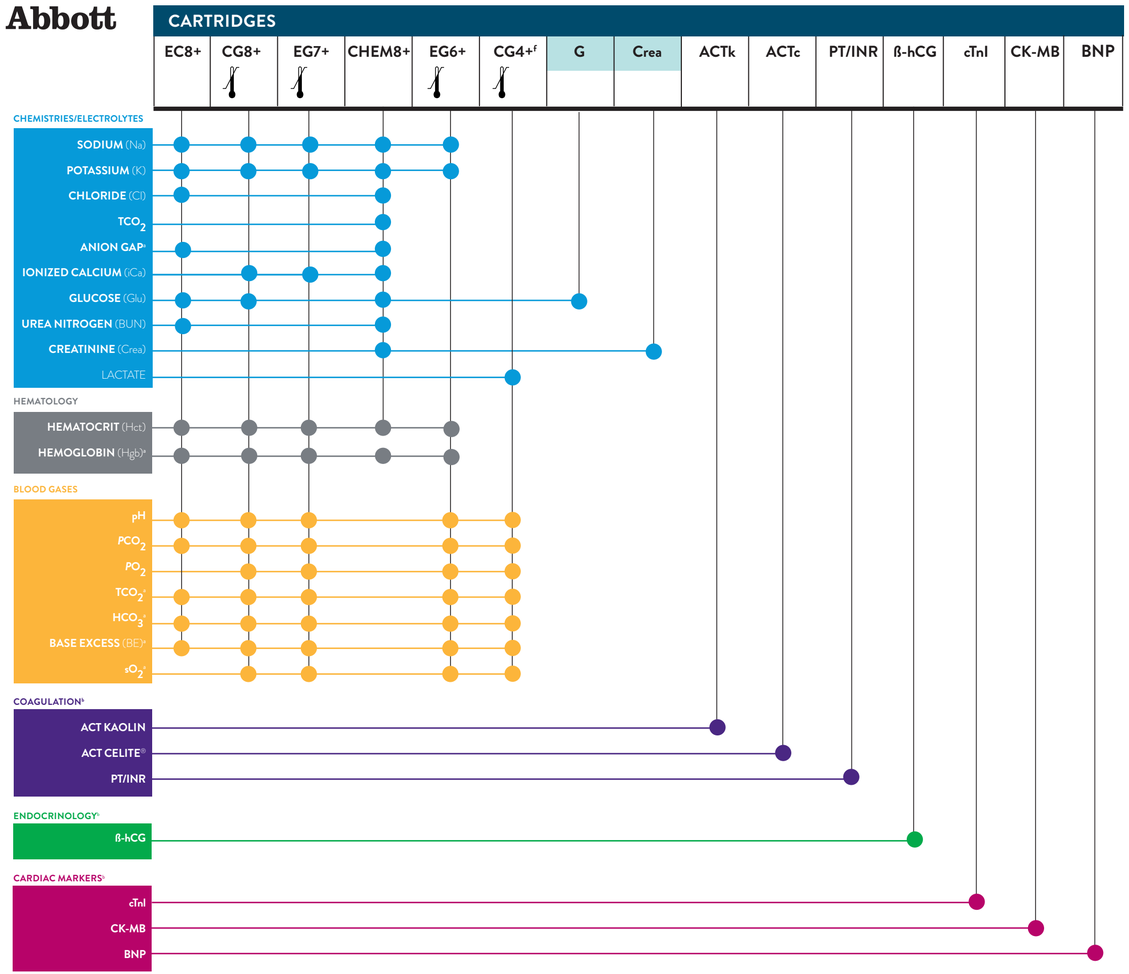
PROVIDING LAB-QUALITY RESULTS IN MINUTES:

# CARTRIDGES TO MEET A WIDE RANGE OF CLINICAL NEEDS

**THIS TEST MENU IS INTENDED FOR USE ONLY IN THE UNITED STATES FOR *IN VITRO* DIAGNOSTIC USE ONLY**




[a]Calculated - note that $TCO_2$ is measured on CHEM8+ cartridge and calculated on all others.
[b]See Intended Use information at right

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

= CLIA waived: granted waived status for lithium heparin whole-blood venous samples only collected in a lithium heparin evacuated tube.

## EXPECTED VALUES & TIME TO RESULT

| ANALYTE | REPORTABLE RANGE | REFERENCE RANGE, ARTERIAL | REFERENCE RANGE, VENOUS | APPROX. TIME TO RESULT | i-STAT TEST CARTRIDGES |
|---|---|---|---|---|---|
| Sodium (Na) | 100-180 mmol/L | 138-146 mmol/L | 138-146 mmol/L | 2 min | EC8+, CG8+, EG7+, CHEM8+, EG6+ |
| Potassium (K) | 2.0-9.0 mmol/L | 3.5-4.9 mmol/L | 3.5-4.9 mmol/L | 2 min | EC8+, CG8+, EG7+, CHEM8+, EG6+ |
| Chloride (Cl) | 65-140 mmol/L | 98-109 mmol/L | 98-109 mmol/L | 2 min | EC8+, CHEM8+ |
| $TCO_2$ | 5-50 mmol/L | 23-27 mmol/L | 24-29 mmol/L | 2 min | CHEM8+ |
| Anion Gap[a] | (-10)-(+99) mmol/L | 10-20 mmol/L | 10-20 mmol/L | 2 min | EC8+, CHEM8+ |
| Ionized Calcium (iCa) | 0.25-2.50 mmol/L | 1.12-1.32 mmol/L | 1.12-1.32 mmol/L | 2 min | CG8+, EG7+, CHEM8+ |
| Glucose (Glu) | 20-700 mg/dL | 70-105 mg/dL | 70-105 mg/dL | 2 min | EC8+, CG8+, CHEM8+, G |
| Urea Nitrogen (BUN) | 3-140 mg/dL | 8-26 mg/dL | 8-26 mg/dL | 2 min | EC8+, CHEM8+ |
| Creatinine (Crea) | 0.2-20.0 mg/dL | 0.6-1.3 mg/dL | 0.6-1.3 mg/dL | 2 min | CHEM8+, CREA |
| Lactate[b] | 0.30-20.0 mmol/L | 0.36-1.25 mmol/L | 0.90-1.70 mmol/L | 2 min. | CG4+ |
| Hematocrit (Hct) | 15-75 %PCV | 38-51%PCV | 38-51%PCV | 2 min | EC8+, CG8+, EG7+, CHEM8+, EG6+ |
| Hemoglobin (Hgb)[a] | 5.1-25.5 g/dL | 12-17 g/dL | 12-17 g/dL | 2 min | EC8+, CG8+, EG7+, CHEM8+, EG6+ |
| pH[f] | 6.50-8.20[f] | 7.35-7.45 | 7.31-7.41 | 2 min | EC8+, CG8+, EG7+, CG4+, EG6+ |
| $PCO_2$[f] | 5-130 mmHg[f] | 35-45 mmHg | 41-51 mmHg | 2 min | EC8+, CG8+, EG7+, EG6+, CG4+, EG6+ |
| $PO_2$[f] | 5-800 mmHg[f] | 80-105 mmHg | | 2 min | CG8+, EG7+, EG6+, CG4+, EG6+ |
| $TCO_2$[a] | 5-50 mmol/L | 23-27 mmol/L | 24-29 mmol/L | 2 min | EC8+, CG8+, EG7+, EG6+, CG4+, EG6+ |
| $HCO_3$[a] | 1.0-85.0 mmol/L | 22-26 mmol/L | 23-28 mmol/L | 2 min | EC8+, CG8+, EG7+, EG6+, CG4+, EG6+ |
| Base Excess (BE)a | (-30)-(+30) mmol/L | (-2)-(+3) mmol/L | (-2)-(+3) mmol/L | 2 min | EC8+, CG8+, EG7+, EG6+, CG4+, EG6+ |
| $sO_2$[a] | 0-100 % | 95-98 % | | 2 min | CG8+, EG7+, EG6+, CG4+, EG6+ |
| ACT Kaolin | 50-1000 Seconds | 74-137 Seconds (Prewrm) | 74-137 Sec. (Prewrm) | Max 16.7 min | ACT k |
| ACT Celite® | 50-1000 Seconds | 74-125 Seconds (Prewrm) | 74-125 Sec. (Prewrm) | Max 16.7 min | ACT c |
| PT/INR | 0.9-8.0 INR[c] | | | Max 16.7 min | PT/INR |
| ß-hCG | 5.0-2000.0 IU/L | | <5 IU/L | 10 min | Total ß-hCG |
| cTnI | 0.00-50.00 ng/mL | | 0.00-0.08 ng/mL[d] | 10 min | cTnI |
| CK-MB | 0.0-150.0 ng/mL | | 0.0-3.5 ng/mL[e] | 5 min | CK-MB |
| BNP | 15-5000 pg/mL | | <15-50 pg/mL[e] | 10 min | BNP |

[c] Performance characteristics have not been established for INR values over 6.0.
[d] Represents the 0-99% range of results.
[e] Represents the 0-95% range of results.
[f] **Reportable ranges for the (blue) CG4+ cartridge** are: pH = 7.00-7.70; $PO_2$ = 15-530; $PCO_2$ = 15-130


2-MONTH, ROOM-TEMPERATURE STORAGE

FOR COMPLETE TEST CARTRIDGE INFORMATION AND INSTRUCTIONS FOR USE, REFER TO THE *CARTRIDGE & TEST INFORMATION SHEETS* AT

**WWW.POINTOFCARE.ABBOTT**

## INTENDED USE

### LACTATE

The *i-STAT CG4+* cartridge with the *i-STAT 1 System* is intended for use in the *in vitro* quantification of pH, $PO_2$, $PCO_2$, and lactate in arterial or venous whole blood in point of care or clinical laboratory settings. pH, $PO_2$ and $PCO_2$ measurements are used in the diagnosis, monitoring, and treatment of respiratory disturbances and metabolic and respiratory-based acid-base disturbances. Lactate measurements are used in (1) the diagnosis and treatment of lactic acidosis in conjunction with measurements of blood acid/base status, (2) monitoring tissue hypoxia and strenuous physical exertion, and (3) diagnosis of hyperlactatemia.

### COAGULATION

**ACT Kaolin**

The *i-STAT Kaolin Activated Clotting Time* ($^{Kaolin}$ACT) test is an *in vitro* diagnostic test that uses fresh, whole blood, and is used to monitor high-dose heparin anticoagulation frequently associated with cardiovascular surgery.

**ACT Celite®**

The *i-STAT Celite Activated Clotting Time* ($^{Celite}$ACT) test is an *in vitro* diagnostic test that uses fresh, whole blood, and is useful for monitoring patients receiving heparin for treatment of pulmonary embolism or venous thrombosis, and for monitoring anticoagulation therapy in patients undergoing medical procedures, such as catheterization, cardiac surgery, surgery, organ transplant, and dialysis.

**PT/INR**

The *i-STAT PT*, a prothrombin time test, is useful for monitoring patients receiving oral anticoagulation therapy such as Coumadin® or warfarin

### ENDOCRINOLOGY

**ß-hCG**

The *i-STAT Total Beta-Human Chorionic Gonadotropin* (ß-hCG) test is an *in vitro* diagnostic test for the quantitative and qualitative determination of ß-hCG in venous whole blood or plasma samples using the *i-STAT 1 Analyzer Systems*. The test is intended to be used as an aid in the early detection of pregnancy and is for prescription use only.

### CARDIAC MARKERS

**cTnI**

The *i-STAT cardiac troponin I* (cTnI) test is an *in vitro* diagnostic test for the quantitative measurement of cardiac troponin I (cTnI) in whole blood or plasma. Measurements of cardiac troponin I are used in the diagnosis and treatment of myocardial infarction and as an aid in the risk stratification of patients with acute coronary syndromes with respect to their relative risk of mortality.

**CK-MB**

The *i-STAT CK-MB* test is an *in vitro* diagnostic test for the quantitative measurement of creatine kinase MB mass in whole blood or plasma samples. CK-MB measurements can be used as an aid in the diagnosis and treatment of myocardial infarction (MI).

**BNP**

The *i-STAT BNP* test is an *in vitro* diagnostic test for the quantitative measurement of B-type natriuretic peptide (BNP) in whole blood or plasma samples using EDTA as the anticoagulant. BNP measurements can be used as an aid in the diagnosis and assessment of the severity of congestive heart failure.