


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 1 Analyzer* 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. Refer to the cartridge box for room temperature storage requirements.
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, β-hCG or BNP testing.)</i> cTnI, β-hCG 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:	17 µL, 20 µL, 40 µL, 65 µL, or 95 µL 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 with balanced heparin 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, PCO₂, PO₂ 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, β-hCG and BNP. Remix thoroughly before testing.

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

- 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, β -hCG and BNP cartridges: 600 sec (10 min)
 - CK-MB cartridge: 300 sec (5 min)
 - Other cartridges: typically 130 to 200 sec

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 lithium heparin anticoagulant (tubes must be filled to capacity) 	<ul style="list-style-type: none"> • 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 measure Troponin I or CK-MB	<ul style="list-style-type: none"> • With sodium or lithium heparin anticoagulant (syringe must be filled to labeled capacity) • Without anticoagulant if tested within one minute of patient draw 	<ul style="list-style-type: none"> • With sodium or lithium heparin anticoagulant (tubes must be filled to capacity) • Without anticoagulant if tested within one minute of patient draw 	<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 measure Total β -hCG	<ul style="list-style-type: none"> • With sodium or lithium anticoagulant (syringe must be filled to labeled capacity) • Without anticoagulant if tested within one minute of patient draw • Syringes must be plastic 	<ul style="list-style-type: none"> • With sodium or lithium heparin anticoagulant (tubes must be filled to capacity) 	<ul style="list-style-type: none"> • Not recommended 	<ul style="list-style-type: none"> • Not recommended
Cartridges which measure BNP	<ul style="list-style-type: none"> • With EDTA anticoagulant (syringe must be filled to labeled capacity) • Syringes must be plastic 	<ul style="list-style-type: none"> • With EDTA anticoagulant (tubes must be filled to capacity) • Tubes must be plastic 	<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 or balanced heparin anticoagulant (syringe must be filled to labeled capacity) 	<ul style="list-style-type: none"> • Without anticoagulant • With lithium heparin anticoagulant (tubes must be filled to capacity) 	<ul style="list-style-type: none"> • With balanced heparin anticoagulant • With 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, APOC 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
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 <small>(on the CHEM8+ cartridge only)</small>	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	15 – 75	38 – 51	38 – 51
	Fraction	0.15 – 0.75	0.38 – 0.51	0.38 – 0.51
Celite Activated Clotting Time / CeliteACT	seconds	50 – 1000	74 – 125 (Prewarm)	74 – 125 (Prewarm)
			84 – 139 (Nonwarm)	84 – 139 (Nonwarm)
<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 (Prewarm)	74 – 137 (Prewarm)
			82 – 152 (Nonwarm)	82 – 152 (Nonwarm)
<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>				

EXPECTED VALUES (CONT.)**Measured: (CONT.)**

TEST	UNITS	REPORTABLE RANGE	REFERENCE RANGE	
			(arterial)	(venous)
B-Type Natriuretic Peptide / BNP	pg/mL (ng/L)	15 – 5000		<15 – 50#
<i># Represents the 0 to 95% range of results.</i>				
Total Beta-Human Chorionic Gonadotropin /β-hCG	IU/L	5.0 – 2000.0		<5.0

Calculated:

TEST	UNITS	REPORTABLE RANGE	REFERENCE RANGE	
			(arterial)	(venous)
Hemoglobin/Hb	g/dL	5.1 – 25.5	12 – 17	12 – 17
	g/L	51 – 255	120 – 170	120 – 170
	mmol/L	3.2 – 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-STAT^G 6⁺ (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^E 3⁺ (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^{TOTAL B-hCG} (17µL)

Total Beta-Human Chorionic
Gonadotropin

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} (17 µL)

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)

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

*Calculated