Wake Forest™
Baptist Medical Center

i-STAT Testing: Blood Gas, Electrolyte, Hgb/Hct, Lactate, Creatinine, ACT & PT/INR

Prepared by Laboratory Compliance, Quality, Safety, and

Point-of-Care Testing Team
Updated December 2016

GENERAL INFORMATION

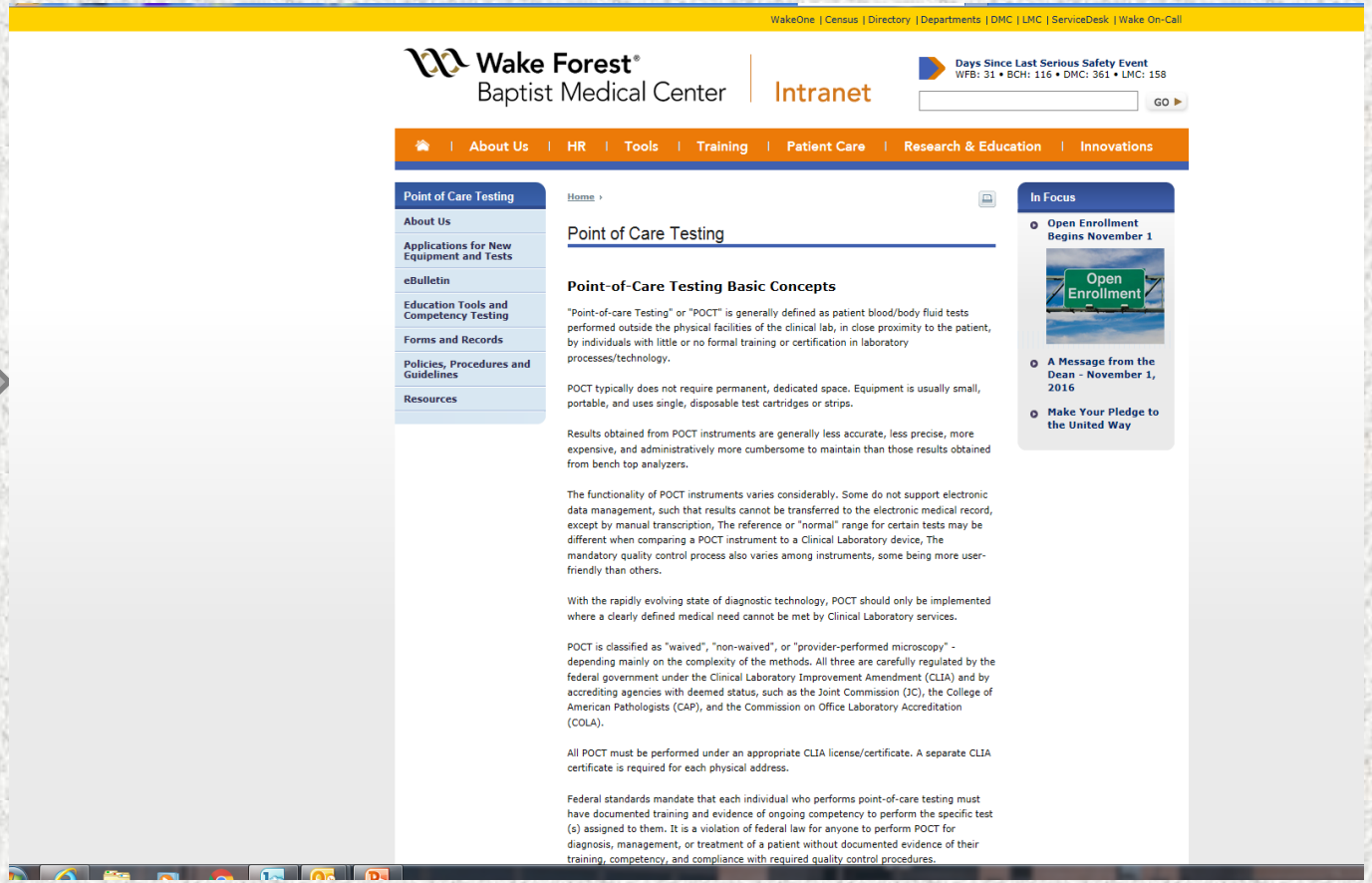
- Contact Information
- Policies/Procedures
- Training and Competency
- i-STAT Access
- Safety
- Components
- Testing Process Overview

i-STAT Support: Contact Information

- Trish Sorensen 713-4136
- Liz Gregory 713-0377
- Ray Dyer 713-4137
- OR Blood Gas Lab 716-2181 (M-F 7am-7pm)
- Site-specific preceptors
- Refer to the i-STAT System Manual and medical center specific i-STAT policies
- WFBMC POCT web site

i-STAT Policies/Procedures/Guidelines

- Posted on the WFBMC Intranet—Go to: *Departments—Point of Care Testing—Policies/Procedures/Guidelines*
- The i-STAT System Manual (Abbott POC website) can be found under *Resources--Resource Links—Manuals*



Only Authorized Users May Perform i-STAT Testing: Training and Competency Requirements

- Initial training and evaluation for proper test performance
- 6 month competency assessment-NEW users
- On-going Annual competency assessment
  - Must meet all 6 points of competency assessment, as defined by CLIA— refer to page 1 of competency observation form
- Failure to maintain competency will result in loss of testing privileges
- Competency observation may only be completed by an authorized staff member
- Written exams 80% correct or remediation will be required (All necessary exams must be complete PRIOR to competency observation)

i-STAT Access (Operator ID)

- Training=i-STAT access
- Employee ID=operator ID
- Do NOT share your employee/operator ID
- Do NOT enter your ID into analyzer and allow testing by another individual

Safety

- Always wear gloves
  - Patient testing
  - Performing/handling Quality Controls (QC)
  - Disinfecting analyzer
- Disinfect analyzers/printers
  - When contaminated with blood AND
  - Between EACH patient
  - Follow medical center policies
- DO NOT lean over the cartridge when filling
  - A safety shield is recommended
- Place gauze or tissue over snap when closing

Components of the i-STAT System

Primary System Components

Cartridge

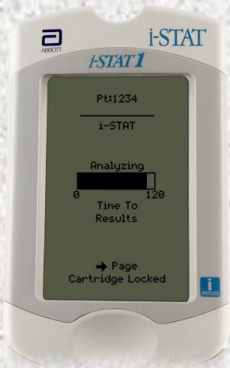
Handheld

Downloader

Printer

Quick Overview:
The i-STAT System Testing Process

1. Enter information into handheld
2. Obtain the blood specimen and fill cartridge
3. Insert cartridge; results will appear within minutes
4. Download results



THE I-STAT ANALYZER

- External Components
- Battery Replacement/Charging
- Barcode Scanner
- Test Menu
- Menu Options

i-STAT Analyzer

- Turns off after 2 minutes of non-use
- Can be turned on by pressing the on/off keypad—circle with line—Show on/off keypad
- If operator, patient, and cartridge information has been entered, the analyzer will remain on for 15 minutes

Handheld External Components

Cartridge port

Infrared eye

Battery compartment

Barcode scanner

Batteries: Hands On

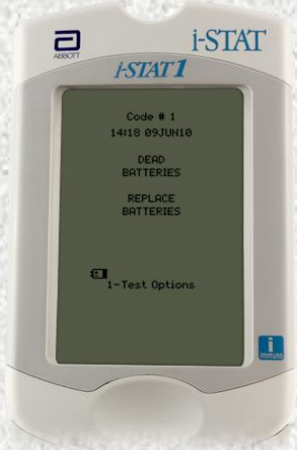
- 9-volt lithium disposable batteries or battery pack
  - Main campus sites use the Abbott rechargeable battery pack

9-volt lithium disposable batteries

Abbott rechargeable battery pack

Change/charge the batteries:

- Flashing battery icon
- "Battery Low " message
- Do not discard rechargeable batteries
- Green light will be on if battery in compartment is seated properly and charging



Battery compartment

Battery compartment

The Barcode Scanner

To scan

- Hold 3 to 12 inches away from the barcode
- Press and hold down the SCAN key
- Laser beam must cover the entire length of the barcode
- Wait for the beep or for laser beam to disappear
- Release the SCAN key

The barcode scanner is a class II laser device. Momentary exposure is not known to be harmful—however you should never point the scanner at anyone or look into the laser beam.

Handheld Test Menu—Hands On

Test Menu

- First menu to appear

Important Note:

This menu is used for patient tests only!

Cartridge Test Menu options

- 1 = Last Result
- 2 = i-STAT Cartridge (for a patient test)

Administration Menu Options

Hands On

- **1--Analyzer Status**
  - Battery voltage
    - Maintain charge above 8 volts
  - Shows Total records and Unsent records
- **2--Data Review**
  - Review/print stored data
  - #7 – List All Results
- **3--Quality Tests**
  - Quality control checks

CARTRIDGES

- i-STAT Supplies
- General Information
- Labeling
- Storage
- Handling

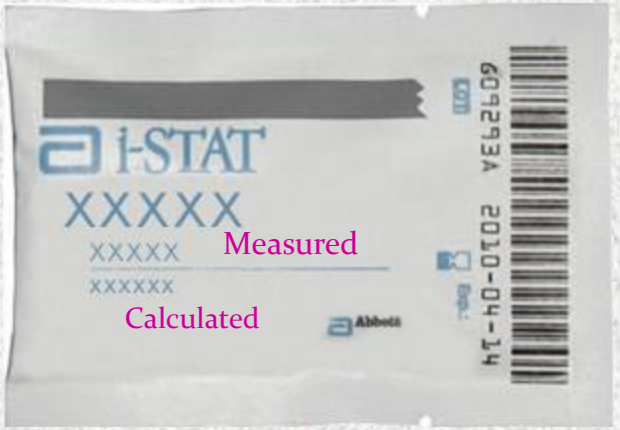
i-STAT Supplies

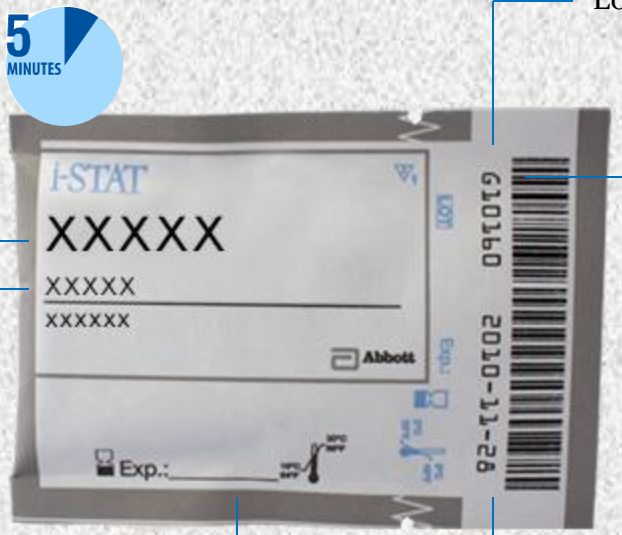
- Main campus sites obtain cartridges and paper from OR Blood Gas Lab
  - The site is responsible for room temperature dating of the cartridges
- NEVER take cartridges that are marked with **"Do Not Use"**
  - **Do not use any cartridges BEHIND this "Do Not Use" sign**
- Accurately complete i-STAT cartridge sign-out log
- Only take the amount of cartridges that will be used within the room temperature expiration dating period
- Replacement analyzers/printers-- obtain from the POCT office

General Cartridge Information

- Self-contained lab analyzers
- Analysis, sample manipulation, and waste are confined within the cartridge
- Single use
- 24 or 25 per box
- Use IMMEDIATELY after opening
- Requires only a few drops of blood
- Cartridges contain biosensors that “measure” the analytes being tested.
- Abbott offers different i-STAT cartridge configurations.
  - Only use cartridges authorized for your test site.

i-STAT Cartridge Labeling





Lot number

Cartridge barcode

Panel name

Analytes

Room temperature storage expiration date

Refrigerated expiration date

Cartridges MUST be brought to room temperature

- 5 minutes for a single cartridge
- 1 hour for a box of cartridges

Do NOT manipulate the cartridge in any way to bring it to room temperature more quickly.

i-STAT Supplies: Cartridge Sign-Out Log

Room Temperature Expiration Date= 2 Months
NOT to exceed manufacturer expiration date

Date	Location	Cartridge Type	Lot #	# of Cartridges	Expiration Dates		How will cartridges be stored in the user site?	Box #'s of Issued Cartridges	Initials	Printed Name
					Modified Room Temperature Exp Date	Manufacturer Exp. Date	Room Temp or Refrigerated?			
		G3								
		G3								
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I-stat cartridge signout log G3.091316

i-STAT Sites and Cartridges Used

- Brenner Respiratory Therapy (Peds ED, NICU, PICU, Transport): G3, CG4, EG7
- Cancer Center Radiology: Creatinine
- Cath Lab: ACT-CELITE, PT/INR, EG7
- CV-OR (Perfusion): ACT-Kaolin
- Dialysis Access Group: E3
- ECMO: G3, CG4, EG7
- EP Lab: ACT-CELITE, PT/INR
- Family Medicine Lab (Piedmont Plaza): Chem 8
- HemOnc Clinics (Elkin, Mt. Airy, Statesville): Chem 8
- Interventional Radiology: ACT-CELITE
- MRI: Creatinine
- OR Blood Gas Lab: Creatinine
- Special Isolation Unit: CG4, Chem 8
- Other:

Cartridge Storage

- ALL refrigerated cartridges must be stored **2- 8˚C**
  - Storage environment MUST BE MAINTAINED and monitored 24/7/365
    - Monitored by SPOT
- If temperature is ever outside of 2 to 8˚C, contact the POCT office for assistance.
  - **Do NOT use the cartridges for patient testing, until consulting the POCT office.**
- **Cartridges should NOT be returned to refrigerated storage once they reach temperatures above 8˚C.**
- Do NOT store or expose cartridges to extreme cold or heat such as freezing or stored **above lights or computers**

Cartridge Storage (continued)

Room temperature (RT) storage

- 14 days or 2 months, depending upon cartridge type
- **Room temperature expiration should NEVER exceed manufacturer expiration date**
- RT 18°C - 30°C (64-86°F)
- Monitored by color change indicators

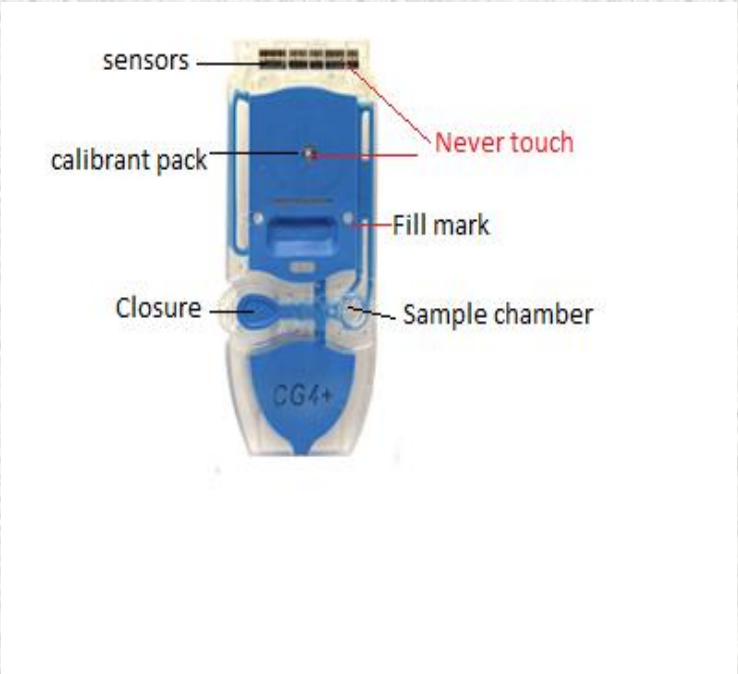
Do NOT use past manufacturer's expiration date or past room temperature expiration date.

i-STAT Cartridge Handling

Important note: To avoid a Quality Check Code, do not touch the sensors or apply pressure to the center of the cartridge!

- Do NOT reuse cartridges
- Open cartridge IMMEDIATELY prior to use.
- Carefully tear open the cartridge pouch where indicated (do NOT leave cartridges exposed to air or moisture)
- Hold the cartridge by the sides or the bottom
- Do not touch the sensors or apply pressure to the center of the cartridge (be careful when putting room temperature expiration date on cartridges – write or apply sticker at line on bottom – not in the middle)

i-STAT Cartridge Components



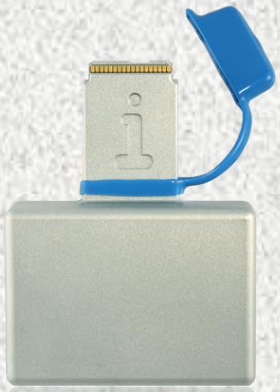
QUALITY CONTROLS (QC)

- Simulators
- Liquid QC

i-STAT System Quality Control

i-STAT System Quality Control

- Internal Electronic Simulator
- External Electronic Simulator
- Liquid Quality Controls



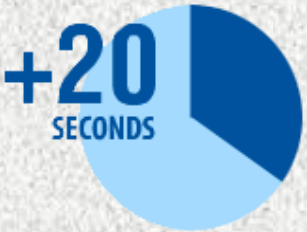
Simulators

- Electronic Quality Control
  - Validates i-STAT analyzer
  - Pass or Fail

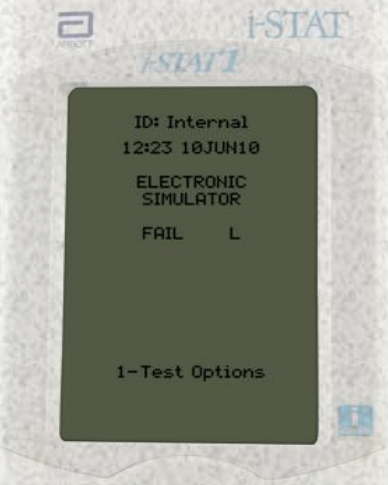
- QC results automatically documented when analyzer downloaded

Internal Electronic Simulator

- Internal checks ensure proper and accurate functioning



- Performed automatically
  - Every 8 hours of patient use
  - With each cartridge type
- If simulator passes, testing proceeds/patient results will be displayed
- Results will not be given if the simulator fails.
- If the "*Electronic Simulator Fail*" message appears,
  - Do Not proceed with patient testing until issue is resolved.
  - Test external electronic simulator



External Electronic Simulator--Hands On

External Electronic Simulator

Same as the internal simulator but is an external device and can be tested upon demand.

Simulator is performed if:

- Handheld is dropped
- Internal Electronic Simulator failure
- Error code occurs that indicates the simulator should be tested
- Questionable analyzer performance
- Ceramic cartridge cleaning procedure

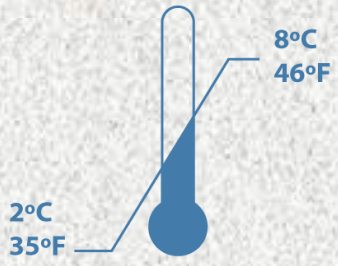
Do not remove simulator when "Simulator Locked" is displayed

Liquid Quality Control

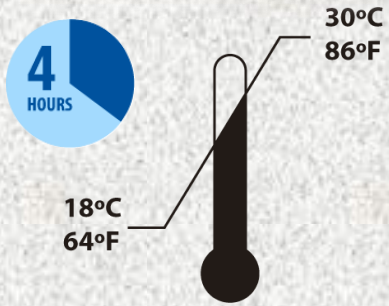
- Validates performance of test cartridges
- Consists of multiple levels—test specific
- Should be performed:
  - Each new cartridge shipment, per cartridge type, per cartridge lot #, PRIOR to patient use—by Clinical Lab staff
  - Monthly—by testing site staff
  - Questionable performance cartridges/analyzer

Liquid Quality Controls for G3, CG4, EG7, Chem8, Creatinine (area specific)

- 3 levels
- Monitors cartridge performance
- Store 2°C to 8°C
- Room temperature for **4 hours** (G3, CG4, EG7)
- Room temperature for **30 minutes** (Chem 8 or creatinine)



Expiration Date



Liquid Quality Control
ACT and PT/INR (area specific)

- 2 levels
- Monitors cartridge performance
- Each level must be reconstituted from:
  - One vial dry lyophilized human plasma
  - One vial diluent
  - Handle using Standard Precautions
    - Always wear gloves
- Store 2°C to 8°C
- Must be left at room temperature for 45 minutes prior to reconstitution

Liquid QC Important Notes/Reminders

- Analyzers programmed with QC ranges for the liquid QC.
  - Pass or Fail will display

- If liquid QC fails, a comment code and corrective action is required:
    - Use comment code 5—recheck/confirm
    - Repeat liquid QC
    - Creates a **STOP** point for the testing staff member
    - ***Patient testing lockout does NOT occur***

- Staff MUST ensure QC results are within acceptable limits PRIOR to proceeding with patient testing.

PATIENT IDENTIFICATION

- Process Flow
- Patient Identity

Process Flow

- Ensure documented physician order or documented protocol before performing i-STAT testing.
- Patient ID:
  - CSN for that specific date of service or current admission CSN
- After testing is completed, analyzer should be downloaded.
- If ID match is found, results post to Wake One and billing occurs, regardless of provider order

Patient identity

- Follow medical center policy for verification of patient identity—
  - 2 patient identifiers at the patient side (name and Date of Birth (DOB))
- Scan patient ID DIRECTLY from the patient armband attached to the patient
- **If an ID barcode is scanned that is not physically attached to the patient, 4 identifiers (name, DOB, MRN, CSN) MUST be verified.**
  - **Include label/armband verification in the procedure time-out.**
- Ensure sample identity throughout entire testing and reporting process.
  - Verify patient ID again on analyzer display.

SAMPLE INFORMATION

- Sample Collection/Sample Considerations
- Filling the cartridge
- Running a patient test

Sample Collection/Considerations:

- **ONLY whole blood should be tested on the i-STAT**
  - Arterial
  - Venous
  - Capillary
    - Use a SINGLE-use auto-disabling skin puncture device that provides free-flowing blood
    - Use a heparinized capillary tube
    - **NOTE:** ***Capillary tubes are NOT acceptable for use when testing ACT or PT/INR cartridges***

Important notes:

- ***Make sure to follow medical center procedures for proper sample collection.***
- ***Always correlate results with the status of the patient!***

Consult Intended Use Statements for APOC Products in the Cartridge and Test Information (CTI) sheets at:

- www.abbottpointofcare.com
- Within the i-STAT 1 System Manual

In-Dwelling Line

- **Adequately 'clear' line**
  - Inaccurate results will be given if samples are contaminated.
    - Saline Contamination can cause:
      - Falsely elevated sodium
      - Falsely decreased potassium, hemoglobin, hematocrit, pCO_2,
    - Contamination with potassium-containing fluids can cause:
      - Falsely elevated potassium

- **i-STAT Recommendation:**
  - Five to six times the volume of the catheter, connectors, and needle should be collected as 'waste'

- **ACT cartridges:**
  - To avoid possible heparin contamination and specimen dilution, the line should be flushed with 5mL of saline and the first 5mL of blood **or** six dead space volumes of the catheter should be discarded

Chemistry Cartridges—CHEM 8 and Creatinine

Chem 8 and Creatinine ONLY

- Whole blood sample
  a. 4 ml Lithium Heparin green-top tube—**MUST be filled to capacity**
  b. Heparinized syringe
  c. Non-heparinized syringe
- For heparinized samples, test within 30 minutes
- For non-heparinized samples, test Immediately

Blood Gas Cartridges—G3, CG4, EG7

- Use a syringe
- **Seal sample with cap** IMMEDIATELY after collection.
  - Do not contaminate with air
    - pO2 will be falsely increased if air contamination occurs
- Heparinized samples, test within 10 minutes
- Non-heparinized samples, test immediately
- EG7 (ionized calcium) use balanced heparin

ALWAYS test CG4 cartridge immediately after collection--lactate will be falsely increased if testing is delayed

Important Notes:
Do not introduce air into the sample.
Do not use an iced sample.
Do not allow the blood to drip into the sample well.

PT/INR Cartridge

- **Capillary or venous sample**
- **Filling a PT/INR Cartridge**
  - Gently squeeze finger to obtain hanging drop of blood
  - Avoid milking the finger as this factor may impact results
  - Bring the cartridge sample well up to the bottom of drop of blood until they touch
- **Do NOT use a filling device/transfer device/capillary tube.**
  - **Preferred method: Fill cartridge DIRECTLY from finger**
- **Use the FIRST drop of blood to test**
- Venous sample: collect in a **plastic** syringe without anti-coagulant. Metal needles should not be used when filling an i-STAT cartridge.
- **Test Immediately!**
- **If sample testing is delayed, falsely decreased results will be obtained**

ACT Cartridges :
IMPORTANT Information

- **ENSURE the correct ACT cartridge is used for your test site. ACT methods are NOT interchangeable.**

- There are multiple ACT methodologies in use at WFBMC, which may yield different results

ACT Cartridges

- **NON-heparinized Whole blood sample**
  - Use a plain, plastic syringe
- Do NOT fill cartridge with a metal needle
- Test Immediately!
  - **NO DELAY IN TESTING** or results will be falsely decreased
- Wait until the final ACT result displays
- Contamination may be indicated by:
  - Falsely prolonged ACT results

Cartridge Filling Overview

- Mix the sample thoroughly and gently for 15 seconds
  - Hematocrit is most affected by an improperly mixed sample
- Discard first few drops to check for clots and to get rid of any micro air bubbles
  - NEVER test a sample that has or has had a clot. Inaccurate results may be obtained.
- Fill to the fill mark and close the closure to seal
- Insert IMMEDIATELY into the analyzer
- Do not move analyzer after cartridge has been inserted

closure is closed

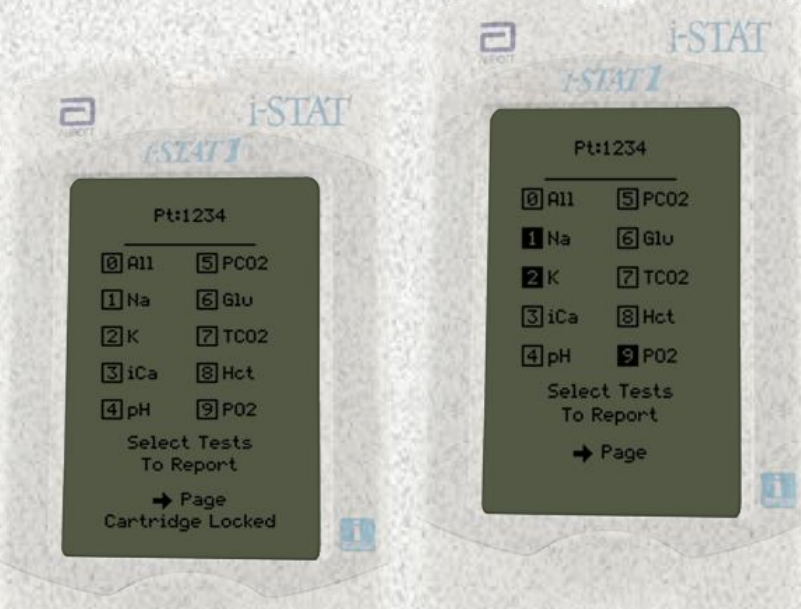
Using a Capillary Tube to Fill a Cartridge

(Do NOT use with ACT or PT/INR cartridges)

- Test Immediately!
- Direct one end of capillary tube into sample well
- Fill to fill mark
- Close the closure

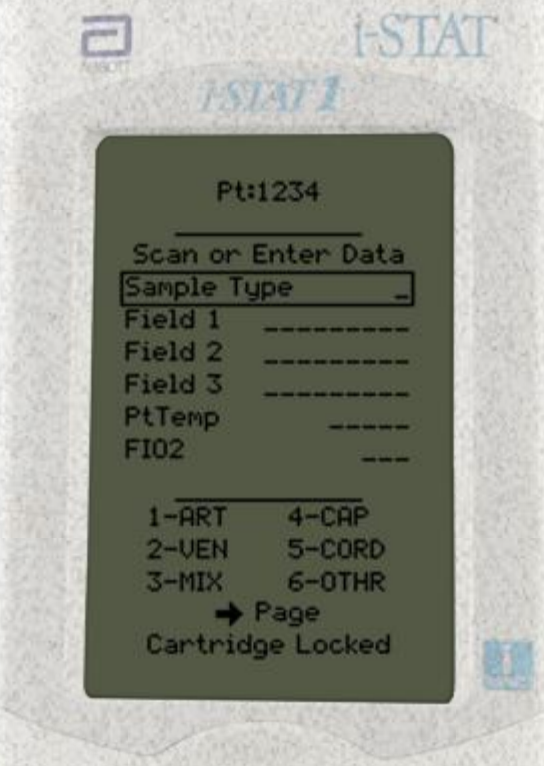
Running a Patient Test: Using the Test Select Function

- Used to view and report selected results
- Refer to list of analytes displayed
- Press corresponding numbers on keypad
- Press again to deselect
- Only select tests that the clinical provider has ordered or the documented protocol indicates



Running a Patient Test: Overview of the Chart Page

- Allows entry of patient data
  - Sample type
    - Enter the number next to the sample type
    - Press the ENT key
  - Patient temperature
    - ONLY if requested by provider
  - FIO_2
  - Free fields for additional info
    - Free fields do not populate the electronic medical record



Citrate Dialysis Testing:

only applies to Respiratory Therapy in PICU (iCa on EG7 cartridge)

- When testing Dialysis Circuit sample,
  - Enter C in field 1 of the i-STAT analyzer
  - C causes results to post in Wake One with the comment: Whole Blood Dialysis Circuit

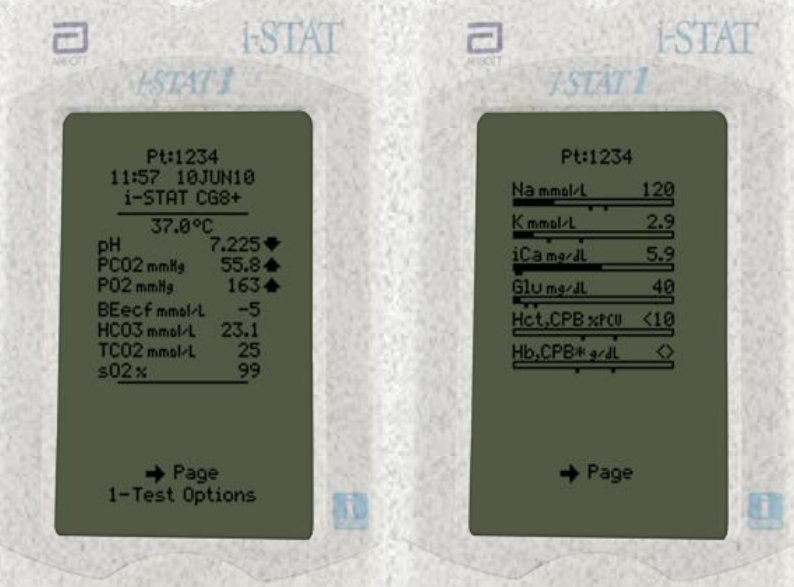
- If you forget to enter C in field 1, Wake One enter/edit will have to be used to add the comment, "Whole Blood Dialysis Circuit"

RESULTS

- Interpreting Results
- Comment Codes
- Result Considerations
- Quality Check Codes
- Printing Results
- Transmitting Results
- Enter/Edit of Results – Wake One
- Supporting Documents

Interpreting Test Results: The Results Screen

- Patient ID
- Time and date of test
- Type of cartridge
- Test results
  - EG7 and Chem 8 results appear on 2 pages
  - Use right Arrow key to navigate



Interpreting Test Results: Critical Value Alerts

- Indicated by ⬆ up or ⬇ down arrows
- Evaluate with patient's clinical symptoms
  - As appropriate, perform repeat testing
    - Values not consistent with patient symptoms --repeat and validate by an alternate test method
      - Use ICU Blood Gas Lab (except Creatinine – use Main Lab)
- Follow medical center policy for handling critical results

Critical Values – found in i-STAT procedure on POCT website

Critical Results

Revision 08/2016

Critical results are test results that fall outside high and low critical limits, which define the boundaries of life-threatening values for a test. Critical results represent an emergency condition and should be reported immediately to the patient's attending physician, nurse, or mid-level provider. Documentation of notification should be noted in the patient record. Documentation should include: notifying individual's initials/signature, the result, date, time, and the name of the person that is notified of the critical value. The author's name should be legible and authenticated. Documentation pertaining to the person that is notified of the critical value should be identifiable for future questions. At a minimum, last name and credentials should be documented. It is preferred that the full name of the provider be documented. Critical values should be properly evaluated with the patient's clinical symptoms and followed-up by necessary laboratory confirmation. Any unexpected result should be repeated on the i-STAT or sent to the laboratory for confirmation.
Critical Results of Tests and Diagnostic Procedures, formerly PPB-NCBH-10, should be followed regarding read back of verbally reported critical values.

Critical value limits defined by the Clinical Laboratory in conjunction with the Medical Directors for i-STAT user sites, are as follows:

Analyte	Adult	Pediatric	Neonate (Patient in NICU)	Comments
Sodium mEq/L or mmol/L	<120 >160	<120 >160	<120 >150	
Potassium mEq/L or mmol/L	<3.0 >6.0	<3.0 >6.0	<3.0 >6.0	Unexpected results >6.0 should be verified by the laboratory. Hemolysis falsely elevates results. For potassium results to be considered critical, they should also fail the normal range defined for the patient's age.
Total CO2 mEq/L or mmol/L	<10 >40	<10 >40	<10 >40	
Ionized Calcium mmol/L	<0.75 >1.40	<0.75 >1.40	<0.80 >1.40	
pH	<7.2 >7.6	<7.15 >7.6	<7.20 >7.45	
pCO2 mm/Hg	<25 >60	<30 >80	<35 >80	
pO2 mm/Hg	<50	<30	<30	ARTERIAL
Glucose mg/dL	<50 >600	<50 >300	<50 >300	
Hemoglobin g/dl	<=6 >=20	<=6 >=20	<=6 >=20	
Hematocrit %PCV	<=18 >=60	<=18 >=60	<=18 >=60	
PT/INR	>= 5 or value not calculated	>= 5 or value not calculated	>= 5 or value not calculated	INR values equal to or greater than 4.0, as reported by i-STAT will have a reflex venous PT/INR ordered and sent to the Clinical Laboratory for confirmatory testing.

The patient provider must be notified of critical values:

- Documentation must include:
  - Result
  - Date/Time of notification
  - Name of provider notified
  - Name of notifying staff member
  - Critical values must be notified within 15 minutes

Estimated Glomerular Filtration Rate (eGFR)

- Estimated Glomerular Filtration Rate (eGFR) values will be reported when Creatinine results are downloaded into the electronic medical record.
- The values may be accessed via Wake One.
- The i-STAT handheld will NOT report eGFR values.
- May use online calculator in POCT website (under Resources - Resource Links)

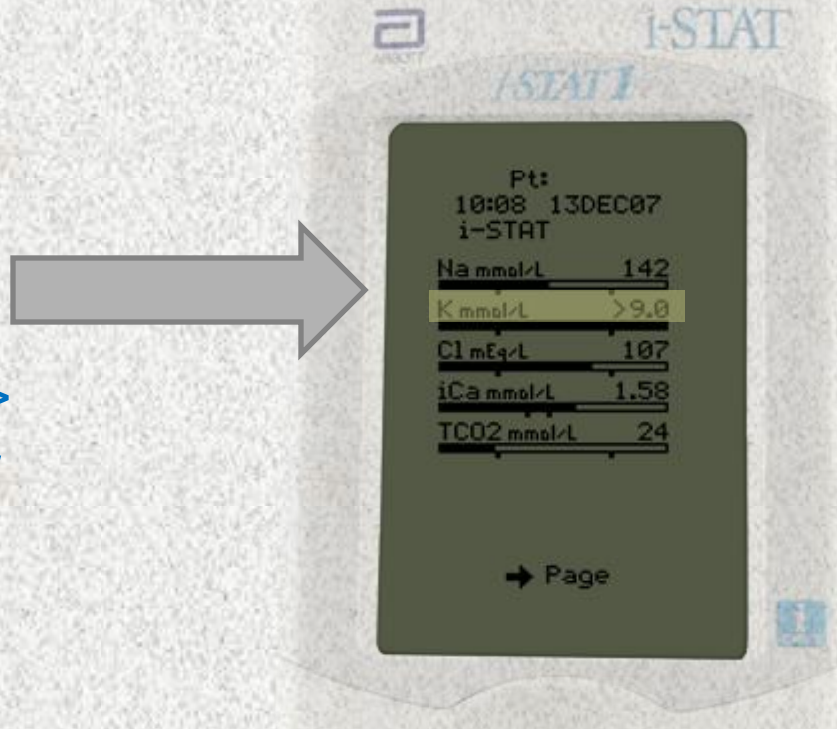
Interpreting Test Results: Out of Reportable Range Flags

Out of Reportable Range flag

- Indicated with a <xxx or >xxx

Suppressed Result Flag <>

- Result dependent on the out of reportable range result



Interpreting Test Results: Star Outs (***)

- *** appears in place of the test result
  - Sensor on the cartridge is unable to report a result
- Use comment code 0 (zero) to prevent result from posting to the patient record
  - Failure to enter comment code 0 into the i-STAT handheld at the time of testing=results post to Wake One
    - The star out result will report as INSTRUMENT ERROR.
- ACTION REQUIRED:
  - Retest the sample
  - If star out values continue, send the sample to the Clinical lab for testing.

Responding to Patient Tests: Comment Codes

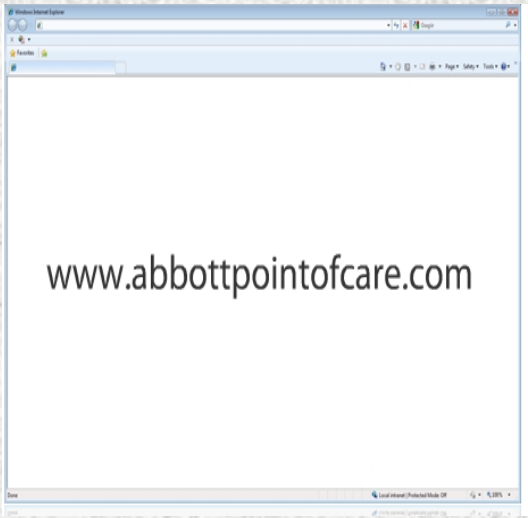
- Numeric codes
  - 'Automates' result hold or posting of result to the patient record
  - Affects patient billing for testing

- Comment field--top of the first page of the results screen
  - MUST be entered at the time of testing AND before the analyzer powers down
  - *Question: What can you do if you realize that you have misidentified a patient sample immediately after inserting the cartridge?*

Code	Translation	Result Post to Wake One	Allows charge to patient	Use
0 (zero)	Procedure Error	NO	NO	• Star out • Questionable Results • Error in testing
5	Recheck/Confirm	Yes	NO	• Result may be accurate and test will be repeated
6	To Notify Provider	Yes	Yes	• Documents intent to notify provider of result
123	Lab Confirmation to Follow	Yes	NO	• Use when sending repeat testing to the laboratory

Result Considerations: Factors That May Affect Results

- *Avoid factors that may affect the sample prior to analysis*
- ***Always correlate results with the status of the patient***
- Do NOT Move/Carry the analyzer during sample testing
  - NO Vibration or tilting analyzer



References:

- Cartridge and Test Information Sheets (CTI Sheets)
  - i-STAT 1 System Manual
  - www.abbottpointofcare.com

Result Considerations: Cartridge and Test Information Sheet

LACTATE/LAC

Lactate is measured amperometrically. The enzyme lactate oxidase, immobilized in the lactate biosensor, selectively converts lactate to pyruvate and hydrogen peroxide (H_2O_2). The liberated hydrogen peroxide is oxidized at a platinum electrode to produce a current which is proportional to the sample lactate concentration.

$$\text{L-Lactate} + O_2 \xrightarrow{\text{Lactate Oxidase}} \text{Pyruvate} + H_2O_2$$

$$H_2O_2 \xrightarrow{\text{Platinum electrode}} 2H^+ + O_2 + 2e^-$$

See below for information on factors affecting results. Certain substances, such as drugs, may affect analyte levels *in vivo*.[1]

If results appear inconsistent with the clinical assessment, the patient sample should be retested using another cartridge.

Intended Use

The test for lactate, as part of the i-STAT System, is intended for use in the *in vitro* quantification of lactate in arterial, venous, or capillary whole blood.

The i-STAT lactate test is useful for (1) the diagnosis and treatment of lactic acidosis in conjunction with measurements of blood acid/base status, (2) monitoring tissue hypoxia and strenuous physical exertion, and (3) diagnosis of hyperlactatemia.

Contents

Each i-STAT cartridge contains one reference electrode (when potentiometric sensors are included in the cartridge configuration), sensors for the measurement of specific analytes, and a buffered aqueous calibrant solution that contains known concentrations of analytes and preservatives. For cartridges that contain a sensor for the measurement of lactate, a list of reactive ingredients is indicated below:

Reactive Ingredient	Biological Source	Minimum Quantity
Lactate	N/A	1.8 mmol/L
Lactate Oxidase	*Aerococcus viridans*	0.001 IU

Metrological Traceability

The i-STAT System test for lactate measures L-lactate amount-of-substance concentration in the plasma fraction of arterial, venous, or capillary whole blood (dimension mmol L^{-1}) for *in vitro* diagnostic use. Presently, no international conventional reference measurement procedure or international conventional calibrator for lactate is available. Lactate values assigned to i-STAT's controls and calibration verification materials are traceable to i-STAT's working calibrator prepared from sodium L-lactate (Sigma-Aldrich

Precision Data (mmol/L)	Aqueous Control	n	Mean	SD	%CV
	Level 1	120	6.35	0.08	1.21
	Level 3	120	0.81	0.03	3.27

Method Comparison (mmol/L)	Radiometer ABL 725 (whole blood vs. whole blood)	Hitachi 917 (i-STAT whole blood vs. Hitachi plasma)
n	47	47
Sxx	0.123	0.084
Syy	0.136	0.079
Slope	1.02	1.06
Int't	0.12	-0.32
Sy.x	0.18	0.17
Xmin	0.80	1.77
Xmax	14.20	14.24
r	0.998	0.997

Factors Affecting Results*

Special collection procedures are necessary to prevent changes in lactate both during and after the blood is drawn. For steady state lactate concentrations, patients should be at rest for 2 hours and fasting. Venous samples should be obtained without the use of a tourniquet or immediately after the tourniquet is applied. Both venous and arterial samples may be collected into heparinized syringes.

Samples for lactate should be analyzed immediately on drawing as lactate increases by as much as 70% within 30 minutes at 25 °C as a result of glycolysis.[2]

Interference studies were based on CLSI guideline EP7-A2.[15] Test concentrations used were as per the CLSI guideline unless otherwise indicated.

When added to a plasma pool the following substances (at the concentrations indicated) were found to interfere with the i-STAT lactate assay:

Substance	Test Concentration (mmol/L)	Interference
Bromide	37.5	Use another method. See Note below
Glycolic Acid	10.0 [16]	Increased i-STAT lactate results. Use another method.
Hydroxyurea	0.92	Increased i-STAT lactate results. Use another method.

The following substances are known not to significantly interfere with the i-STAT lactate assay at the stated test concentrations:

Substance	Test Concentration (mmol/L)
Acetaldehyde	0.045 [16]
Acetaminophen	1.32
Acetylcysteine	10.2
Ascorbate	0.34
Bromide *(therapeutic)*	2.5 [17,18,19]
Dopamine	0.006
Formaldehyde	0.133 [16]
β-Hydroxybuterate	6.0 [20]
Pyruvate	0.31
Salicylate	4.34
Uric Acid	1.4

Result Considerations: i-STAT INR

Consideration	Action
Error Code 19	• Draw venous sample and send to Core Lab for testing
INR >=4.0	• Use comment code 123 • Draw venous sample and send to Core Lab for testing
Chlorhexidine Gluconate	• i-STAT PT/INR may be falsely elevated in samples contaminated with Chlorhexidine Gluconate. This chemical can be found in some skin cleansing solutions.

Result Considerations: Effects of Hemolysis on Potassium Result

(Hemolysis is the destruction of red blood cells, caused by disruption of the cell membrane, and results in the release of hemoglobin)

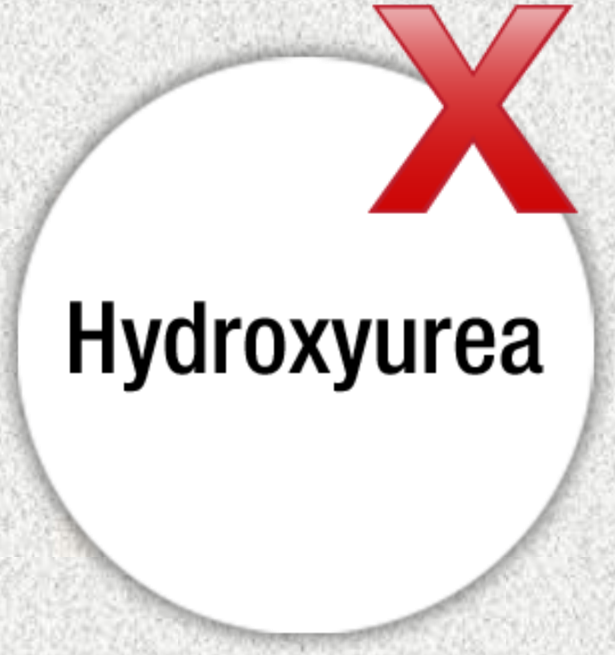
- i-STAT tests whole blood. Hemolysis can NOT be determined.
  - Potassium values will be falsely increased
- DO NOT report/treat high potassium results until verified via an alternate method.
  - If asked to do so, OR/ICU Blood Gas Labs will spin down sample to check for hemolysis

Result Considerations: Factors That May Affect Creatinine Results

Avoid affecting creatinine results:

- Use another testing method if the patient has been administered hydroxyurea (Droxia®, Hydrea®)
  - Send sample to Main Lab
    - Do NOT use Blood Gas Lab
- i-STAT creatinine results will be falsely elevated

Important note:
Always mix properly and test promptly!



Quality Check Codes:

i-STAT Quality System

- Numerous quality checks during patient test cycle
- **Failed quality check**
  - Cause message— pay attention to the code number
  - Action message
  - Quality Check Code
    - Do NOT continue with testing until the cause of the error is clearly understood
    - If the same error code occurs multiple times with no apparent cause, notify the Clinical Laboratory POCT office
    - Consider using a different analyzer and a different batch of test cartridges

Quality Check Codes

Quality Check Codes

i-STAT® TECHNICAL BULLETIN

ANALYZER CODED MESSAGES

From the time it powers up until the time it powers down, the i-STAT® Analyzer performs numerous quality checks. The failure of any quality check causes the analyzer to halt the test cycle and display a "cause", an "action" message, and a code.

The Cause Message:
This message describes the likely cause of the failed quality check. For example, when an overfilled cartridge is detected, the analyzer will display "Sample Positioned Beyond Fill Mark".

The Action Message:
This message indicates the appropriate action. For example, if it is likely the quality check will fail again the next time the analyzer is used, the instruction "Use Electronic Simulator" will be displayed. If the problem is related to an operator or cartridge, the instruction "Use Another Cartridge" will be displayed.

The Cause Code:
This is a numeric code associated with the failed quality check. Since multiple codes can be associated with a single cause message, this is essential information when contacting i-STAT Technical Services or your local support organization for further assistance. The codes are stored in the analyzer's memory along with other test records and are transmitted to the Central Data Station. The code list can be viewed and printed.

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

Code Number	Cause/Action Message on Display	Explanation
1	**Dead Batteries** / Replace Batteries	There is insufficient battery power to complete the testing cycle. Replace the disposable lithium batteries in the analyzer or recharge the rechargeable batteries. If you are experiencing this code frequently and use disposable batteries with the i-STAT 1 Analyzer, you may want to consider the rechargeable battery system available with the i-STAT 1 Analyzer.

Abbott Point of Care

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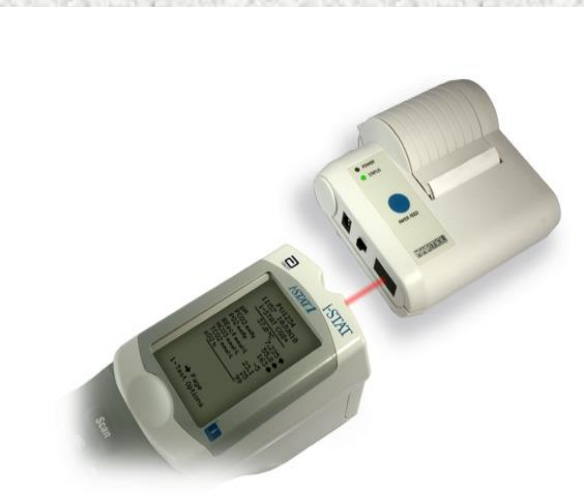
Art: 714260-00V Rev. Date: 14-JUL-16

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

Code Number	Cause/Action Message on Display	Explanation
19	**No Clot Detected** / See Manual	During the PT/INR cycle, no clot was detected. Run another cartridge. If code 19 reappears, run the sample on an alternate methodology.
22, 25	**Cartridge Error** / Use Another Cartridge	These codes occur only for coagulation cartridges if the mixing of the sample and reagent is compromised. This can be caused by an insufficient or clotted sample, or by air bubbles in the sample.
24	**Cartridge Error** / Use Another Cartridge	The electrical resistance of the calibrant fluid (Rcal) used to verify the electrolyte concentration is out of specification. This could occur if the calibrant pack was ruptured well before the test allowing evaporation to result in a higher electrolyte concentration. Besides the electrolyte concentration, the Rcal is also affected by the temperature and the height and width of the fluid segment over the conductometric sensor. The analyzer accounts for the temperature, but the height and width of the fluid segment can vary from cartridge lot to cartridge lot. The analyzer has been programmed to compensate for these lot-to-lot differences by maintaining a running average of the Rcal values measured from the most recent cartridge runs. Occasionally, the difference between the Rcal values for two cartridge lots is large enough to cause the introduction of a new lot to trigger code 24 on the first few cartridge runs. The Code 24 errors should disappear as the running average adjusts. However, if code 24 persists after more than 3 cartridge runs on each analyzer, contact i-STAT Technical Services or your local support organization.
26	**Cartridge Error** / Use Another Cartridge	This code occurs if there was a coagulation specific quality check failure: premature substrate activation, abnormally low levels of substrate, or invalid fluid motion.
20, 27-29, 32, 33, 40, 41, 45, 87	**Cartridge Error** / Use Another Cartridge	These codes identify problems with the cartridge such as: calibrant fluid arriving too soon, too late, or not at all, or noise in the calibrant fluid signals. Codes 20, 27, 41, and 87 can be caused by poor contact that can sometimes be corrected by conditioning the pins in the analyzer using the ceramic conditioning cartridge. The specific conditioning procedure is described at the end of this bulletin. The rate of quality check code 45 can be elevated when cartridges are run without allowing sufficient time for the cartridges to equilibrate to room temperature. To minimize the number of quality check codes, review i-STAT cartridge storage conditions and allow sufficient time for refrigerated cartridges to equilibrate to room temperature.
42, 43	**Cartridge Error** / Use Another Cartridge	These codes indicate that the conductometric sensor (code 42) or the amperometric sensor (code 43) was out of specification. This could be caused by a pre-burst calibrant pack, dirty cartridge contact pads, or a dirty connector in the analyzer.

Printing Results with the i-STAT Portable Printer

- Used in NICU, PICU, Cath Lab, Peds ED, other
- Display results and align the infrared eyes of each device
- Press the printer icon key on the handheld
- Printer uses rechargeable batteries—MUST remain plugged into outlet and turned off when not in use
- Verify patient ID on printout against patient sample ID



Transmitting Results: Downloader

Transmit results after each test/case:

- Turn handheld off
- Place handheld in the Downloader
- Look for display screen to show arrows and the message "*Communication in Progress*"

When transmission is complete:

- Screen goes blank
- Handheld turns off

Transmitting Results: Troubleshooting

- If the downloader does Not display “Communication in Progress” or an error message appears
  - Check for a green power light
  - Check all cord/cable connections to the down loader
  - Try unplugging and re-plugging the cables
  - If troubleshooting does not resolve problem, report problem to the Help Desk (Call 6-HELP)

Editing of results once posted to Wake One

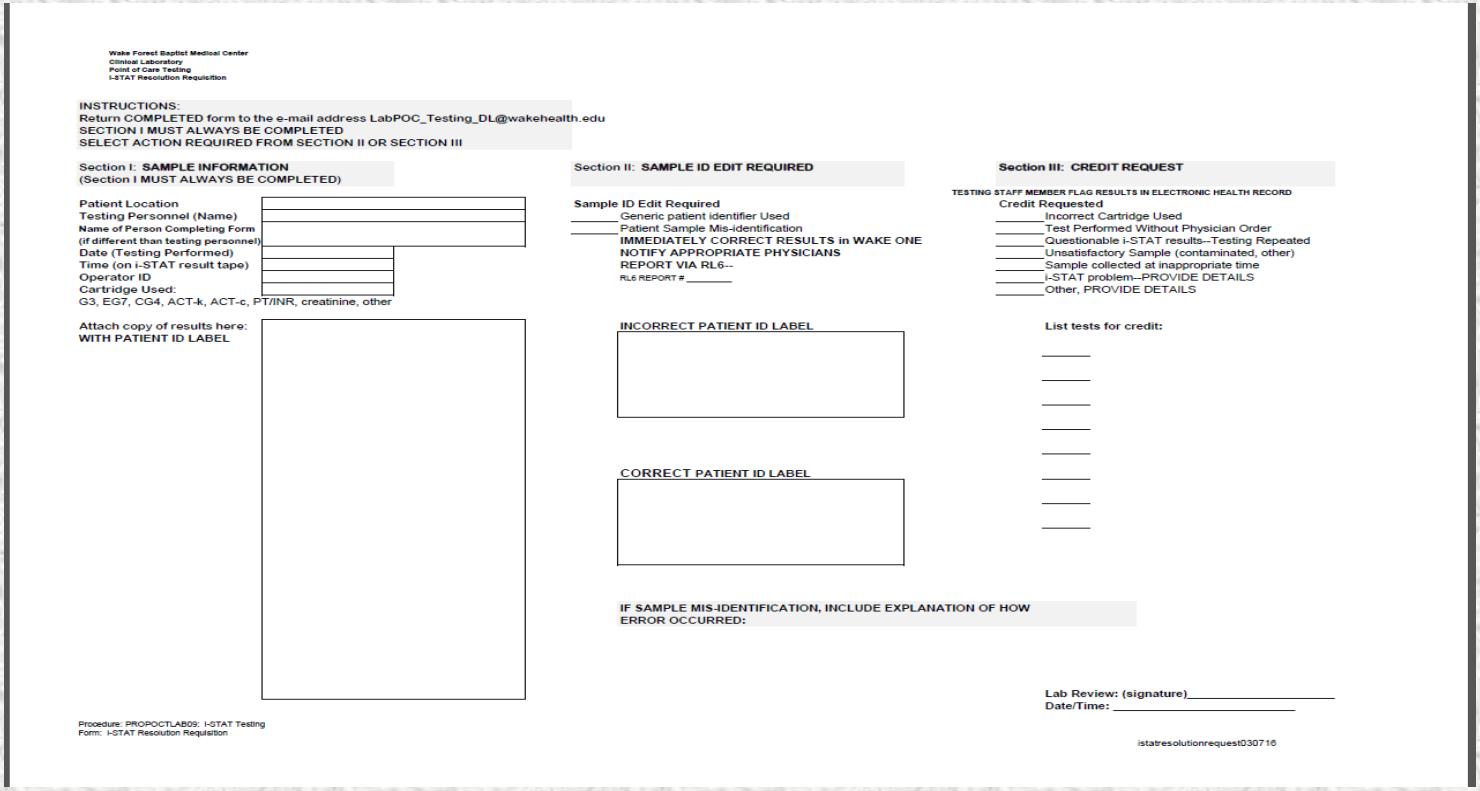
- Refer to i-STAT Procedure or "*Tips and Tricks: Procedure to correct i-STAT results in Wake One*"

- **Situations that require editing of results**:
  - Sample Misidentification
    - Also requires i-STAT resolution requisition found on POCT web site
  - Erroneous temperature corrected blood gas
  - Questionable i-STAT results if posted to Wake One
  - Tests performed but not ordered by the physician
  - Documentation of critical value notification if not done in another section of Wake One
  - Adding comment to citrate dialysis samples, where C was not used in Field 1 at the time of testing

Supporting Document(s)

- i-STAT Resolution Requisition

  (Located on POCT website – Forms and Records)



Wake Forest Baptist Medical Center
Clinical Laboratory
Point of Care Testing
I-STAT Resolution Requisition

INSTRUCTIONS:
Return COMPLETED form to the e-mail address LabPOC_Testing_DL@wakehealth.edu
SECTION I MUST ALWAYS BE COMPLETED
SELECT ACTION REQUIRED FROM SECTION II OR SECTION III

Section I: **SAMPLE INFORMATION**
(Section I MUST ALWAYS BE COMPLETED)

Patient Location
Testing Personnel (Name)
Name of Person Completing Form
(if different than testing personnel)
Date (Testing Performed)
Time (on i-STAT result tape)
Operator ID
Cartridge Used:
G3, EG7, CG4, ACT-k, ACT-c, PT/INR, creatinine, other

Attach copy of results here:
WITH PATIENT ID LABEL

Section II: **SAMPLE ID EDIT REQUIRED**

Sample ID Edit Required
_____Generic patient identifier Used
_____Patient Sample Mis-identification
IMMEDIATELY CORRECT RESULTS in WAKE ONE
NOTIFY APPROPRIATE PHYSICIANS
REPORT VIA RL6--
RL6 REPORT # _____

INCORRECT PATIENT ID LABEL

CORRECT PATIENT ID LABEL

IF SAMPLE MIS-IDENTIFICATION, INCLUDE EXPLANATION OF HOW ERROR OCCURRED:

Section III: **CREDIT REQUEST**

TESTING STAFF MEMBER FLAG RESULTS IN ELECTRONIC HEALTH RECORD
Credit Requested
_____Incorrect Cartridge Used
_____Test Performed Without Physician Order
_____Questionable i-STAT results--Testing Repeated
_____Unsatisfactory Sample (contaminated, other)
_____Sample collected at inappropriate time
_____i-STAT problem--PROVIDE DETAILS
_____Other, PROVIDE DETAILS

List tests for credit:

Lab Review: (signature)_____
Date/Time: _____

Procedure: PROPOCTLAB09: I-STAT Testing
Form: I-STAT Resolution Requisition

istatresolutionrequest030716

CONGRATULATIONS

- This concludes the i-STAT education module.
- Please note that this power point does not replace the i-STAT policies and procedures.
- The presentation only gives highlights of i-STAT information.
- Please complete the on-line i-STAT exams within 1 week of training.

HANDS ON EXPERIENCE

- Change batteries and check battery voltage
- Discuss Menu Options
- Test External electronic simulator
- Test/Discuss Liquid QC
- Test sample as a patient
- Recall results
- Download of results