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PROCEDURE MANUAL

FOR THE i-STAT SYSTEM

This document is intended for use as a template for creating a Procedure Manual customized for site-specific policies and procedures and is not intended to replace the System Manual.

For additional information pertaining to cartridges, refer to Instructions for Use (IFU) and Cartridge and Test Information (CTI) sheets found on the Abbott | Point of Care Diagnostics website at:

 [www.globalpointofcare.abbott](http://www.globalpointofcare.abbott/)

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# SYSTEM OVERVIEW

The i-STAT System incorporates comprehensive components needed to perform blood analysis at the point of care. The system consists of the following primary components:

## i-STAT 1 and i-STAT Alinity Analyzers

When a sample-filled i-STAT cartridge is inserted into the i-STAT 1 or i-STAT Alinity Analyzer for analysis, the analyzer automatically controls all functions of the testing cycle, including fluid movement within the cartridge, calibration, and continuous quality monitoring.

## Analysis Time

* ACT cartridge: to detection of end point – up to 1000 sec (16.7 min)
* PT*plus* cartridge: to detection of end point – up to 300 sec (5 min)
* TBI and hs-TnI cartridge: 900 sec (15 min)
* Other cartridges: typically, 130 to 200 sec

## Cartridges

A single-use disposable cartridge contains micro-fabricated sensors, a calibrant solution, fluidics system, and a waste chamber. Sensors for analysis of pH, ***P***CO2, ***P***O2, TCO2, sodium, potassium, chloride, ionized calcium, glucose, lactate, creatinine, urea nitrogen (BUN) and hematocrit are available in a variety of panel configurations. Cartridges are also available for Celite-ACT, Kaolin-ACT, PT*plus*, TBI, and Troponin I (hs-TnI) (Table 1).

## Data Manager (DM)

A Data Manager (DM) provides the ability to store, organize, edit, and transfer data to a laboratory or hospital information system. The data is transmitted by Downloaders and Downloader/Rechargers for the i-STAT 1 System and by the base station for the i-STAT Alinity System. Wireless transmission is also an option when using the Wireless i-STAT 1 System and i-STAT Alinity System. A wide variety of reports can be generated for management of the system.

# SUPPLIES and STORAGE REQUIREMENTS

## Cartridges

* Store cartridges in the refrigerator at 2-8 °C (35-46 °F).
	+ Do not allow cartridges to freeze
	+ Cartridges should not be exposed to temperatures above 30 °C (86 °F).
* Cartridges in the refrigerator can be used until the expiration date on the cartridge pouch/pack or box.
	+ Do not use cartridges beyond expiration date.
* Cartridges must be at room temperature (18-30 °C or 64-86 °F) prior to use. Allow 5 minutes for an individual cartridge and one hour for a box of cartridges to come to room temperature.
	+ Once at room temperature, cartridges cannot be returned to the refrigerator.
	+ Once at room temperature, cartridge expiration date changes to the time frame indicated on the cartridge pouch/pack or box. Indicate new expiration date online provided on the pouch/pack.
	+ Do not use cartridges beyond expiration date.
* Cartridges are sealed in individual pouches or portion packs and must remain in pouches until time of use.
* If a pouch/pack has been punctured, do not use the cartridge.

**Note:** See the ***Receiving New Cartridges, Liquid Quality Control and Calibration Verification Material*** section for information regarding the four-window temperature indicator included with cartridge shipment.

**Controls *i- STAT Controls and i-STAT TriControls for blood gases, electrolytes, and chemistries***

* Store at 2 - 8 °C (35 - 46 °F).
* Controls may be stored unopened at room temperature (18 - 30 °C or 64 - 86 °F) for five days.
* Do not use after expiration date on the box and ampules.

***ACT and PTplus Controls***

* Store at 2- 8 °C (35 - 46 °F).
* Controls should be used immediately after reconstitution.
* Do not use after expiration date on the box and vials.

***TBI and hs-TnI***

* Store frozen at ≤ -20 °C (-4°F) until the expiration date printed on the box and vial labels.
* Do not use beyond the expiration date on the box and vial labels.

***Electronic Simulator***

* Store at room temperature.
* While not in use, protect contact pads by use of plastic cap.
* Store in protective case.

# BLOOD TESTING

**For sample types, test timing, and collection options see the** *Instructions for Use (IFU)***,** *‘Cartridge and Test Information (CTI)’* **for i-STAT Cartridges and** *Section 8: Blood Collection* **in the i-STAT 1 System Manual located at** [www.globalpointofcare.abbott.](http://www.globalpointofcare.abbott./) Use information from these documents to populate this section of the Procedure Manual.

**Blood Volume** (See Table 1)

|  |
| --- |
| **Table 1: Cartridge Panel Configurations and Blood Volume** (shading denotes calculated values)  |
| Cartridge | Vol (mL) | pH | PCO2 | PO2 | Na | K | CI | iCa | GLU | BUN | Creat | Lact | Hct | TCO2 | ACT | PT/INR | hs-TnI | GFAP | UCH-L1 | HCO3 | TCO2 | SO2 | BE | Anion Gap | Hb |
| CHEM8+ | 95 |  |  |  | ● | ● | ● | ● | ● | ● | ● |  | ● | ● |  |  |  |  |  |  |  |  |  | ● | ● |
| CG8+ | 95 | ● | ● | ● | ● | ● |  | ● | ● |  |  |  | ● |  |  |  |  |  |  | ● | ● | ● | ● |  | ● |
| EG7+ | 95 | ● | ● | ● | ● | ● |  | ● |  |  |  |  | ● |  |  |  |  |  |  | ● | ● | ● | ● |  | ● |
| EG6+ | 95 | ● | ● | ● | ● | ● |  |  |  |  |  |  | ● |  |  |  |  |  |  | ● | ● | ● | ● |  | ● |
| CG4+ | 95  | ● | ● | ● |   |   |   |   |   |   |   | ● |   |   |   |   |   |   |   | ● | ● | ● | ● |   |   |
| G3+ | 95  | ● | ● | ● |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | ● | ● | ● | ● |  |  |
| G | 65  |   |   |   |   |   |   |   | ● |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Crea | 65  |   |   |   |   |   |   |   |   |   | ●  |  |   |   |   |   |   |   |   |   |   |   |   |   |   |
| ACT | 40  |   |   |   |   |   |   |   |   |   |   |   |   |   | ● |   |   |   |   |   |   |   |   |   |   |
| PT*plus* | 20  |   |   |   |   |   |   |   |   |   |   |   |   |   |   | ● |   |   |   |   |   |   |   |   |   |
| hs-TnI | 22  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | ● |   |   |   |   |   |   |   |   |
| TBI Plasma | 20  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | ● | ● |   |   |   |   |   |   |
| TBI | 20  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | ● | ● |   |   |   |   |   |   |

## Specimen Labeling

Unless the specimen is analyzed immediately after collection and then discarded, the specimen container must be labeled according to facility policy.

**Criteria for Specimen Rejection**

Use information from hospital policy to populate this section.

## Precautions: avoid the following circumstances

* Drawing a specimen from an arm with an I.V.
* Stasis (tourniquet left on longer than one minute before venipuncture)
* Extra muscle activity (fist pumping)
* Hemolysis (alcohol left over puncture site, or a traumatic draw)
* Icing before filling cartridge
* Time delays before filling cartridge, especially lactate, ACT and PT*plus*
* Exposing the sample to air when measuring pH, ***P***CO2, ***P***O2 and TCO2

## PROCEDURE FOR ANALYSIS – i-STAT 1

### Prerequisites

* Ensure cartridges and analyzers are at room temperature.
* Scan the cartridge barcode before opening the cartridge pouch/pack.
* Use a cartridge immediately after removing it from its protective pouch/pack. Prolonged exposure may cause a cartridge to fail a Quality Check.

### Procedure

1. Press to turn on analyzer.

1. Press for i-STAT.
2. Follow the analyzer prompts.
3. Scan the lot number on the cartridge pouch/pack.
	* Position barcode 3-9 inches from scanner window on analyzer.
	* Press and hold  to activate the scanner.
	* Align the red laser light so it covers the entire barcode.
	* The analyzer will beep when it reads the barcode successfully.
4. Continue normal procedures for preparing the sample, filling, and sealing the cartridge.
5. Push the sealed cartridge into the analyzer port until it clicks into place. Wait for the test to complete.

**Note:** For ACT, PT*plus*, hs-TnI, Hct, and immunoassay testing, the analyzer must remain on a level surface with the display facing up during testing. A level surface includes running the analyzer in the downloader/recharger.

1. Review results.

## PROCEDURE FOR ANALYSIS – i-STAT Alinity

### Prerequisites

* Ensure cartridges and analyzers are at room temperature.
* Scan the cartridge barcode before opening the cartridge pouch/pack.
* Use a cartridge immediately after removing it from its protective pouch/pack. Prolonged exposure may cause a cartridge to fail a Quality Check.


### Procedure

1. Press to turn on analyzer.
2. Press for i-STAT Alinity.

1. Scan the Operator ID.
	* Position barcode 3-9 inches from scanner window on analyzer.
	* On-screen graphic assists with scanning. After scanning is complete, the instrument will advance to the next step in the pathway.

* + To enter information manually, touch the  icon. A numeric keyboard displays automatically. For alpha, touch the Abc button. After entering the information, touch Enter, and the instrument will advance to the next step in the pathway.

1. Scan or Enter the Patient ID

1. Scan (Cartridge Pouch/Portion Pack Barcode)



1. This screen will display if more than one sample type is applicable.

1. Close and Insert the filled Cartridge

* + Below the Patient ID is the sample type selected from the previous screen or single sample type that is appropriate for the cartridge scanned. The action buttons at the bottom of the screen allow forward, backward and pause functionality

* + Once the cartridge is inserted, Contacting Cartridge will display followed by the countdown bar. This allows the user to estimate the time to results. Alerts such as Cartridge Locked and Instrument Must Remain Level are also displayed.

1. Results
	* When the test is complete, the test results are displayed as shown to the right.
	* An audible cue will be heard when results are ready. Touch **Silence** or remove cartridge to silence the audio.
	* The result page shown here is the default. The system administrator must specify the ranges used in your facility.
	* The blinking page button at the bottom of the screen appears when there is more than one page of results. All action tabs are inactive until the second page of results has been viewed.
	* Occasionally, numeric results will be replaced with the following symbols. When displayed, a new test must be performed.
		+ <> – Instrument cannot calculate the result.
		+ \*\*\* – (Starouts) Instrument is unable to determine a result

### Alternative Procedure

Should the i-STAT 1 or i-STAT Alinity Systems become inoperable for any reason, specimens should be collected and submitted to the laboratory in accordance with the Laboratory Procedure Manual.

# RESULTS

## Calculations

The i-STAT 1 and i-STAT Alinity Analyzers contain a microprocessor that performs all calculations required for reporting results.

## Displayed Results

Results are displayed numerically with their units. On the i-STAT 1 analyzer, electrolyte, chemistry and hematocrit results are also depicted as bar graphs with reference ranges marked under the graphs.

## Suppressed Results

There are three conditions under which the i-STAT 1 or i-STAT Alinity System will not display results:

1. Results outside the 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 **<**.

**Action:**

Send specimen(s) to the laboratory for analysis, if necessary.

1. Cartridge results which are not reportable based on internal QC rejection criteria are flagged with

**\*\*\***.

**Action:**

Analyze the specimen again using a fresh sample and another cartridge. If the specimen integrity is not in question, the results that are not suppressed should be reported in the usual manner. If the result is suppressed again, send specimen(s) to the laboratory for analysis in accordance with the Laboratory Procedure Manual.

1. A Quality Check message will be reported instead of results if the analyzer detects a problem with the sample, calibrant solution, sensors, or mechanical or electrical functions of the analyzer during the test cycle.

**Action:**

Take the action displayed with the message that identifies the problem. Refer to the Troubleshooting section of the i-STAT 1 System Manual if necessary.

## Printing and Transmitting Results

***Printing Results from the i-STAT 1 Analyzer to the i-STAT Printer Without Downloader or***

***Downloader/Recharger (i-STAT 1) or from the i-STAT Alinity analyzer to the i-STAT Printer without the***

***Base Station***

1. Turn printer on if green power light is not on.
2. Align IR windows of analyzer and printer.
3. Display results.
4. Press the Print key.
5. Do not move analyzer or printer until printing is complete.
6. If printer is not powered from a wall outlet, turn printer off.

***With Downloader or Downloader/Recharger (i-STAT 1) or with the Base Station (i-STAT Alinity)***

1. Place i-STAT 1 analyzer in Downloader or Downloader/Recharger or the i-STAT Alinity Analyzer in the Base Station that is wired to the printer.
2. Display results.
3. Press the Print key.
4. Do not move analyzer or printer until printing is complete.

***Printing more than one result – i-STAT 1***

* 1. Turn the analyzer on.
	2. Press the Menu key.
	3. Press 2 for Data Review.
	4. Press 7 for List.
	5. Scroll through the test records using the  and  keys.
	6. Press the numbered key for the test record(s). (Press the numbered key again to deselect a record.)
	7. Align analyzer and printer IR window or place in Downloader or Downloader/Recharger attached to printer. Press the Print key.
	8. Do not move analyzer or printer until printing is complete.
	9. If printer is not powered from a wall unit using the AC adapter, turn printer off.

***Transmitting Results from the i-STAT 1 Analyzer to the Data Manager as applicable***

* 1. Place analyzer in a Downloader or Downloader/Recharger.
	2. Do not move analyzer while the message “Communication in Progress” is displayed.

***Printing more than one result – i-STAT Alinity***

1. Turn the analyzer on
2. From the instrument's Home screen, touch More Options > Review Results > All Results
3. Scan or Enter Operator ID.
4. Choose results by touching the checkbox in front of the result identifier. Use Page ➡ key to advance the page if applicable.
5. Ensure that the instrument and the printer are on a flat, level and horizontal surface. Align the instrument's IR port with the printer IR window.
6. Touch Print Selected. An audible beep is heard when the instrument has successfully transmitted all results to the printer. Printer may still be printing when beep is heard. Please note that the i-STAT Alinity can only print one receipt at a time.

***Transmitting Results from the i-STAT Alinity to the Data Manager as applicable***

* 1. Place analyzer in the base station.
	2. Do not move analyzer while the message “Communication in Progress” is displayed.

# Reference Ranges,1, 2 Reportable Ranges, and Test Unit Conversions

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 system’s results have been shown to be valid. The following table contains the Reference Ranges (for adults) and Reportable Ranges applicable to the i-STAT 1 and i-STAT Alinity Systems.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  **ANALYTE**  |  **UNIT**  |  | **REFERENCE RANGE**  | **REPORTABLE**  |  **UNIT CONVERSION**  |
|  | **(arterial)**  | **(venous)**  | **RANGE**  |
| **Sodium**  | mmol/L (mEq/L)  |  | 138 – 146  | 138 – 146  | 100 – 180  | mmol/L x 1 = mEq/L Example: 140 mmol/L = 140 mEq/L  |
| **Potassium**  | mmol/L (mEq/L)  |  | 3.5 – 4.9  | 3.5 – 4.9  | 2.0 – 9.0  | mmol/L x 1 = mEq/L  |
| **Chloride**  | mmol/L (mEq/L)  |  | 98 – 109  | 98 – 109  | 65 – 140  | mmol/L x 1 = mEq/L  |
| **BUN**  | mg/dL  |  | 8 – 26  | 8 – 26  | 3 – 140  |   |
| **Glucose**  | mg/dL  |  | 70 – 105  | 70 – 105  | 20 – 700  | mg/dL x 0.055 = mmol/L Example: 100 mg/dL = 5.55 mmol/L  |
|
|   | g/L  |  | 0.70 – 1.05  | 0.70 – 1.05  | 0.20 – 7.00  | g/L x 5.556 = mmol/L  |
|   | mmol/L  |  | 3.9 – 5.8  | 3.9 – 5.8  | 1.1 – 38.9  |   |
| **Creatinine**  | mg/dL  |  | 0.6 – 1.3  | 0.6 – 1.3  | 0.2 – 20.0  | mg/dL x 88.4 = µmol/L  |
|   | µmol/L  |  | 53 – 115  | 53 – 115  | 18 – 1768  |   |
| **Ionized Calcium**  | mmol/L mg/dL  |  | 1.12 – 1.32 4.5 – 5.3  | 1.12 – 1.32 4.5 – 5.3  | 0.25 – 2.50 1.0 – 10.0  | mmol/L x 4 = mg/dL Example: 1.13 mmol/L x 4 = 4.52 mg/dL  |
| **pH**  |   |  | 7.35 – 7.45  | 7.31 – 7.41  | 6.50 – 7.80  | N/A  |
| ***P*CO2**  | mmHg  kPa  |   | 35 – 45  4.67 – 6.00  | 41 – 51 5.47 – 6.80  | 5 – 130  0.67 – 17.33  | mmHg x 0.133 = kPa Example: 35 mmHg x 0.133 = 4.66 kPa  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  **ANALYTE**  |  **UNIT**  | **REFERENCE RANGE**  | **REPORTABLE**  |  **UNIT CONVERSION**  |
| **(arterial)**  | **(venous)**  | **RANGE**  |
| ***P*O2**  | mmHg  kPa  | 80 – 105  10.7 – 14.0  | -- | 5 – 700  0.7 – 93.3  | mmHg x 0.133 = kPa Example: 83 mmHg x 0.133 = 11.04 kPa  |
| **TCO2**  |  mmol/L (mEq/L)  |  23 – 27  | 24 – 29  |  5 – 50  |  mmol/L x 1 = mEq/L  |
| **Hematocrit †**  | % PCV  Fraction  | 38 – 51  0.38 – 0.51  | 38 – 51 0.38 – 0.51  | 15 – 75  0.15 – 0.75  | % PCV x 0.01 = Volume fraction Example: 40% PCV = 0.40 PCV  |
| **Lactate**  | mmol/L  | 0.36 –1.25  | 0.90 – 1.70  | 0.30 – 20.00  | mmol/L x 9.01 = mg/dL  |
|   | mg/dL  | 3.2 – 11.3  | 8.1–15.3  | 2.7 – 180.2  |   |
| **HCO3 \***  | mmol/L (mEq/L)  | 22.0 – 26.0  | 23.0 - 28.0  | 1.0 – 85.0  | mmol/L x 1 = mEq/L  |
| **BE \***  | mmol/L (mEq/L)  | (-2) – (+3)  | (-2) – (+3)  | (-30) – (+30)  |   |
| **Anion Gap \***  | mmol/L (mEq/L)  | 10 – 20  | 10 – 20  | (-10) – (+99)  |   |
| **sO2 \***  | %  | 95 – 98  | - | 0 - 100  | % x 0.01 = fraction saturated  |
| **Hb\***  | g/dL  | 12 – 17  | 12 – 17  | 5.1 – 25.5  |  |
| **Celite ACT**  | sec  | 74 – 125 (PREWARM)  | 74 – 125 (PREWARM)  | 50 – 1000  |   |
|   |   | 84 – 139 (NONWARM)  | 84 – 139 (NONWARM)  |   |  |
| **Kaolin ACT**  | sec  | 74 – 137 (PREWARM)  | 74 – 137 (PREWARM)  | 50 – 1000  |   |
|   |   | 82 – 152 (NONWARM)  | 82 – 152 (NONWARM  |   |  |
| **PT*plus*** | INR sec   |  | - | 0.8 – 8.0 8.1 – 80.8  |   |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **ANALYTE**  | **UNIT**  | **REFERENCE RANGE**  | **REPORTABLE**  |  **UNIT CONVERSION**  |
|  **(arterial) (venous)**  | **RANGE**  |
| **GFAP**  | pg/mL   |  Cutoff: 65  | 47 - 10000  |  |
| **UCH-L1**  | pg/mL   | Cutoff: 360  | 87 - 3200  |  |
| **hs-TnI**  | ng/L (pg/mL)  | Female: 13\*\* Male: 28\*\*   | 2.9 – 1000.0  |  |

 \* Calculated values.

 † See CHEM8+ IFU for additional reference ranges.

 # Performance characteristics have not been established for INRs above 6.0.

\*\* Represents the 99th percentile upper reference limit (URL) of an apparently healthy population for the i-STAT hs-TnI test. Each facility should establish its own reference range using the i-STAT hs-TnI assay.

# Critical Results 3

Critical results are test results that fall outside high and low critical limits that define the boundaries of life- threatening values for a test. Follow facility policy regarding notification of the critical values observed. The table is an example and should not be used as the definitive values.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **ANALYTE (units)**  | **ADULT** **low**  |  **high** | **CHILDREN**  **low high**  | **NEONATES**  **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)  | 11  | 40  | 11  | 39  | –  | –  |
| Ionized Calcium (mmol/L)  | 0.78  | 1.58  | 0.74  | 1.57  | –  | –  |
| pH  | 7.21  | 7.59  | 7.21  | 7.59  | –  | –  |
| ***P***CO**2** (mmHg)  | 19  | 67  | 21  | 66  | –  | –  |
| ***P***O**2** (mmHg)  | 43  | –  | 45  | 124  | 37  | 92  |
| BUN (mg/dL)  | –  | 104  | –  | 55  | –  | 55  |
| Glucose (mg/dL)  | 46  | 484  | 46  | 445  | 32  | 328  |
| Creatinine  | –  | 7.4  | –  | 3.8  | –  | –  |
| Lactate  | – | – | – | – | – | – |
| Hematocrit (% PCV)  | 18  | 61  | 20  | 62  | 33  | 71  |
| Celite ACT  | – | – | – | – | – | – |
| Kaolin ACT  | – | – | – | – | – | – |
| PT*plus*  | – | – | – | – | – | – |
| GFAP  | – | – | – | – | – | – |
| UCH-L1  | – | – | – | – | – | – |
| Troponin-I/hs-TnI  | – | – | – | – | – | – |

# Interferences

An interferent is a substance which, if present at significant levels in the blood specimen being analyzed, will affect the results obtained for the analyte being measured. Refer to Instructions for Use or Cartridge and Test Information Sheets for details about interferences.

# QUALITY CONTROL

## Daily Procedures

***Analyzer Verification***

Verify the performance of each analyzer in the i-STAT 1 and i-STAT Alinity Systems using the internal or external Electronic Simulator every 24 hours of use.

**Action:**

External Electronic Simulator – if PASS is displayed on the analyzer screen:

* Remove the Electronic Simulator, place the cap back on and store in box.
* Use the analyzer as required.

Internal Electronic Simulator – If simulator test passes, results of cartridge being run will display. The Internal Electronic Simulator results are stored in the analyzer and data manager. **Remedial Action:**

External Electronic Simulator - If FAIL is displayed on the analyzer screen:

* Repeat testing with the same external Electronic Simulator
	+ If FAIL is displayed again, repeat test with a different external Electronic Simulator.

 If FAIL continues to display, contact Abbott Point of Care Technical Services. o If PASS is displayed, use the analyzer as required.

Internal Electronic Simulator - If FAIL is displayed on the analyzer screen (Internal Simulator Schedule – Lockout Enabled):

* Run the external Electronic Simulator.
	+ If FAIL is displayed contact Abbott Point of Care Technical Services.
	+ If PASS is displayed, use the analyzer as required.

***Verification of Cartridge Storage Conditions***

## Refrigerated Cartridges

* Verify that the cartridges stored in the refrigerator are all within the expiration date printed on the boxes.
* For expired cartridges, follow facility policy for removal from use.
* Verify that the refrigerator did not exceed the limits of 2 - 8 °C (35 - 46 °F).
* Document per facility or hospital policy

**Action:**

If the temperature of the cartridge storage refrigerator is within the range of 2 - 8 °C (35 - 46 °F) use cartridges as required.

**Remedial Action:**

If the temperature is outside the range of 2 - 8 °C (35 - 46 °F):

* Quarantine the cartridges.
* Notify the i-STAT System coordinator.
* DO NOT USE the cartridges
* Document per facility or hospital policy.

## Room Temperature Cartridges

* Verify that all cartridges at room temperature do not exceed room temperature expiration date written on the cartridge pouch/pack.
* For expired cartridges, follow facility policy for removal from use.
* Verify that room temperature has not exceeded 30 °C (86 °F).
* Document per facility or hospital policy.

**Action:**

If the measured temperature of the room has been continuously below 30 °C (86 °F) use cartridges as required.

**Remedial Action:**

If the measured room temperature has exceeded 30 °C (86 °F) for any period of time:

* Quarantine the cartridges.
* Notify the i-STAT System coordinator.
* DO NOT USE the cartridges.
* Document per facility or hospital policy.

**Monthly Procedures**

Review schedule based on facility or hospital policy.

**Every 6 Months Procedures**

## Update i-STAT 1 and i-STAT Alinity Analyzers Software

* Update the software as provided by Abbott Point of Care.
* Perform an external Electronic Simulator test after software update.
* Verify thermal probe reading as described below.

## Thermal Probe Check Procedure – i-STAT 1

1. Equilibrate the analyzer and simulator to the same room temperature for 30 minutes. Handle the simulator as little as possible to maintain its thermal uniformity and stability.

1. Insert the simulator into the analyzer.

1. When results are displayed, press the period key to view the difference between the thermal probes.

1. Interpretation of the thermal check value:
	* Acceptable: a value from -0.1 to +0.1, inclusive
	* Repeat the procedure if FAIL is displayed with a “t” Quality Check Code or a value less than -0.1 or greater than 0.1 is displayed.
	* If --.-- is displayed, partially insert the simulator into the analyzer and let stand for 15 minutes before inserting all the way to repeat the test.
	* Contact Technical Services if the repeat thermal check value is greater than 0.1 or less than -0.1 or if a Quality Check Code is displayed.

## Thermal Probe Check Procedure – i-STAT Alinity

1. Equilibrate the analyzer and simulator to the same room temperature for 30 minutes. Handle the simulator as little as possible to maintain its thermal uniformity and stability.

1. From the Home screen, touch More Options > Quality Options > Perform Electronic Simulator Test and then follow the screen prompts.

1. Insert the Electronic Simulator into the instrument.

1. When results are displayed, the difference between the thermal probes can be viewed on the instrument’s screen by touching the View Entered Infotab on the right side of the screen.

1. Interpret the thermal probe check value:
	* Acceptable: PASS
	* Not acceptable: FAIL message with a Quality Check Failure Code. Repeat the procedure to confirm results. If the repeat test fails contact Technical Support.

**Miscellaneous Procedures as Needed**

## Receiving New Cartridges, Liquid Quality Control and Calibration Verification Material

 Verify that the transit temperatures were satisfactory by reading the temperature strip included in each shipping container.

## Receiving New or Replacement Analyzers

 Use the Electronic Simulator, internal or external, to verify operation of a new or replacement analyzer before use.

**Procedure for testing cartridges with TriControls or i-STAT Controls:**

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 (G, Crea or CHEM8+) ampules may be used once the fluid has reached room temperature, approximately 30 minutes for individual ampules. 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***CO2, or ***P***O2 (EG6+, EG7+, CG4+, CG8+ or CHEM8+) a separate ampule must be used for each cartridge being tested; if these sensors are not present (i.e., the G and Crea cartridges), 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.
2. When testing on the i-STAT 1, access the Control option under Quality Tests in the Administration Menu. Enter the required information. The analyzer allows 15 minutes (or the customized timeout period) to insert the cartridge after the last data entry.
3. Immediately before use, shake the ampule vigorously for 5 to 10 seconds to equilibrate the liquid and gas phases. To shake, hold the ampule at the top 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 neck.
4. Immediately transfer the solution from the ampule into a plain capillary tube or plain syringe, and then immediately transfer the solution into a cartridge. Immediately 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 (1 cc or 3 cc syringes with 16- to 20- gauge needles are recommended), slowly draw approximately 1 cc 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.
	* Do not use solution left in the syringe, ampule, or capillary tube for additional testing of the cartridges that contain sensors for ionized calcium, pH, ***P***CO2, or ***P***O2. However, cartridges without these sensors may be tested with remaining fluids if within 10 minutes of opening the ampule.
5. Compare results to the Value Assignment Sheet (VAS) ranges. 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. If all results are within expected ranges, use the cartridges as needed.

**Remedial Action:**

If any results are outside the published expected ranges:

* + Test using a new box of control solutions and a new cartridge.
	+ If results are still out of range, quarantine the suspect cartridge lot.
	+ DO NOT USE the cartridges from the suspect lot.
	+ Document per facility or hospital policy.

## Procedure for testing cartridges with i-STAT ACT or PT*plus* Controls on the i-STAT 1 Analyzer

1. Prior to use, allow one vial each of the lyophilized plasma and calcium chloride reconstituting fluid to stand at room temperature for a minimum of 45 minutes.
2. Access the Control option under Quality Tests in the Administration Menu. Enter the required information. The analyzer allows 15 minutes (or the customized timeout period) to insert the cartridge after the last data entry.
3. Remove the cap and stopper from the vials and pour the entire contents of the calcium chloride vial into the lyophilized plasma vial. Place the stopper back on the reconstituted vial.
4. Allow the vial to sit for 1 minute and then mix the contents by swirling gently for 1 minute, then inverting slowly for 30 seconds.
5. Use a plastic pipette, plastic syringe, or plastic capillary tube without anticoagulant to transfer the solution to an ACT cartridge.
6. Immediately seal the cartridge and insert it into an analyzer. This process must be completed within 30 seconds of the complete reconstitution of the control sample.
7. Compare results to the Value Assignment Sheet (VAS) ranges. If results are within the expected ranges, use the cartridges as needed.

**Remedial Action:**

If any results are outside the VAS ranges:

* + Repeat test using vials from new box of controls and a new cartridge.
	+ If results are still out of range, quarantine the suspect cartridge lot.
	+ DO NOT USE the cartridges from the suspect lot.
	+ Document per facility or hospital policy.

## Procedure for testing cartridges with i-STAT 1 hs-TnI controls

1. On the i-STAT 1 Analyzer, access the Control option under Quality Tests in the Administration Menu. Enter the required information. The analyzer allows 15 minutes (or the customized timeout period) to insert the cartridge after the last data entry.
2. The controls are housed in dropper vials to enable convenient transfer of the fluid from the vial into the cartridge. Before transferring the fluid to the cartridge, gently invert the vial at least 10 times to ensure homogeneity.
	* Note: To minimize foaming of the control sample, avoid vigorous or rapid mixing motion.
3. Remove the cap and direct the dropper tip into the cartridge sample well. Fill the cartridge to the fill mark.
4. Seal the cartridge and immediately insert it into the i-STAT 1 Analyzer.

Compare results to the Value Assignment Sheet ranges. If results are within the expected ranges, use the cartridges as needed.

## Procedure for testing cartridges with i-STAT Alinity TBI Controls

1. On the i-STAT Alinity, access the Control option from the Home screen by touching More Options > Quality Options > Quality Control. Select the button that is appropriate for the testing. Continue to follow the prompts on the screen. Enter the required information. The analyzer allows 15 minutes (or the customized timeout period) to insert the cartridge after the last data entry.
2. The controls are housed in dropper vials to enable convenient transfer of the fluid from the vial into the cartridge. Before transferring the fluid to the cartridge, gently invert the vial at least 10 times to ensure homogeneity.
* Note: To minimize foaming of the control sample, avoid vigorous or rapid mixing motion.
1. Remove the cap and direct the dropper tip into the cartridge sample well. Fill the cartridge to the fill mark.
2. Seal the cartridge and immediately insert it into the i-STAT Alinity Analyzer.
3. Compare results to the Value Assignment Sheet ranges. If results are within the expected ranges, use the cartridges as needed.

**Remedial Action:**

If any results are outside the published expected ranges:

* 1. Repeat the test using a new box of controls and a new cartridge.
	2. If result is still out of range, quarantine the suspect cartridge lot.
	3. DO NOT USE cartridges from the suspect lot.
	4. Document per facility or hospital policy.

# CALIBRATION

For blood gas and chemistry cartridges, a one-point calibration is automatically performed as part of the test cycle each time a cartridge is tested. A multi-point calibration curve, defined by coefficients in the CLEW software, are stable over many lots and are adjusted as needed with the CLEW updates scheduled two times a year. Operator intervention is not necessary.

# PRINCIPLES OF MEASUREMENT

**Sodium, Potassium, Chloride, Ionized Calcium, pH, and *P*CO2** are measured by ion-selective electrode 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 lactate concentration.

***P*O2** 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.

## Hematocrit

is determined conductometrically. The measured conductivity, after correction for electrolyte concentration, is inversely related to the hematocrit.

**ACT** is determined amperometrically. The conversion of a thrombin substrate is initiated by mixing a whole blood sample (without anticoagulant) with a particulate clotting activator – either Celite brand diatomaceous earth or kaolin. The substrate used in the electrogenic assay has an amide linkage that mimics the thrombin-cleaved amide linkage in fibrinogen. The product of the thrombin-substrate reaction is the electroactive compound that is detected amperometrically. The time of detection is measured in seconds and the result is reported as a whole blood time (WBT).

**PT*plus*** measures prothrombin time electrochemically. Coagulation is initiated by exposing a whole blood sample to tissue thromboplastin. Unlike traditional tests that detect fibrin formation, the i-STAT PT*plus* test uses an electrochemical sensor to detect the conversion of a thrombin substrate. The time of detection is measured in seconds and the result is reported as an International Normalized Ratio (INR).

**TBI** measures GFAP and UCH-L1 in whole blood using the i-STAT Alinity instrument. It aids in evaluating patients (18+) with suspected mild traumatic brain injury (Glasgow Coma Scale score 13-15) based on specific clinical criteria. The test helps determine the need for a head CT scan and is used with venous whole blood collected with EDTA anticoagulant in point-of-care or clinical laboratory settings.

## hs-TnI

The i-STAT High Sensitivity Troponin-I (i-STAT hs-TnI) test is an immunoassay test for cardiac troponin I. The i-STAT hs-TnI test uses an enzyme-linked immunosorbent assay (ELISA) method with electrochemical detection of the resulting enzyme signal. The test reports a quantitative measurement of the sample concentration of cTnI in units of ng/L.

## TCO2

The measured TCO2 test method is calibrated to the International Federation of Clinical Chemistry (IFCC) TCO2 reference method with an algorithm based on the Henderson-Hasselbach equation, which uses pH, ***P***CO2, and ionic strength (Na) measurements.

# REFERENCES

1. Statland, B.E., Clinical Decision Levels for Lab Tests. Medical Economics Books. 1987.
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.
3. Kost, Gerald J., Using critical limits to improve patient outcome. Medical Laboratory Observer. March 1993; 25(3): 22–27.

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PREPARED BY: DATE:

 Adopted: Date:

 Reviewed: Date:

 Reviewed: Date:

 Revised: Date:

Revised: Date:

# i-STAT QC LOG: INCOMING QC

 **Cartridge Type:** \_\_\_\_\_\_\_\_\_\_\_\_ \_\_ **Lot No.:** \_\_\_\_\_\_\_\_\_\_\_\_\_ **Rec’d. Date:** \_\_\_\_\_\_\_\_\_\_\_\_ **Quant.:** \_\_\_\_\_\_\_\_\_\_\_\_ **Temp. Strip:** \_\_\_\_\_\_\_\_\_\_\_\_

**Control Name:**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Lot No.:** \_\_\_\_\_\_\_\_\_\_\_\_­­\_\_\_\_ **Level:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Exp. Date:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_ **CLEW:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_

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| **Results**  |   |   |   |   |   |   |   |   |   |

**Control Name:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_­  **Lot No.:**\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Level:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Exp. Date:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_ **CLEW:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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# i-STAT QC ACTION LOG

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# i-STAT QC LOG: EXPIRATION DATE AND STORAGE CONDITIONS: REFRIGERATED

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# i-STAT QC LOG: EXPIRATION DATE AND STORAGE CONDITIONS: ROOM TEMPERATURE

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 **i-STAT ELECTRONIC SIMULATOR LOG FOR ANALYZER, SERIAL NUMBER: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_YEAR: \_\_\_\_\_\_\_\_\_\_\_\_\_**

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# i-STAT ELECTRONIC SIMULATOR ACTION LOG

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