OLIVE VIEW-UCLA MEDICAL CENTER
DEPARTMENT OF PATHOLOGY
POLICY & PROCEDURE

NUMBER: 11833
VERSION: 2

SUBJECT/TITLE: POCT -16-01 BLOOD GAS TEST BY I-STAT

0POLICY: Blood Gas By i-STAT® - Moderately Complex

PURPOSE: The i-STAT System consists of handheld analyzer that automatically controls all functions of testing cycle and a single-use disposable cartridge available in a variety of panel configurations. One of the i-STAT cartridge panel configurations is CG8+ for Blood Gas testing.

DEPARTMENTS: PATHOLOGY & LABORATORY SERVICES

DEFINITIONS: i-STAT cartridge CG8+ includes the tests listed below:

Sodium
Tests for sodium in the blood are important in the diagnosis and treatment of patients suffering from hypertension, renal failure or impairment, cardiac distress, disorientation, dehydration, nausea and diarrhea. Some causes of increased values for sodium include dehydration, diabetes insipidus, salt poisoning, skin losses, hyperaldosteronism, and CNS disorders. Some causes for decreased values for sodium include dilutional hyponatremia (cirrhosis), depletional hyponatremia and syndrome of inappropriate ADH.

Potassium
Tests for potassium in the blood are important in the diagnosis and treatment of patients suffering from hypertension, renal failure or impairment, cardiac distress, disorientation, dehydration, nausea and diarrhea. Some causes of increased values of potassium renal glomerular disease, adrenocortical insufficiency, diabetic ketoacidosis (DKA), sepsis and in vitro hemolysis. Some causes of decreased values for potassium include renal tubular disease, hyperaldosteronism, treatment of DKA, hyperinsulinism, metabolic alkalosis and diuretic therapy.

Ionized Calcium
Although most of the calcium in blood is bound to protein or complexed to smaller anionic species, the biologically active fraction of calcium is free ionized calcium. Through its role in a number of enzymatic reactions and in membrane transport mechanisms, ionized calcium is vitally important in blood coagulation, nerve conduction, neuromuscular transmission and in muscle contraction. Increased ionized calcium (hypercalcemia) may result in coma. Other symptoms reflect

neuromuscular disturbances, such as hyperreflexia and/or neurologic abnormalities such as neurasthenia, depression or psychosis. Decreased ionized calcium (hypocalcemia) often results in cramps (tetany), reduced cardiac stroke work and depressed left ventricular function. Prolonged hypocalcemia may result in bone demineralization (osteoporosis) which can lead to spontaneous fractures. Measurements of ionized calcium have proven of value under the following clinical conditions: transfusion of citrated blood, liver transplantation, open heart surgery, neonatal hypocalcemia, renal disease, hyperparathyroidism, malignancy, hypertension and pancreatitis.

Glucose
Glucose is a primary energy source for the body and the only source of nutrients for brain tissue. Measurements for determination of blood glucose levels are important in the diagnosis and treatment of patients suffering from diabetes and hypoglycemia. Some causes for increased values of glucose include diabetes mellitus, pancreatitis, endocrine disorders (e.g. Cushing's syndrome), drugs (e.g. steroids, thyrotoxicosis), chronic renal failure, stress or I.V. glucose infusion. Some causes of decreased values of glucose include insulinoma, adrenocortical insufficiency, hypopituitarism, massive liver disease, ethanol ingestion, reactive hypoglycemia, and glycogen storage disease.

Hematocrit
Hematocrit is a measurement of the fractional volume of red blood cells. This is a key indicator of the body's state of hydration, anemia or severe blood loss, as well as the blood's ability to transport oxygen. A decreased hematocrit can be due to either overhydration, which increases the plasma volume, or a decrease in the number of red blood cells caused by anemia or blood loss. An increased hematocrit can be due to loss of fluids, such as dehydration, diuretic therapy, and burns, or an increase in red blood cells, such as in cardiovascular and renal disorders, polycythemia vera, and impaired ventilation.

pH
pH is an index of the acidity or alkalinity of the blood with an arterial pH of <7.35 indicating an acidemia and >7.45 alkalemia

PCO_2
PCO_2 along with pH is used to assess acid-base balance. PCO_2 (partial pressure of carbon dioxide), the respiratory component of acid-base balance, is a measure of the tension or pressure of carbon dioxide dissolved in the blood. PCO_2 represents the balance between cellular production of CO_2 and ventilatory removal of CO_2 and a change in PCO_2 indicates an alteration in this balance. Causes of primary respiratory acidosis (increase in PCO_2) are airway obstruction, sedatives and anesthetics, respiratory distress syndrome, and chronic obstructive pulmonary disease. Causes of primary respiratory alkalosis (decreased PCO_2) are hypoxia (resulting in hyperventilation) due to chronic heart failure, edema and neurologic disorders, and mechanical hyperventilation.

PO_2

PO_2 (partial pressure of oxygen) is a measurement of the tension or pressure of oxygen dissolved in blood. Some causes for decreased values of PO_2 include decreased pulmonary ventilation (e.g. airway obstruction or trauma to the brain), impaired gas exchange between alveolar air and pulmonary capillary blood (e.g. bronchitis, emphysema, or pulmonary), and alteration in the flow of blood within the heart or lungs (e.g. congenital defects in the heart or shunting of venous blood into the arterial system without oxygenation in the lungs).

HCO_3

HCO_3 (bicarbonate), the most abundant buffer in the blood plasma, is an indicator of the buffering capacity of blood. Regulated primarily by the kidneys, HCO_3 is the metabolic component of acid-base balance. Causes of primary metabolic acidosis (decrease in HCO_3) are ketoacidosis, lactate acidosis (hypoxia), and diarrhea. Causes of primary metabolic alkalosis (increase in HCO_3) are vomiting and antacid treatment.

Principle

Sodium, Potassium, 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.

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.

PO_2

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

Hematocrit

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

PROCEDURE: **TEST UTILIZATION:**

The i-STAT analyzer is used in conjunction with i-STAT cartridges for the simultaneous quantitative determination of specific analytes in whole blood. 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. v

TEST PERFORMANCE AND SUPERVISION:

The i-STAT analyzer may be performed by Olive View-UCLA Medical Center personnel, including physicians, respiratory therapists, clinical laboratory scientists, and other staff members, who satisfy California State and CLIA requirements for testing personnel and have been trained and authorized to do such testing under the Olive View-UCLA Medical Center Point-of-Care Testing Program. Supervision of testing personnel is the responsibility of the testing site section managers, i.e. nursing, clinical laboratory, etc.

SPECIMEN:

- 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.

SPECIMEN COLLECTION AND HANDLING:

Patient Identification and Preparation:
Before collecting blood, you must positively identify the patient. Ask the patient to state his/her full name and date of birth. Check the patient's full name, date of birth and financial number (FIN) against the identification band. The puncture site should be cleaned and thoroughly dried before obtaining the blood sample.

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

Venous Specimen
Collect sample into an evacuated blood collection tube or a syringe containing lithium, or balanced heparin anticoagulant. For ionized calcium measurements, balanced heparin or 10U of sodium or lithium heparin/mL. Fill tubes to capacity; fill syringes for correct heparin-to-blood ratio.

Test samples for pH, PCO_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.

Criteria for Specimen Rejection:

- Evidence of clotting
- Specimens collected in vacuum tubes with anticoagulant other than lithium heparin
- Syringe with air bubbles in sample
- Incompletely filled vacuum tube
- Syringe with needle

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
- Exposing the sample to air

EQUIPMENT AND MATERIALS:

Equipment:

- I-STAT Analyzer and Operator's Guide
- I-STAT Downloader/Recharger that serves as a docking station
- I-STAT Electronic Simulator
- I-STAT Printer Kit
- I-STAT Rechargeable Battery 9V

Materials:

- I-STAT CG8+ Cartridge (Catalog #03P88-25)
- I-STAT Tricontrols Level 1 (Catalog #05P71-01)
- I-STAT Tricontrols Level 2 (Catalog #05P72-01)
- I-STAT Tricontrols Level 3 (Catalog #05P73-01)
- Green top tubes with lithium heparin
- Tourniquet
- Vacutainer
- Plastic syringe or blood gas syringe
- Alcohol Prep pads
- Gloves
- PDI Super Sani-Cloth / Sani-Cloth Bleach wipes or recommended germicidal wipes
- Gauze pads or lint-free tissues

REAGENT STORAGE AND HANDLING REQUIREMENTS:

I-STAT CG8+ and Cartridge - A single-use disposable cartridge contains microfabricated sensors, a calibrant solution, fluidics system, and a waste chamber. Sensors for analysis of pH, pCO_2, pO_2, TCO_2, sodium, potassium, chloride, ionized calcium, glucose, and hematocrit are available in a variety of panel configurations. Cartridges are sealed in individual pouches or portion packs.

Storage and Handling

- Follow the instruction on the temperature card that comes with the shipment
- Store the main supply of cartridges at a temperature between 2 to 8ºC (35 to 46ºF). Do not allow cartridges to freeze. Storage temperature must be monitored and documented.
- Cartridges may be stored at room temperature (18 to 30ºC or 64 to 86ºF) for 14 days. Write the date on the cartridge box or individual cartridge pouches to indicate the two-week room temperature expiration date. Cartridges should not be returned to the refrigerator once they have been at room temperature.
- Must not be exposed to temperatures above 30ºC (86ºF).
- If the pouch has been punctured, the cartridge should not be used. Cartridge should remain in pouches until time of use.
- Do not use after the labeled expiration date.

Preparation

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.

Calibration

Calibration is automatically performed as part of the test cycle on each cartridge type. Operator intervention is not necessary.
Calibration Verification – Performed twice a year.

I-STAT Tricontrols Level I, II and III

- Each level of control is packaged in a box of 10 ampules.
- Storage temperature must be monitored and documented.
- Stable up to the expiration date printed on the box and ampule label if stored at 2 to 8ºC (35 to 46ºF).
- Stable up to 5 days is stored at room temperature (18 to 30ºC or 64 to 86ºF). New open expiration date should be written on the box once stored at room temperature.
- If stored at refrigerated temperature, the ampule must be equilibrated to

room temperature for 30 minutes.

External 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.

QUALITY CONTROL:

External – analyzed to verify the integrity of the reagent cartridge
I-STAT Tricontrols Level 1, 2 and 3 Control Solutions are used to verify the performance of the I-STAT CG8+ Hospital blood gas monitoring *s*ystem:

- Every 8 hours on each patient testing day
- With a valid IQCP in place, QC will be run once a week
- With every new lot or shipment
- If the meter is dropped
- When troubleshooting the system
- Acceptable Ranges: Download to the system via EVAS or print Value Assignment Sheet as follows:
  →Go to www.abbottpointofcare.com
  →Double click on the Value Assignment Sheet on the left side of the page
  →Locate: type of QC, lot number and CLEW
  →Double click on the QC and PRINT

External Electronic Simulator:
- Frequency of use:
- to validate an internal simulator failure(2x)
- to reset the internal simulator schedule
- for on-demand testing at any time (e.g. the analyzer dropped)
- to perform thermal probe check following a software update

Internal electronic simulator – performed automatically when a cartridge is inserted after the customized interval is reached.

Procedure – Quality Control:

Internal Electronic Simulator
- Is automatically activated when a cartridge is inserted after the customized interval is reached.
- The cartridge test cycle proceeds if the analyzer passes the simulator test.
- The analyzer displays "Electronic Simulator Fail" if the analyzer fails the simulator test
- Internal simulation occurs every eight hours and may turn on during a

patient test. Allow simulation to finish (20 secs) and patient testing will continue.

External Electronic Simulator

1. Press ON/OFF key to turn the analyzer on
2. Press the MENU key to access the Administration Menu
3. Press 3 for Quality Tests
4. Press 4 for Simulator
5. Scan or Enter Operator ID
6. Scan or Enter Simulator ID (serial number)
7. Remove the cover protecting the contact pads
8. Insert the simulator into the cartridge port (avoid touching the contact pads)
9. Do not remove the simulator while testing is in progress
10. Result screen displays:
    ID of simulator
    Date and time
    ELECTRONIC SIMULATOR
    PASS OR FAIL
    1 – Test Options
11. If FAIL is displayed for the external simulator, reinsert the simulator. If FAIL is displayed a second time, do not use the analyzer and contact POCT at X73684 or X73153

External Liquid Control
Procedure:

1. Turn the device ON
2. Press the Menu key
3. Press #3, Quality Test
4. Press #1, Control
5. Enter Operator ID
6. Scan or Enter Control lot number
7. Scan or Enter cartridge lot number
8. Remove the cartridge from its pouch. Avoid touching the contact pads or exerting pressure over the calibrant pack in the center of the cartridge.
9. Shake the ampule vigorously for 5-10 seconds by holding the ampule at the tip and bottom with forefinger and thumb to minimize increasing the temperature of the solution.
10. Tap the tip of the ampule to restore the solution to the bottom of the ampule.
11. Snap the tip off the ampule at the neck. Protect finger with gauze or ampule breaker.
12. Using a syringe, slowly draw approximately 1 mL of solution from the bottom of the ampule.
13. Discard the ampule and syringe if air bubbles are continually drawn into the syringe or if a bubble is trapped near the tip of the syringe; use a fresh ampule and syringe. Expel one or two drops from the syringe before filling the cartridge.

14. Dispense the sample using a steady flow technique until it reaches the fill mark on the cartridge and the well is about half full.
15. Close the cover over the sample well until it snaps into place. (Do not press over the sample well.)
16. Insert the cartridge into the device
17. When results appear, ensure that all the values are within the expected ranges.

To run the next level of quality control solution

18. Press #1, Test Options
19. Press #1, Next Level
20. Repeat steps 4-17.

Note:

- Check that the software version listed on the insert matches the software installed in the analyzer.
- If all results are within expected ranges, use the cartridges as needed. If fail, repeat the level of control that failed and document in corrective action log.
- Transmit the results to the HIS:
  - At the completion of the test, place handheld into the downloader.
  - I-Stat screen will show "Communication in Progress"
  - Do not interrupt communication
  - Screen goes blank when communication is completed.
  - Leave handheld in rechargeable downloader to "rest and recharge."

Patient Test:

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.

1. Turn the device ON.
2. From the Test Menu, Select Option #2 – i-STAT cartridge
3. Enter an operator ID number. Repeat if required.
4. Scan or Enter the patient ID (FIN) number. Repeat if required.
5. Scan or Enter Cartridge Lot Number
6. The display will read "Insert Cartridge"- (you have approximately 15 minutes to prepare the patient specimen)
7. Remove the cartridge from its pouch. Avoid touching the contact pads or exerting pressure over the calibrant pack in the center of the cartridge.
8. Collect the patient sample. The syringe must be capped immediately after collection. Whole blood samples for blood gas/electrolyte/glucose and lactate analysis should be analyzed as soon as possible (within 5 minutes of collection for glucose/lactate testing).
9. Following thorough mixing of the sample, discard 2 or more drops onto gauze.
10. Direct the dispensing tip or capillary tube containing the blood into the sample well.
11. Dispense the sample until it reaches the fill mark on the cartridge.

12. Close the cover over the sample well until it snaps into place. (Do not press over the sample well.)
13. Insert the cartridge into the cartridge port on the analyzer until it clicks into place. The analyzer must remain horizontal during the testing cycle.
14. Never attempt to remove a cartridge while the "Cartridge Locked" message is displayed.
15. Enter additional parameters on the Chart Page if required:
    - Patient temperature can be entered as degrees Centigrade or Fahrenheit. Use the * key on the i-STAT Portable Analyzer for a decimal point.
    - FIO2, can be entered as the number of liters or as a percentage of the oxygen a patient is receiving.
    - Choose the number corresponding to the type of sample used when prompted at the Sample Type field.
16. View results shown on the analyzer's display screen.
17. Remove the cartridge after the "Cartridge Locked", messages disappear is ready for a new cartridge immediately.
18. Keep analyzer clean with recommended hospital wipes. See CLEANING and DISINFECTING.
19. Results are documented in patient's electronic health record.
    Note: See attached for manual entry of results in HIS.

Results

Quality Control Results

Type of QC	Displayed Result	Action
Internal Simulator: Automatically performed upon insertion of cartridge after the customized interval is reached.	No message - PASS. Test proceeds; test result is displayed. Use the analyzer.	
	FAIL (1st time), first device	Re-insert the same cartridge
	No message - PASS. Test proceeds; test result is displayed. Use the analyzer.	
	FAIL (2nd time), first device	Rerun the same cartridge on another device. This must be done within 3 minutes.
	No message - PASS. Test proceeds; test result is displayed. Use the analyzer.	
	FAIL (1st time), second device	Repeat on the second device using a new cartridge.
	No message - PASS. Test proceeds; test result is displayed. Use the second device.	
	FAIL (2nd time), second device, new cartridge	Run external electronic simulator on the 1st and 2nd analyzers. Or call POCT x73153/73684 or open a new box of cartridge.
External Simulator (Kept in POCT office)	PASS	Use the analyzer.
	FAIL (1st)	Repeat the test using the same external simulator.
	PASS	Use the analyzer.
	Fail (2nd)	Repeat test using a different external simulator
	PASS	Use the analyzer. Deliver questionable simulator to POCT
	FAIL	Do not use the analyzer, call POCT X73153/73684
External liquid QC	Results are within the expected ranges	Use the cartridge as needed
	If any results are outside the expected ranges	Do not use the lot. Call POCT x73153/73684 Document action taken.

Three conditions under which the i-STAT System will not display results:

1. Results that are outside the validated reportable ranges: flagged with a < or >.
2. Results that are not reportable based on internal QC rejection criteria: flagged with ***.
3. Results that are not reportable due to problems detected on the sample by the analyzer: flagged with a Quality Check Code message

Documentation of Results during Downtime:

- To Print results from i-STAT
  - Turn on instrument if required
  - Press Menu Button to get to the Administration Menu
  - Choose option 2- Data review
  - Choose option 7- List
  - Identify and press the number containing the patient FIN. Repeat for each result. Press right arrow key if required to retrieve additional results and continue until all have been highlighted.
  - Enter Operator ID if required

- Align i-STAT IR windows with Martel Portable Printer
  - Turn printer ON if required
  - Press the PRT key on i-STAT
  - Do not move analyzer and printer until printing is complete
- Affix result print out onto the i-STAT Results Form
- Make a copy of the form with the result print out affixed on it to go into the patient's permanent medical record along with the original.

Reportable Ranges and Reporting Format

Analytes	Units	Reportable Range
pH		6.80-8.00
pCO2	mm Hg	17-90
pO2	mm Hg	30-600
Sodium	mmol/L	100-180
Potassium	mmol/L	2.0-8.5
Chloride	mmol/L	70-130
I. Calcium	mg/dL	1.0-10.0
Glucose	mg/dL	20-700
Hematocrit	%	15-75
Derived Analytes	Units	
Hemoglobin	g/dL	
HCO3	mmol/L	
TCO2(all cart. except Chem8+)	mmol/L	
BE	mmol/L	
sO2	%	

Reference Ranges

Tests	Reference Range		Unit of Measure
	Arterial	Venous	
pH	7.35 - 7.45	7.33 - 7.43	pH
pCO2	35 - 45	38 - 50	mm Hg
pO2	>75	35 - 50	mm Hg
Sodium	135 - 145		mmol/L
Potassium	3.3 - 4.9		mmol/L
Bicarbonate	22 - 27	20 - 30	mmol/L
iCalcium	4.5 - 5.3		mg/dL

Hematocrit	Male	Female	
Birth up to 8 days	42.0 - 60.0		%
8-15 days	39.0 - 60.0		%
15 days-2 months	31.0 - 55.0		%
2-6 months	28.0 - 42.0		%
6 months-2 years	33.0 - 40.0		%
2-3 years	33.0 - 42.0		%
3-6 years	33.0 - 43.0	33.0 - 44.0	%
6-12 years	36.0 - 42.0	36.0 - 43.0	%
12-16 years	37.0 - 47.0	36.0 - 43.0	%
≥ 16 years	40.0 - 49.0	36.0 - 44.0	%
Glucose	Reference Range		Unit of Measure
0-1 Day Old	41-99		mg/dL
>1 Day to 30 Days Old (one month)	50-99		mg/dL
1 month-16 years	65-99		mg/dL

Total Hemoglobin	Male	Female	Unit of Measure
Birth up to 8 days	13.5 - 21.9		g/dL
8-15 days	12.5 - 21.0		g/dL
15 days-2 months	10.0 - 20.0		g/dL
2-6 months	10.0 - 14.0		g/dL
6 months-2 years	10.5 - 13.5		g/dL
2-3 years	11.0 - 14.0		g/dL
3-6 years	11.0 - 14.5	11.8 - 14.7	g/dL
6-12 years	12.0 -14.5		g/dL
12-16 years	12.8 - 16.0	12.2 - 14.8	g/dL
≥ 16 years	13.5 - 16.5	12.0 - 14.6	g/dL
O2 Saturation	Arterial: 94 - 98		%
Base Excess(B)			
Arterial	Arterial: -2 to +2		mmol/L
Venous	No Reference Range Established		mmol/L

Handling of Critical Laboratory Values (if applicable)

- Prompt notification of the provider
- Document notification: Test result, date, time and person notified

Note: High and low critical values and any results that do not correlate with the patient's clinical condition may be repeated on the i-STAT or verified in Core Lab based upon the provider's assessment and discretion.

TEST	PATIENT AGE	UNIT	LOW	HIGH
Arterial or Venous pH	0 -1 month		<7.21	>7.49
	>1 month to adult		<7.21	>7.59
Umbilical Cord Arterial Blood pH	at birth		<7.01	
Umbilical Cord Venous Blood pH	at birth		<7.21	
Arterial or Venous pCO2	0 -1 month	mmHg	<31	>69
	>1 month to adult	mmHg	<21	>69
Arterial pO2		mmHg	<55	
Venous pO2		mmHg	<21	
Sodium		mmol/L	<121	>159
Potassium	0 -1 month	mmol/L	<2.6	>5.9
	>1 month to adult	mmol/L	<3.0	>5.9
Calcium, ionized		mg/dL	<3.5	>6.0
Glucose	0 -1 month	mg/dL	<41	>199
	>1 month to 16 years	mg/dL	<41	>249
	>16 years	mg/dL	<41	>449
Hematocrit	<2 months	%	<19.6	>65.9
	2 months to adult	%	<19.6	>59.9

Limitations of the Procedure

ANALYTE	INTERFERENT	INTERFERENT CONCENTRATION	EFFECT ON ANALYTE RESULT
Sodium	Bromide	37.5 mmol/L	Increase (↑) Na
Ionized Calcium	Acetaminophen	1.32 mmol/L	Decrease (↓) iCa
	Magnesium	1.0 mmol/L	Increase (↑) iCa by 0.04 mmol/L
	Acetylcysteine	10.2 mmol/L	Decrease (↓) iCa

	Bromide	37.5 mmol/L	Increase (↑) iCa
	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	*P*O2 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

Grossly elevated white blood cell counts (WBC)	May increase Hematocrit results
Hematocrit results are affected by the level of	
total protein as follows:	
For measured Hematocrit of <40%	
For each g/dL below 6.5	Decrease Hct by 1% PCV
For each g/dL above 8.0	Increase Hct by 1% PCV
For measured Hematocrit of ³40%	
For each g/dL below 6.5	Decrease Hct by 0.75% PCV
For each g/dL above 8.0	Increase Hct by 0.75% PCV
Abnormally high Lipid	Increase Hct

PROFICIENCY TESTING:

Olive View – UCLA Medical Center participates in a proficiency testing survey three times a year through the College of American Pathologist. The unknown tests

are performed by trained operators at the testing site.

Analysis of the CAP survey specimens:

- Must be rotated among the performing staff
- Must be analyzed in the same manner as the patient sample
- Must not be referred to another laboratory

Reporting of proficiency testing results by the POCT Laboratory:

- Information regarding the results must not be shared with the other testing sites until the results have been submitted to College of American Pathologist
- Results must be submitted within ten working days or prior to the due date indicated on the instruction sheet

Result Evaluation from the College of American Pathologist:

- Results of the CAP survey are received and reviewed by the Department of Laboratories and Pathology
- The testing locations will be notified by the POCT Laboratory if the evaluation is unacceptable
- Investigation will be performed, and corrective action must be developed if an evaluation demonstrates bias or unacceptability.

CORRELATION STUDY:

A correlation study at least twice annually is used to verify the comparability of patient results against the main laboratory and to ensure that patient results are consistently interpreted across the continuum of care. Fresh human samples (whole blood) are used to directly address whether a patient sample yields the same result on different analytical instruments.

CLEANING AND DISINFECTING:

Drying a Wet Analyzer or Downloader:

If the analyzer is placed on a wet surface or if any liquid is spilled onto it, dry the analyzer immediately. If liquid enters the following compartments, the analyzer may be damaged:

- The electronics compartment
- The battery compartment
- The cartridge port

The Downloader may also be damaged by liquid contamination. Unplug the power supply from the outlet and dry the Downloader completely.

Cleaning the Analyzer and Downloader:

Clean the display screen and the case using a gauze pad moistened with any

of the following:

- A mild non-abrasive cleaner
- Detergent
- Soap and water
- Alcohol
- 10% bleach solution
- PDI Super Sani-Cloth (solution of IPA, n-Alkyl dimethyl ethylbenzyl- and benzyl- ammonium chloride)

Rinse the case using another gauze pad moistened with water and dry. Avoid getting excess fluids in the seam between the display screen and the case.

Caution:

Exercise universal safety precautions at all times when handling the analyzer, cartridges, and peripherals to prevent exposure to blood-born pathogens.
The analyzer is NOT designed to be sterilized or autoclaved by any method, including those using gas (e.g. steam, ethylene oxide, etc...) high heat, bead, radiation, or other chemical processes. The analyzer is splash resistant, but should not be immersed in any liquids.
Dispose of analyzer, peripheral electronics, and batteries according to local, state, and/or national guidelines.
If the analyzer is not to be used for an extended period of time, the batteries should be removed to prevent leakage.
Decontaminate the analyzer or Downloader whenever a specimen is spilled onto it or if the item is to be returned to i-STAT for repair. Wear gloves while performing the following procedure.

TROUBLESHOOTING:

Startup Messages

Message on Display	Explanation	How to Respond
Electronic Simulator Test Required	Analyzer customized to alert the operator that a scheduled simulator test is due.	Insert the external Electronic Simulator at the earliest convenient time.
Stored Memory Low	Memory space for 50 unsent test records available before the "Stored Memory Full" message is displayed	Place the analyzer in a Downloader.
Stored Memory Full	The analyzer is customized to alert the operator that the memory for unsent records is full. If the operator does not transmit the test records	Place the analyzer in a Downloader.

	to the Point-of-Care Central Workstation, the analyzer will either block further testing or will overwrite oldest records depending on how the analyzer is customized.	
Upload Required	The analyzer is customized to alert the operator that a scheduled transmission of test records to the Central Data Station is due.	Place the analyzer in a Downloader.
Battery Low	Battery voltage has dropped to 7.4 volts. There is sufficient power to test a few more cartridges, the number depending mainly on the types of cartridges in use. Under this condition, a flashing battery icon will also appear on the result page, the Test Menu screen, and the Administration Menu screen.	Change the disposable lithium batteries or recharge the rechargeable battery.
CLEW Expiring, Update Required	Message appears 15 days before the software expires.	Update the analyzer before the expiration date

Environmental Conditions

Message on Display	Cause	Action
Date Invalid, Check Clock	The analyzer will not allow a date that precedes or exceeds the six months lifetime of the CLEW software	Press Menu once to go to the Test Menu and then again to go to the Administration Menu. Press 5 to go to the Set Clock screen and correct the date.
Dead Batteries, Replace Batteries	There is insufficient battery power to complete a test cycle	Change the disposable lithium batteries or recharge the rechargeable battery.
Temperature Out of Range, Check Status Page	The analyzer makes a temperature measurement before initiating a test cycle.	Check the temperature reading on the Analyzer Status screen (under the Administration Menu). If below the operating range, move to a warmer area. If above the operating range, move to a cooler area. Allow time for the analyzer to equilibrate to the new temperature. Check the Analyzer Status screen periodically

Invalid or Expired CLEW	The software has become corrupt or has expired. The Product Update for each software update includes the expiration date.	Verify that the date in the analyzer is correct. Change the software if expired. Update the software again if not expired. If the message is displayed again, refer to Support Services information at the end of this section.
Analyzer Interrupted, Use Another Cartridge	The analyzer detected that the last cartridge run was not completed. This can happen if battery voltage is low, or if batteries were removed or making poor contact while a cartridge was still in the analyzer.	Check that the battery pack is inserted properly. Turn the analyzer on and check for the Low Battery message; replace or recharge if needed.

Error in Cartridge or Fluid Movement

Message on Display	Cause	Action
Cartridge Error Use Another Cartridge	These codes can all be caused by a variety of reasons including sample-related problems, users, cartridges or analyzers. Single or sporadic errors are most likely a sample related problem (an interferent), an aberrant cartridge, or a user-induced situation such as touching cartridge contacts, pressing on center of cartridge or bubbles in the sample (“frothy” samples).	Use another cartridge. If the same code repeats more than twice, there may be an analyzer problem. Try another analyzer if available.
Cartridge Preburst Use Another Cartridge	This code indicates that the analyzer detected fluid on the sensors before it should have. Possible causes: • Cartridges may have been frozen. • Calibrant pack may have been burst by operator exerting too much pressure on the center of the cartridge	Try another cartridge. Make sure that the cartridges were not frozen.
Unable to Position Sample Use Another Cartridge	The analyzer did not detect movement of sample across the sensors. This could be due to: • not closing the snap closure on the cartridge.	Use another cartridge

	• a clot in the sample preventing movement of the sample. • an aberrant cartridge	
Sample Positioned Short of Fill Mark Use Another Cartridge	The cartridge was under-filled	The sample must reach the fill mark. Try another cartridge
Sample Positioned Beyond Fill Mark Use Another Cartridge	The cartridge was overfilled	The sample was past the fill mark. Try another cartridge
Insufficient Sample Use Another Cartridge	This is most likely due to insufficient sample in the sample well of the cartridge, but can also be caused by bubbles in the sample	Try another cartridge
Cartridge Not Inserted Properly Reinsert Cartridge	The code indicates the cartridge or external Electronic Simulator may not be pushed in all the way.	Reinsert the cartridge or Electronic Simulator. If problem is recurrent and/ or the user is certain the cartridge or Simulator is properly inserted, it may indicate an instrument problem. Refer to Support Services
Test Cancelled by Operator	No response to mandatory prompt before analyzer time out.	No action required. Training may be required if a particular operator has a high rate of cancelled tests

Electrical or Mechanical Failures

Message on Display	Cause	Action
Analyzer Error Use Electronic Simulator	The analyzer usually recovers from these errors when the Electronic Simulator is run. This error can occur if the cartridge or Electronic Simulator was “angled” when inserted	Push cartridge or Simulator straight through the cartridge port. This error can also occur if the Electronic Simulator is malfunctioning (has it been dropped?). Try another Simulator. If the analyzer passes the Electronic Simulator check, continue to use it. If not, or if the Quality Check Code is recurrent, the analyzer may need repair.
Analyzer Error See Manual	These are mechanical or electronic failures from which the analyzer may not be able to recover	Use an external Electronic Simulator twice and use a cartridge with sample or control solution. If an error condition occurs, refer to Support Services. If not, continue to use the analyzer.
Cartridge Type Not Recognized Use Another Cartridge	This error could be due to use of a cartridge type that is not compatible with the version of software in the analyzer	If this is a new cartridge type being used, update the software. If the cartridge type has been used before, check to see if the cartridges

		have expired. Otherwise, an analyzer problem is indicated and the analyzer may need repair
Internal Simulator Failure	This error can occur if poor contact is made between the handheld pins and the contact pads of the cartridge.	Lockout Enabled: Immediately rerun the cartridge in the same handheld. If the simulator test fails again, rerun the cartridge is another handheld. Note: the cartridge should not be run if there is more than a three minute delay from the time it was filled. Verify the failed handheld using an external electronic simulator. Lockout Not Enabled: Immediately rerun the cartridge in another handheld. Note: the cartridge should not be run if there is more than a three minute delay from the time it was filled. Verify the failed handheld using an external electronic simulator.

No Display

Symptom	Possible Cause	Action
The display screen remains blank, either after a cartridge has been properly inserted or after the On/Off key has been pressed	Batteries dead. Keypad not responding. Internal Start switch broken	Change or recharge batteries. If this does not fix the problem, reinstall the current software in the analyzer. If the problem persists, the analyzer should be returned for repair. If using the analyzer recharging function of the i-STAT 1 Downloader/Recharger, ensure that the Downloader/Recharger is working as intended. If experiencing an issue, contact your support representative and use disposable batteries for continued use of the analyzer

"Cartridge Locked" Not Removed

Symptom	Possible Cause	Action
Normally the analyzer will reset and release the cartridge after the testing cycle is completed. If the analyzer cannot reset, the "Cartridge Locked" message will remain on the screen.	Dead batteries. Mechanical problem	Wait until the analyzer turns off or turn the analyzer off. Then turn the analyzer on. If it can reset, it will release the cartridge and remove the "Cartridge Locked" message. If the cartridge is not released, change or recharge the battery and turn the analyzer on. If the "Cartridge Locked" message does not disappear, do not attempt to remove the cartridge and refer to Support Services.

ANALYZER CODED MESSAGES

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.
2	**Temperature Out of Range** / Check Status Page	The analyzer is recording a temperature outside its operating range. Move the analyzer to an area within the operating temperature of the test being performed and allow the analyzer to come to the new room temperature. Check the analyzer's temperature reading on the Status Page.
3	**New Software Installed** / Use Electronic Simulator	This message appears on the Portable Clinical Analyzer after new software has been installed or, in some cases, when a new customization profile is received.
4, 8	**Analyzer Interrupted** / Use Another Cartridge	The analyzer has detected that the last test cycle was not completed. This can happen if the batteries were removed or were making poor contact while a cartridge was still in the analyzer. Batteries that are too short will not make proper contact. Check that the batteries are inserted properly and seated well in the analyzer; check the battery voltage on the analyzer's Status Page and replace batteries if low. NOTE: Patient results displayed before this code are valid.

5, 6, 9	**Analyzer Interrupted** / Ready for Use	The Portable Clinical Analyzer is unable to refresh the display. This can happen if power is interrupted before the analyzer powers itself down. Check that batteries are inserted properly and seated well in the analyzer. Batteries that are too short will not make proper contact. Check the battery voltage on the Status Page.
7	**Batteries Changed** / Ready for Use	This is a normal response on the Portable Clinical Analyzer when the batteries are changed after a code 1 has occurred.
10	**Temperature In Range** / Ready for Use	Temperature is back in range following a code 2 on the Portable Clinical Analyzer.
11	**Date Invalid** / Check Clock on Status Page	If the date in the real time clock precedes the release date programmed into the application software, code 11 is triggered. Check the date on the real time clock. The accuracy of the clock is checked at the beginning of a coagulation test. If the clock is inaccurate, Code 11 is triggered.
12	**Invalid or Expired CLEW** / See Manual	The CLEW standardization has expired. Download a valid CLEW. The date on the real time clock exceeds the expiration date of the CLEW software. Check the date on the real time clock.
13	**Invalid or Expired CLEW** / See Manual	The CLEW is corrupt or not compatible with the application software (JAMS), or there is no CLEW in the analyzer. Download a valid CLEW. If this code occurs after a software upgrade and the customization application is enabled in the CDS, change the CLEW version in the Customization Profile to the latest version and re-transmit the profile to the analyzer
14	**Analyzer Error** / See Manual	Customization profile is corrupted. Retransmit the customization profile. If code 14 reoccurs, contact i-STAT Technical Services or your local support organization for further assistance.
15	**Barcode Does Not Match Cartridge Type**	The barcode scanned by the user does not match the immunoassay cartridge type indicated by the identification chip in the cartridge. The user should run another cartridge, being careful to scan the barcode from the portion pack of the specific cartridge type being run on the analyzer.
95	**Test Cancelled by Operator**	This message will appear in the stored test records on the i-STAT 1 Analyzer if the analyzer powers down before mandatory information was entered.

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

Code Number	Cause/Action Message on Display	Explanation
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

Code Number	Cause/Action Message on Display	Explanation
79-81	**Cartridge Error** / Use Another Cartridge	Bad contact between the thermal probes in the analyzer and the metalization on the back of the chips in the cartridge trigger these codes. Causes are: poor metalization of the chips, dirt on the metalization, or bent or broken thermal probes in the analyzer.
21	**Cartridge Preburst** / Use Another Cartridge	This code indicates that the analyzer detected fluid on the sensors before it should have. Possible causes: mishandling of cartridges (putting pressure in the center of the cartridge), poor storage conditions of cartridges (frozen), or rerunning used cartridges.
31, 34, 44	**Unable to Position Sample** / Use Another Cartridge	The analyzer did not detect movement of sample across the sensors. This could be due to a clot in the sample (especially in neonates), to not closing the snap closure on the cartridge, or to an aberrant cartridge.
35, 36	**Sample Positioned Short of Fill Mark** / Use Another Cartridge	The cartridge was underfilled. The sample must reach the fill mark. Try another cartridge.
30, 37	**Sample Positioned Beyond Fill Mark** / Use Another Cartridge	The cartridge was overfilled. The sample was past the fill mark. Try another cartridge.
38, 39	**Insufficient Sample** / Use Another Cartridge	This is most likely due to insufficient sample in the sample well of the cartridge, but can also be caused by bubbles in the sample. Try another cartridge and ensure sufficient sample is in the sample well.
46	**Cartridge Error** / Use Another Cartridge	The analyzer did not detect movement of sample across the sensors. This could be due to a clot in the sample (especially in neonates), to not closing the snap closure on the cartridge, or to an aberrant cartridge.
47	**Cartridge Not Inserted Properly** / Reinsert Cartridge	This code indicates the cartridge or Electronic Simulator may not be pushed in all the way. Reinsert the cartridge or Electronic Simulator. If the problem persists and/or the user is certain the cartridge or Simulator is properly inserted, it may indicate an analyzer problem. Contact i-STAT Technical Services or your local support organization for further assistance.
48	**Analyzer Error** / See Manual	This code indicates the cartridge or Electronic Simulator may have been “cocked” when inserted. Push the cartridge or Simulator straight through the cartridge port. If the problem persists, and the user is certain the cartridge or Simulator is properly inserted, it may indicate an analyzer problem. Contact i-STAT Technical Services or your local support organization for further assistance.
49	**Poor Contact Detected** / See Manual	The system detected a contact problem with one of the connector pins while reading the identification chip in the immunoassay cartridge. This can sometimes be corrected by conditioning the pins in the analyzer using the ceramic conditioning cartridge. The specific conditioning procedure is described at the end of this bulletin. **Note:** If you do not have a ceramic conditioning cartridge, please contact i-STAT Technical Support at 1-800-366-8020, option 1.

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

Code Number	Cause/Action Message on Display	Explanation
50	**Analyzer Error** / Use Electronic Simulator	The motor has moved too far. Running a simulator may not detect this problem. Run the simulator and if the analyzer passes, run a cartridge to see if the code reoccurs. If not, continue to use the analyzer. If the code reoccurs, contact i-STAT Technical Services or your local support organization for further assistance. If testing immunoassay cartridges on an i-STAT 1 Analyzer, this code can be related to poor electrical connection between the i-STAT 1 Analyzer and the cartridge. This can sometimes be corrected by conditioning the pins in the analyzer using the ceramic conditioning cartridge. The specific conditioning procedure is described at the end of this bulletin. **Note:** If you do not have a ceramic conditioning cartridge, please contact i-STAT Technical Support at 1-800-366-8020, option 1. Codes 126 and 128 are sometimes related to electrical connection as well. If you experience multiple occurrences of these 3 codes (50, 126, and 128) in a short period of time, consider returning the analyzer for servicing and replacement The presence of sample bubbles when running immunoassay cartridges may, under some circumstances, also elicit this
51	**Analyzer Error** / Use Electronic Simulator	The motor moved for too long. Run a simulator. If the error occurred while running an ACT cartridge, also run a cartridge. If the code does not reoccur, continue to use the analyzer. Under some conditions, a low battery will cause this error instead of code 1. Try fresh batteries. If the code reoccurs, contact i-STAT Technical Services or your local support organization for further assistance.
52	**Analyzer Error** / Use Electronic Simulator	The motor stalled while moving. Run a simulator. If the error occurred while running an ACT cartridge, also run a cartridge. If the code does not reoccur, continue to use the analyzer. If the code reoccurs, contact i-STAT Technical Services or your local support organization for further assistance
58-62	**Analyzer Error** / Use Electronic Simulator	The analyzer usually recovers from these error conditions. These error conditions can be detected by the Electronic Simulator. If the analyzer passes the Electronic Simulator test, continue to use it. If not, check the battery voltage and check the analyzer with another simulator to rule out a simulator problem. If the code persists, contact i-STAT Technical Services or your local support organization for further assistance.

Code Number	Cause/Action Message on Display	Explanation
23, 53, 55-57, 63, 65-68, 70, 72-74, 82, 83-85, 86, 89-94, 96, 97	**Analyzer Error** / See Manual	These are mechanical or electronic failures from which the analyzer\ may not be able to recover. Code 23 may be caused by poor contact between the analyzer pins and the cartridge chip. This can sometimes be corrected by conditioning the pins in the analyzer using the ceramic conditioning cartridge. The specific conditioning procedure is described at the end of this bulletin. Code 70 can occur on the Portable Clinical Analyzer if the user presses the DIS key before the Electronic Simulator is run after a software update. If this happens, reseat the batteries to reset the analyzer, and then run the Electronic Simulator. Codes 82 and 92 typically indicate a problem with the pressure transducers in the analyzer. If these codes persist, contact i-STAT Technical Services or your local support organization for further assistance. Codes 83 and 84 indicate an underlying hardware failure in the i-STAT 1 Wireless Analyzer. If these codes persist, contact i-STAT Technical Support or your local support organization for further assistance. The rate of quality check code 55 can be elevated when cartridges are run without allowing sufficient time for the cartridges to equilibrate to room temperature. To minimize the number of quality check codes, review i-STAT cartridge storage conditions and allow sufficient time for refrigerated cartridges to equilibrate to room temperature. Code 56 occurs when the analyzer detects noise on the thermal circuit. The noise may be the result of electronic interference. If this code occurs, the analyzer should be moved to a different location away from potential sources of interference. If the code persists in the new area, the analyzer should be returned. Code 86 can occur when an i-STAT Analyzer is stored in an i-STAT Downloader/Recharger without adequate ventilation. This problem can usually be resolved by moving the Downloader/Recharger to an open location which is free of obstructions and external heat sources such as heater vents or other electronic equipment. If this code persists, or if code 86 occurs with the Portable Clinical Analyzer or i-STAT 1 Analyzer without a Downloader/ Recharger, contact i-STAT Technical Services or your local support organization for further assistance. For other codes, run the Electronic Simulator twice, then run a cartridge with a sample. If the analyzer passes the simulator check and a quality check does not occur with the sample run, continue to use the analyzer. If the analyzer does not pass the simulator check and/or a quality code occurs with the sample run, contact i-STAT Technical Services or your local support organization for further assistance.

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

Codes in the range of 120 to 138 and 140 to 151 indicate a failure during an immuno or barcoded pouch cartridge cycle. In most cases, the cartridge is spent and another cartridge must be used. Only the i-STAT 1 Analyzer produces these codes, as the Portable Clinical Analyzer does not support immune cycles.

Code Number	Cause/Action Message on Display	Explanation
120-122, 124, 125, 133, 144, 148	**Cartridge Error /** Use Another Cartridge	These codes indicate a problem with the movement of the analysis fluid during the cartridge run. Try another cartridge.
123	**Cartridge Error /** Use Another Cartridge	The quality control during the cartridge run failed to verify the presence of active immuno reagents. Try another cartridge.

Code Number	Cause/Action Message on Display	Explanation
126	**Cartridge Error /** Use Another Cartridge	The quality control during the cartridge run failed to verify the integrity of the analysis fluid. However, this code can also be related to poor electrical connection between the i-STAT 1 Analyzer and the cartridge. This can sometimes be corrected by conditioning the pins in the analyzer using the ceramic conditioning cartridge. The specific conditioning procedure is described at the end of this bulletin. **Note:** If you do not have a ceramic conditioning cartridge, please contact i-STAT Technical Support at 1-800-366-8020, option 1. Codes 50 and 128 are sometimes related to electrical connection as well. If you experience multiple occurrences of these 3 codes (50, 126, and 128) in a short period of time, consider returning the analyzer for replacement.
127	**Cartridge Error /** Use Another Cartridge	A wet sensor was detected before the initial sample movement. Possible overfilled or used cartridge. Try another cartridge.
128, 131, 132, 134, 135 - 138	**Cartridge Error /** Use Another Cartridge	These codes are most often related to poor filling of an immunoassay cartridge, the presence of sample bubbles, or the abrupt insertion of a cartridge into the analyzer. **Guidelines for proper filling:** 1. **Discard** *(always)* 1 drop from delivery device to clear unseen bubbles. 2. **Hang** single drop slightly larger than round target well. 3. **Touch** one drop *(only)* to round target well allowing cartridge to draw sample in. 4. **Confirm** sample volume lines up with top of RED FILL LINE diagram. 5. **Close** slide cover from left to right. **Guidelines for cartridge insertion:** 1. After closing the cartridge, grasp the cartridge closure between your first finger and thumb. There is a recess for your thumb in the closure. 2. Guide the cartridge into the analyzer gently, until a soft click is heard.
129, 142, 143	**Cartridge Error /** Use Another Cartridge	The analyzer detected analysis fluid mixed with the sample. Try another cartridge.
130	**Cartridge Error /** Use Another Cartridge	The analyzer detected an air bubble in the sample segment. Try another cartridge.
140	**Lot Expired**	The analyzer detected an expired cartridge lot. Check the expiration date and repeat the test using a non-expired cartridge lot.
141	**Test Canceled by Operator**	This code will be displayed if the cartridge barcode is not scanned within 60 seconds of cartridge insertion. The correct barcode to scan is the barcode on the cartridge portion pack, not the one on the cartridge box. An example of the portion pack barcode is found in the table listing for code 69 above

Code Number	Cause/Action Message on Display	Explanation
145	**Cartridge Error /** Use Another Cartridge	The analyzer failed to detect fluid arrival upon the initial sample push. This may be caused by a(n): • cartridge leak, • failure to close the cartridge completely. Ensure that the slide cover is fully engaged before inserting the cartridge into the analyzer • underfilled cartridge. Once a single drop of sample Is touched to the target well, immunoassay cartridges will fill automatically by wicking the sample at a fixed speed. Trying to inject the sample into the cartridge or adding more sample to the target well will not make the cartridge fill faster. Wait for the sample to reach the “fill to” mark, and then close the cartridge.
146	**Cartridge Error /** Use Another Cartridge	Overfilled cartridge. Repeat the test.

The following conditions are related to the Electronic Simulator

Code	Explanation	How to Respond
L	Potentiometric channel out of limits. Can occur if moisture collects on the contact pins inside the analyzer when the analyzer is subjected to ambient temperature change.	Allow analyzer to equilibrate in new environment for 30 minutes and repeat test. If code reoccurs, return anlayzer
G	Amperometric channel out of limits. Can occur if external simulator not inserted straight.	Reinsert the simulator straight. If code reoccurs, return analyzer.
R, r	Resistance reading on conductometric channel out of limits.	Return analyzer
t	Thermal probe failure.	Return analyzer
B	Potentiometric channel out of limits.	Return analyzer

NOTE: Any time repetitive codes occur which cannot be addressed or corrected through training, contact i-STAT Technical Services 1-800-366-8020

References: Abbott Point of Care Testing i-STAT System Manual Rev. Date: 01/20/12	
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