ammonium chloride)
- Rinse the printer casing, using another gauze pad moistened with water and dry.
- **Do NOT immerse the printer in any fluid at any time.**

Appendix 14: *i-STAT System – Ceramic Conditioning Cartridge*

Using the i-STAT Ceramic Conditioning Cartridge (CCC)

Error codes can sometimes be corrected by conditioning the pins in the analyzer using the CCC as follows:

1. Run an external e-simulator
    a. The analyzer should not be configured with the internal electronic simulator enabled, however best practice is to run an external electronic simulator prior to running the CCC. Running the external e-simulator ensures the internal e-simulator cycle will not execute during the pin conditioning process, which could lead to the premature termination of the process.

2. Run the CCC two (2) times
    1. Initiate the CCC cycle as you would initiate an external e-simulator cycle. The instrument will identify the CCC as an external e-simulator and display a Simulator Failure Code (i.e. rRGL) when the cycle is complete. Disregard the code, as this is expected behavior.

3. Update the CCC Usage Log
    1. See Appendix 6 Ceramic Conditioning Usage Log. Updating the log allows the user to keep track of the number of pin conditioning cycles performed with the current ceramic strip in the CCC. If necessary, replace or rotate the ceramic strip so the CCC is ready for future use. Refer to section below for the CCC maintenance instructions

4. Return the analyzer to service.

Maintaining the Ceramic Conditioning Cartridge:

Rotating the strip:

1. Using a small Phillips head screwdriver, loosen and remove the screw and retainer
2. While wearing gloves, remove the ceramic strip. The ceramic strip in brittle and should be handled with care to avoid damaging or contaminating it.
3. Inspect the ceramic strip for damage. Replace is cracked or chipped. **Cracked strips must be replaced before using the ceramic cartridge in an analyzer.**
4. Inspect the aluminum base. Clean if necessary with isopropanyl alcohol and a soft, lint-free cloth. Avoid using paper that might leave fibers on the ceramic cartridge which might be carried into the analyzer.
5. Rotate the ceramic strip to the next orientation (either spin around or flip over). The ceramic cartridge may be used to perform 25 repairs (2 runs per repair) before rotating or replacing the strip. The strip may be rotated 3 times before replacing it (i.e. the strip has a total of 4 positions; original position of the strip plus 3 rotations). The 4 orientations are:
    a. Initial position
    b. The strip rotated by “spinning it” 180 degrees, same side up
    c. The strip rotated by turning it over, now back side up
    d. The strip rotated by “spinning it” again 180 degree, back side still up

Appendix 15: *i-STAT Ceramic Conditioning Cartridge (CCC) Usage Log*

Ceramic Cartridge Serial #[1]: _____ Site/Location: _____

i-STAT Serial #: _____

NEW STRIP
Check one box (below) for each time the ceramic cartridge is run in the analyzer. Typically this means two boxes are checked each time an analyzer is restored with the ceramic cartridge. There are 50 boxes. If the strip is damaged[2] replace the strip and start a new log. After all the boxes immediately below are checked, rotate the strip as instructed and continue to check off boxes for each analyzer restoration.

FIRST ROTATION
Rotate the strip 180°, keeping the same side up. Check one box for each time the ceramic cartridge is run in the analyzer. Typically this means two boxes are checked each time an analyzer is restored with the ceramic cartridge. There are 50 boxes. If the strip is damaged[2], replace the strip and start a new log. After all the boxes immediately below are checked, rotate the strip as instructed and continue to check off boxes for each analyzer repair.

SECOND ROTATION
Flip the strip over, so the bottom side is now up. Check one box for each time the ceramic cartridge is run in the analyzer. Typically this means two boxes are checked each time an analyzer is restored with the ceramic cartridge. There are 50 boxes. If the strip is damaged[2], replace the strip and start a new log. After all the boxes immediately below are checked, rotate the strip as instructed and continue to check off boxes for each analyzer repair.

THIRD AND LAST ROTATION
Rotate the strip 180°, keeping the same side up. Check one box for each time the ceramic cartridge is run in the analyzer. Typically this means two boxes are checked each time an analyzer is restored with the ceramic cartridge. There are 50 boxes. If the strip is damaged[2], replace the strip and start a new log. After all the boxes immediately below are checked, discard the strip as instructed below.

DISCARD STRIP
Replace the strip with a new strip and start a new log.

[1] = Serial Number etched on the cartridge base
[2] = Inspect the ceramic cartridge for damage. Check to make sure the ceramic strip is centered (i.e. not hanging over either edge), that the screw is secure, and that the ceramic is not chipped or cracked. Wear marks (appearing as small lines on the ceramic) are normal.

Reviewed by: _____ Date: _____

Appendix 16: *i-STAT System – Troubleshooting and Test Flags Job Aid*

If:	Then:
Results do not reflect the patient's condition (unexpected results),	Repeat the test using a fresh cartridge and sample
Results are still suspect,	Send sample to a reference lab
The analyzer fails to provide a test result or displays an error code message,	Repeat the test using a fresh cartridge
The condition persists,	**DO NOT** use the analyzer Log the error condition in the equipment log book Send sample to the lab
There is no display on the analyzer,	The rechargeable battery may not be charged Recharge battery
"Cartridge Locked" does not disappear after the test cycle is completed,	Wait until device turns off; turn back on. If it resets, remove the cartridge; if not recharge the battery and then turn the device on.
Analyzer Messages / Codes	**Operator Action**
Dead Batteries / Replace Batteries	Recharge device
Cartridge Error	Use a fresh cartridge
Cartridge Preburst	Use a fresh cartridge
Unable to Position Sample	Use a fresh cartridge
Sample Positioned Short of Fill Mark	Use a fresh cartridge
Sample Positioned Beyond Fill Mark	Use a fresh cartridge
Test Flags	**Operator Action**
******* Results are not reportable due to sensor errors or interfering substances	Collect a new sample and repeat test; record on next line on log sheet. **Note:** If results are flagged again, send sample to a reference lab
<, > and <> Results below or above the reportable range or are dependent on results that are outside the reportable range	Send sample to a reference lab
↑ and ↓ Results that are above or below the action range	Follow procedure for samples with critical values

NOTE: *Any time a new sample is run or a new cartridge is used, document with a comment on the patient log.*

Appendix 17: *i-STAT Analyzer Coded Messages*

Use this appendix to troubleshoot quality check failures. If code number is not in the charts, or the error does not resolve after suggested actions are taken, call Abbott Technical Support and provide them with the error code number displayed on the handheld.

Codes 1-15 and 95 usually indicate a condition related to the environment or the state of the analyzer. These conditions are usually benign and go away after the next cartridge or Electronic Simulator is inserted, or after the offending condition is corrected.

Code Number	Cause/Action Message on Display	Explanation
1	**Dead Batteries** / Replace Batteries	There is insufficient battery power to complete the testing cycle. Replace the disposable lithium batteries in the analyzer or recharge the rechargeable batteries. If you are experiencing the code frequently and use disposable batteries with the i-STAT 1 analyzer, you may want to consider the rechargeable battery system available.
2	**Temperature Out of Range** / Check Status Page	The analyzer is recording a temperature outside its operating range. Move the analyzer to an area within the operating temperature of the test being performed and allow the analyzer to come to the new room temperature. Check the analyzer's temperature reading on the Status Page.
4,8	**Analyzer Interrupted** / Use Another Cartridge	The analyzer has detected that the last test cycle was not completed. This can happen if the batteries were removed or were making poor contact while a cartridge was still in the analyzer. Batteries that are too short will not make proper contact. Check that the batteries are inserted properly and seated well in the analyzer; check the battery voltage on the analyzer's Status Page and replace batteries if low. NOTE: Patient results displayed before this code are valid.
11	**Date Invalid** / Check Clock on Status Page	If the date in the real time clock precedes the release date programmed into the application software, code 11 is triggered. Check the date on the real time clock. The accuracy of the clock is checked at the beginning of a coagulation test. If the clock is inaccurate, code 11 is triggered.
12	**Expired Software Update Required** / See Manual	The standardization software (CLEW) has expired. Download a valid CLEW. The date on the real-time clock in the analyzer exceeds the expiration date of the CLEW. Check the date on the real-time clock and adjust if necessary.
13	**Invalid CLEW Update Required** / See Manual	The standardization software (CLEW) is corrupt or not compatible with the application software The standardization software (CLEW) is corrupt or not compatible with the application software (JAMS), or there is no CLEW in the analyzer. Download a valid CLEW. If this code occurs after a software upgrade and the customization application is enabled in the Data Manager, change the CLEW version in the Customization Profile to the latest version and re-transmit the profile to the analyzer.
14	**Analyzer Error** / See Manual	Customization profile is corrupted. Download analyzer to the data manager. If code 14 reoccurs, contact i-STAT Technical Services or your local support organization for further assistance
15	**Barcode Does Not Match Cartridge Type**	The barcode scanned by the user does not match the immunoassay cartridge type indicated by the identification chip in the cartridge. The user should run another cartridge, being careful to scan the barcode from the portion pack of the specific cartridge type being run on the analyzer.
95	**Test Cancelled by Operator**	This message will appear in the stored test records on the i-STAT 1 Analyzer if the analyzer powers down before mandatory information was entered.

The following codes are associated with the cartridge or fluid movement within a cartridge. These conditions can be operator or sample related. In most cases, a new cartridge must be used. If a condition persists, especially if isolated to one analyzer, there may be an analyzer problem.

Code Number	Cause/Action Message on Display	Explanation
17-19	**No Clot Detected / ****Error** / See Manual	During the coagulation test cycle, no clot was detected. Run another cartridge. If the code reappears, run the sample on an alternate methodology
22, 25	**Cartridge Error** / Use Another Cartridge	These codes occur only for coagulation cartridges if the mixing of the sample and reagent is compromised. This can be caused by an insufficient or clotted sample, or by air bubbles in the sample.

Code Number	Cause/Action Message on Display	Explanation
24	**Cartridge Error** / Use Another Cartridge	The electrical resistance of the calibrant fluid (Rcal) used to verify the electrolyte concentration is out of specification. This could occur if the calibrant pack was ruptured well before the test allowing evaporation to result in a higher electrolyte concentration. Besides the electrolyte concentration, the Rcal is also affected by the temperature and the height and width of the fluid segment over the conductometric sensor. The analyzer accounts for the temperature, but the height and width of the fluid segment can vary from cartridge lot to cartridge lot. The analyzer has been programmed to compensate for these lot-to-lot differences by maintaining a running average of the Rcal values measured from the most recent cartridge runs. Occasionally, the difference between the Rcal values for two cartridge lots is large enough to cause the introduction of a new lot to trigger code 24 on the first few cartridge runs. The Code 24 errors should disappear as the running average adjusts. However, if code 24 persists after more than 3 cartridge runs on each analyzer, contact i-STAT Technical Services or your local support organization.
26	**Cartridge Error** / Use Another Cartridge	This code occurs if there was a coagulation specific quality check failure: premature substrate activation, abnormally low levels of substrate, or invalid fluid motion.
20, 27-29, 32, 33, 40, 41, 45, 87	**Cartridge Error** / Use Another Cartridge	These codes identify problems with the cartridge such as: calibrant fluid arriving too soon, too late, or not at all, or noise in the calibrant fluid signals. Codes 20, 27, 41, and 87 can be caused by poor contact that can sometimes be corrected by conditioning the pins in the analyzer using the ceramic conditioning cartridge. The specific conditioning procedure is described at the end of this bulletin. The rate of quality check code 45 can be elevated when cartridges are run without allowing sufficient time for the cartridges to equilibrate to room temperature. To minimize the number of quality check codes, review i-STAT cartridge storage conditions and allow sufficient time for refrigerated cartridges to equilibrate to room temperature.
42, 43	**Cartridge Error** / Use Another Cartridge	These codes indicate that the conductometric sensor (code 42) or the amperometric sensor (code 43) was out of specification. This could be caused by a pre-burst calibrant pack, dirty cartridge contact pads, or a dirty connector in the analyzer.
79-81	**Cartridge Error** / Use Another Cartridge	Bad contact between the thermal probes in the analyzer and the metalization on the back of the chips in the cartridge trigger these codes. Causes are: poor metalization of the chips, dirt on the metalization, or bent or broken thermal probes in the analyzer.
21	**Cartridge Preburst** / Use Another Cartridge	This code indicates that the analyzer detected fluid on the sensors before it should have. Possible causes: mishandling of cartridges (putting pressure in the center of the cartridge), poor storage conditions of cartridges (frozen), or rerunning used cartridges.
31, 34, 44	**Unable to Position Sample** / Use Another Cartridge	The analyzer did not detect movement of sample across the sensors. This could be due to a clot in the sample (especially in neonates), to not closing the snap closure on the cartridge, or to an aberrant cartridge.
35 ,36	**Sample Positioned Short of Fill Mark** / Use Another Cartridge	The cartridge was underfilled. The sample must reach the fill mark. Try another cartridge.
30, 37	**Sample Positioned Beyond Fill Mark** / Use Another Cartridge	The cartridge was overfilled. The sample was past the fill mark. Try another cartridge.
38, 39	**Insufficient Sample /** Use Another Cartridge	This is most likely due to insufficient sample in the sample well of the cartridge, but can also be caused by bubbles in the sample. Try another cartridge and ensure sufficient sample is in the sample well.
46	**Cartridge Error** / Use Another Cartridge	The analyzer did not detect movement of sample across the sensors. This could be due to a clot in the sample (especially in neonates), to not closing the snap closure on the cartridge, or to an aberrant cartridge.
47	**Cartridge Not Inserted Properly** / Reinsert Cartridge	This code indicates the cartridge or Electronic Simulator may not be pushed in all the way. Reinsert the cartridge or Electronic Simulator. If the problem persists and/or the user is certain the cartridge or Simulator is properly inserted, it may indicate an analyzer problem. Contact i-STAT Technical Services or your local support organization for further assistance.
48	**Analyzer Error** / See Manual	This code indicates the cartridge or Electronic Simulator may have been “cocked” when inserted. Push the cartridge or Simulator straight through the cartridge port. If the problem persists, and the user is certain the cartridge or Simulator is properly inserted, it may indicate an analyzer problem. Contact i-STAT Technical Services or your local support organization for further assistance.
23, 49	**Poor Contact Detected** / See Manual	Code 23 may be caused by poor contact between the analyzer contact pins and the cartridge sensor contact pads. Code 49 may be caused by poor contact between the analyzer contact pins and the cartridge identification chip contact pads. These quality check codes can sometimes be corrected by conditioning the analyzer contact pins using the ceramic conditioning cartridge. The conditioning procedure is described at the end of this bulletin.

The following conditions are related to electronic or mechanical failures in the analyzer.

Code Number	Cause/Action Message on Display	Explanation
50	**Analyzer Error** / Use Electronic Simulator	The motor has moved too far. Running a simulator may not detect this problem. Run the simulator and if the analyzer passes, run a cartridge to see if the code reoccurs. If not, continue to use the analyzer. If the code reoccurs, contact i-STAT Technical Services or your local support organization for further assistance. If testing immunoassay cartridges on an i-STAT 1 Analyzer, this code can be related to poor electrical connection between the i-STAT 1 Analyzer and the cartridge. This can sometimes be corrected by conditioning the pins in the analyzer using the ceramic conditioning cartridge. The specific conditioning procedure is described at the end of this bulletin. Note: If you do not have a ceramic conditioning cartridge, please contact i-STAT Technical Support at 1-800-366-8020, option 1. Codes 126 and 128 are sometimes related to electrical connection as well. If you experience multiple occurrences of these 3 codes (50, 126, and 128) in a short period of time, consider returning the analyzer for servicing and replacement. The presence of sample bubbles when running immunoassay cartridges may, under some circumstances, also elicit this code.
51	**Analyzer Error** / Use Electronic Simulator	The motor moved for too long. Run a simulator. If the error occurred while running an ACT cartridge, also run a cartridge. If the code does not reoccur, continue to use the analyzer. Under some conditions, a low battery will cause this error instead of code 1. Try fresh batteries. If the code reoccurs, contact i-STAT Technical Services or your local support organization for further assistance.
52	**Analyzer Error** / Use Electronic Simulator	The motor stalled while moving. Run a simulator. If the error occurred while running an ACT cartridge, also run a cartridge. If the code does not reoccur, continue to use the analyzer. If the code reoccurs, contact i-STAT Technical Services or your local support organization for further assistance.
58-62	**Analyzer Error** / Use Electronic Simulator	The analyzer usually recovers from these error conditions. These error conditions can be detected by the Electronic Simulator. If the analyzer passes the Electronic Simulator test, continue to use it. If not, check the battery voltage and check the analyzer with another simulator to rule out a simulator problem. If the code persists, contact i-STAT Technical Services or your local support organization for further assistance.
53, 55-57, 63, 65-68, 72-74, 82, 83-85, 86, 89-94, 96, 97	**Analyzer Error** / See Manual	These are mechanical or electronic failures from which the analyzer may not be able to recover. Codes 82 and 92 typically indicate a problem with the pressure transducers in the analyzer. If these codes persist, contact i-STAT Technical Services or your local support organization for further assistance. Codes 83 and 84 indicate an underlying hardware failure in the i-STAT 1 Wireless Analyzer. If these codes persist, contact i-STAT Technical Support or your local support organization for further assistance. The rate of quality check code 55 can be elevated when cartridges are run without allowing sufficient time for the cartridges to equilibrate to room temperature. To minimize the number of quality check codes, review i-STAT cartridge storage conditions and allow sufficient time for refrigerated cartridges to equilibrate to room temperature. Code 56 occurs when the analyzer detects noise on the thermal circuit. The noise may be the result of electronic interference. If this code occurs, the analyzer should be moved to a different location away from potential sources of interference. If the code persists in the new area, the analyzer should be returned. Code 86 can occur when an i-STAT Analyzer is stored in an i-STAT Downloader/Recharger without adequate ventilation. This problem can usually be resolved by moving the Downloader/Recharger to an open location which is free of obstructions and external heat sources such as heater vents or other electronic equipment. If this code persists, or if code 86 occurs with the i-STAT 1 Analyzer without a Downloader/Recharger, contact i-STAT Technical Services or your local support organization for further assistance. For other codes, run the Electronic Simulator twice, then run a cartridge with a sample. If the analyzer passes the simulator check and a quality check does not occur with the sample run, continue to use the analyzer. If the analyzer does not pass the simulator check and/or a quality code occurs with the sample run, contact i-STAT Technical Services or your local support organization for further assistance.

Code Number	Cause/Action Message on Display	Explanation
69	**Cartridge Type Not recognized** / Use Another Cartridge	This code could be due to use of a cartridge type that is not compatible with the version of software in the analyzer, or the use of expired cartridges. Check the cartridge expiration date on the cartridge box or pouch. If the cartridges have not expired, and if a new cartridge type is being run, contact i-STAT Technical Services or your local support organization for a software update. When running coagulation cartridges, Code 69 may be caused by poor contact between the analyzer pins and the cartridge chip. This can sometimes be corrected by conditioning the pins in the analyzer using the ceramic conditioning cartridge. The specific conditioning procedure is described at the end of this bulletin. This code will be displayed if incorrect information is entered in response to the prompt "Scan Cartridge Lot Number". The instrument expects the barcode on the individual cartridge pouch to be scanned. The instrument will not accept keypad entries of the cartridge lot number nor a scan of the barcode on the cartridge box. This condition may be due to an aberrant cartridge. However, if the condition occurs repeatedly on one analyzer, the analyzer may need repair. Contact i-STAT Technical Services or your local support organization for further assistance.

Codes in the range of 120 to 138 and 140 to 151 indicate a failure during an immune or barcoded pouch cartridge cycle. In most cases, the cartridge is spent and another cartridge must be used.

Code Number	Cause/Action Message on Display	Explanation
120-122, 124, 125, 133, 144, 148	**Cartridge Error** / Use Another Cartridge	These codes indicate a problem with the movement of the analysis fluid during the cartridge run. Try another cartridge.
123	**Cartridge Error** / Use Another Cartridge	The quality control during the cartridge run failed to verify the presence of active immuno reagents. Try another cartridge.
126	**Cartridge Error** / Use Another Cartridge	The quality control during the cartridge run failed to verify the integrity of the analysis fluid. However, this code can also be related to poor electrical connection between the i-STAT 1 Analyzer and the cartridge. This can sometimes be corrected by conditioning the pins in the analyzer using the ceramic conditioning cartridge. The specific conditioning procedure is described at the end of this bulletin. Note: If you do not have a ceramic conditioning cartridge, please contact i-STAT Technical Support at 1-800-366-8020, option 1. Codes 50 and 128 are sometimes related to electrical connection as well. If you experience multiple occurrences of these 3 codes (50, 126, and 128) in a short period of time, consider returning the analyzer for replacement.
127	**Cartridge Error** / Use Another Cartridge	A wet sensor was detected before the initial sample movement. Possible overfilled or used cartridge. Try another cartridge.
128, 131, 132, 134, 135-138	**Cartridge Error** / Use Another Cartridge	These codes are most often related to poor filling of an immunoassay cartridge, the presence of sample bubbles, or the abrupt insertion of a cartridge into the analyzer. **Guidelines for proper filling:** 1. Discard (always) 1 drop from delivery device to clear unseen bubbles. 2. Hang single drop slightly larger than round target well. 3. Touch 1 drop (only) to round target well allowing cartridge to draw sample in. 4. Confirm sample volume lines up with top of fill mark. 5. Close cartridge. **Guidelines for cartridge insertion:** 1. After closing the cartridge, grasp the cartridge for insertion. • Original thumbwell design: grasp the closure between your thumb and first finger. There is a recess for your thumb on the closure. • Large thumbwell cartridge: grasp the thumbwell between your thumb and first finger. 2. Guide the cartridge into the analyzer gently, until a soft click is heard.
129, 142, 143	**Cartridge Error** / Use Another Cartridge	The analyzer detected analysis fluid mixed with the sample. Try another cartridge.
130	**Cartridge Error** / Use Another Cartridge	The analyzer detected an air bubble in the sample segment. Try another cartridge.

Code Number	Cause/Action Message on Display	Explanation
140	**Lot Expired**	The analyzer detected an expired cartridge lot. Check the expiration date and repeat the test using a non-expired cartridge lot.
141	**Test Canceled by Operator**	This code will be displayed if the cartridge barcode is not scanned within 60 seconds of cartridge insertion. The correct barcode to scan is the barcode on the cartridge portion pack, not the one on the cartridge box. An example of the portion pack barcode is found in the table listing for code 69 above.
145	**Cartridge Error** / Use Another Cartridge	The analyzer failed to detect fluid arrival upon the initial sample push. This may be caused by a(n): • Cartridge leak. • Failure to close the cartridge completely. Ensure that the closure is fully engaged before inserting the cartridge into the analyzer. • Underfilled cartridge. Once a single drop of sample is touched to the target well, immunoassay cartridges will fill automatically by wicking the sample at a fixed speed. Trying to inject the sample into the cartridge or adding more sample to the target well will not make the cartridge fill faster. Wait for the sample to reach the fill mark and then close the cartridge.
146	**Cartridge Error** / Use Another Cartridge	Overfilled cartridge. Repeat the test.
147	**Analyzer Error** / See Manual	In order to run an immunoassay cartridge, the i-STAT 1 Analyzer must bear the  symbol:
149-151	**Cartridge Error** / Use Another Cartridge	The analyzer detected an atypical data stream from the cartridge. Try another cartridge. For BNP, if code 150 is encountered when running a whole blood sample, it is recommended that the sample be centrifuged and the test be repeated with the resulting plasma.

A code in the range of 165-175 indicates a failure during a coagulation cycle. In all cases, cartridge is spent and another cartridge should be used.

Code Number	Cause/Action Message on Display	Explanation
165	**Cartridge Error** / Use Another Cartridge	This code indicates that the analyzer detected fluid on the sensors before it should have. Possible causes: user is attempting to run a used cartridge or user did not allow the cartridge to equilibrate to room temperature before opening the cartridge pouch. (Individual cartridges should equilibrate for 5 minutes at room temperature or a box of cartridges for 1 hour before opening the cartridge pouch.)
166	**Cartridge Error** / Use Another Cartridge	The sample arrived at the sensors too late. This may indicate that the cartridge was underfilled or that there was a bubble in the sample. Try another cartridge.
167	**Cartridge Error** / Use Another Cartridge	The sample arrived at the sensors too early. This may indicate that the cartridge was overfilled. Try another cartridge.
170	**Cartridge Error** / Use Another Cartridge	A resistance value detected during the testing cycle was too high. Try another cartridge.
171-175	**Cartridge Error** / Use Another Cartridge	The analyzer detected a bubble on or near the sensors. Try another cartridge.

The following conditions are related to the Electronic Simulator.

Code Number	Cause/Action Message on Display	Explanation
Numerical Code	See under Analyzer Coded Messages.	See under Analyzer Coded Messages.
L	Potentiometric channel out of limits. Can occur if moisture collects on the contact pins inside the analyzer when the analyzer is subjected to ambient temperature change.	Contact i-STAT Technical Services or your local support organization for further assistance.
G	Amperometric channel out of limits. Can occur if external simulator not inserted straight.	
R, r	Resistance reading on conductometric channel out of limits.	
T	Thermal probe failure.	
B	Potentiometric channel out of limits.	