Procedure Manual

for the i-STAT 1 System

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

For additional information pertaining to cartridges, refer to
Instructions for Use (IFU) and
Cartridge and Test Information (CTI) sheets
found on the APOC website at
www.pointofcare.abbott

REV. DATE: 15-SEP-2020 ART: 714446-00AD

PROCEDURE MANUAL FOR THE i-STAT 1 SYSTEM

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SYSTEM OVERVIEW

The i-STAT 1 System incorporates comprehensive components needed to perform blood analysis at the point of care. The system consists of the following primary components:

i-STAT 1 Analyzer

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

Analysis Time

- ACT cartridge: to detection of end point – up to 1000 sec (16.7 min)
- PT/INR cartridge: to detection of end point – up to 300 sec (5 min)
- cTnI, BNP, and Total β-hCG cartridges: 600 sec (10 min)
- CK-MB Cartridge: 300 sec (5 min)
- Other cartridges: typically, 130 to 200 sec

Cartridges

A single-use disposable cartridge contains micro-fabricated sensors, a calibrant solution, fluidics system, and a waste chamber. Sensors for analysis of pH, ***P***CO_2, ***P***O_2, TCO_2, sodium, potassium, chloride, ionized calcium, glucose, lactate, creatinine, urea nitrogen (BUN) and hematocrit are available in a variety of panel configurations. Cartridges are also available for Celite-ACT, Kaolin-ACT, PT/INR, Troponin I (cTnI), CK-MB, BNP, and Total β-hCG (Table 1).

Data Manager (DM)

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

SUPPLIES and STORAGE REQUIREMENTS

Cartridges

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

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

Controls

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

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

ACT and PT/INR Controls

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

cTnI, BNP, CK-MB and β-hCG Controls

- These controls are ready-to-use liquids and are stable until the expiration date on the vial label when stored unopened at 2 - 8 °C (35 - 46 °F).
- Once opened, the controls are stable for 30 days when stored tightly capped at 2 - 8 °C.
- Do not use after expiration date on the box and vials.

Electronic Simulator

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

BLOOD TESTING

For sample types, test timing, and collection options see the *Instructions for Use (IFU)***,** *'An Introduction to Cartridge and Test Information (CTI)'* **for i-STAT Cartridges and** *Section 10: Sample Collection* **in the i-STAT 1 System Manual located at** www.pointofcare.abbott. Use information from these documents to populate this section of the Procedure Manual.

Blood Volume (See Table 1)

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

Cartridge	Vol. (µL)	pH	**P**CO_2	**P**O_2	Na	K	Cl	iCa	Glu	BUN	Creat	Lact	Hct	TCO_2	ACT	PT/INR	CK-MB	cTnI	BNP	Total β-hCG	HCO_3	TCO_2	SO_2	BE	Anion Gap	Hb
CHEM8+	95				•	•	•	•	•	•	•		•	•											•	•
CG8+	95	•	•	•	•	•		•	•				•								•	•	•	•		•
EG7+	95	•	•	•	•	•		•					•								•	•	•	•		•
EG6+	95	•	•	•	•	•							•								•	•	•	•		•
CG4+	95	•	•	•								•									•	•	•	•		
EC8+	65	•	•		•	•	•		•	•			•								•	•		•	•	•
G	65								•																	
Crea	65										•															
ACT	40														•											
PT/INR	20															•										
cTnI	17																	•								
CK-MB	17																•									
BNP	17																		•							
Total β-hCG	17																			•						

Specimen Labeling

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

Criteria for Specimen Rejection

Use information from hospital policy to populate this section.

Precautions: avoid the following circumstances

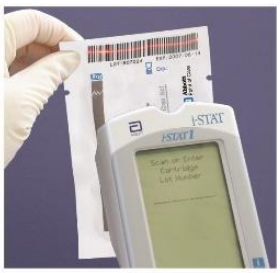
- ❑ Drawing a specimen from an arm with an I.V.
- ❑ Stasis (tourniquet left on longer than one minute before venipuncture)
- ❑ Extra muscle activity (fist pumping)
- ❑ Hemolysis (alcohol left over puncture site, or a traumatic draw)
- ❑ Icing before filling cartridge
- ❑ Time delays before filling cartridge, especially lactate, ACT, and PT/INR
- ❑ Exposing the sample to air when measuring pH, $\boldsymbol{P}CO_2$, $\boldsymbol{P}O_2$ and TCO_2

PROCEDURE FOR ANALYSIS

Prerequisites

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

Procedure



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

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

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

7. Review results.

Alternative Procedure

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

RESULTS

Calculations

The i-STAT 1 Analyzer contains a microprocessor that performs all calculations required for reporting results.

Displayed Results

Results are displayed numerically with their units. Electrolyte, chemistry and hematocrit results are also depicted as bar graphs with reference ranges marked under the graphs.

Suppressed Results

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

1. Results outside the reportable ranges are flagged with a < or >, indicating that the result is below the lower limit or above the upper limit of the reportable range respectively. (See the table of Reportable Ranges.) The < > flag indicates that the results for this test were dependent on the result of a test flagged as either > or <.

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

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

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

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

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

Printing and Transmitting Results

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

Without Downloader or Downloader/Recharger

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

With Downloader or Downloader/Recharger

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

Printing more than one result

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

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

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

Reference Ranges,[1, 2] Reportable Ranges, and Test Unit Conversions

Reference range means the range of test values expected from 95% of fasting individuals presumed to be healthy. Reportable range means the range of test values throughout which the measurement system's results have been shown to be valid. The following table contains the Reference Ranges (for adults) and Reportable Ranges applicable to the i-STAT 1 System.

ANALYTE	UNIT	REFERENCE RANGE (arterial)	REFERENCE RANGE (venous)	REPORTABLE RANGE	UNIT CONVERSION
Sodium	mmol/L (mEq/L)	138 – 146	138 – 146	100 – 180	mmol/L x 1 = mEq/L Example: 140 mmol/L = 140 mEq/L
Potassium	mmol/L (mEq/L)	3.5 – 4.9	3.5 – 4.9	2.0 – 9.0	mmol/L x 1 = mEq/L
Chloride	mmol/L (mEq/L)	98 – 109	98 – 109	65 – 140	mmol/L x 1 = mEq/L
BUN	mg/dL	8 – 26	8 – 26	3 – 140	mg/dL BUN x 0.357 = mmol urea/L Example: 20 mg/dL BUN = 7.1 mmol urea/L
UREA	mmol/L	2.9 – 9.4	2.9 – 9.4	1 – 50	
Glucose	mg/dL	70 – 105	70 – 105	20 – 700	mg/dL x 0.055 = mmol/L Example: 100 mg/dL = 5.55 mmol/L
	g/L	0.70 – 1.05	0.70 – 1.05	0.20 – 7.00	g/L x 5.556 = mmol/L
	mmol/L	3.9 – 5.8	3.9 – 5.8	1.1 – 38.9	
Creatinine	mg/dL	0.6 – 1.3	0.6 – 1.3	0.2 – 20.0	mg/dL x 88.4 = µmol/L
	µmol/L	53 – 115	53 – 115	18 – 1768	
Ionized Calcium	mmol/L	1.12 – 1.32	1.12 – 1.32	0.25 – 2.50	mmol/L x 4 = mg/dL Example: 1.13 mmol/L x 4 = 4.52 mg/dL
	mg/dL	4.5 – 5.3	4.5 – 5.3	1.0 – 10.0	
pH (CG4+ Blue)		7.35 – 7.45	7.31 – 7.41	7.00-7.70	N/A
pH (all others)		7.35 – 7.45	7.31 – 7.41	6.50 – 8.20	N/A
***P*CO$_2$ (CG4+ Blue)**	mmHg	35 – 45	41 – 51	15 – 130	mmHg x 0.133 = kPa Example: 35 mmHg x 0.133 = 4.66 kPa
	kPa	4.67 – 6.00	5.47 – 6.80	2.00 – 17.33	
***P*CO$_2$ (all others)**	mmHg	35 – 45	41 – 51	5 – 130	mmHg x 0.133 = kPa Example: 35 mmHg x 0.133 = 4.66 kPa
	kPa	4.67 – 6.00	5.47 – 6.80	0.67 – 17.33	

ANALYTE	UNIT	REFERENCE RANGE (arterial)	REFERENCE RANGE (venous)	REPORTABLE RANGE	UNIT CONVERSION
***P*O₂ (CG4+ Blue)**	mmHg kPa	80 – 105 10.7 – 14.0		15 – 530 2.0– 70.6	mmHg x 0.133 = kPa Example: 83 mmHg x 0.133 = 11.04 kPa
***P*O₂ (all others)**	mmHg kPa	80 – 105 10.7 – 14.0		5 – 800 0.7 – 106.6	mmHg x 0.133 = kPa Example: 83 mmHg x 0.133 = 11.04 kPa
TCO_2 (CHEM8+ cartridge only)	mmol/L (mEq/L)	23 – 27	24 – 29	5 – 50	mmol/L x 1 = mEq/L
Hematocrit †	% PCV Fraction	38 – 51 0.38 – 0.51	38 – 51 0.38 – 0.51	15 – 75 0.15 – 0.75	% PCV x 0.01 = Volume fraction Example: 40% PCV = 0.40 PCV
Lactate	mmol/L mg/dL	0.36 –1.25 3.2 – 11.3	0.90 – 1.70 8.1–15.3	0.30 – 20.00 2.7 – 180.2	mmol/L x 9.01 = mg/dL
HCO_3 *	mmol/L (mEq/L)	22 – 26	23 - 28	1.0 – 85.0	mmol/L x 1 = mEq/L
TCO_2 * (all cartridges except CHEM8+)	mmol/L (mEq/L)	23 – 27	24 – 29	5 – 50	mmol/L x 1= mEq/L
BE *	mmol/L (mEq/L)	(-2) – (+3)	(-2) – (+3)	(-30) – (+30)	
Anion Gap *	mmol/L (mEq/L)	10 – 20	10 – 20	(-10) – (+99)	
sO_2 *	%	95 – 98		0 - 100	% x 0.01 = fraction saturated
Hb*	g/dL g/L mmol/L	12 – 17 120 – 170 7 – 11	12 – 17 120 – 170 7 – 11	5.1 – 25.5 51 – 255 3.2 – 15.8	g/dL x 10 = g/L
Celite ACT	sec	74 – 125 (PREWARM) 84 – 139 (NONWARM)	74 – 125 (PREWARM) 84 – 139 (NONWARM)	50 – 1000	
Kaolin ACT	sec	74 – 137 (PREWARM) 82 – 152 (NONWARM)	74 – 137 (PREWARM) 82 – 152 (NONWARM	50 – 1000	
Prothrombin Time/PT	INR			0.9 – 8.0 #	

ANALYTE	UNIT	REFERENCE RANGE (arterial) (venous)	REPORTABLE RANGE	UNIT CONVERSION
Troponin I/ cTnI	ng/mL (µg/L)	0.00 – 0.03 ** 0.00 – 0.08 ***	0.00 – 50.00 ##	ng/mL x 1 = µg/L
Creatine Kinase MB/ CK-MB	ng/mL (µg/L)	0.0 – 3.5 ****	0.0 – 150.0	ng/mL x 1 = µg/L
B-Type Natriuretic Peptide/BNP	pg/mL (ng/L)	<15-50 ****	15 – 5000	pg/mL x 1 = ng/L
Total β-hCG	IU/L	<5.0	5.0 – 2000.0	

* Calculated values.
† See CHEM8+ IFU for additional reference ranges.
\# Performance characteristics have not been established for INRs above 6.0.
** Represents the 0–97.5% range of results. Each facility should establish its own reference range using the i-STAT cTnI assay.
Performance characteristics have not been established for cTnI values above 35.00 ng/mL.
*** Represents the 0–99% range of results. Each facility should establish its own reference range using the i-STAT cTnI assay.
**** Represents the 0–95% range of results. Each facility should establish its own reference range using the i-STAT assay.

Critical Results [3]

Critical results are test results that fall outside high and low critical limits that define the boundaries of life-threatening values for a test. Follow facility policy regarding notification of the critical values observed.

ANALYTE (units)	ADULT		CHILDREN		NEONATES	
	low	high	low	high	low	high
Sodium (mmol/L)	120	158	121	156	121	156
Potassium (mmol/L)	2.8	6.2	2.8	6.4	2.8	6.5
Chloride (mmol/L)	75	126	77	121	77	121
TCO_2 (mmol/L)	11	40	11	39	–	–
Ionized Calcium (mmol/L)	0.78	1.58	0.74	1.57	–	–
pH	7.21	7.59	7.21	7.59	–	–
$\boldsymbol{P}CO_2$ (mmHg)	19	67	21	66	–	–
$\boldsymbol{P}O_2$ (mmHg)	43	–	45	124	37	92
BUN (mg/dL)	–	104	–	55	–	55
Glucose (mg/dL)	46	484	46	445	32	328
Creatinine	–	7.4	–	3.8	–	–
Lactate						
Hematocrit (% PCV)	18	61	20	62	33	71
Celite ACT						
Kaolin ACT						
PT/INR						
Troponin I/cTnI						
Creatine Kinase MB/ CK-MB						
B-Type Natriuretic Peptide/ BNP						
Total β-hCG						

Interferences

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

QUALITY CONTROL

Daily Procedures

Analyzer Verification

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

Action:

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

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

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

Remedial Action:

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

- ❑ Repeat testing with the same external Electronic Simulator
  - o If FAIL is displayed again, repeat test with a different external Electronic Simulator.
    - ▪ If FAIL continues to display, contact Abbott Point of Care Technical Services.
  - o If PASS is displayed, use the analyzer as required.

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

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

Verification of Cartridge Storage Conditions

Refrigerated Cartridges

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

Action:

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

Remedial Action:

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

- ❑ Quarantine the cartridges.
- ❑ Notify the i-STAT 1 System coordinator.
- ❑ DO NOT USE the cartridges
- ❑ Document per facility or hospital policy.

Room Temperature Cartridges

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

Action:

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

Remedial Action:

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

- ❑ Quarantine the cartridges.
- ❑ Notify the i-STAT 1 System coordinator.
- ❑ DO NOT USE the cartridges.
- ❑ Document per facility or hospital policy.

Monthly Procedures

Review schedule based on facility or hospital policy.

Every 6 Months Procedures

Update i-STAT 1 Analyzer Software

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

Thermal Probe Check Procedure

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

2. Insert the simulator into the analyzer.

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

4. Interpretation of the thermal check value:

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

Miscellaneous Procedures as Needed

Receiving New Cartridges, Liquid Quality Control and Calibration Verification Material

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

Receiving New or Replacement Analyzers

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

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

1. Prior to testing cartridges that measure ***P***O_2, ampules should stand at room temperature a minimum of 4 hours before use. When testing other cartridges (G, Crea, CHEM8+, or EC8+), ampules may be used once the fluid has reached room temperature, approximately 30 minutes for individual ampules. For best results, ampules, cartridges, and analyzers should be at the same temperature. When using cartridges that contain sensors for measuring ionized calcium, pH, ***P***CO_2, or ***P***O_2 (EG6+, EG7+, CG4+, CG8+, CHEM8+, or EC8+), a separate ampule must be used for each cartridge being tested; if these sensors are not present (i.e., the G and Crea cartridges), the contents of one ampule may be used to fill more than one cartridge as long as the cartridges are filled and inserted into an analyzer within 10 minutes of opening the ampule.
2. Access the Control option under Quality Tests in the Administration Menu. Enter the required information. The analyzer allows 15 minutes (or the customized timeout period) to insert the cartridge after the last data entry.
3. Immediately before use, shake the ampule vigorously for 5 to 10 seconds to equilibrate the liquid and gas phases. To shake, hold the ampule at the top and bottom with forefinger and thumb to minimize increasing the temperature of the solution. If necessary, tap the tip of the ampule to send solution back into the bottom section of the ampule. Protect fingers with gauze, tissue, or glove, or use an ampule breaker to snap off the tip of the ampule at the neck.
4. Immediately transfer the solution from the ampule into a plain capillary tube or plain syringe, and then immediately transfer the solution into a cartridge. Immediately seal the cartridge and insert it into an analyzer. It is important not to expose the solution to room air since this will alter the results.
   - When using a capillary tube, fill from the bottom of the ampule. Avoid drawing solution from the surface by covering the far end of the tube as it is inserted into the ampule. Once the open end of the tube rests at the bottom of the ampule, uncover the other end to allow filling by capillary action.
   - When using a syringe (1 cc or 3 cc syringes with 16- to 20- gauge needles are recommended), slowly draw approximately 1 cc of solution from the bottom of the ampule. If air is trapped between the leading edge of the solution and the plunger, do not invert the syringe to expel it; this will not affect solution near the tip of the syringe. If air bubbles are continually drawn into the syringe, or if a bubble is trapped near the tip of the syringe, discard the ampule and syringe and use a fresh ampule and syringe. Expel one or two drops from the syringe before filling the cartridge.
   - Do not use solution left in the syringe, ampule, or capillary tube for additional testing of the cartridges that contain sensors for ionized calcium, pH, ***P***CO_2, or ***P***O_2. However, cartridges without these sensors may be tested with remaining fluids if within 10 minutes of opening the ampule.
5. Compare results to the Value Assignment Sheet (VAS) ranges. Check that the lot number on the control ampule matches the lot number on the VAS and that the software version listed on the VAS matches the software installed in the analyzer. If all results are within expected ranges, use the cartridges as needed.

Remedial Action:

If any results are outside the published expected ranges:

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

Procedure for testing cartridges with i-STAT ACT or PT/INR Controls

1. Prior to use, allow one vial each of the lyophilized plasma and calcium chloride reconstituting fluid to stand at room temperature for a minimum of 45 minutes.
2. Access the Control option under Quality Tests in the Administration Menu. Enter the required information. The analyzer allows 15 minutes (or the customized timeout period) to insert the cartridge after the last data entry.
3. Remove the cap and stopper from the vials and pour the entire contents of the calcium chloride vial into the lyophilized plasma vial. Place the stopper back on the reconstituted vial.
4. Allow the vial to sit for 1 minute and then mix the contents by swirling gently for 1 minute, then inverting slowly for30 seconds.
5. Use a plastic pipette, plastic syringe, or plastic capillary tube without anticoagulant to transfer the solution to an ACT cartridge.
6. Immediately seal the cartridge and insert it into an analyzer. This process must be completed within 30 seconds of the complete reconstitution of the control sample.
7. Compare results to the Value Assignment Sheet (VAS) ranges. If results are within the expected ranges, use the cartridges as needed.

Remedial Action:

If any results are outside the VAS ranges:

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

Procedures for testing cartridges with i-STAT cTnI, BNP, CK-MB or β-hCG controls

1. i-STAT cTnI, BNP, CK-MB and β-hCG Controls are ready-to-use liquids. They are stable until the expiration date on the vial label when stored unopened at 2–8 °C (35 - 46 °F). Once opened, the i-STAT cTnI, BNP, CK-MB and β-hCG Controls are stable for 30 days when stored tightly capped at 2–8 °C.
2. Access the Control option under Quality Tests in the Administration Menu. Enter the required information. The analyzer allows 15 minutes (or the customized timeout period) to insert the cartridge after the last data entry.
3. Immediately before use, gently mix the contents of the control vial to ensure homogeneity. Avoid foaming of the sample.
4. Open the vial and transfer a drop of the solution into the i-STAT cartridge using a plain capillary tube, plain syringe, plastic transfer pipette or the vial dropper. Tightly recap the control vial and store it at 2–8 °C (35 to 46 °F).
5. Seal the cartridge and immediately insert it into the i-STAT 1 Analyzer.
6. Compare results to the Value Assignment Sheet ranges. If results are within the expected ranges, use the cartridges as needed.

Remedial Action:

If any results are outside the published expected ranges:

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

CALIBRATION

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

CLINICAL SIGNIFICANCE

Analyte	Some Causes of Increased Values	Some Causes of Decreased Values
Sodium	Dehydration Diabetes insipidus Salt poisoning Skin losses Hyperaldosteronism CNS disorders	Dilutional hyponatremia (cirrhosis) Depletional hyponatremia Syndrome of inappropriate ADH
Potassium	Renal glomerular disease Adrenocortical insufficiency Diabetic Ketoacidosis (DKA) Sepsis *In vitro* hemolysis	Renal tubular disease Hyperaldosteronism Treatment of DKA Hyper-insulinism Metabolic alkalosis Diuretic therapy
Chloride	Prolonged diarrhea Renal tubular disease Hyperparathyroidism Dehydration	Prolonged vomiting Burns Salt-losing renal disease Over-hydration Thiazide therapy
BUN	Impaired renal function Prerenal azotemia (e.g., shock) Postrenal azotemia GI bleeding High protein diet	Pregnancy Severe liver insufficiency Over-hydration Malnutrition
Glucose	Diabetes mellitus Pancreatitis Endocrine disorders (e.g., Cushing's syndrome) Drugs (e.g., steroids, thyrotoxicosis) Chronic renal failure Stress I.V. glucose infusion	Insulinoma Adrenocortical insufficiency Hypopituitarism/ Massive liver disease Ethanol ingestion/ Reactive hypoglycemia Glycogen storage disease
Creatinine	Impaired renal function	
Lactate	Hypoxia (shock, hypovolemia, left ventricular failure) Diabetes mellitus Neoplasia Liver disease Drug or toxins (ethanol, methanol, salicylates)	
***P*CO$_2$**	Primary Respiratory Acidosis: • *Airway obstruction* • *Sedatives and anesthetics* • *Respiratory distress syndrome* • *Chronic Obstructive Pulmonary Disease*	Primary Respiratory alkalosis: • *Hypoxia due to chronic heart failure* • *Edema* • *Neurologic disorders* • *Mechanical hyperventilation*

Analyte	Some Causes of Increased Values	Some Causes of Decreased Values
***P*O$_2$**		Decreased pulmonary ventilation (airway obstruction or trauma to the brain) Impaired gas exchange between alveolar air and pulmonary capillary blood (bronchitis, emphysema or pulmonary edema) Blood flow alteration within the heart or lungs (congenital defects in the heart or shunting of venous blood into the arterial system without oxygenation in the lungs)
Hematocrit	Dehydration Diuretic therapy Burns Impaired ventilation Cardiovascular and Renal disorders Polycythemia Vera	Anemias Blood loss Overhydration
ACT Celite	Administration of heparin for medical or surgical procedures.	
PT/INR	Administration of oral anticoagulant therapy.	
ACT Kaolin	Administration of heparin for medical or surgical procedures.	
cTnI	Myocardial Infarction Blunt trauma Rhythm disturbance (SVT, AF) Chemotherapy (e.g., Adriamycin) Myocarditis Congestive heart failure Left ventricular hypertrophy	
CK-MB	Myocardial Infarction Myocardial damage Blunt trauma Myocarditis Strenuous exercise Skeletal muscle injury	
BNP	Congestive heart failure Chronic obstructive pulmonary disease (COPD) Left Ventricular Dysfunction	
Total β-hCG	Pregnancy Gestational trophoblastic disease Nontrophoblastic neoplasms Menopause	

PRINCIPLES OF MEASUREMENT

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

are measured by ion-selective electrode potentiometry. Concentrations are calculated from the measured potential through the Nernst equation.

Urea

is first hydrolyzed to ammonium ions in a reaction catalyzed by the enzyme urease. The ammonium ions are measured by an ion-selective electrode and the concentration is calculated from the measured potential through the Nernst equation.

Glucose

is measured amperometrically. Oxidation of glucose, catalyzed by the enzyme glucose oxidase, produces hydrogen peroxide. The liberated hydrogen peroxide is oxidized at an electrode to produce an electric current which is proportional to the glucose concentration.

Creatinine

is hydrolyzed to creatine in a reaction catalyzed by the enzyme creatinine amidohydrolase. Creatine is then hydrolyzed to sarcosine in a reaction catalyzed by the enzyme creatine amidinohydrolase. The oxidation of sarcosine, catalyzed by the enzyme sarcosine oxidase, produces hydrogen peroxide. The liberated hydrogen peroxide is oxidized at the platinum electrode to produce a current which is proportional to the creatinine concentration.

Lactate

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

***P*O_2**

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

Hematocrit

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

ACT

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

PT/INR

is determined amperometrically. The conversion of a thrombin substrate is initiated by mixing a whole blood sample (without anticoagulant) with tissue thromboplastin. The substrate used in the electrogenic assay has as amide linkage that mimics the thrombin–cleaved amide linkage in fibrinogen. The product of the thrombin–substrate reaction is the electroactive compound that is detected amperometrically. The time of detection is measured in seconds and reported as INR and/or seconds.

Troponin I/cTnI

is determined amperometrically using a two-site ELISA method. Antibodies specific for human cardiac troponin I (cTnI) are located on an electrochemical sensor fabricated on a silicon chip. Also deposited in another location on the sensor silicon chip is an antibody/alkaline phosphatase enzyme conjugate specific to a separate portion of the cTnI molecule. The whole blood or plasma sample is brought into contact with the sensors allowing the enzyme conjugate to dissolve into the sample. The cTnI within the sample becomes labeled with alkaline phosphatase and is captured onto the surface of the electrochemical sensor during an incubation period of approximately seven minutes. The sample, as well as excess enzyme conjugate, is washed off the sensors. Within the wash fluid is a substrate for the alkaline phosphatase enzyme. The enzyme bound to the antibody/antigen/antibody sandwich cleaves the substrate releasing an electrochemically detectable product. The electrochemical (amperometric) sensor measures this enzyme product which is proportional to the concentration of cTnI within the sample.

Creatine Kinase MB/CK-MB

is determined amperometrically using a two-site ELISA method. Antibodies specific for an epitope unique to the CK-MB subunit, that therefore do not bind CK-MM or CK-BB, are located on an electrochemical sensor fabricated on a silicon chip. Also deposited in another location on the sensor silicon chip is an antibody/alkaline phosphatase enzyme conjugate specific to an epitope on the B subunit of creatine kinase. The specificity of the conjugate antibody to the B subunit allows this conjugate to recognize CK-MB and CK-BB, but not CK-MM. The whole blood or plasma sample is brought into contact with the sensors allowing the enzyme conjugate to dissolve into the sample. The CK-MB within the sample becomes labeled with alkaline phosphatase and is captured onto the surface of the electrochemical sensor during an incubation period of approximately three minutes. The sample is washed off the sensors, as well as excess enzyme conjugate. Within the wash fluid is a substrate for the alkaline phosphatase enzyme. The enzyme bound to the antibody/antigen/antibody sandwich cleaves the substrate releasing an electrochemically detectable product. The electrochemical (amperometric) sensor measures this enzyme product which is proportional to the concentration of CK-MB within the sample.

B-Type Natriuretic Peptide/BNP

is determined amperometrically using a two-site ELISA method. Antibodies specific for BNP are located on an electrochemical sensor fabricated on a silicon chip. Also deposited in another location on the sensor silicon chip is an antibody/alkaline phosphatase enzyme conjugate specific to a separate portion of the BNP molecule. The whole blood or plasma sample is brought into contact with the sensors allowing the enzyme conjugate to dissolve into the sample. The BNP within the sample becomes labeled with alkaline phosphatase and is captured onto the surface of the electrochemical sensor during an incubation period of approximately seven minutes. The sample is washed off the sensors, as well as excess enzyme conjugate. Within the wash fluid is a substrate for the alkaline phosphatase enzyme. The enzyme bound to the antibody/antigen/antibody sandwich cleaves the substrate releasing an electrochemically detectable product. The electrochemical (amperometric) sensor measures this enzyme product which is proportional to the concentration of BNP within the sample.

Total Beta-Human Chorionic Gonadotropin (β-hCG)

The i-STAT Total β-hCG test uses a two-site enzyme-linked immunosorbant assay (ELISA) method. Antibodies specific for β-hCG are located on an electrochemical sensor fabricated on a silicon chip. Also deposited in another location on the sensor silicon chip is an anti-β-hCG antibody/alkaline phosphatase enzyme conjugate specific to a separate portion of the β subunit of the hCG molecule. The system is capable of detecting whole molecule (intact) hcg as well as the free β subunit, but not the β core fragment (β subunit missing the carboxyl terminal end). The whole blood or plasma sample is brought into contact with the sensors allowing the enzyme conjugate to dissolve into the sample. The hCG within the sample becomes labeled with alkaline phosphatase and is captured onto the surface of the electrochemical sensor during an incubation period of approximately seven minutes. The sample, as well as excess enzyme conjugate, is washed off the sensors. Within the wash fluid is a substrate for the alkaline phosphatase enzyme. The enzyme bound to the antibody/antigen/antibody sandwich cleaves the substrate, releasing an electrochemically detectable product.

The electrochemical (amperometric) sensor measures this enzyme product, which is proportional to the concentration of β-hCG within the sample. Also positioned on the silicon chip is a (conductivity) sensor to assess the hematocrit value of the sample. This value is required in the calculation of the β-hCG concentration in whole blood samples.

TCO_2

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

REFERENCES

1. Statland, B.E., Clinical Decision Levels for Lab Tests. Medical Economics Books. 1987.
2. Tietz, N.W., Tietz Textbook of Clinical Chemistry, third edition, Ed. C.A. Burtis, E.R. Ashwood, W.B. Saunders Company, Philadelphia, 1999. Table 50-20, Appendix.
3. Kost, Gerald J., Using critical limits to improve patient outcome. Medical Laboratory Observer. March 1993; 25(3): 22–27.

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Prepared By: Date:

Adopted: Date:

Reviewed: Date:

Reviewed: Date:

Reviewed: Date:

Revised: Date:

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i-STAT QC Log: Incoming QC

Cartridge Type:__________________Lot No.:__________________Rec'd. Date:_____________ _ Quant.:_____________Temp. Strip: _________

Control Name:___________________Lot No.:__________________Level:______________Exp. Date:_______________CLEW: _______________

Test									
Range									
Results									
Results									

Control Name:___________________Lot No.:__________________Level:______________Exp. Date:_______________CLEW: _______________

Test									
Range									
Results									
Results									

Control Name:___________________Lot No.:_________________ _ Level:_____________Exp. Date:_______________CLEW: _______________

Test									
Range									
Results									
Results									

Lot/Shipment accepted by:____Date: __________________________

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i-STAT QC Action Log

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

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

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

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

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

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

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

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i-STAT Electronic Simulator Action Log

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