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. The Procedure Manual is provided on CD-ROM for this purpose. This Procedure Manual is not intended to replace the System Manual.

Abbott
Point of Care

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PROCEDURE MANUAL FOR THE i-STAT SYSTEM

Contents

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:

Analyzers

Analyzers (handhelds) can be the i-STAT Portable Clinical Analyzer or the i-STAT 1 Analyzer. When a sample-filled i-STAT cartridge is inserted into a handheld for analysis, the handheld automatically controls all functions of the testing cycle including fluid movement within the cartridge, calibration and continuous quality monitoring.
A PCx™ Plus Glucose Test Strip is scanned and inserted into the i-STAT 1 Analyzer (Model Number 300) and a drop of whole blood is applied to the target area of the test strip. (**N/A at UAMS)**

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
- MediSense Precision PCx or PCx Plus Glucose Test Strip: 20 seconds

Cartridges

A single-use disposable cartridge contains microfabricated sensors, a calibrant solution, fluidics system, and a waste chamber. Sensors for analysis of pH, ***P***CO_2, ***P***O_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.

Glucose Test Strips (NA/at UAMS)

The i-STAT Analyzer (handheld) Model Number (MN) 300 has the capability to run the Precision PCx Plus glucose test strip, while the i-STAT Analyzer MN 300-G does <u>not</u> have this same capability. The MN number for the handheld is found on a label located on the underside of the handheld near the top where the battery compartment is located.

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. IR Links for Portable Clinical Analyzers and Downloaders and Downloader/Rechargers for the i-STAT 1 Analyzers 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.**

Glucose Test Strips (N/A at UAMS)

Test strips are sealed in individual foil packets. Store the strips at a temperature between 4 and 30°C (39 and 86°F). When stored properly, the unopened test strips remain stable until the expiration date printed on the barcode label. Do not freeze and keep out of direct sunlight.

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 and BNP

Store at ≤ -18°C (-1°F) in a non-defrosting freezer. After thawing, the opened or unopened 1.0 mL vial is stable for 4 hours when capped and stored at 2 to 8°C (35° to 46°F). Do not refreeze

CLINIQA Liquid Cardiac Marker Control for CK-MB (N/A at UAMS)

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.

MediSense Precision Glucose Control Solutions for test strips(N/A at UAMS)

Store the controls at temperatures between 4 and 30°C (39 and 86°F). Do not freeze. Each bottle of control solution is stable for 90 days after opening. Write the date of opening on the bottle label. Always make sure the cap is returned to the correct bottle and tightly closed immediately 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

Glucose Test Strips(N/A at UAMS)

- Skin puncture: lancet and capillary collection tube with lithium heparin, sodium heparin, or EDTA or direct application of sample to test strip
- Venipuncture and arterial puncture: collection tube or syringe with lithium heparin, sodium heparin, or EDTA

Cartridges for PT/INR (N/A at UAMS)

- 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-(N/A at UAMS)

- 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. For the glucose test strip, sufficient sample to cover target area - approximately one drop, is required.

Table 1: Cartridge Panel Configurations and Blood Volume (Shading denotes calculated values)

Cartridge	Vol. µL	pH	PCO_2	PO2	Na	K	Cl	iCa	Glu	BUN	Creat	Lact	Hct	TCO_2	ACT	PT/INR	CK-MB	cTnI	BNP	HCO3	TCO2	SO2	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 (N/A at UAMS)

- 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 Glucose Test Strip (N/A at UAMS)

- Fresh capillary whole blood collected in a capillary collection tube containing sodium heparin, lithium heparin, or EDTA. Test immediately.
- Fresh venous whole blood collected in a collection tube containing sodium heparin, lithium heparin, or EDTA. Test within 30 minutes of collection.
- Fresh arterial whole blood collected in a syringe containing sodium heparin, lithium heparin, or EDTA. Test within 30 minutes of collection.

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. Collection tubes must be filled at least half full.
- 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 (N/A at UAMS)

- EDTA whole blood plasma samples collected in plastic syringes or evacuates tubes containing EDTA. Collection tubes must be filled at least half full.

Specimen Labeling:

Unless the specimen is analyzed immediately after collection and then discarded, the specimen container must be labeled with the following information: **(Verify the patients name and date of birth before collection by asking patient to tell you their name and birthdate and checking the armband.)**

Patient name, sex, age
Patient ID number
Time and date of collection-(stored in meter)
Phlebotomist ID (stored in meter)
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 $\boldsymbol{P}CO_2$ may decrease, pH may increase and $\boldsymbol{P}O_2$ may decrease if the value is above or increase if the value is below the $\boldsymbol{P}O_2$ of room air (approximately 150 mmHg).

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

For glucose test strips, fill to capacity a syringe or collection tube containing lithium heparin, sodium heparin, or EDTA.(N/A at UAMS).

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 property remix a sample in a 1.0 cc syringe. For the glucose test strip and 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 $\boldsymbol{P}$CO2, 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 strip or 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, $\boldsymbol{P}$CO2, TCO_2 and ionized calcium within 10 minutes of sample draw. If not tested immediately, remix the 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, $\boldsymbol{P}CO_2$, $\boldsymbol{P}O_2$ and TCO_2 with air bubbles in sample
- Incompletely filled vacuum tube for the measurement of ionized calcium, $\boldsymbol{P}CO_2$, 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, $\boldsymbol{P}CO_2$, $\boldsymbol{P}O_2$ 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.

Glucose test strips require no preparation for use.

Note: In departments where both i-STAT ACT cartridges and glucose test strips are used on the same handhelds – **do not run** ACT cartridges while the handheld is in the Downloader/Recharger.

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

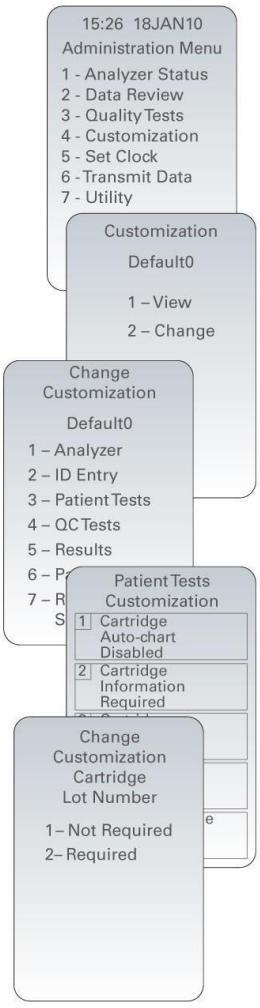
The procedure to customize the Handheld varies, depending on whether the customization is being done directly using the Handheld's keypad, or whether it is being done through the Customization Workspace in Central Data Station (CDS) Version 5 or i-STAT/DE.

- 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

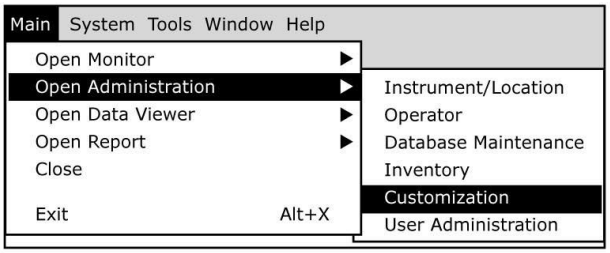
Cartridge use requires operators to turn on the Handheld, enter an Operator ID and Patient ID, and then scan the cartridge lot number before inserting a cartridge into the Handheld for testing. To customize the Handheld:

1. Press ⏻ to turn on the Handheld.
2. Press MENU to change screen to Administration Menu.
3. Press 4 (Customization).
4. Press 2 (Change).
5. Press ENT (No password is required).
6. Press 3 (Patient Tests).
7. Press 2 (Cartridge Information).
8. Press 2 to change setting to "Required".
9. Press 4 (Cartridge Lot Number).
10. Press 2 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).

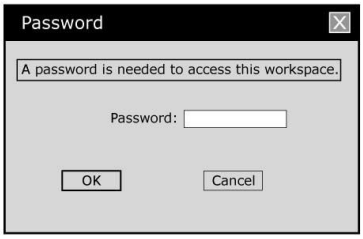


B. Customizing the Handheld for Cartridge Testing Using CDS Version 5

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.

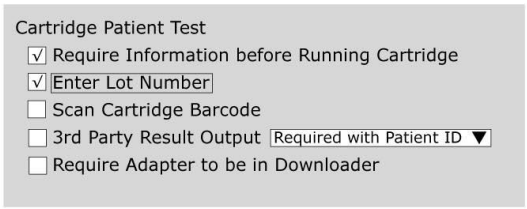
Location-based customization profiles:

Location	Enable Updates	Use Default Profile	Update CLEW	i-STAT Analyzer CLEW	Philips BAM CLEW	Preferences	STATNotes
A_10.10.90.17	√	√	√	A18		DEFAULT0	CHART0
A_10.10.90.24	√	√	√	A18		DEFAULT0	CHART0
A_10.10.90.31	√	√	√	A18		DEFAULT0	CHART0
A_10.10.90.32	√	√	√	A18		DEFAULT0	CHART0

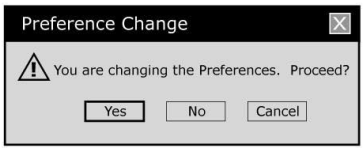
4. If the location where this Handheld is assigned has a check mark under the **Use Default Profile** column, double click on the alphanumeric code under **Preferences** in the **Default Customization Profile** column. Otherwise, double click on the alphanumeric code under **Preferences** for the specific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

5. Once the **Preferences** screen opens, click on the **Test** tab.

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



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

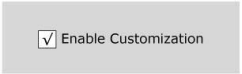


8. Download the Handheld(s) to the CDS from a downloader in the location to which this Handheld is assigned. This action should upload the chosen customization features into the Handheld. Repeat step 8 for all Handhelds from this same location to be customized. To customize Handhelds from other locations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

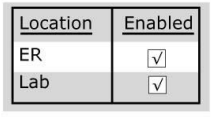
C. Customizing the Handheld for Cartridge Testing Using i-STAT/DE

1. 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**.

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

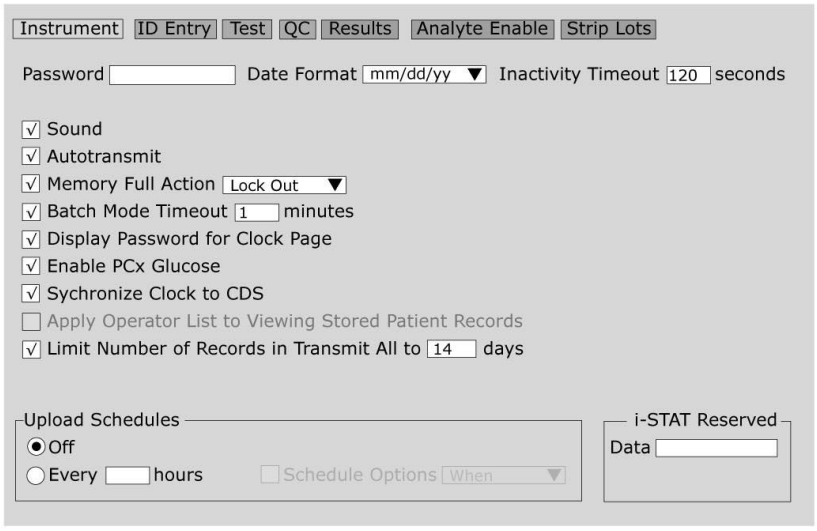


Also, make certain that the **Enable Updates** box is checked for the particular location to which this i-STAT 1 Handheld is assigned.

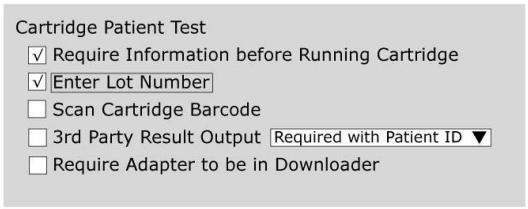


3. If the location where this Handheld is assigned has a check mark under the **Use Default Profile** column, double click on the alphanumeric code under **Preferences** in the **Default Customization Profile** column. Otherwise, double click on the alphanumeric code under **Preferences** for the specific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

4. Once the **Preferences** screen opens, click on the **Test** tab.



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



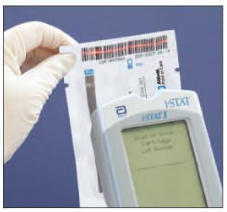
6. Click OK and answer YES to the question about changing the preferences.

7. 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.

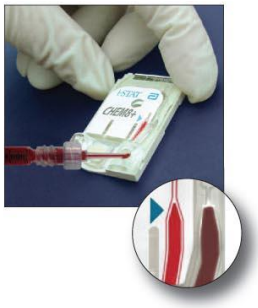
Procedure for Cartridge Testing

- 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 2 for i-STAT
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 SCAN 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 ENT to bypass this prompt. You may ignore any letters in the lot number.



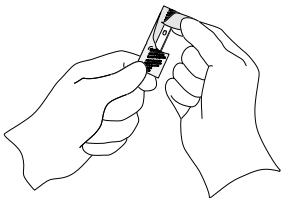
5. Continue normal procedures for preparing the sample, filling and sealing the cartridge.
6. Push the sealed cartridge into the Handheld port until it clicks into place. Wait for the test to complete.

   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.

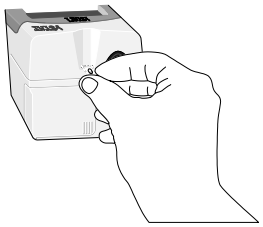
7. Review results

PCx Glucose Test Strip Procedure (N/A at UAMS)

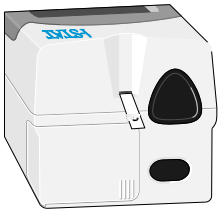
The i-STAT Analyzer (handheld) Model Number (MN) 300 has the capability to run the Precision PCx Plus glucose test strip, while the i-STAT Analyzer MN 300-G does <u>not</u> have this same capability. The MN number for the handheld is found on a label located on the underside of the handheld near the top where the battery compartment is located.



1. Press the ⏻ (On/Off) key to turn the handheld on.
2. Press 3 for PCx Glucose Strip.
3. Press 1 for Patient.
4. Scan or enter operator ID. Repeat if prompted.
5. Scan or enter patient ID. Repeat if prompted.
6. Scan or enter test strip lot number.
7. Press 1 for Arterial/Capillary or 2 for venous sample if prompted.
8. Open foil packet, remove test strip and insert into handheld test strip port with black contact bars facing up and forward.



9. Apply drop of blood to target area of test strip. Cover the entire area. Do not touch the test strip after sample is applied. (If test fails to start after second drop applied or if more than 30 seconds have passed, discard test strip and repeat the test.)
10. Enter chart page information if applicable.
11. View results on handheld's display.
12. Enter Comment Code if applicable.
13. Remove and discard test strip.
    a. Do not handle test strip with wet or dirty hands.
    b. Do not scan the barcode of another test strip.
    c. Do not use test strips that are wet, scratched or damaged in any way.
    d. Do not re-use test strips.



Alternative Procedure

Should the i-STAT System become inoperable for any reason, or results are questionable or inconsistant with patient's condition, specimens should be collected and submitted to the laboratory in accordance with the Laboratory Procedure Manual. Notify the POCT Coordinator at 686-7066 with any instrument problems. A backup analyzer may be obtained from the clinical lab support services by calling 686-6230.

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. **Enter a critical value comment code of 9 to indicate a nurse or doctor was notified or 10 to indicate that a stat specimen is being sent to the lab.**

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. Specimens should be sent to the clinical lab if unable to resolved. **Contact the POCT Coordinator at 686-7044 or 686-7066 or IStat technical support at 1-800-366-8020 if you have repeated quality code errors. A backup Istat Analyzer is available in the clinical lab (tel# 686-6230) if necessary. Include documentation of problems with the analyzer when bringing your IStat to the lab for replacement.**

   Printing and Transmitting Results

Printing Results from the i-STAT Portable Clinical Analyzer to the HP Portable Printer (N/A at UAMS)

1. Place the handheld in the cradle of an IR Link or align the IR windows of the handheld and printer. Turn the printer on (printer light red) or press the paper advance switch to reactivate.
2. To print the displayed test record, press the PRT key on the handheld.
3. To print a stored test record(s), select "Print Results" from the Stored Results menu. Select records to be printed by pressing the Key(s) corresponding to the numbers beside the record(s). Press the numbered key again to deselect a record. Then press the PRT Key.
4. Do not move the handheld while "Printing" is displayed.

   Optional: Write the patient's name on the "Pt Name" line and the physician's name on the "Physician" line.

   Note: Results printed on thermal paper will fade with time and are therefore not acceptable as a permanent chartable record.

Printing Results from the i-STAT Portable Clinical Analyzer to the Martel Portable Printer (N/A at UAMS)

1. Place the handheld in the cradle of an IR Link or align the IR windows of the handheld and printer. Turn the printer on by pressing the **Mode** button. The green status indicator will light.
2. To print the displayed test record, press the PRT key on the handheld.

3. To print a stored test record(s), select "Print Results" from the Stored Results menu. Select records to be printed by pressing the Key(s) corresponding to the numbers beside the record(s). Press the numbered key again to deselect a record. Then press the PRT Key
4. **Optional:** Write the patient's name on the "Pt Name" line and the physician's name on the "Physician" line.

   Note: Results printed on thermal paper will fade with time and are therefore not acceptable as a permanent chartable record.

Printing Results from the i-STAT 1 Analyzer to the Martel Portable Printer or to the i-STAT Printer (Note: The HP printer and the Martel printers used with Portable Clinical Analyzer cannot be used with the i-STAT 1 Analyzer.)

Without Downloader or Downloader/Recharger –this is method used at UAMS.

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.
7. Write the patients name on the PT name line or attach a patient label and give to dr/nurse. Be sure to dock the meter to send results to the lab computer system for a permanent record.

With Downloader or Downloader/Recharger

1. Place handheld in Downloader or Downloader/Rechrager 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.
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 Portable Clinical Analyzer to the Central Data Station (n/a at UAMS)

1. Place the handheld in the cradle of an IR Link. The IR status light must be green.
2. With a test record on the display screen, press the * key.
3. Do not move the handheld while "Transmitting" is displayed. During transmission the IR Link's light will blink alternately red and green. If transmission is successful, the IR Link will emit a single high-pitched beep and the light will return to green. An unsuccessful transmission is indicated by three low tone beeps. In this case repeat the transmission process. If unsuccessful the second time, notify the i-STAT System Coordinator.

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. If the "communication in progress' message does not appear in 10 seconds, disconnect and then reconnect the power connection and/or computer access line

from the back of the docking station and from the wall computer communication port. Contact the POCT Coordinator at 686-7044 or 686-7066 if problems persist.

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 (arterial) (venous)	REPORTABLE RANGE	UNIT CONVERSION
Sodium	mmol/L (mEq/L)	135 – 145 135 – 145 Neonate: 133-155	100 – 180	mmol/L x 1 = mEq/L Example: 140 mmol/L = 140 mEq/L
Potassium	mmol/L (mEq/L)	3.5 – 5.0 3.5 – 5.0 Neonate: 3.5-5.5	2.0 – 9.0	mmol/L x 1 = mEq/L
Chloride	mmol/L (mEq/L)	100 – 109 100 – 109 Neonate: 100-117	65 – 140	mmol/L x 1 = mEq/L
BUN **UREA**	mg/dL mmol/L	6 – 20 6 – 20 Neonate: 8-34 2.9 – 9.4 2.9 – 9.4	3 – 140 1 – 50	mg/dL BUN x 0.357 = mmol urea/L Example: 20 mg/dL BUN = 7.1 mmol urea/L
Glucose	mg/dL g/L mmol/L	70 – 105 70 – 105 Neonate: D1 50-100 D2: 70-105 0.70 – 1.05 0.70 – 1.05 3.9 – 5.8 3.9 – 5.8	20 – 700 0.20 – 7.00 1.1 – 38.9	mg/dL x 0.055 = mmol/L Example: 100 mg/dL = 5.55 mmol/L g/L x 5.556 = mmol/L
Creatinine	mg/dL	0. - 1.1 0.5 - 1.1 Pediatric 2-12 years 0.5-1.0	0.2 - 20.0 18 - 1768	mg/dL x 88.4 = µmol/L
Ionized Calcium	mmol/L mg/dL	1.12 – 1.32 1.12 – 1.32 4.5 – 5.3 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 7.35 – 7.45	6.50 – 8.20	N/A
***P*CO$_2$**	mmHg kPa	35 – 45 41 – 51 4.67 – 6.00 5.47 – 6.80	5 – 130 0.67 – 17.33	mmHg x 0.133 = kPa Example: 35 mmHg x 0.133 = 4.66 kPa
***P*O$_2$**	mmHg kPa	80 – 105 10.7 – 14.0	5 – 800 0.7 – 106.6	mmHg x 0.133 = kPa Example: 83 mmHg x 0.133 = 11.04 kPa

TCO_2 (on the CHEM8+ cartridge only	mmol/L (mEq/L)	23-27 22-31 Neonates: 22-31	5-50	mmol/L x 1 = mEq/L

ANALYTE	UNIT	REFERENCE RANGE (arterial)	REFERENCE RANGE (venous)	REPORTABLE RANGE	UNIT CONVERSION
Hematocrit	%PCV Fraction	M-40-52 F-34-47 Neonate: 45-64 0.38 – 0.51	M-40-52 F-34-47 0.38 – 0.51	10 – 75 0.10 – 0.75	% PCV x 0.01 = Volume fraction Example: 40% PCV = 0.40 PCV
Lactate	mmol/L mg/dL	0.36 –1.25 3.2 – 11.3	0.90-1.70 8.1–15.3	0.30 – 20.00 2.7 – 180.2	mmol/L x 9.01 = mg/dL
HCO_3*	mmol/L (mEq/L)	22 – 26	23 - 28	1.0 – 85.0	mmol/L x 1 = mEq/L
TCO_2* (on all cartridges but CHEM8+)	mmol/L (mEq/L)	23 – 27	22 - 31	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)	
sO_2*	%	95 – 98		0 - 100	% x 0.01 = fraction saturated
Hb*	g/dL g/L mmol/L	M-14.0 – 18.0 F-12.0- 16.0 120 – 170 7 – 11	M-14.0-18.0 F-12.0-16.0 120 – 170 7 – 11	3.4 – 25.5 34 – 255 2.1 – 15.8	g/dL x 10 = g/L
Celite ACT	seconds	74 – 125 (PREWRM) 84 – 139 (NONWRM) UAMS range is non warmed	74 – 125 (PREWRM) 84 – 139 (NONWRM)	50 - 1000	
Kaolin ACT	seconds	74 – 137 (PREWRM) 82 – 152 (NONWRM)	74 – 137 (PREWRM) 82 – 152 (NONWRM)	50 - 1000	
Prothrombin Time/PT	INR			0.9-8.0#	
Troponin I/cTnI	ng/mL (µg/L)	<0.08 ng/mL=Negative 0.08-0.6 ng/mL =indeterminate > 0.6 ng/mL = Positive		0.00 –50.00##	ng/mL x 1 = µg/L
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

Precision PCx Glucose Test Strip

UNIT	REFERENCE RANGE	REPORTABLE RANGE	UNIT OF CONVERSION
mg/dL	Fasting: 70 – 105 Two hours after meal: less than 140	20 – 600	mg/dL x 0.055 = mmol/L
mmol/L	Fasting: 3.9 – 5.8 Two hours after meal: less than 7.8	1.1 – 33.3	

Precision PCx Plus Glucose Test Strip

UNIT	REFERENCE RANGE	REPORTABLE RANGE	UNIT OF CONVERSION
mg/dL	Fasting: 70 – 105 Two hours after meal: less than 140	20 – 500	mg/dL x 0.055 = mmol/L
mmol/L	Fasting: 3.9 – 5.8 Two hours after meal: less than 7.8	1.1 – 27.8	

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. 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	>155	<120	>155	< OR =130	> or =146
Potassium (mmol/L)	<3.0	>6.0	<3.0	>6.0	<3.0	>6.0
Chloride (mmol/L)	<80	>120	<80	>120	< or = 90	> or = 120
TCO_2 (mmol/L)	<10	>40	<10	>40	< or =10	> or =40
Ionized Calcium (mmol/L)	0.78	1.58	0.74	1.57	–	–
pH	7.21	7.59	7.21	7.59	–	–
$\boldsymbol{P}CO_2$ (mmHg)	19	67	21	66	–	–
$\boldsymbol{P}O_2$ (mmHg)	43	–	45	124	37	92
BUN (mg/dL)	–		–		–	
Glucose (mg/dL)	<50	>450	<50	>450	<50	>150
Creatinine	–		–		–	–
Lactate						
Hematocrit (%PCV)	<21	>55	<21	>55	<40	>60
Celite ACT						
Kaolin ACT						
PT/INR						
Troponin I/cTnI	. 0.6= Positive					
Creatine Kinase MB/ CK-MB						
B-Type Natriuretic Peptide/ BNP						

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
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	Acetominophen	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
Glucose (Cartridge)	Acetominophen	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 result by approx. 5 mg/d/L
	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
Glucose (Precision PCx Test Strip)	Hematocrit	<20%PCV	Increase (↑) glucose
		>70%	Decrease (↓) glucose
	Acetominophen	>100 µg/mL	Decrease (↓) glucose
Glucose (Precision PCx Plus Test Strip)	See package insert for full details.		

ANALYTE	INTERFERENT	INTERFERENT CONCENTRATION	EFFECT ON ANALYTE RESULT
Lactate	Bromide	37.5 mmol/L	Decrease (↓) lactate
	Hydroxyurea	0.92 mmol/L	Increase (↑) lactate
	Glycolic Acid	10.0 mmol/L	Increase (↑) lactate
Creatinine	Acetaminophen	1.32 mmol/L	Increase (↑) creatinine
	Ascorbate	0.34 mmol/L	Increase (↑) creatinine by 0.3 mg/dL
	Bromide	37.5 mmol/L	Increase (↑) creatinine
<2 mg/dL	***P***CO_2	Above 40 mmHg	Increase (↑) creatinine by 6.9% per 10 mmHg ***P***CO_2
		Below 40 mmHg	Decrease (↓) creatinine by 6.9% per 10 mmHg ***P***CO_2
>2 mg/dL	***P***CO_2	Above 40 mmHg	Decrease (↓) creatinine by 3.7% per 10 mmHg ***P***CO_2
		Below 40 mmHg	Increase (↑) creatinine by 3.7% per 10 mmHg ***P***CO_2
	Hydroxyurea	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
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
Celite ACT	Aprotinin		Falsely extends Celite ACT times
***P*CO_2**	Propofol (Diprovan®)		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.
	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, PT/INR, cTnI, CK-MB, and BNP. **The internal electronic simulation is automatically programmed to run every 8 hours of use, The IStat is automatically programmed to lock out being used if the internal or external simulator does not pass the quality control.**

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. Contact the POCT Coordinator at 686-7044 or 686-7066.
- ❑ Deliver the faulty handheld to the i-STAT System Coordinator or clin. lab support services for a backup meter.
- ❑ Record the failure in the i-STAT QC Log along with the action taken.

- ❑ **The IStat will lock out users from performing patient testing until the simulator displays PASS and electronic control is successful.**

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. **The clinical lab stores IStat cartridges in a 24 hour a day monitored refrigerator**.

Remedial Action:

If the temperature is outside the range of 2 to 8°C (35 to 46°F), quarantine the cartridges in the storage refrigerator. Notify the i-STAT System Coordinator immediately. DO NOT USE the cartridges from this refrigerator. Record the QC failure in the i-STAT QC Log along with the action taken. Contact the physical plant to request service for this refrigerator.

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**. **Note: The ACT Stat cartridges can only be out at room temperature for 12 hours unlike the 2 weeks for most of IStat cartridges.** 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.

Periodic Procedures for Glucose Test Strips (N/A for UAMS)

- ❑ Two levels, usually the Low and High Controls, are tested:
- ❑ When a new lot of test strips is opened.
- ❑ When diabetes medication plan is adjusted.
- ❑ When the strips have been exposed to temperatures outside the storage conditions (4-30°C, 39-86 °F).

1. Press the ⏻ (On/Off) key to turn the handheld on.
2. Press 3 for PCx Glucose Strip.
3. Press 2 for Control.
4. Scan or enter operator ID. Repeat if prompted.
5. Scan or enter Low Level Control lot number.
6. Scan or enter test strip lot number.
7. Open foil packet, remove test strip and insert into handheld test strip port with black contact bars facing up and forward.
8. Apply Control solution to target area of test strip. Cover the entire area. Do not touch the test strip after sample is applied. (If test fails to start after second drop applied or if more than 30 seconds have passed, discard test strip and repeat the test.)
9. Enter chart page information if applicable.
10. View results on handheld's display.
11. Enter Comment Code if applicable.
12. Remove and discard test strip.
    a. Do not handle test strip with wet or dirty hands.
    b. Do not scan the barcode of another test strip.
    c. Do not use test strips that are wet, scratched or damaged in any way.
    d. Do not re-use test strips.
13. Press 1 for Test Options and 1 for Next Level if testing another level of control.

Action:

If the results are PASS, use the test strips as needed.

Remedial Action:

If the result is outside the acceptable range:

- ❑ Check that the correct lot numbers for control and test strip were scanned.
- ❑ Check storage conditions and that bottle has not been opened for more than 90 days.
- ❑ Use a new test strip. If results are in range, continue to use the test strips. If not, do not use the strips from this lot and notify the i-STAT System Coordinator.

Monthly Procedures

Print Electronic Simulator Results- At UAMS simulator results are stored in the QCM program.

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

- ❑ CDS version lower than 5: Click on System and Electronic Simulator.
- ❑ CDS version 5 and above: Click on the Simulator Viewer.

Print Control Fluid Analysis Results-Control results are logged into the Stat quality control manual.

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

- ❑ CDS version lower than 5: Use the Trend function.
- ❑ 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.

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.

Integrity Testing

From each lot of blood gas/chemistry cartridges received, use a representational number of cartridges to analyze i-STAT Level 1 and 3 Controls. For CHEM8+ cartridges, analyze i-STAT CHEM8+ Control Levels 1 and 3. If hematocrit is included, also analyze RNA Medical Hematocrit Control Level 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 Cardiac Marker Controls. For CK-MB cartridges, analyze 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. Transmit the results to the Central Data Station. Use the expected values published in the Value Assignment Sheet to verify the integrity of the cartridges.

Procedure for testing cartridges with i-STAT Level 1 and Level 3 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, 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, ***P***CO_2, or ***P***O_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, ***P***CO_2, or ***P***O_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. Transmit the results to the Central Data Station.

Procedure for testing CHEM8+ cartridges with i-STAT CHEM8+ controls. (N/A at UAMS)

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. Immeditely 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. Transmit the results to the Central Data Station.

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 Central Data Station.

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. Transmit results to the Central Data Station.

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 cTnI cartridges with i-STAT Level 1, 2, or 3 Cardiac Marker Controls:

1. Remove vial from freezer and thaw at room temperature (18-30ºC) for 15 minutes.
2. Thoroughly mix by gently swirling the bottle. Avoid foaming of the sample.
3. Dispense a drop of sample directly from the vial into the i-STAT cTnI cartridge and seal the cartridge. If short-term storage (<4 hrs) is desired, tightly recap the bottle immediately, and store at 2-8ºC.
4. Insert cartridge into an i-STAT 1 Analyzer.

Target Values and Ranges: See value assignment sheet accompanying the control or calibration verification material. The value assignment sheet displays target values and ranges expected when materials and equipment are performing properly. Should results fall outside the range, refer to the System Manual.

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.

Target values are specific to the i-STAT System. Results may differ if used with other methods (i.e., other IVD instrumentation).

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

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-N/A at UAMS

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 Central Data Station.

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 BNP cartridges with i-STAT BNP Level 1, 2, or 3 Controls (N/A at UAMS)

1. Remove vial from freezer and thaw at room temperature (18-30°) for 15 minutes.
2. Gently invert the vial 10 times, then swirl the vial 10 times. Inspect the sides of the vial to ensure that no particulate matter is clinging to the sides of the vial. If solids are observed in the control fluid or on the vial wall, repeat the mixing procedure. If further mixing does not homogenize the sample, discard the vial and thaw a fresh vial.
3. Open the vial and transfer a drop of solution directly into the BNP cartridge and seal the cartridge. If short term storage (<4 hours) is desired, tightly recap the bottle immediately, and store at 2-8°C.
4. Seal the cartridge and insert into the i-STAT 1 Analyzer.
5. Compare the i-STAT BNP result to the Value Assignment Sheet ranges. Always ensure that the lot number and the 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 Central Data Station.

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.

For glucose test strips, lot-specific calibration information is encoded in the test strip barcode label.

CLINICAL SIGNIFICANCE

Analyte	Some Causes of Increased Values	Some Causes of Decreased Values
Sodium	Dehydration Diabetes insipidus Salt poisoning Skin losses Hyperaldosteronism CNS disorders	Dilutional hyponatremia (cirrhosis) Depletional hyponatremia Syndrome of inappropriate ADH
Potassium	Renal glomerular disease Adrenocortical insufficiency Diabetic Ketoacidosis (DKA) Sepsis *In vitro* hemolysis	Renal tubular disease Hyperaldosteronism Treatment of DKA Hyperinsulinism Metabolic alkalosis Diuretic therapy
Chloride	Prolonged diarrhea Renal tubular disease Hyperparathyroidism Dehydration	Prolonged vomiting Burns Salt-losing renal disease 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

Analyte	Some Causes of Increased Values	Some Causes of Decreased Values
Creatinine	Impaired renal function	
Lactate	Hypoxia (shock, hypovolumia, 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
***P*CO_2**	Acute Respiratory Acidosis: • *Depression of respiratory center* • *Suppressed neuromuscular system* • *Pulmonary disorders* • *Inadequate mechanical ventilation* Chronic respiratory acidosis • *Decreased alveolar ventilation* • *Hypoventilation* Compensation in metabolic alkalosis	Respiratory alkalosis: • *Increased stimulation of respirator center* • *Hypermetabolic states* • *Mechanical hyperventilation* Compensation in metabolic acidosis
***P*O_2**	Breathing oxygen-enriched air	Carbon-monoxide exposure Pulmonary disorders Myocardial infarction Congestive heart failure
HCO_3 *and* *T*CO_2	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.	

Analyte	Some Causes of Increased Values	Some Causes of Decreased Values
PT/INR	Administration of oral anticoagulant therapy.	
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 *P*CO_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.

***P*O_2**

is measured amperometrically. The oxygen sensor is similar to a conventional Clark electrode. Oxygen permeates through a gas permeable membrane from the blood sample into an internal electrolyte solution where it is reduced at the cathode. The oxygen reduction current is proportional to the dissolved oxygen concentration.

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).

Glucose Test Strip

is determined amperometrically. Each strip includes an electrode containing the enzyme glucose oxidase (Precision PCx) or glucose dehydrogenase (PCx Plus). When a drop of blood is applied to the target area of the test strip, the glucose oxidase or dehydrogenase catalyzes the oxidation of glucose in the drop to produce gluconic acid. During the reaction, electrons are transferred by an electrochemical mediator to the electrode surface. This generates a current that is measured by the system. The size of the current generated is proportional to the amount of glucose present in the blood drop.

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 as 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.

TCO_2

The measured TCO_2 test method is calibrated to the International Federation of Clinical Chemistry (IFCC) TCO_2 reference method with an algorithm, based on the Henderson-Hasselbach equation, which uses pH, $\boldsymbol{P}CO_2$, and ionic strength (Na) measurements.

FOOTNOTES

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.

Prepared By: _____ Date: _____

Adopted: _____ Date: _____

Reviewed: _____ Date: _____

Reviewed: _____ Date: _____

Reviewed: _____ 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: _______________

Test									
Range									
Results									
Results									

Control Name: ___________________ Lot No.: __________________ Level: _____________ Exp. Date: _______________ CLEW: _______________

Test									
Range									
Results									
Results									

Control Name: ___________________ Lot No.: __________________ Level: _____________ Exp. Date: _______________ CLEW: _______________

Test									
Range									
Results									
Results									

Lot/Shipment accepted by: ____ Date: ___________________________

i-STAT QC Action Log

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

i-STAT QC Log: Expiration Date and Storage Conditions: Refrigerated

Date	Location	Cartridge Type	Lot #	Exp. Date	Quantity	Temp.	Action	Operator

i-STAT QC Log: Expiration Date and Storage Conditions: Room Temperature

Date	Location	Cartridge Type	Lot #	Exp. Date	Quantity	Temp.	Action	Operator

i-STAT Electronic Simulator Log for Analyzer Serial Number:_____ Year:_____

Date	Time	Pass Fail	Simulator ID	Operator	Time	Pass Fail	Simulator ID	Operator	Time	Pass Fail	Simulator ID	Operator

i-STAT Electronic Simulator Action Log

Date	Time	Analyzer	Failure Code or Letter	Simulator ID	Action	Pass Fail	Operator

i-STAT 1 Analyzer PCx and PCx Plus Glucose Test Strip QC Log

Date	Time	Control Level	Control Lot	Strip Lot	Pass Fail	If Fail Expected Range	Result	Action	Operator