

Procedure Manual

for the i-STAT[®] System

This Procedure Manual is intended to be a template for the Procedure Manual required by CLIA and laboratory accreditation bodies. This Procedure Manual should be customized for site-specific policies and procedures. This Procedure Manual is not intended to replace the System Manual.

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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 Analyzer

When a sample-filled i-STAT cartridge is inserted into the i-STAT 1 handheld for analysis, the handheld 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 seconds (16.7 min.)
- PT/INR cartridge: to detection of end point – up to 300 seconds (5 min.)
- cTnI and BNP cartridges: 600 seconds (10 min.)
- CK-MB Cartridge: 300 seconds (5 min.)
- Other cartridges: typically 130 to 200 seconds

Cartridges

A single-use disposable cartridge contains microfabricated sensors, a calibrant solution, fluidics system, and a waste chamber. Sensors for analysis of pH, PCO_2 , PO_2 , TCO_2 , 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/INR, Troponin I/cTnI, CK-MB and BNP (Table 1). A whole blood sample of approximately 1 to 3 drops is dispensed into the cartridge sample well, and the sample well is sealed before inserting it into the analyzer.

Central Data Station or Data Manager

A dedicated desktop computer with the i-STAT Central Data application provides the primary information management capabilities for the i-STAT System. Downloaders and Downloader/Rechargers for the i-STAT 1 Analyzer allow for transmission of patient records from a widely distributed network of handhelds to the Central Data Station application. Data can be stored, organized, edited, and transferred to a laboratory information system or other computer system. Cartridge usage and efficiency reports can be generated for management of the System.

SUPPLIES and STORAGE REQUIREMENTS

Cartridges

Cartridges are sealed in individual pouches or portion packs. Store the main supply of cartridges at a temperature between 2 to 8°C (35 to 46°F). **Do not allow cartridges to freeze.** Cartridges may be stored at room temperature (18 to 30°C or 64 to 86°F) for the time frame indicated on the cartridge box. Cartridges should not be returned to the refrigerator once they have been at room temperature, and should not be exposed to temperatures above 30°C (86°F). If the pouch has been punctured, the cartridge should not be used. Write the date on the cartridge box or individual cartridge pouches to indicate the room temperature expiration date. Cartridges should remain in pouches until time of use. Do not use after the labeled expiration date.

Note: See the Check Temperature Monitor section for information regarding the four-window temperature indicator shipped with cartridges during transit.

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Controls

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

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

i-STAT Controls for ACT and PT/INR

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

i-STAT Controls for cTnI, BNP, and CK-MB

These controls require no reconstitution or frozen storage. They are stable until the expiration date on the vial label when stored unopened at 2 to 8°C. Once opened, the i-STAT cTnI, BNP, and CK-MB Controls are stable for 30 days when stored tightly capped at 2 to 8°C.

CLINIQA Liquid Cardiac Marker Control for CK-MB

This control requires no reconstitution or frozen storage. It is stable until the expiration date on the vial label when stored unopened at 2 to 8°C. Once opened, CLINIQA Liquid Cardiac Marker Control is stable for 30 days when stored tightly capped at 2 to 8°C.

RNA Medical Hematocrit Control

RNA Medical Hematocrit Control is stable until the expiration date stated on the ampule when stored at temperatures of 2 to 25°C. Do not freeze or expose ampules to temperatures greater than 30°C. If stored refrigerated, the control material should be equilibrated to room temperature for at least 4 hours prior to testing.

Electronic Simulator

Store at room temperature and protect contact pads from contamination by replacing the plastic cap and placing the Electronic Simulator in its protective case after use.

BLOOD SPECIMENS

Blood Collection Equipment

Cartridges for Blood Gas/Electrolytes/Chemistries/Hematocrit

- Skin puncture: lancet and capillary collection tube (plain, lithium heparin, or balanced heparin for electrolytes and blood gases)
- Venipuncture: lithium or sodium heparin collection tubes and disposable transfer device.
- Arterial puncture: Plain syringe or blood gas syringe with heparin and labeled for the assays performed or with the least amount of heparin to prevent clotting (10 U heparin/mL of blood)

Cartridges for ACT

- Skin puncture: not recommended
- Venipuncture and arterial puncture: plain plastic syringe without anticoagulant

Cartridges for PT/INR

- Skin puncture: lancet only needed. Cartridge can be filled directly from the finger.
- Venipuncture: plain plastic syringe without anticoagulant.

Cartridges for Troponin I/ cTnI and CK-MB

- Skin puncture: not recommended.
- Venipuncture: lithium or sodium heparin collection tubes and disposable transfer device (e.g. 1 cc syringe and a. Alternately, 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.

Cartridges for BNP

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- Skin puncture: not recommended.
- Venipuncture: plastic EDTA collection tubes and disposable transfer device or plastic EDTA syringe.

Blood Volume

See Table 1 below for cartridge volumes.

Table 1: Cartridge Panel Configurations and Blood Volume

(Shading denotes calculated values)

Cartridge	Vol. μ L	pH	PCO ₂	PO ₂	Na	K	Cl	iCa	Glu	BUN	Creat	Lact	Hct	TCO ₂	ACT	PT/INR	CK-MB	cTnI	BNP	HCO ₃	TCO ₂	SO ₂	BE	Anion Gap	Hb	
CHEM8+	95				•	•	•	•	•	•	•		•	•										•	•	
CG8+	95	•	•	•	•	•		•	•				•								•	•	•	•		•
EG7+	95	•	•	•	•	•		•					•								•	•	•	•		•
EG6+	95	•	•	•	•	•							•								•	•	•	•		•
CG4+	95	•	•	•								•									•	•	•	•		
G3+	95	•	•	•																	•	•	•	•		
EC8+	65	•	•		•	•	•		•	•			•								•	•	•	•	•	•
6+	65				•	•	•		•	•			•												•	•
EC4+	65				•	•			•				•												•	•
E3+	65				•	•							•												•	•
G	65								•																	
Crea	65										•															
ACT	40													•												
PT/INR	20															•										
cTnI	17																	•								
CK-MB	17																•									
BNP	17																		•							

Suitable Specimens for Cartridges for Blood Gases, Electrolytes, Chemistries, and Hematocrit

- Fresh whole blood collected in a plain capillary collection tube or capillary collection tube with balanced heparin.
- Fresh whole blood collected in a collection tube with lithium or sodium heparin anticoagulant. Fill collection tubes to capacity.
- Fresh whole blood collected in a plain plastic syringe or in a blood gas syringe labeled for the assays to be performed. Fill syringes for correct blood-to-heparin ratio.

Suitable Specimens for ACT

- Fresh whole blood without anticoagulant collected in a plastic syringe. If from an indwelling line, flush the line with 5mL saline and discard the first 5mL of blood or six dead space volumes of the catheter.
- Fresh whole blood collected in a plastic tube without anticoagulant, clot activators, or serum separators. Device used to transfer sample to cartridge must be plastic.

Suitable Specimens for PT/INR

- Fresh whole blood without anticoagulant collected in a plastic syringe or plastic evacuated tube without clot activators or serum separators. Device used to transfer sample to cartridge must be plastic.
- Fresh capillary whole blood dispensed directly into the cartridge from the finger.

Suitable Specimens for Troponin I/cTnI and CK-MB

- Fresh heparinized whole blood or plasma samples collected in syringes or evacuated tubes containing lithium or sodium heparin. Fill collection tube to capacity.
- Non heparinized whole blood samples tested within one minute of patient draw collected into a plastic syringe or plastic evacuated tube containing no additives.

Suitable Specimens for BNP

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- ❑ EDTA whole blood plasma samples collected in plastic syringes or evacuated tubes containing EDTA. Fill collection tubes to capacity.

Specimen Labeling

Unless the specimen is analyzed immediately after collection and then discarded, the specimen container must be labeled with the following information:

Patient name, sex, age
Patient ID number
Time and date of collection
Phlebotomist ID
Doctor's name

Specimen Collection and Handling

In-Dwelling Line

Back flush line with sufficient amount of blood to remove intravenous solution, heparin, or medications that may contaminate the sample. Recommendation: five to six times the volume of the catheter, connectors, and needle. If collecting sample for ACT, clear the line first with 5mL saline and discard the first 5mL of blood or six dead space volumes of the catheter.

Arterial Specimens

For cartridge testing of blood gases, electrolytes, chemistries, and hematocrit, fill a plain syringe or fill a blood gas syringe, labeled for the assays to be performed, to the recommended capacity, or use the least amount of liquid heparin anticoagulant that will prevent clotting. Under-filling syringes containing liquid heparin will decrease results due to dilution and will decrease ionized calcium results due to binding. For ionized calcium, balanced or low volume heparin blood gas syringes should be used. Do not expose sample to air or PCO_2 may decrease, pH may increase and PO_2 may decrease if the value is above or increase if the value is below the PO_2 of room air (approximately 150 mmHg).

For cartridge testing of ACT, use only a plain, plastic syringe without anticoagulant.

Mix blood and anticoagulant by rolling syringe between palms for at least 5 seconds each in two different directions, then invert the syringe repeatedly for at least 5 seconds. Discard the first two drops of blood. For blood gas testing, avoid or remove immediately any air drawn into syringe to maintain anaerobic conditions.

Test samples collected without anticoagulant immediately. Test samples for ACT and lactate immediately. For pH, blood gases, TCO_2 and ionized calcium, test within 10 minutes of collection. If not tested immediately, remix the sample and discard the first two drops of blood from a syringe before testing. Note that it may be difficult to properly remix a sample in a 1.0 cc syringe. For other cartridge tests, test sample within 30 minutes of collection.

Venous Specimens

For cartridge testing of electrolytes, chemistries, and hematocrit, collect sample into an evacuated blood collection tube or a syringe containing sodium, lithium, or balanced heparin anticoagulant. For ionized calcium measurements, balanced heparin or 10 U of sodium or lithium heparin/mL of blood is recommended. Fill tubes to capacity; fill syringes for correct heparin-to-blood ratio. Incomplete filling causes higher heparin-to-blood ratio, which will decrease ionized calcium results and may affect other results. The use of partial – draw tubes (evacuated tubes that are adjusted to draw less than the tube volume, e.g. a 5 mL tube with enough vacuum to draw only 3 mL) is not recommended for blood gas or CHEM8+ cartridges because of the potential for decreased PCO_2 , HCO_3 and TCO_2 values.

For cartridge testing of ACT or PT/INR, use only a plain, plastic syringe or collection tube containing no anticoagulant. Use a plastic capillary tube, pipette, or syringe to transfer sample from a tube to a cartridge.

For glucose cartridge testing, EDTA is also an acceptable anticoagulant. ***EDTA is the only acceptable anticoagulant for BNP Cartridge testing.***

Mix blood and anticoagulant by inverting a tube gently at least ten times. Roll a syringe vigorously between the palms for at least 5 seconds each in two different directions, then invert the syringe repeatedly for at least 5 seconds, then discard the first two drops of blood. Note that it may be difficult to properly mix a sample in a 1 cc syringe.

Test Sample collected without anticoagulant immediately. Test samples for ACT, lactate and PT/INR immediately. Test samples for pH, PCO_2 , TCO_2 and ionized calcium within 10 minutes of sample draw. If not tested immediately, remix the

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sample before testing and discard the first two drops of blood from a syringe before testing. For the glucose test strip and other cartridge tests, test sample within 30 minutes of collection.

Finger and Heelstick Specimens

For tests other than PT/INR, wipe away the first drop of blood, which contains excess tissue fluid which can increase the potassium result and decrease other test results. Avoid drawing air into the capillary tube. Use balanced heparin or plain capillary tubes for ionized calcium. Test samples immediately to avoid clotting (especially in neonates). **Capillary samples are NOT recommended for ACT, Troponin I/cTnI, CK-MB and BNP.**

Criteria For Specimen Rejection

- Evidence of clotting
- Specimens collected in vacuum tubes with anticoagulant other than lithium or sodium heparin (or EDTA for BNP or glucose cartridges).
- Specimens for ACT or PT/INR collected in glass syringes or tubes or with anticoagulant of any kind
- Syringe for pH, PCO_2 , PO_2 and TCO_2 with air bubbles in sample
- Incompletely filled vacuum tube for the measurement of ionized calcium, PCO_2 , HCO_3 or TCO_2
- Other sample types such as urine, CSF, and pleural fluid

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/INR
- Exposing the sample to air when measuring pH, PCO_2 , PO_2 and TCO_2 .

PROCEDURE FOR ANALYSIS

Preparation for Use

An individual cartridge may be used after standing 5 minutes, in its pouch, at room temperature. An entire box should stand at room temperature for one hour before cartridges are used.

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CUSTOMIZING THE i-STAT 1 HANDHELD TO RUN i-STAT CARTRIDGES

Before testing barcoded cartridges, the i-STAT 1 Handheld must be customized for the following options:












- Cartridge Information First Required, AND
- Cartridge Lot Number Required

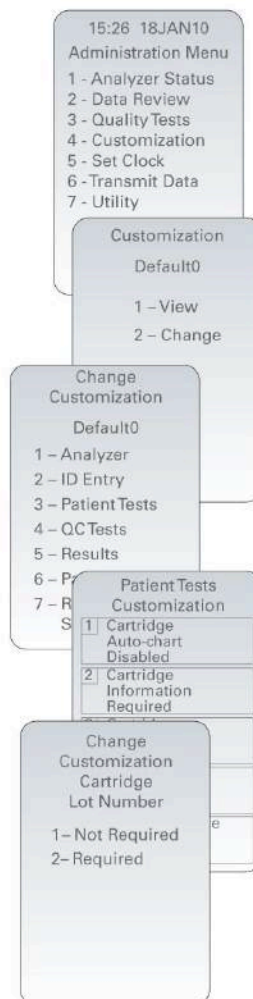
The procedure to customize the Handheld varies, depending on whether the customization is being done directly using the Handheld's keypad, or whether it is being done through the Customization Workspace in Central Data Station (CDS) Version 5 or i-STAT/DE.

- Users who do not have CDS Version 5 or i-STAT/DE → Proceed to Section A
- Users who have CDS Version 5 → Proceed to Section B
- Users who have i-STAT/DE → Proceed to Section C

A. Customizing the Handheld for Cartridge Testing Using the Handheld Keypad

Cartridge use requires operators to turn on the Handheld, enter an Operator ID and Patient ID, and then scan the cartridge lot number before inserting a cartridge into the Handheld for testing. To customize the Handheld:

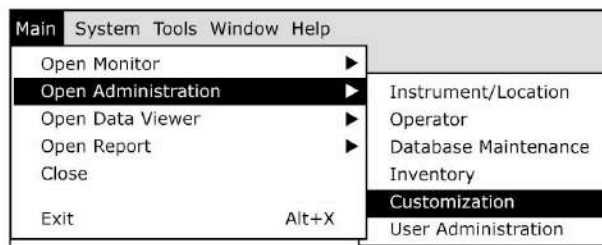
1. Press  to turn on the Handheld.
2. Press  to change screen to Administration Menu.
3. Press  (Customization).
4. Press  (Change).
5. Press  (No password is required).
6. Press  (Patient Tests).
7. Press  (Cartridge Information).
8. Press  to change setting to "Required".
9. Press  (Cartridge Lot Number).
10. Press  to change setting to "Required".
11. Both "Cartridge Information" and "Cartridge Lot Number" should be now appear on display as "Required".
12. Press  to turn Handheld off and save the settings. (If settings are not shown as "Required", return to Step 7).



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B. Customizing the Handheld for Cartridge Testing Using CDS Version 5

1. Click on **Main** → **Open Administration Function** → **Customization**.



2. Type in your password and click OK. The default password is the word *istat*.



3. Make sure the **Enable Customization** box has a check mark in it.



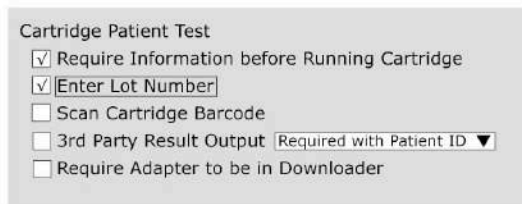
Also, make certain that the **Enable Updates** box is checked for the particular location to which this i-STAT 1 Handheld is assigned.

Location-based customization profiles:							
Location	Enable Updates	Use Default Profile	Update CLEW	i-STAT Analyzer CLEW	Philips BAM CLEW	Preferences	STATNotes
A_10.10.90.17	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	A18		DEFAULT0	CHART0
A_10.10.90.24	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	A18		DEFAULT0	CHART0
A_10.10.90.31	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	A18		DEFAULT0	CHART0
A_10.10.90.32	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	A18		DEFAULT0	CHART0

4. If the location where this Handheld is assigned has a check mark under the **Use Default Profile** column, double click on the alphanumeric code under **Preferences** in the **Default Customization Profile** column. Otherwise, double click on the alphanumeric code under **Preferences** for the specific location to which this Handheld is assigned.

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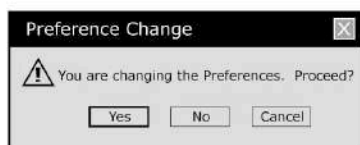
- Once the **Preferences** screen opens, click on the **Test** tab.
- At the top of the **Test** tab screen, check the box next to **Require Information before Running Cartridge** and **Enter Lot Number**.



Cartridge Patient Test

- Require Information before Running Cartridge
- Enter Lot Number
- Scan Cartridge Barcode
- 3rd Party Result Output Required with Patient ID ▼
- Require Adapter to be in Downloader

- Click **OK** and answer **YES** to the question about changing the preferences.



- Download the Handheld(s) to the CDS from a downloader in the location to which this Handheld is assigned. This action should upload the chosen customization features into the Handheld. Repeat step 8 for all Handhelds from this same location to be customized. To customize Handhelds from other locations for the same features, return to step 1.

C. Customizing the Handheld for Cartridge Testing Using i-STAT/DE

- Access the Customization Workspace
 - RALS-Plus Users:
 - RALS-Plus application, pick i-STAT from the drop-down menu.
 - Click on **Device Customization**
 - PrecisionWeb Users:
 - Double click on the desktop shortcut or Internet Explorer Favorites for **i-STAT Customization**.
- Make sure the "**Enable Customization**" box has a check mark in it.



Enable Customization

Also, make certain that the **Enable Updates** box is checked for the particular location to which this i-STAT 1 Handheld is assigned.

Location	Enabled
ER	<input checked="" type="checkbox"/>
Lab	<input checked="" type="checkbox"/>

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- If the location where this Handheld is assigned has a check mark under the **Use Default Profile** column, double click on the alphanumeric code under **Preferences** in the **Default Customization Profile** column. Otherwise, double click on the alphanumeric code under **Preferences** for the specific location to which this Handheld is assigned.
- Once the **Preferences** screen opens, click on the **Test** tab.

The screenshot shows the 'Test' tab of the i-STAT Preferences screen. At the top, there are tabs for 'Instrument', 'ID Entry', 'Test', 'QC', 'Results', 'Analyte Enable', and 'Strip Lots'. Below the tabs, there are several settings:

- Password: []
- Date Format: mm/dd/yy
- Inactivity Timeout: 120 seconds
- Sound
- Autotransmit
- Memory Full Action: Lock Out
- Batch Mode Timeout: 1 minutes
- Display Password for Clock Page
- Enable PCx Glucose
- Synchronize Clock to CDS
- Apply Operator List to Viewing Stored Patient Records
- Limit Number of Records in Transmit All to: 14 days

At the bottom, there are two sections:

- Upload Schedules:** Off, Every [] hours, Schedule Options: When []
- i-STAT Reserved Data:** []

- At the top of the **Test** tab screen, check the box next to **Require Information before Running Cartridge and Enter Lot Number**.

The screenshot shows the 'Cartridge Patient Test' settings. The following options are visible:

- Require Information before Running Cartridge
- Enter Lot Number
- Scan Cartridge Barcode
- 3rd Party Result Output: Required with Patient ID
- Require Adapter to be in Downloader

- Click OK and answer YES to the question about changing the preferences.







- Download the Handheld(s) to the CDS from a downloader in the location to which this Handheld is assigned. This action should upload the chosen customization features into the Handheld. Repeat step 7 for all Handhelds from this same location to be customized. To customize Handhelds from other locations for the same features, return to step 1.

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Procedure for Cartridge Testing

- **DO NOT** insert cartridge to start test
- **DO NOT** open cartridge pouch before scanning the barcode (if applicable)
- If Quality Check Codes 69, 140, or 147 appear, see Analyzer Coded Messages Technical Bulletin for Troubleshooting Information

1. Press  to turn on Handheld.
2. Press  for i-STAT Cartridge
3. Follow Handheld prompts.
4. Scan the lot number on the cartridge pouch.
 - Position barcode 3-9 inches from scanner window on the Handheld.
 - Press and hold  to activate the scanner.
 - Align the red laser light so it covers the entire barcode.
 - The Handheld will beep when it reads the barcode successfully.

Note: If the cartridge pouch does not have a barcode, enter the lot number manually using the numbered keys or press  to bypass this prompt. You may ignore any letters in the lot number.

5. Continue normal procedures for preparing the sample, filling and sealing the cartridge.
6. Push the sealed cartridge into the Handheld port until it clicks into place. Wait for the test to complete.

Note: For ACT, PT/INR, Hct, and immunoassay testing, the Handheld must remain on a level surface with the display facing up during testing. A level surface includes running the handheld in the downloader/recharger.

7. Review results



Alternative Procedure

Should the i-STAT System 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 handheld contains a microprocessor that performs all calculations required for reporting results.

Displayed Results

Results are displayed numerically with their units. 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 System will not display results:

1. 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 dependant on the result of a test flagged as either > or <.

Action:

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

2. 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.

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

Action:

Take the action displayed with the message that identifies the problem. Refer to the i-STAT or i-STAT 1 System Manual's Troubleshooting section or the "Analyzer Coded Messages" Technical Bulletin if necessary.

Printing and Transmitting Results

Printing Results from the i-STAT 1 Analyzer to the Martel Portable Printer or to the i-STAT Printer

Without Downloader or Downloader/Recharger

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

With Downloader or Downloader/Recharger

1. Place handheld in Downloader or Downloader/Recharger that is wired to the printer.
2. Display results.
3. Press the Print key.
4. Do not move handheld or printer until printing is complete.

Printing more than one result

1. Turn the handheld 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.

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6. Press the numbered key for the test record(s). (Press the numbered key again to deselect a record.)
7. Align handheld and printer IR window or place in Downloader or Downloader/Recharger attached to printer. Press the Print key.
8. Do not move handheld 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

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

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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 System.

Cartridges

ANALYTE	UNIT	REFERENCE RANGE		REPORTABLE RANGE	UNIT CONVERSION
		(arterial)	(venous)		
Sodium	mmol/L (mEq/L)	138 – 146	138 - 146	100 – 180	mmol/L x 1 = mEq/L <u>Example:</u> 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	mg/dL BUN x 0.357 = mmol urea/L <u>Example:</u> 20 mg/dL BUN = 7.1 mmol urea/L
UREA	mmol/L	2.9 – 9.4	2.9 – 9.4	1 – 50	
Glucose	mg/dL	70 – 105	70 – 105	20 – 700	mg/dL x 0.055 = mmol/L <u>Example:</u> 100 mg/dL = 5.55 mmol/L
	g/L	0.70 – 1.05	0.70 – 1.05	0.20 – 7.00	100 mg/dL = 5.55 mmol/L
	mmol/L	3.9 – 5.8	3.9 – 5.8	1.1 – 38.9	g/L x 5.556 = mmol/L
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	1.12 – 1.32	1.12 – 1.32	0.25 – 2.50	mmol/L x 4 = mg/dL
	mg/dL	4.5 – 5.3	4.5 – 5.3	1.0 – 10.0	<u>Example:</u> 1.13 mmol/L x 4 = 4.52 mg/dL
pH		7.35 – 7.45	7.31 – 7.41	6.50 – 8.20	N/A
PCO₂	mmHg	35 – 45	41 – 51	5 – 130	mmHg x 0.133 = kPa
	kPa	4.67 – 6.00	5.47 – 6.80	0.67 – 17.33	<u>Example:</u> 35 mmHg x 0.133 = 4.66 kPa
PO₂	mmHg	80 – 105		5 – 800	mmHg x 0.133 = kPa
	kPa	10.7 – 14.0		0.7 – 106.6	<u>Example:</u> 83 mmHg x 0.133 = 11.04 kPa
TCO₂ (on the CHEM8+ cartridge only)	mmol/L (mEq/L)	23-27	24-29	5-50	mmol/L x 1 = mEq/L

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ANALYTE	UNIT	REFERENCE RANGE		REPORTABLE RANGE	UNIT CONVERSION
		(arterial)	(venous)		
Hematocrit	%PCV	38 – 51	38 – 51	10 – 75	% PCV x 0.01 = Volume fraction <u>Example:</u> 40% PCV = 0.40 PCV
	Fraction	0.38 – 0.51	0.38 – 0.51	0.10 – 0.75	
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 – 26	23 - 28	1.0 – 85.0	mmol/L x 1 = mEq/L
TCO₂[*] (on all cartridges but CHEM8+)	mmol/L (mEq/L)	23 – 27	24 - 29	5 – 50	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	3.4 – 25.5	g/dL x 10 = g/L
	g/L	120 – 170	120 – 170	34 – 255	
	mmol/L	7 – 11	7 – 11	2.1 – 15.8	
Celite ACT	seconds	74 – 125 (PREWRM)	74 – 125 (PREWRM)	50 - 1000	
		84 – 139 (NONWRM)	84 – 139 (NONWRM)		
Kaolin ACT	seconds	74 – 137 (PREWRM)	74 – 137 (PREWRM)	50 - 1000	
		82 – 152 (NONWRM)	82 – 152 (NONWRM)		
Prothrombin Time/PT	INR			0.9-8.0 [#]	
Troponin I/cTnI	ng/mL (µg/L)		0.00 – 0.03**	0.00 – 50.00 ^{##}	ng/mL x 1 = µg/L
			0.00 – 0.08***		
Creatine Kinase MB/ CK-MB	ng/mL (µg/L)		0.0 – 3-5****	0.0-150.0	ng/mL x 1 = µg/L
B-Type Natriuretic Peptide/BNP	pg/mL (ng/L)		<15-50****	15-5000	pg/mL x 1 = ng/L

*Calculated values.

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

**Represents the 0 – 97.5% range of results. Each facility should establish it's own reference range using the i-STAT cTnI assay.

##Performance characteristics have not been established for cTnI values above 35.00 ng/mL.

***Represents the 0-99% range of results. Each facility should establish it's own reference range using the i-STAT cTnI assay.

****Represents the 0-95% range of results. Each facility should establish it's own reference range using the i-STAT assay

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Critical Results³

Critical results are test results that fall outside high and low critical limits that define the boundaries of life-threatening values for a test. Critical results represent an emergency condition and must be reported immediately to the patient's attending physician or nurse.

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)	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	–	–
PCO ₂ (mmHg)	19	67	21	66	–	–
PO 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/INR						
Troponin I/cTnI						
Creatine Kinase MB/ CK-MB						
B-Type Natriuretic Peptide/ BNP						

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Interferences

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.

ANALYTE	INTERFERENT	INTERFERENT CONCENTRATION	EFFECT ON ANALYTE RESULT
Sodium	Bromide	37.5 mmol/L	Increase (↑) Na
Potassium	Bromide	37.5 mmol/L	Increased rate of star (***) outs.
Chloride	Acetylcysteine	10.2 mmol/L	Decrease (↓) Cl
	Bromide	37.5 mmol/L	Increase (↑) Cl
	Bromide (therapeutic)	2.5 mmol/L	Increase (↑) Cl
	Salicylate	4.34 mmol/L	Increase (↑) Cl
	Thiocyanate	6.9 mmol/L	Increase (↑) Cl
Ionized Calcium	Acetaminophen	1.32 mmol/L	Decrease (↓) iCa
	Magnesium	1.0 mmol/L	Increase (↑) iCa by 0.04 mmol/L
	Acetylcysteine	10.2 mmol/L	Decrease (↓) iCa
	Bromide	37.5 mmol/L	Increase (↑) iCa
	Lactate	6.6 mmol/L	Decrease (↓) iCa by 0.07 mmol/L
	Salicylate (therapeutic)	0.5 mmol/L	Decrease (↓) iCa by approx. 0.03 mmol/L
	Salicylate	4.34 mmol/L	Decrease (↓) iCa
	Thiocyanate	6.9 mmol/L	Decrease (↓) iCa. Use Another Method.
Glucose	Acetaminophen	1.32 mmol/L	Increase (↑) glucose
	Acetylcysteine	10.2 mmol/L	Decrease (↓) glucose
	Bromide	37.5 mmol/L	Decrease (↓) glucose
	Bromide (therapeutic)	2.5 mmol/L	Decrease (↓) glucose
	pH	pH: per 0.1 pH units below 7.4 @ 37°C	Decrease (↓) glucose by 0.9 mg/dL (0.05 mmol/L)
		pH: per 0.1 pH units above 7.4 @ 37°C	Increase (↑) glucose by 0.8 mg/dL (0.04 mmol/L)
	Oxygen	PO ₂ less than 20 mmHg @ 37°C	May decrease (↓) glucose
	Hydroxyurea	0.92 mmol/L	Increase (↑) glucose
Thiocyanate	6.9 mmol/L	Decrease (↓) glucose by approx. 7 mg/dL	
Lactate	Bromide	37.5 mmol/L	Decrease (↓) lactate
	Hydroxyurea	0.92 mmol/L	Increase (↑) lactate. Use Another Method.
	Glycolic Acid	10.0 mmol/L	Increase (↑) lactate. Use Another Method.

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ANALYTE	INTERFERENT	INTERFERENT CONCENTRATION	EFFECT ON ANALYTE RESULT	
BUN/Urea	Bromide	37.5 mmol/L	Increased rate of star (***) outs	
	Hydroxyurea	0.92 mmol/L	Increase (↑) BUN/Urea results	
Creatinine <2 mg/dL >2 mg/dL	Acetaminophen	1.32 mmol/L	Increase (↑) creatinine	
	Ascorbate	0.34 mmol/L	Increase (↑) creatinine by 0.3 mg/dL	
	Bromide (therapeutic)	2.5 mmol/L	Increase (↑) creatinine	
	PCO₂		Above 40 mmHg	Increase (↑) creatinine by 6.9% per 10 mmHg PCO₂
			Below 40 mmHg	Decrease (↓) creatinine by 6.9% per 10 mmHg PCO₂
	PCO₂		Above 40 mmHg	Decrease (↓) creatinine by 3.7% per 10 mmHg PCO₂
			Below 40 mmHg	Increase (↑) creatinine by 3.7% per 10 mmHg PCO₂
		Hydroxyurea	0.92 mmol/L	Increase (↑) Creatinine. Use Another Method.
		Acetylcysteine	10.2 mmol/L	Increase (↑) creatinine
		Creatine	0.382 mmol/L	Increase (↑) creatinine by 0.2 mg/dL
	Glycolic Acid	10.0 mmol/L	Decrease (↓) creatinine. Use Another Method.	
Hematocrit	White Blood Count (WBC)	Greater than 50,000 WBC/μL	May Increase (↑) hematocrit	
	Total Protein	<u>For measured Hct<40%</u> For each g/dL below 6.5 For each g/dL above 8.0	Decrease (↓) Hct by 1% PCV Increase (↑) Hct by 1% PCV	
		<u>For measured Hct≥40%</u> For each g/dL below 6.5 For each g/dL above 8.0	Decrease (↓) Hct by 0.75% PCV Increase (↑) Hct by 0.75% PCV	
	Lipids	Abnormally high	Increase (↑) Hct	
	Bromide	37.5 mmol/L	Increased rate of star (***) outs	
Celite ACT	Aprotinin		Falsely extends Celite ACT times	
PCO₂	Propofol (Diprivan®) Thiopental Sodium		For patients administered propofol or thiopental sodium, i-STAT recommends the use of G3+, 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.	
PT/INR	Cubicin® (daptomycin for injection)		Falsely extends prothrombin time (PT) and INR	
	Chlorhexidine Gluconate		May falsely extend prothrombin time (PT) and INR	

QUALITY CONTROL

Daily Procedures

Handheld Verification

Verify the performance of each handheld in the i-STAT System using the internal or external Electronic Simulator every 24 hours of use, or as needed for regulatory compliance. In the USA, verification is required every 8 hours for blood gases, hematocrit, ACT, and PT/INR.

Action:

If PASS is displayed on the handheld screen (after using the external Electronic Simulator):

- Remove the external Electronic Simulator after the LCK or Simulator Locked message disappears from the display screen.
- Transmit the result to the Central Data Station.
- Use the handheld as required.

Note: If the internal Electronic Simulator is used, the “PASS” message will not be displayed on the handheld screen. The “PASS” record will appear in the handheld’s stored results for transmission to the Central Data Station.

Remedial Action:

If FAIL is displayed on the analyzer screen:

- Repeat the procedure with the same external Electronic Simulator or rerun the cartridge if the internal Electronic Simulator is being used. If PASS is displayed use the handheld as required.
- If FAIL is displayed repeat the procedure with a different external Electronic Simulator.

If PASS is displayed with the second external Electronic Simulator:

- Use the handheld as required.
- Deliver the questionable external Electronic Simulator to the i-STAT System Coordinator.

If FAIL is displayed with the second external Electronic Simulator:

- DO NOT analyze patient samples with the handheld.
- Transmit the results to the Central Data Station.
- Deliver the faulty handheld to the i-STAT System Coordinator.
- Record the failure in the i-STAT QC Log along with the action taken.

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. Deliver any expired cartridges to the i-STAT System Coordinator.
- Verify that the refrigerator did not exceed the limits of 2 to 8°C (35 to 46°F).
- Document in the i-STAT QC Log.

Action:

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

Remedial Action:

If the temperature is outside the range of 2 to 8 °C (35 to 46 °F), notify the i-STAT System Coordinator immediately. Record the QC failure in the i-STAT QC Log along with the actions taken as described in Section 14 (Quality Control) of the i-STAT 1 System Manual.

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Room Temperature Cartridges

- ❑ Verify that all boxes of cartridges at room temperature have been out of the refrigerator less than the time frame indicated on the cartridge box. Deliver any expired cartridges to the i-STAT System Coordinator.
- ❑ Verify that room temperature has not exceeded 30°C.
- ❑ Document in the i-STAT QC log.

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 immediately.
- ❑ DO NOT USE the cartridges.
- ❑ Record the out-of-control event in the i-STAT QC Log and the action taken.

Monthly Procedures

Print Electronic Simulator Results

Print a copy of the Electronic Simulator results from the Central Data Station. Include the report in the i-STAT QC Log.

- ❑ CDS version 5 and above: Click on the Simulator Viewer.

Print Control Fluid Analysis Results

Print results for any control fluids analyzed from the Central Data Station. Include the report in the i-STAT QC Log.

- ❑ CDS version 5 and above: Click on the Control Results Viewer.

Periodic Procedures for Cartridges

For acceptance of newly received cartridge lots, check the Temperature Monitor and perform integrity testing.

Check Temperature Monitor

i-STAT cartridges are shipped refrigerated with a four-window indicator to monitor temperature during transit.

Note: All control and calibration verification materials, except for those shipped on dry ice, will also include a four-window indicator to monitor temperature during transit.

Action:

- ❑ Fill out the record of receipt and forward materials to refrigerator.
- ❑ If all windows are white or if only the A or B windows are blue or the 1 or 2 windows are red, then transit temperatures were satisfactory and the cartridges can be used.

Remedial Action:

If the C or D windows are blue, or the 3 or 4 windows are red:

- ❑ Quarantine the suspect cartons.
- ❑ Notify the i-STAT System Coordinator immediately.
- ❑ DO NOT USE cartridges from the suspect cartons.
- ❑ Record the out-of-control event in the i-STAT QC Log.

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Integrity Testing

From each lot of blood gas/chemistry cartridges received, use a representational number of cartridges to analyze i-STAT or TriControls Level 1 and 3 Controls. For CHEM8+ cartridges, analyze i-STAT CHEM8+ or TriControls Control Levels 1 and 3. If not using TriControls and hematocrit is included on the cartridge type being tested, also analyze RNA Medical Hematocrit Control Levels 1 and 3. For ACT cartridges, analyze i-STAT Level 1 and Level 2 ACT Controls. For PT/INR cartridges, analyze i-STAT Level 1 and Level 2 PT Controls. For cTnI cartridges, analyze i-STAT Level 1 and Level 3 cTnI Controls. For CK-MB cartridges, analyze i-STAT Level 1 and Level 3 CK-MB Controls or CLINIQA Cardiac Marker Level 1 and 3 controls. For BNP cartridges, analyze i-STAT BNP Control Levels 1 and 3. Use any verified analyzer for control testing. If available, transmit the results to the Data Manager. Use the expected values published in the Value Assignment Sheet to verify the integrity of the cartridges.

Note: the above information is not a manufacturer's system instruction; it is a suggestion to comply with regulatory requirements.

Procedure for testing cartridges with i-STAT Level 1 and Level 3 Controls:

1. Prior to testing cartridges that measure *PO*₂, ampules should stand at room temperature a minimum of 4 hours before use. When testing other cartridges (G, Crea, E3+, EC4+, 6+, or EC8+), ampules may be used once the fluid has reached room temperature, approximately 30 minutes for individual ampules. For best results, ampules, cartridges, and handhelds should be at the same temperature. When using cartridges that contain sensors for measuring ionized calcium, pH, *PCO*₂, or *PO*₂ (G3+, EG6+, EG7+, CG4+, CG8+, or EC8+), a separate ampule must be used for each cartridge being tested; if these sensors are not present (i.e., the 6+ cartridge), the contents of one ampule may be used to fill more than one cartridge as long as the cartridges are filled and inserted into a handheld within 10 minutes of opening the ampule.
2. 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 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 neck.
3. 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 a handheld. 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 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.
 - ❑ 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, *PCO*₂, or *PO*₂. However, cartridges without these sensors may be tested with remaining fluids if within 10 minutes of opening the ampule.
4. Compare results to the value assignment sheet ranges. Check that the lot number on the control ampule matches the lot number on the package insert and that the software version listed on the insert matches the software installed in the handheld. If all results are within expected ranges, use the cartridges as needed. If available, transmit the results to the Data Manager.

Procedure for testing cartridges with TriControls Level 1 and Level 3 Controls:

1. Prior to testing cartridges that measure *PO*₂, ampules should stand at room temperature a minimum of 4 hours before use. When testing other cartridges (G, Crea, E3+, EC4+, 6+, EC8+, 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 handhelds should be at the same temperature. When using cartridges that contain sensors for measuring ionized calcium, pH, *PCO*₂, or *PO*₂ (G3+, EG6+, EG7+, CG4+, CG8+, EC8+, or CHEM8+), a separate ampule must be used for each cartridge being tested; if these sensors are not present (i.e., the 6+ cartridge), the contents of one ampule may be used to fill more than one cartridge as long as the cartridges are filled and inserted into a handheld within 10 minutes of opening the ampule.

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2. 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 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 neck.
3. 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 a handheld. 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 placing a finger over 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 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.
 - ❑ 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, PCO_2 , or PO_2 . However, cartridges without these sensors may be tested with remaining fluids if within 10 minutes of opening the ampule.
4. Compare results to the Value Assignment Sheet ranges. Ensure that the lot number printed on the Value Assignment Sheet matches the lot number on the label of the ampule and that the software version above the target value table matches the software version in the handheld. If all results are within expected ranges, use the cartridges as needed. If available, transmit the results to the Data Manager.

Procedure for testing CHEM8+ cartridges with i-STAT CHEM8+ controls.

1. Equilibrate the ampule for approximately 30 minutes at room (ambient) temperature.
2. Immediately before use, shake the ampule vigorously for 5-10 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.
3. 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.
5. Immediately seal the cartridge and insert it into a handheld – 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 tubes 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 16-20 gauge 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.
 - ❑ Do not use solution left in the syringe, ampule, or capillary tube for additional testing of CHEM8+ cartridges.
6. Compare results to the value assignment sheet ranges. Check that the lot number on the control ampule matches the lot number on the package insert that the software version listed on the insert matches the software installed in the handheld. If all results are within expected ranges, use the cartridges as needed. If available, transmit the results to the Data Manager.

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Procedure for testing cartridges with RNA Medical Hematocrit controls

1. If stored refrigerated, the control material should be equilibrated to room temperature for at least four (4) hours prior to use. If stored at room temperature, no equilibration of the control material is necessary.
2. Gently invert the ampule to mix the solution. Tap the ampule to restore the liquid to the bottom of the ampule.
3. Open the ampule by snapping off the tip at the neck. Use gauze, tissue, gloves, or an appropriate ampule opener to protect fingers from cuts.
4. Fill and seal a cartridge and insert immediately into the handheld. Note: the Control option from the Quality Tests menu must be used on the i-STAT 1 Analyzer for RNA Medical Hematocrit Control.
5. Compare the i-STAT System Hematocrit result to the value assignment sheet ranges. Note: the only value assigned to this fluid is for hematocrit. All other cartridge analyte results obtained with this control material should be ignored.
6. If available, transmit results to the Data Manager.

Remedial Action:

If any results are outside the published expected ranges:

- DO NOT USE cartridges from the suspect lot.
- Quarantine the suspect lot.
- Notify the i-STAT System Coordinator immediately.
- Record the QC failure in the i-STAT QC Action Log along with the action taken.

Procedure for testing cartridges with i-STAT Level 1 and Level 2 ACT or PT/INR Controls

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. 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.
3. 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.
4. Use a plastic pipette, syringe, or capillary tube without anticoagulant to transfer the solution to an ACT cartridge.
5. Immediately seal the cartridge and insert it into a handheld. This process must be completed within 30 seconds of the complete reconstitution of the control sample.
6. Compare results to the value assignment sheet ranges. If results are within the expected ranges, use the cartridges as needed. If available, transmit results to the Data Manager.

Remedial Action:

If any results are outside the published expected ranges:

- DO NOT USE cartridges from the suspect lot.
- Quarantine the suspect lot.
- Notify the i-STAT System Coordinator immediately.
- Record the QC failure in the i-STAT QC Action Log along with the action taken.

Procedures for testing cartridges with i-STAT cTnI, BNP, and CK-MB controls

1. i-STAT cTnI, BNP, and CK-MB Controls are ready-to-use liquid control requiring no reconstitution or frozen storage. They are stable until the expiration date on the vial label when stored unopened at 2-8°C. Once opened, the i-STAT cTnI, BNP, and CK-MB Controls are stable for 30 days when stored tightly capped at 2-8°C.
2. Access the Control option under Quality Tests in the Administration Menu. Enter the required information. The handheld allows 15 minutes (or the customized timeout period) to insert the cartridge after the last data entry.
3. Immediately before use, gently mix the contents of the control vial to ensure homogeneity. Avoid foaming of the sample.
4. Open the vial and transfer a drop of the solution into the i-STAT cartridge using a plain capillary tube, plain syringe, or plastic transfer pipette. Tightly recap the control vial and store it at 2-8°C.

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5. Seal the cartridge and immediately insert it into the i-STAT 1 Analyzer.
6. Compare the result to the Value Assignment Sheet value. Always ensure that the lot number and software revision on the Value Assignment Sheet matches the lot number of the vial in use and the software revision in the handheld. Should results fall outside the range, refer to the Troubleshooting section of i-STAT 1 System Manual section 14 (Quality Control).
7. If available, transmit results to the Data Manager.

Remedial Action

If any results are outside the published expected ranges:

- DO NOT USE cartridges from the suspect lot.
- Quarantine the suspect lot.
- Notify the i-STAT System Coordinator immediately.
- Record the QC failure in the i-STAT QC Action Log along with the action taken.

Procedures for for testing CK-MB cartridges with CLINIQA Cardiac Marker controls for i-STAT

1. CLINIQA Liquid QC Cardiac Marker Control is a ready-to-use liquid control requiring no reconstitution or frozen storage. It is stable until the expiration date on the vial label when stored unopened at 2-8°C. Once opened, CLINIQA Liquid QC Cardiac Marker Control is stable for 30 days when stored tightly capped at 2-8°C.
2. Immediately before use, gently mix the contents of the control vial to ensure homogeneity. Avoid foaming of the sample.
3. Open the vial and transfer a drop of the solution into the i-STAT CK-MB cartridge using a plain capillary tube, plain syringe, or plastic transfer pipette. Tightly recap the control vial and store it at 2-8°C.
4. Seal the cartridge and immediately insert it into the i-STAT 1 Analyzer.
5. Compare the i-STAT CK-MB result to the Value Assignment Sheet value. Always ensure that the lot number and software revision on the Value Assignment Sheet matches the lot number of the vial in use and the software revision in the handheld. Should results fall outside the range, refer to the Troubleshooting section of i-STAT 1 System Manual section 14 (Quality Control).
6. If available, transmit results to the Data Manager.

Remedial Action

If any results are outside the published expected ranges:

- DO NOT USE cartridges from the suspect lot.
- Quarantine the suspect lot.
- Notify the i-STAT System Coordinator immediately.
- Record the QC failure in the i-STAT QC Action Log along with the action taken.

CALIBRATION

For cartridges, calibration is automatically performed as part of the test cycle on each cartridge type, except coagulation and immunoassay cartridges. Operator intervention is not necessary.

CLINICAL SIGNIFICANCE

PROCEDURE MANUAL FOR THE i-STAT SYSTEM

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 <i>In vitro</i> 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 Overhydration 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
BUN	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	

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Analyte	Some Causes of Increased Values	Some Causes of Decreased Values
Lactate	Hypoxia (shock, hypovolemia, left ventricular failure); diabetes mellitus, neoplasia, liver disease; drug or toxins (ethanol, methanol, salicylates); glycolic acid as a product of ethylene glycol metabolism	
pH	Respiratory alkalosis Metabolic alkalosis	Respiratory acidosis Metabolic acidosis
PCO₂	Acute Respiratory Acidosis: <ul style="list-style-type: none"> • <i>Depression of respiratory center</i> • <i>Suppressed neuromuscular system</i> • <i>Pulmonary disorders</i> • <i>Inadequate mechanical ventilation</i> Chronic respiratory acidosis <ul style="list-style-type: none"> • <i>Decreased alveolar ventilation</i> • <i>Hypoventilation</i> Compensation in metabolic alkalosis	Respiratory alkalosis: <ul style="list-style-type: none"> • <i>Increased stimulation of respirator center</i> • <i>Hypermetabolic states</i> • <i>Mechanical hyperventilation</i> Compensation in metabolic acidosis
PO₂	Breathing oxygen-enriched air	Carbon-monoxide exposure Pulmonary disorders Myocardial infarction Congestive heart failure
HCO₃ and TCO₂	Primary metabolic alkalosis Primary respiratory acidosis	Primary metabolic acidosis Primary respiratory alkalosis
Hematocrit	Dehydration Burns Impaired ventilation Renal disorders	Hemolytic anemias Iron deficiency Marrow depression Blood loss
ACT Celite	Administration of heparin for medical or surgical procedures. Administration of aprotinin.	
PT/INR	Administration of oral anticoagulant therapy.	

PROCEDURE MANUAL FOR THE i-STAT SYSTEM

Analyte	Some Causes of Increased Values	Some Causes of Decreased Values
ACT Kaolin	Administration of heparin for medical or surgical procedures.	
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
CK-MB	Myocardial Infarction Coronary vasospasm Cardiac contusion/trauma Myocarditis/pericarditis Infiltrative diseases (ex. Amyloidosis, sarcoidosis, hemochromatosis, connective tissue disease) Cardiac procedures (PTCA, DC cardioversion) Intracranial hemorrhage/stroke Pulmonary embolism Pulmonary hypertension Chronic renal insufficiency Sepsis Strenuous exercise Certain drug ingestions (cocaine) Skeletal muscle disease	Lean muscle mass
BNP	Congestive heart failure Chronic obstructive pulmonary disease (COPD) Asthma Pulmonary hypertension Cor pulmonale Pulmonary embolism Acute coronary syndrome Chronic renal failure Age Female sex	Obesity (BMI>30 Kg/m ²) Flash pulmonary edema (elevation may be delayed)

PRINCIPLES OF MEASUREMENT

Sodium, Potassium, Chloride, Ionized Calcium, pH, and PCO_2

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.

PO_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.

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/INR

is determined amperometrically. The conversion of a thrombin substrate is initiated by mixing a whole blood sample (without anticoagulant) with tissue thromboplastin. 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 reported as INR and/or seconds.

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.

Creatine Kinase MB/CK-MB

is determined amperometrically using a two-site ELISA method. Antibodies specific for an epitope unique to the CK-MB subunit, that therefore do not bind CK-MM or CK-BB, 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 an epitope on the B subunit of creatine kinase. The specificity of the conjugate antibody to the B subunit allows this conjugate to recognize CK-MB and CK-BB, but not CK-MM. The whole blood or plasma sample is brought into contact with the sensors allowing the enzyme conjugate to dissolve into the sample. The CK-MB within the sample becomes labeled with alkaline phosphatase and is captured onto the surface of the electrochemical sensor during an incubation period of approximately three minutes. The sample is washed off the sensors, as well as excess enzyme conjugate. 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 CK-MB within the sample.

B-Type Natriuretic Peptide/BNP

is determined amperometrically using a two-site ELISA method. Antibodies specific for BNP 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 BNP molecule. The whole blood or plasma sample is brought into contact with the sensors allowing the enzyme conjugate to dissolve into the sample. The BNP 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 is washed off the sensors, as well as excess enzyme conjugate. 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 BNP within the sample.

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, PCO₂, and ionic strength (Na) measurements.

FOOTNOTES

PROCEDURE MANUAL FOR THE i-STAT SYSTEM

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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