




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.

Note: Cartridge-specific Instructions for Use (IFU) and individual analyte CTI Sheets are available for download and printing from the Support page of the Abbott Point of Care website: www.globalpointofcare.abbott.

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 for direct application is only recommended for the PT/INR cartridge.)</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. β-hCG cartridges require the use of heparinized whole blood or plasma samples. 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, PCO_2, PO_2, TCO_2 and iCa. Maintain anaerobic conditions. Remix before filling cartridge. <i>Within 30 minutes after collection</i> <ul style="list-style-type: none">• Samples collected with anticoagulant for the measure of 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 |
| ACT Celite and ACT Kaolin Cartridges | <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 |
| PT/INR Cartridge | <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 |
| CK-MB and cTnI Cartridges | <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 |
| Total β -hCG Cartridge | <ul style="list-style-type: none"> • With sodium or lithium anticoagulant (syringe must be filled to labeled capacity) • 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 |
| BNP Cartridge | <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 |

Note: For information regarding cartridges not listed in the Collection Options table, please refer to the Instructions for Use (IFU) documents found on the APOC website at:
<https://www.pointofcare.abbott/us/en/offerings/support/i-stat/cartridge-test-information-sheets>.

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.**

CARTRIDGE CONFIGURATIONS AND SAMPLE VOLUME

i-STAT^{EC} 8⁺ (65 µL)

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^{CHEM8+} (95 µL)

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)

i-STAT^G (65 µL)

Glucose (Glu)

i-STAT^{CREA} (65 µL)

Creatinine (Crea)

i-STAT^{EG} 7⁺ (95 µL)

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

i-STAT^{EG} 6⁺ (95 µL)

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

i-STAT^{CG} 4⁺ (95 µL)

pH
PCO₂
PO₂
Lactate
TCO₂*
HCO₃*
BE*
sO₂*

i-STAT^{CG} 8⁺ (95 µL)

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

i-STAT^{Celite} ACT (40 µL)

Celite ACT

i-STAT^{KAOLIN} ACT (40 µL)

Kaolin ACT

i-STAT^{TOTAL B-hCG} (17 µL)

Total Beta-Human Chorionic
Gonadotropin

i-STAT^{PT/INR} (20 µL)

Prothrombin Time

i-STAT^{cTnI} (17 µL)

Troponin I

i-STAT^{CK-MB} (17 µL)

Creatine Kinase MB

i-STAT^{BNP} (17 µL)

B-type Natriuretic Peptide

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*Calculated

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