Quality Check Messages and Codes (continued)

Message	Cause	Action
Analyzer Error, Use Electronic Simulator	Handheld detects problem from which it is likely to recover.	Insert the Electronic Simulator. If PASS, continue to use handheld
Analyzer Error, See Manual	Handheld detects problem from which it may not recover.	Insert Electronic Simulator. If PASS, insert a cartridge with sample or control. If the code does not reappear, continue to use handheld.
No display	Disposable batteries dead or rechargeable battery fully discharged. Keypad not responding. Start switch broken.	Change disposable batteries or recharge battery. If still no display, call Support Services.
Cartridge Locked does not disappear after test cycle completed	Dead battery(s). Mechanical problem.	Wait until handheld turns off. Turn handheld on. If resets, remove cartridge. If not, change or recharge battery(s) and turn handheld on.

REF 06F16-56
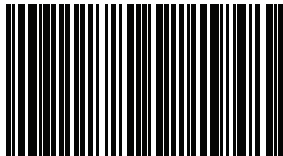
(01)00054749001286

Abbott Point of Care Inc.
Abbott Park, IL 60064 • USA

EC REP   Emergo Europe
Molenstraat 15
2513 BH The Hague
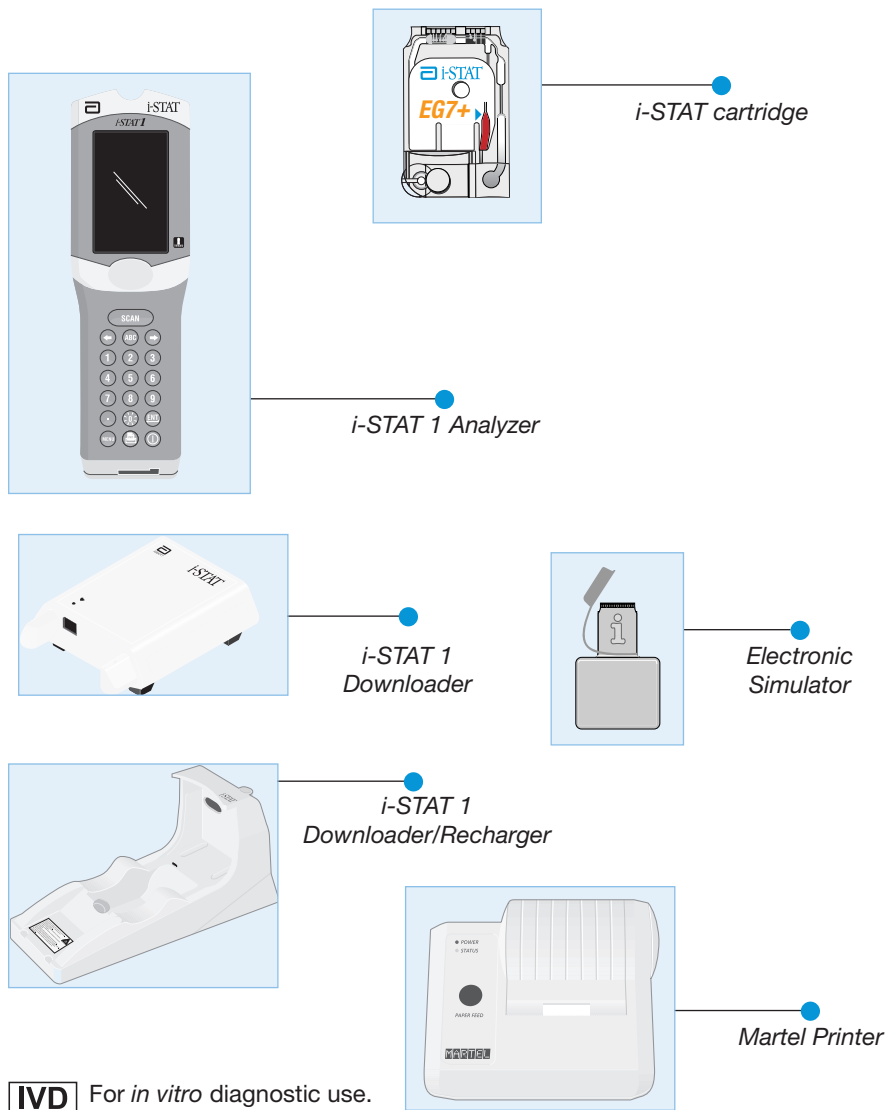The Netherlands
Tel: (31)70 345 8570
Fax: (31)70 346 7299

For information related to Article 33 of the EU REACH regulation (EC No. 1907/2006), please refer to PMIS.abbott.com. If you have issues logging into the website, contact Abbott at: abbott.REACH@abbott.com.

CE

Art: 714254-00R

Rev. Date: 16-OCT-12

i-STAT ®

i-STAT®1
User Guide

Abbott
Point of Care

System Components

i-STAT cartridge

i-STAT 1 Analyzer

i-STAT 1 Downloader

Electronic Simulator

i-STAT 1 Downloader/Recharger

Martel Printer

IVD For *in vitro* diagnostic use.

See System Manual for instructions.

Intended Use: The i-STAT 1 Analyzer is intended for use with i-STAT cartridges for the *in vitro* quantification of various analytes in whole blood.

Quality Check Messages and Codes

Message	Cause	Action
Date Invalid, Check Clock	Date outside six month lifetime of software.	Select 5-Clock Set from Administration Menu. (Password protected.)
Dead Batteries, Replace Batteries	Insufficient power to complete a test cycle.	Replace disposable batteries or recharge the rechargeable battery.
Temperature Out of Range, Check Status page	Temperature outside operating range of 16 to 30 °C.	Check handheld temperature by pressing 1 for Analyzer Status under the Administration Menu. Move handheld to warmer area if below operating range or to cooler area if above the range.
Invalid or Expired CLEW	Software expired or corrupt.	Verify that the handheld's date is correct. Change software if expired. Update again if not expired.
Analyzer Interrupted, Use Another Cartridge	Last cartridge run not completed.	Check the battery pack inserted properly. Check for Low Battery startup warning.
Cartridge Error	Usually problem with sample or cartridge filling.	Use another cartridge. If same code repeats more than twice, try another handheld.
Cartridge Preburst	Calibrant pack burst before cartridge inserted into handheld.	Use another cartridge - do not press on center of cartridge. Check that cartridges have not been frozen.
Unable to Position Sample	Cartridge not sealed. Clot in sample. Aberrant cartridge.	Use another cartridge.
Sample Positioned Short of Fill Mark	Cartridge underfilled.	Use another cartridge - fill to Fill Mark.
Sample Positioned Beyond Fill Mark	Cartridge overfilled.	Use another cartridge - do not fill beyond Fill Mark.
Test Cancelled by Operator	User did not respond to mandatory prompt before handheld time out.	No action required.
Cartridge Type Not Recognized	Software does not recognize cartridge.	Update software. Check to see if cartridges are expired.

Replacing Paper in the i-STAT Printer

1. Open the paper compartment lid by pulling up on the release lever and remove any remaining paper.

2. Reel off a few centimeters of paper from the new paper roll, with the leading edge of the paper feeding forward from the bottom of the roll.

3. Sit the new paper roll in the compartment such that the leading edge is resting outside the compartment on the printer casing.

4. Close the lid until it snaps into place.

Troubleshooting

Unexpected Results

When results do not reflect the patient's condition, repeat the test using a fresh cartridge and sample. If results are still suspect, test the lot of cartridges in use with i-STAT control solutions. If the controls are in range, there may be an interfering substance in the sample. Check the Cartridge and Test Information sheets for the test in question. Test by another method to verify the result. If the controls are out of range there may be a problem with the cartridge lot number. Use another lot number or repeat the test using another method, and refer to Support Services Information in the Technical Bulletin section of the i-STAT 1 System Manual.

Startup Messages

The handheld performs self-checks when it is turned on. If a condition that should be corrected in the near future, but that will not affect results, is detected, a warning is displayed. The operator presses the 1 key to access the Test Menu. The handheld can be customized to lock out the operator until the corrective action is taken.

Message	Action
Electronic Simulator Test Required	Insert Electronic Simulator.
Stored Memory Low	Place handheld in Downloader.
Stored Memory Full	Place handheld in Downloader.
Upload Required	Place handheld in Downloader.
Battery Low	Replace batteries or recharge battery.
CLEW Expiring, Update Required	Update software.

Blood Collection

Acceptable Samples for Cartridges

- Arterial: Plain syringe, heparinized syringe labeled for analytes to be tested and filled to capacity, or syringe with minimum volume of heparin to prevent clotting (10 U/mL of blood). For ionized calcium, use balanced heparin syringes. Mix heparinized syringes by rolling between palms for at least 5 seconds in 2 directions, then invert the syringe repeatedly for at least 5 seconds. Test for lactate immediately. Samples for pH, $P\text{CO}_2$, $P\text{O}_2$, $T\text{CO}_2$ and ionized calcium should be tested within 10 minutes. Test for other analytes within 30 minutes.
  - Avoid drawing air into syringes for blood gas and ionized calcium tests.
  - If not tested immediately, remix and discard 2 drops of blood before filling cartridge.
  - Do not use iced samples.

- Venous: Collection tube with lithium or sodium heparin filled to capacity and mixed by gentle inversion at least 10 times. Test within 10 minutes.
  - Do not leave tourniquet on for more than 2 minutes.
  - Do not draw above an I.V.

- Skin puncture: Lithium heparin capillary tubes for testing all analytes but ionized calcium. For all analytes including ionized calcium, use plain or balanced heparin capillary tubes. Test immediately.
  - Allow alcohol to dry over puncture site before collecting sample.
  - Do not "milk" finger or heel while collecting sample.

- Coagulation Tests:
  - The ACT test can be performed using venous or arterial samples, while the PT/INR test can be performed using capillary or venous samples.
  - Use plain plastic syringes or plastic evacuated tubes with no anticoagulant, activators, or serum separators.
  - Test sample immediately upon draw.
  - For venipuncture, some experts recommend drawing and discarding a sample of at least 1 mL prior to drawing samples for coagulation testing.
  - If a second measurement is needed, draw a fresh sample.
  - For Indwelling line testing for ACT:
    a. Fluid drip through the line must be discontinued.
    b. If blood must be drawn from an indwelling line, possible heparin contamination and specimen dilution should be considered. The line should be flushed with 5 mL of saline and the first 5 mL of blood or six dead space volumes should be discarded.
    c. Withdraw the sample into a fresh plastic syringe with no anticoagulant, and test immediately.
  - For extracorporeal line testing for ACT:
    a. Flush the extracorporeal blood access line by withdrawing 5 mL of blood into a syringe and discard the syringe.

b.   Withdraw the sample into a fresh plastic syringe with no anticoagulant, and test immediately.

■ CHEM8+ Cartridges

  • CHEM8+ cartridges require the use of:

   a.   whole blood collected in non-heparinized capillary tubes, evacuated tubes, or syringes, as long as sample is tested immediately upon draw,

   b.   heparinized whole blood collected in balanced heparin syringes or capillary tubes, or

   c.   heparinized whole blood collected in evacuated tubes containing lithium or sodium heparin, as long as the tubes are filled to capacity.

■ Troponin I/cTnI and CK-MB Tests

  • cTnI and CK-MB cartridges require the use of either:

   a.   heparinized whole blood or plasma samples collected in syringes or evacuated tubes containing lithium or sodium heparin, or

   b.   non-heparinized whole blood or plasma samples tested within one minute of drawing from a patient into a plastic syringe or plastic evacuated tube containing no additives.

  • The use of whole blood or plasma samples containing other anticoagulants such as EDTA, oxalate, and citrate will cause deactivation of the alkaline phosphatase, resulting in decreased cTnI or CK-MB readings.

  • Capillary tubes and direct skin punctures (e.g. fingersticks) should not be used with the cTnI or CK-MB cartridge.

■ BNP Tests

  • BNP cartridges require the use of EDTA whole blood or plasma samples collected in plastic syringes or evacuated tubes containing EDTA.

  • The use of whole blood or plasma samples containing other anticoagulants such as oxalate and citrate is not recommended.

  • Capillary tubes and direct skin punctures (e.g. fingersticks) should not be used with the BNP cartridge.

Limitations

Interfering substances in the patient's sample may cause an increase or decrease in a result. Refer to the Cartridge and Test Information Sheets and Technical Bulletins for substances and/or conditions that may interfere with cartridge tests.

Charging Rechargeable Battery in External Recharge Compartment

Placing a rechargeable battery into the recharging compartment will automatically initiate trickle recharging. The indicator light near the recharging compartment will be green when a rechargeable battery is placed in the compartment.

STEP	ACTION
1	The battery pack has two labels: one for orientation in the handheld and one for orientation in the Downloader/Recharger. With the label with the Downloader facing up and the electrical contact end of the pack facing the contacts in the battery compartment, insert the pack into the compartment as shown on the label.
2	To remove the battery after it is charged, back the pack out of the compartment.

Full recharge from a discharged state takes approximately 40 hours.

Caution

If you are using rechargeable batteries, use **only** rechargeable batteries and recharging equipment supplied by your i-STAT distributor. Other batteries and rechargers may affect test results and pose other hazards to operators and patients.

Cleaning the Handheld and Downloader

Clean the display and case with a gauze pad moistened with a mild non-abrasive cleaner, detergent, soap and water, alcohol or 10% bleach solution. Rinse with another pad moistened with water and dry.

Replacing Paper in the Martel Printer

1.   Squeeze the front and back of the paper cup to open.

2.   Remove remaining paper by pressing the Paper feed button. Do not pull paper through printer mechanism.

3.   Reel off a few centimeters of paper from the new paper roll and check that the end has a clean straight edge.

4.   Slide the leading edge of the paper through the paper entry slot until you feel resistance. Paper feeds from underneath the roll.

5.   Press the Paper Feed button and feed the paper through the printer mechanism.

6.   Keep the Paper Feed button depressed until the paper passes through the paper exit slot.

7.   Sit the new paper roll in the paper cup and close the lid.

1. Turn the handheld on and press (MENU) to access the Administration Menu.

2. Press (3) for Quality Tests.

3. Press (1) for Control.

4. Press (1) for i-STAT Cartridge (if prompted).

5. Scan or enter Operator ID.

6. Enter the control lot number.

7. Scan the lot number on the cartridge pouch.

8. Fill a cartridge with the control and close the cover.

9. Insert the cartridge into the cartridge port.

10. Enter chart page information if applicable.

11. View results on handheld's display.

12. Remove and discard cartridge when Cartridge Locked message disappears.

13. Press (1) for Test Options on the results page and press (1) for Next Level if testing another level of control.

Hardware Procedures

Replacing Batteries

1. Slide the battery compartment door off.

2. Tilt the handheld slightly to slide out the battery carrier.

3. Remove the old batteries from the carrier and replace with 2 new 9V lithium batteries.

4. Insert the carrier back into the compartment – label facing up and electrical contacts first.

5. Slide the battery compartment door into place.
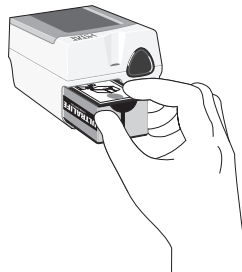
Charging the Rechargeable Battery

Placing a handheld in a Downloader/Recharger will automatically initiate recharging of the rechargeable battery. The indicator light on top of the Downloader/Recharger will be green (trickle charge), red (fast charge), or blinking red (fast charge pending) when a handheld with a rechargeable battery is placed in the Downloader/Recharger.

No damage will be caused if a handheld with disposable batteries installed is placed in the Downloader/Recharger.

Patient Test Procedures

Cartridge Test Procedure

- **The i-STAT 1 handheld must be customized through the Central Data Station (CDS) or through the handheld's Customization menu for the following option(s): Cartridge Information First Required AND Cartridge Lot Number Required.**
- **DO NOT insert cartridge to start test**
- **DO NOT open cartridge pouch before scanning the barcode** (if applicable)

1. Press ( ) to turn on Handheld.

2. Press (2) i-STAT Cartridge

3. Follow Handheld prompts.

4. Scan the lot number on the cartridge pouch.
   - Position barcode 3 - 9 inches from scanner window on the Handheld.
   - Press and hold (SCAN) to activate the scanner.
   - Align the red laser light so it covers entire barcode.
   - The Handheld will beep when it reads the barcode successfully.

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

   ⚠ **Laser Radiation – Do not stare into beam. Class 2 laser product. Laser Diode 650 nm Maximum Output 1.0 mW.**

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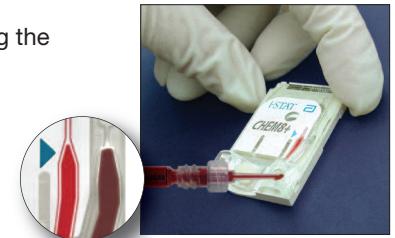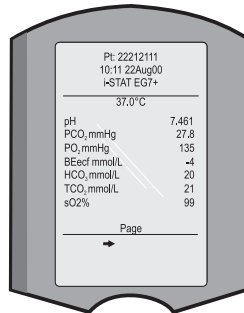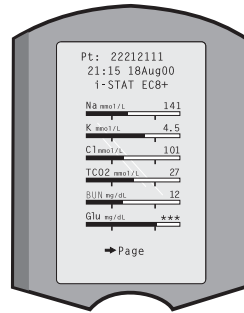
6. Push the sealed cartridge into the handheld port until it clicks into place. Wait for the test to complete.

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

7. Review results.

Reviewing Test Results

- The 0 key can be used to backlight the display to view results in dim lighting. (The backlight turns off after 90 seconds or when the 0 key is pressed again.)

- Test results are displayed numerically and with bar graphs. Tick marks indicate the reference ranges on the bar graphs. (Blood gases and their associated calculated values are not displayed with bar graphs and reference ranges.)

- Test results are displayed for 2 minutes or a customized time. To recall the last set of results to the screen, turn the handheld on and press 1 for Last Result.

- To review results from the same patient, when results are displayed, press 1 for Test Options and then 3 for History. Scroll through test records using the 1 and 2 keys.

- To review another patient's results, turn the handheld on and press the Menu key followed by the 2 key for Data Review and the 1 key for patient. Scan or enter the Patient's ID number. Use the 1 and 2 keys to scroll through the test records. Or, press the Menu key followed by the 7 key for List. Select the test record(s) to be reviewed and press the Enter key.

```
Pt: 22212111
  21:15 18Aug00
   i-STAT EC8+

Na mmol/L         141
K mmol/L          4.5
Cl mmol/L         101
TCO2 mmol/L        27
BUN mg/dL          12
Glu mg/dL         ***

     ➡ Page
```

```
Pt: 22212111
  10:11 22Aug00
   i-STAT EG7+
        37.0°C

pH                7.461
PCO₂ mmHg          27.8
PO₂ mmHg            135
BEecf mmol/L         -4
HCO₃ mmol/L          20
TCO₂ mmol/L          21
sO2%                99

     Page
     ➡
```

Reportable and Reference Range

Measured:

Test	Units	Reportable Range	Reference Range (arterial)	(venous)
Sodium/Na	mmol/L (mEq/L)	100 – 180	138 – 146	138 – 146
Potassium/K	mmol/L (mEq/L)	2.0 – 9.0	3.5 – 4.9	3.5 – 4.9
Chloride/Cl	mmol/L (mEq/L)	65 – 140	98 – 109	98 – 109
Glucose/Glu	mmol/L mg/dL g/L	1.1 – 38.9 20 – 700 0.20 – 7.00	3.9 – 5.8 70 – 105 0.70 – 1.05	3.9 – 5.8 70 – 105 0.70 – 1.05
Lactate/Lac	mmol/L mg/dL	0.30 – 20.00 2.7 – 180.2	0.36 – 1.25 3.2 – 11.3	0.90 – 1.70 8.1 – 15.3
Creatinine/Crea	mg/dL µmol/L	0.2 – 20.0 18 – 1768	0.6 – 1.3 53 – 115	0.6 – 1.3 53 – 115

Quality Assurance

Handheld

Electronic Simulator

Perform an electronic check on each handheld in use once a day with either the internal or external Electronic Simulator or as needed for regulatory compliance. The internal simulator check is initiated, every 24 hours or according to a customized schedule, when a cartridge is inserted into the cartridge port. If the internal simulator result is PASS, the cartridge test proceeds and the simulator results are stored. If FAIL is displayed for the internal simulator, reinsert the cartridge or use an external simulator. The external simulator check is performed as follows:

1. Turn the handheld on.
2. Press MENU to access the Administration Menu.
3. Press 3 for Quality Tests.
4. Press 4 for Simulator.
5. Scan or enter Operator ID.
6. Enter the Simulator ID (serial number).
7. Insert the simulator into the cartridge port.
8. View results on handheld's screen.
9. If PASS is displayed, continue to use the handheld.
10. If FAIL is displayed for the external simulator, reinsert the simulator.

    If FAIL is displayed a second time, do not use the handheld and contact your Support Services representative.

Thermal Probes and Room Temperature Checks
See System Manual for these quality assurance procedures that are performed once or twice per year.

Cartridge

- Immediately check temperature strip enclosed with each shipment of cartridges. Follow the instructions on the card.

- Verify the integrity of a new shipment of cartridges, on receipt, by analyzing 2 levels of i-STAT controls and RNA Medical controls for hematocrit using any handheld that has passed the Electronic Simulator test and a representative sample of the lot(s) of cartridges received. Use expected values published in the Value Assignment Sheets to verify the integrity of the cartridges.

- Verify that the storage conditions listed above have been maintained.

Transmitting Results

1. Place handheld in Downloader or Downloader/Recharger.
2. Do not move handheld until Communication in Progress message disappears.

Storage Conditions and Preparation for Use

Cartridges

■ Store at temperatures between 2 and 8 °C (35-46°F). Do not use after expiration date on cartridge pouch and box.

■ Equilibrate a single cartridge for 5 minutes or a box of cartridges for 1 hour at room temperature before opening pouches.

■ Store cartridges at room temperature for the timeframe indicated on the cartridge box. Mark the cartridge box or cartridge pouches with the room temperature expiration date. Do not expose to temperatures above 30 °C (86°F). Do not return cartridges to the refrigerator after room temperature equilibration.

■ Use cartridge immediately after opening pouch. If the pouch has been punctured, the cartridge should not be used.

Analyzer

■ Storage/Transport temperature: -10 to 46°C (14-115°F)

■ The handheld's operating temperature range is 16 to 30 °C (61-86°F).

■ Store handhelds near the testing location or in an area close to the temperature of the testing area. Do not store handhelds near equipment that gives off heat or in direct sunlight.

Reportable and Reference Range

Measured:

Test	Units	Reportable Range	Reference Range (arterial)	Reference Range (venous)
pH		6.50 – 8.20	7.35 – 7.45	7.31 – 7.41
PCO_2	mmHg	5 – 130	35 – 45	41 – 51
	kPa	0.67 – 17.33	4.67 – 6.00	5.47 – 6.80
TCO_2 (on CHEM8+ cartridge only)	mmol/L (mEq/L)	5-50	23 – 27	24 – 29
PO_2	mmHg	5 – 800	80 – 105	
	kPa	0.7 – 106.6	10.7 – 14.0	
Ionized Calcium/iCa	mmol/L	0.25 – 2.50	1.12 – 1.32	1.12 – 1.32
	mg/dL	1.0 – 10.0	4.5 – 5.3	4.5 – 5.3
Urea Nitrogen/BUN	mg/dL	3 – 140	8 – 26	8 – 26
Urea	mmol/L	1 – 50	2.9 – 9.4	2.9 – 9.4
	mg/dL	6 – 300	17 – 56	17 – 56
Hematocrit/Hct	%PCV	10 – 75	38 – 51	38 – 51
	Fraction	0.10 – 0.75	0.38 – 0.51	0.38 – 0.51
Celite Activated Clotting Time/ Celite ACT	seconds	50 – 1000	74 – 125 (Prewarm) 84 – 139 (Nonwarm)	74– 125 (Prewarm) 84 – 139 (Nonwarm)

The range from 80 - 1000 seconds has been verified through method comparison studies.

Test	Units	Reportable Range	Reference Range (arterial)	Reference Range (venous)
Kaolin Activated Clotting Time/ Kaolin ACT	seconds	50 – 1000	74 – 137 (Prewarm) 82 – 152 (Nonwarm)	74 – 137 (Prewarm) 82 – 152 (Nonwarm)

The range from 77 - 1000 seconds has been verified through method comparison studies

Test	Units	Reportable Range	Reference Range (arterial)	Reference Range (venous)
Prothrombin Time / PT	INR	0.9 – 8.0		

Performance characteristics have not been established for INRs above 6.0

Test	Units	Reportable Range	Reference Range (arterial)	Reference Range (venous)
Troponin I / cTnI	ng/mL (µg/L)	0.00 – 50.0		0.00 – 0.03* 0.00 – 0.08**

Performance characteristics have not been established for cTnI values above 35.00 ng/mL.
* Represents the 0 to 97.5% range of results.
** Represents the 0 to 99% range of results.

Test	Units	Reportable Range	Reference Range (arterial)	Reference Range (venous)
Creatinine Kinase MB / CK-MB	ng/mL (µg/L)	0.0 – 150.0		0.0 – 3.5***

***Represents the 0 to 95% range of results.

Test	Units	Reportable Range	Reference Range (arterial)	Reference Range (venous)
β-Type Natriuretic Peptide / BNP	pg/mL (ng/L)	15 – 5000		<15 – 50#

Represents the 0 to 95% range of results

Celite is a registered trademark of Celite Corporation, Santa Barbara, CA. for its diatomaceous earth products.

Calculated:

Test	Units	Reportable Range	Reference Range (arterial)	(venous)
Hemoglobin/Hb	g/dL	3.4 – 25.5	12 – 17	12 – 17
	g/L	34 – 255	120 – 170	120 – 170
	mmol/L	2.1 –15.8	7 – 11	7 – 11
TCO_2 (for all cartridges but the CHEM8+ only)	mmol/L (mEq/L)	5-50	23 – 27	24 – 29
HCO_3	mmol/L (mEq/L)	1.0 – 85.0	22 – 26	23 – 28
BE	mmol/L (mEq/L)	(-30) – (+30)	(-2) – (+3)	(-2) – (+3)
Anion Gap/AnGap	mmol/L (mEq/L)	(-10) – (+99)	10 – 20	10 – 20
sO_2	%	N/A	95 – 98	

Test Flags and Operator Action

- ***: Results that are not reportable due to sensor errors or interfering substances. Draw a fresh sample and repeat test. If results are flagged again, send sample to the lab.

- < , > and < >: Results that are below or above the reportable range or dependant on results that are outside the reportable range. Send sample to the lab if necessary.

- ↑ and ↓: Results that are above or below the action range. Follow facility procedure for samples with critical values.

Printing Test Results from a Martel Printer or i-STAT Printer

Without Downloader or Downloader/Recharger

1. Turn printer on if green power light is not on.

2. Align IR windows of handheld and printer.

3. Display results.

4. Press PRT .

5. Do not move handheld or printer until printing is complete.

6. If printer is not powered from a wall outlet, turn printer off.

With Downloader or Downloader/Recharger

1. Place handheld in Downloader or Downloader/Recharger that is wired to printer.

2. Display results.

3. Press PRT . Do not move handheld or printer until printing is complete.

4. If printer is not powered from a wall unit using the AC adapter, turn printer off.

Printing more than one result

1. Turn the handheld on.

2. Press MENU .

3. Press 2 for Data Review.

4. Press 7 for List.

5. Scroll through the test records using the ← and → keys.

6. Press the numbered key for the test record(s). (Press the numbered key again to deselect a record.)

7. Align handheld and printer IR window or place in Downloader or Downloader/Recharger attached to printer. Press PRT .

8. Do not move handheld or printer until printing is complete.

9. If printer is not powered from a wall unit using the AC adapter, turn printer off.