


CARTRIDGE AND TEST INFORMATION

i-STAT sensors are available in a variety of panel configurations. Sensors are contained in cartridges with microfluidic components and, in some cartridges, calibration solution. i-STAT cartridges are used with the i-STAT Portable Clinical Analyzer, the i-STAT 1 Analyzer* and the Philips Medical Systems Blood Analysis Module** for the simultaneous quantitative determination of specific analytes and coagulation parameters in whole blood.

CARTRIDGE SPECIFICATIONS

Shelf Life:	Refrigerated at 2 to 8°C (35 to 46°F) until expiration date. Room temperature at 18 to 30°C (64 to 86°F) for two weeks.
Preparation for Use:	Individual cartridges may be used after standing five minutes at room temperature. An entire box of cartridges should stand at room temperature for one hour. All cartridges should be used immediately after opening pouch. If the pouch has been punctured, the cartridge should not be used.
Sample Type:	Fresh whole blood from arterial, venous, or skin punctures <i>(Note: Skin puncture is NOT a recommended sample type for ACT, cTnI, CK-MB, or BNP testing.)</i> cTnI and CK-MB cartridges require the use of heparinized whole blood or plasma, or non-heparinized whole blood tested within one minute of patient draw. BNP cartridges require the use of EDTA whole blood or plasma samples.
Sample Volume:	17µL, 20µL, 40µL, 65µL, or 95µL depending on cartridge type.
Test Timing:	<i>Immediately after collection</i> <ul style="list-style-type: none">• Samples for the measurement of ACT, PT/INR and Lactate <i>Within 3 minutes after collection</i> <ul style="list-style-type: none">• Samples collected in capillary tubes, both with and without anticoagulant• Samples collected in evacuated or non-evacuated tubes and syringes without anticoagulant <i>Within 10 minutes after collection</i> <ul style="list-style-type: none">• Samples collected with anticoagulant for the measurement of pH, PCO_2, PO_2 and iCa. Maintain anaerobic conditions. Remix before filling cartridge. <i>Within 30 minutes after collection</i> <ul style="list-style-type: none">• Sodium, potassium, chloride, glucose, BUN/urea, creatinine, hematocrit, troponin I, CK-MB, and BNP. Remix thoroughly before testing.

* The cTnI, CK-MB, and BNP cartridges can only be used with the i-STAT 1 analyzer bearing the  symbol. The CHEM8+ cartridge can only be used with the i-STAT 1 analyzer.

** Blood Analysis Module supports neither the PT/INR, the CHEM8+, the cTnI, the CK-MB nor the BNP cartridge.

Analysis Time:

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

Cartridges	Collection Options			
	Syringes	Evacuated Tubes	Capillary Tubes	Directly from Skin Puncture
Cartridges which measure ionized calcium	<ul style="list-style-type: none"> • Without anticoagulant • With balanced heparin anticoagulant (syringe must be filled to labeled capacity) 	<ul style="list-style-type: none"> • Without anticoagulant • With sodium or lithium heparin anticoagulant (tubes must be filled to capacity) 	<ul style="list-style-type: none"> • Without anticoagulant • With balanced heparin anticoagulant 	<ul style="list-style-type: none"> • Not recommended • Not recommended for blood gas analysis; arterial specimens are preferred.
Cartridges which perform ACT	<ul style="list-style-type: none"> • Without anticoagulant ONLY • Syringes must be plastic 	<ul style="list-style-type: none"> • Without anticoagulant, clot activators, or serum separators ONLY • Tubes must be plastic • Devices used to transfer sample to cartridge must be plastic 	<ul style="list-style-type: none"> • Not recommended 	<ul style="list-style-type: none"> • Not recommended
Cartridges which perform PT/INR	<ul style="list-style-type: none"> • Without anticoagulant ONLY • Syringes must be plastic 	<ul style="list-style-type: none"> • Without anticoagulant, clot activators, or serum separators ONLY • Tubes must be plastic • Devices used to transfer sample to cartridge must be plastic 	<ul style="list-style-type: none"> • Not recommended 	<ul style="list-style-type: none"> • Recommended
Cartridges which perform Troponin I or CK-MB	<ul style="list-style-type: none"> • With Sodium or lithium heparin anticoagulant. • Without anticoagulant if tested within one minute of patient draw. 	<ul style="list-style-type: none"> • With Sodium or lithium heparin anticoagulant. • Without anticoagulant if tested within one minute of patient draw. • Samples should not be used unless the blood collection tube is filled at least half full. 	<ul style="list-style-type: none"> • Not recommended 	<ul style="list-style-type: none"> • Not recommended

Cartridges	Collection Options			
	Syringes	Evacuated Tubes	Capillary Tubes	Directly from Skin Puncture
Cartridges which perform BNP	<ul style="list-style-type: none"> With EDTA anticoagulant. Syringes must be plastic. 	<ul style="list-style-type: none"> With EDTA anticoagulant. Tubes must be plastic. Samples should not be used unless the blood collection tube is filled at least half full. 	<ul style="list-style-type: none"> Not recommended 	<ul style="list-style-type: none"> Not recommended
All other cartridges	<ul style="list-style-type: none"> Without anticoagulant With lithium, sodium, or balanced heparin anticoagulant 	<ul style="list-style-type: none"> Without anticoagulant With lithium or sodium heparin anticoagulant 	<ul style="list-style-type: none"> Without anticoagulant With balanced heparin anticoagulant With sodium or lithium heparin if labeled for the measurement of electrolytes 	<ul style="list-style-type: none"> While a sample can be transferred directly from a skin puncture to a cartridge, a capillary tube is preferred. Not recommended for blood gas analysis; arterial specimens are preferred.

Note Regarding System Reliability

The i-STAT System automatically runs a comprehensive set of quality checks of analyzer and cartridge performance each time a sample is tested. This internal quality system will suppress results if the analyzer or cartridge does not meet certain internal specifications (see Quality Control section in System Manual for detailed information). To minimize the probability of delivering a result with medically significant error the internal specifications are very stringent. It is typical for the system to suppress a very small percentage of results in normal operation given the stringency of these specifications. If however the analyzer or cartridges have been compromised, results may be persistently suppressed, and one or the other must be replaced to restore normal operating conditions. **Where unavailability of results while awaiting replacement of analyzers or cartridges is unacceptable, i-STAT recommends maintaining both a backup i-STAT System analyzer and cartridges from an alternate lot number.**

EXPECTED VALUES

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	1.1 – 38.9	3.9 – 5.8	3.9 – 5.8
	mg/dL	20 – 700	70 – 105	70 – 105
	g/L	0.20 – 7.00	0.70 – 1.05	0.70 – 1.05
Lactate/Lac	mmol/L	0.30 – 20.00	0.36 – 1.25	0.90 – 1.70
	mg/dL	2.7 – 180.2	3.2 – 11.3	8.1 – 15.3

Measured: (cont.)

TEST	UNITS	REPORTABLE RANGE	REFERENCE RANGE	
			(arterial)	(venous)
Creatinine/Crea	mg/dL	0.2 – 20.0	0.6 – 1.3	0.6 – 1.3
	µmol/L	18 – 1768	53 – 115	53 – 115
pH		6.5 – 8.2	7.35 – 7.45	7.31 – 7.41
PCO₂	mmHg	5 – 130	35 – 45	41 – 51
	kPa	0.67 – 17.33	4.67 – 6.00	5.47 – 6.80
TCO₂ (on the CHEM8+ cartridge only)	mmol/L (mEq/L)	5-50	23 – 27	24 – 29
PO₂	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 Urea	mg/dL	3 – 140	8 – 26	8 – 26
	mmol/L	1 – 50	2.9 – 9.4	2.9 – 9.4
	mg/dL	6 – 300	17 – 56	17 – 56
	g/L	0.06 – 3.00	0.17 – 0.56	0.17 – 0.56
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 / CeliteACT	seconds	50 – 1000	74 – 125 (Prewrm)	74 – 125 (Prewrm)
			84 – 139 (Nonwrm)	84 – 139 (Nonwrm)
<i>The range from 80 - 1000 seconds has been verified through method comparison studies.</i>				
Kaolin Activated Clotting Time / KaolinACT	seconds	50 – 1000	74 – 137 (Prewrm)	74 – 137 (Prewrm)
			82 – 152 (Nonwrm)	82 – 152 (Nonwrm)
<i>The range from 77 - 1000 seconds has been verified through method comparison studies.</i>				
Prothrombin Time / PT	INR	0.9 – 8.0		
<i>Performance characteristics have not been established for INRs above 6.0.</i>				
Troponin I / cTnI	ng/mL (µg/L)	0.00 – 50.00		0.00 – 0.03*
				0.00 – 0.08**
<i>Performance characteristics have not been established for cTnI values above 35.00 ng/mL.</i>				
<i>* Represents the 0 to 97.5% range of results.</i>				
<i>** Represents the 0 to 99% range of results.</i>				
Creatine Kinase MB / CK-MB	ng/mL (µg/L)	0.0 – 150.0		0.0 – 3.5***
<i>***Represents the 0 to 95% range of results.</i>				
B-Type Natriuretic Peptide / BNP	pg/mL (ng/L)	15 – 5000		<15 – 50#
<i># Represents the 0 to 95% range of results.</i>				

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
TCO₂ <small>(on all cartridges but the CHEM8+)</small>	mmol/L (mEq/L)	5-50	23 – 27	24 – 29
HCO₃	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
sO₂	%	0 – 100	95 – 98	

CARTRIDGE CONFIGURATIONS AND SAMPLE VOLUME

i-STAT^{EC}8⁺ (65µL)

Sodium (Na)
Potassium (K)
Chloride (Cl)
pH
PCO₂
Urea Nitrogen (BUN)/Urea
Glucose (Glu)
Hematocrit (Hct)
TCO₂^{*}
HCO₃^{*}
BE^{*}
Anion Gap* (Angap)
Hemoglobin* (Hb)

i-STAT⁶ (65µL)

Sodium (Na)
Potassium (K)
Chloride (Cl)
Urea Nitrogen (BUN)/Urea
Glucose (Glu)
Hematocrit (Hct)
Hemoglobin* (Hb)

i-STAT^{EC}4⁺ (65µL)

Sodium (Na)
Potassium (K)
Glucose (Glu)
Hematocrit (Hct)
Hemoglobin* (Hb)

i-STAT^E3⁺ (65µL)

Sodium (Na)
Potassium (K)
Hematocrit (Hct)
Hemoglobin* (Hb)

i-STAT^G (65µL)

Glucose (Glu)

i-STAT^{CREA} (65µL)

Creatinine (Crea)

i-STAT^{EG}7⁺ (95µL)

Sodium (Na)
Potassium (K)
Ionized Calcium (iCa)
Hematocrit (Hct)
pH
PCO₂
PO₂
TCO₂^{*}
HCO₃^{*}
BE^{*}
sO₂^{*}
Hemoglobin* (Hb)

i-STAT^{EG}6⁺ (95µL)

Sodium (Na)
Potassium (K)
Hematocrit (Hct)
pH
PCO₂
PO₂
TCO₂^{*}
HCO₃^{*}
BE^{*}
sO₂^{*}
Hemoglobin* (Hb)

i-STAT^{G3} (95µL)

pH
PCO₂
PO₂
TCO₂^{*}
HCO₃^{*}
BE^{*}
sO₂^{*}

i-STAT^{CG}4⁺ (95µL)

pH
PCO₂
PO₂
Lactate
TCO₂^{*}
HCO₃^{*}
BE^{*}
sO₂^{*}

i-STAT^{CG}8⁺ (95µL)

Sodium (Na)
Potassium (K)
Ionized Calcium (iCa)
Glucose (Glu)
Hematocrit (Hct)
pH
PCO₂
PO₂
TCO₂^{*}
HCO₃^{*}
BE^{*}
sO₂^{*}
Hemoglobin* (Hb)

i-STAT^{Celite}ACT (40µL)

Celite® ACT

i-STAT^{KAOLIN}ACT (40µL)

Kaolin ACT

i-STAT^{PT/INR} (20µL)

Prothrombin Time

i-STAT^{cTnl} (17µL)

Troponin I

i-STAT^{CK-MB} (17µL)

Creatine Kinase MB

i-STAT^{BNP} (17µL)

B-type Natriuretic Peptide

i-STAT^{CHEM8+} (95µL)

Sodium (Na)
Potassium (K)
Chloride (Cl)
Urea Nitrogen (BUN)/Urea
Glucose (Glu)
Creatinine (Crea)
Ionized Calcium (iCa)
TCO₂
Hematocrit (Hct)
Anion Gap* (Angap)
Hemoglobin* (Hb)

*Calculated

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