GEM PREMIER ChemSTAT™


**INTRODUCING**

# Basic Metabolic Panel.

# STAT.

Acute Care Diagnostics

Instrumentation Laboratory
A Werfen Company

NEW

GEM PREMIER ChemSTAT™

# Lab-quality, actionable results **at the point-of-care**

**The new GEM Premier ChemSTAT system is a whole-blood analyzer for basic metabolic panel (BMP) testing. Designed for the point-of-care (POC)—it delivers rapid, laboratory-quality results on demand, to improve patient management and enhance efficiency.**

### Rapid results from just one sample
Venous or arterial lithium-heparinized, whole-blood samples. Results in 70 seconds, enabling rapid clinical decision-making.

### All-in-one, multi-use cartridge (GEM PAK)
Self-contained and non-refrigerated, simplifying operations at the POC.

### Intelligent Quality Management (iQM®)
Automated, real-time and continuous quality management, ensuring lab-quality results and ease of use at the POC.

## Menu developed for the ED with the flexibility of venous or arterial samples

- Rapid risk stratification and prioritization of high-risk, acutely ill patients
- Expedited time to treatment
- Improved patient management and quality of care

# Assay menu

## Measured parameters

| MENU | $Na^+$ | $K^+$ | $Ca^{++}$ | $Cl^-$ | Glu | Crea | BUN | $tCO_2$ | Hct | Lac | pH | $pCO_2$ |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **BMP** | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | | | |
| **BMP Plus** | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |

## Calculated parameters

| | | | | |
|---|---|---|---|---|
| AG | $HCO_3^{-(m)}$ | BUN/Crea | BEecf | BE(B) |
| tHb(c) | $Ca^{++}(7.4)$ | Osm | eGFR (MDRD)* | eGFR (CKD-EPI)** |

* Two eGFR results are provided by the analyzer if the Crea result, age, gender and ethnicity are available: $eGFR_{AA}$ (MDRD) for African Americans (AA) and eGFR (MDRD) for non-AA.

** Two eGFR results are provided by the analyzer if the Crea result, age, gender and ethnicity are available: $eGFR_{AA}$ (CKD-EPI) for AA and eGFR (CKD-EPI) for non-AA.

Crea (Creatinine), AG (Anion Gap), $HCO_3$ (Bicarbonate), BUN/Crea (BUN/Creatinine ratio), BEecf (Base Excess of Extracellular Fluid [*in vivo*]), BE(B) (Base Excess of Blood [*in vitro*]), tHb(c) (Calculated Total Hemoglobin), $Ca^{++}$ (7.4) (Ionized Calcium normalized to a pH of 7.4), Osm (Osmolality), eGFR (estimated Glomerular Filtration Rate), MDRD (Modification of Diet in Renal Disease), CKD-EPI (Chronic Kidney Disease - Epidemiology Collaboration).

GEM Premier ChemSTAT is not available in all countries. Not currently Health Canada-licensed. Not saleable in Canada.

# Data-driven decisions when minutes matter: on time, every time

**Actionable BMP results at the POC provide vital, time-sensitive information, including renal function, electrolyte, acid/base balance, glucose and lactate levels. Rapid testing allows ED personnel to focus on assessment of life-threatening conditions for timely triage and management.**

## Triage POC Testing (POCT)

Publications have demonstrated that when POCT was performed during ED triage:[1-4]

- Emergency Severity Index (ESI) triage level was modified in 15% of cases
- Patient management was changed in 15% of cases
- 56% of clinicians found POCT helpful during triage
- 6% of patients were immediately brought back for treatment

**Conclusion: Triage POCT in the ED is a helpful adjunct for patients presenting with high-risk complaints.**

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## POCT for timely diagnosis in critical scenarios

### Acute Kidney Injury (AKI) and Contrast-Induced Nephropathy (CIN) [Lytes, Crea, eGFR, BUN]

- CIN is the third-leading cause of AKI in hospitalized patients, with ~12% incidence[5]
- Accurate testing may improve clinical decisions when balancing benefits of radiocontrast-enhanced imaging vs. AKI risk[6]
- Rapid and accurate measurement of Creatinine levels, together with eGFR values, can help prevent CIN[7]

### Sepsis and Septic Shock [Lytes, Lac, pH, $pCO_2$]

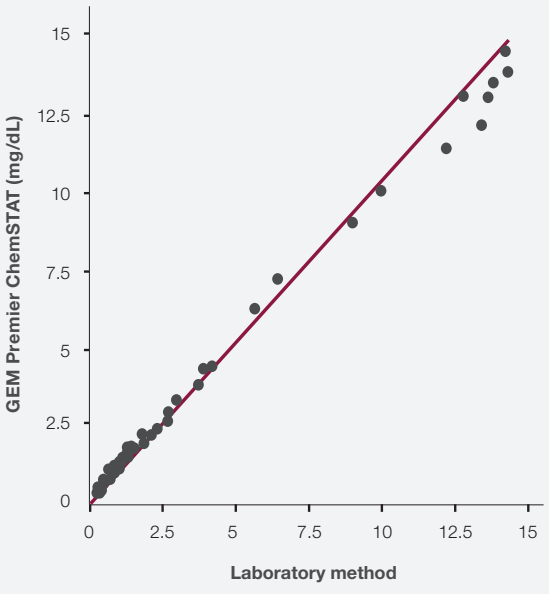
- Claims more lives than breast cancer, prostate cancer and human immunodeficiency virus combined[8]
- Surviving Sepsis Campaign International Guidelines recommend that hospitals have a performance-improvement program for sepsis, including sepsis screening for acutely ill, high-risk patients[9]
- On-demand POC lactate testing can rapidly guide protocolized, quantitative resuscitation and management of sepsis[10]

### Diabetic Ketoacidosis (DKA) [Glu, pH, $HCO_3$]

- Accounts for >110,000 hospitalizations in US annually, with 2–10% mortality[11–13]
- POC BMP testing allows initiation of fluid/electrolyte replacement and insulin therapy in ED, leading to improved patient outcomes[14]
- Integration of clinical findings with venous blood gas results can safely guide management decisions[15]

## Rapid lab-quality Creatinine results in the ED[16]

GEM Premier ChemSTAT system demonstrates excellent correlation with a laboratory enzymatic method*



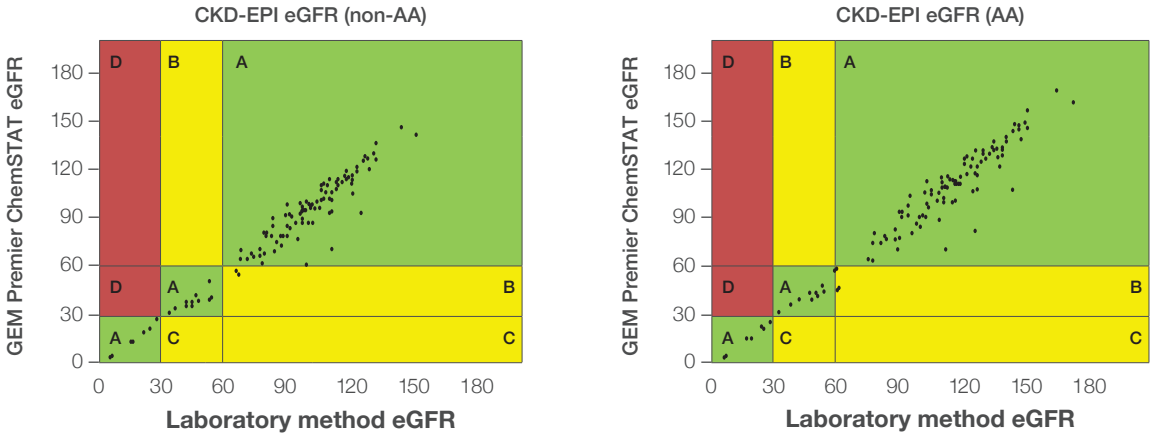

* Isotope dilution, mass spectrometry (IDMS)-traceable, enzymatic assay.

# Lab-quality Creatinine at the POC

## Creatinine and eGFR[17]

While Creatinine is an important marker of renal damage, eGFR—a calculation of a patient's blood Creatinine level, age, gender and race—is an estimate of renal function.

Error grid analysis (as described by Snaith, *et al.*[18]), identifies the impact of discordant results between whole blood- and plasma-calculated eGFRs. GEM Premier ChemSTAT demonstrates excellent concordance with the plasma-calculated laboratory method. In an evaluation of 118 whole-blood samples tested on the GEM Premier ChemSTAT system, 98.3% of the eGFR calculations were categorized in the correct risk zone, as shown below.




| | | CKD-EPI non-AA | CKD-EPI AA |
|---|---|---|---|
| Zone A | Correct risk classification—appropriate management | **116 (98.3%)** | **116 (98.3%)** |
| Zone B | Incorrectly classified, but no implication for clinical management | **2 (1.7%)** | **2 (1.7%)** |
| Zone C | Incorrect classification, potential for unnecessary prophylaxis or withholding of contrast | **0** | **0** |
| Zone D | Incorrect classification and potential for increased risk of CIN due to insufficient prophylaxis | **0** | **0** |

AA= African American

**Conclusion: GEM Premier ChemSTAT system provides rapid, lab-quality Creatinine results, enabling clinicians to accurately assess renal function at the POC.**

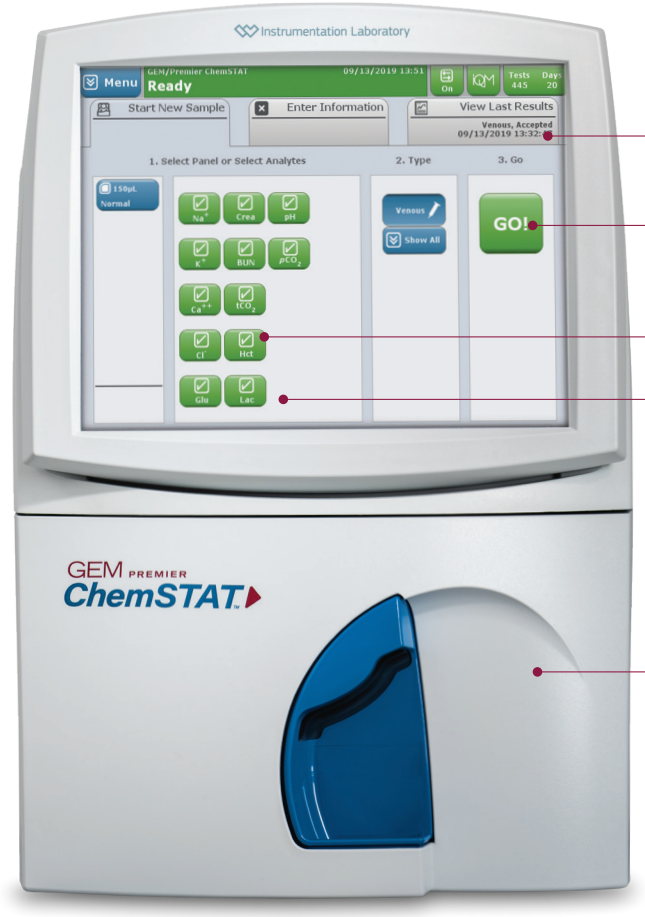
# Real-time quality assurance

iQM® INTELLIGENT QUALITY MANAGEMENT

**Exclusive to GEM Premier systems, iQM is an active quality management program designed to provide continuous monitoring of the analytical process with real-time, automatic error detection, correction, and documentation of all corrective actions, replacing the use of traditional external quality control.**

- Provides rapid, quality-assured results with every sample, not just every 8 hours
- Identifies and reduces risks associated with testing processes
- Documents all corrective actions
- Enables immediate patient management decisions with fast and quality-assured results
- Allows clinicians more time at the bedside, by reducing system maintenance and troubleshooting
- Enhances patient and staff satisfaction by eliminating unnecessary retesting and wait times

# Operational simplicity and reliability, for improved efficiency and reduced cost




Results in 70 seconds

Intuitive, easy-to-use interface—just press GO!

Full BMP menu in a single panel, including Hct

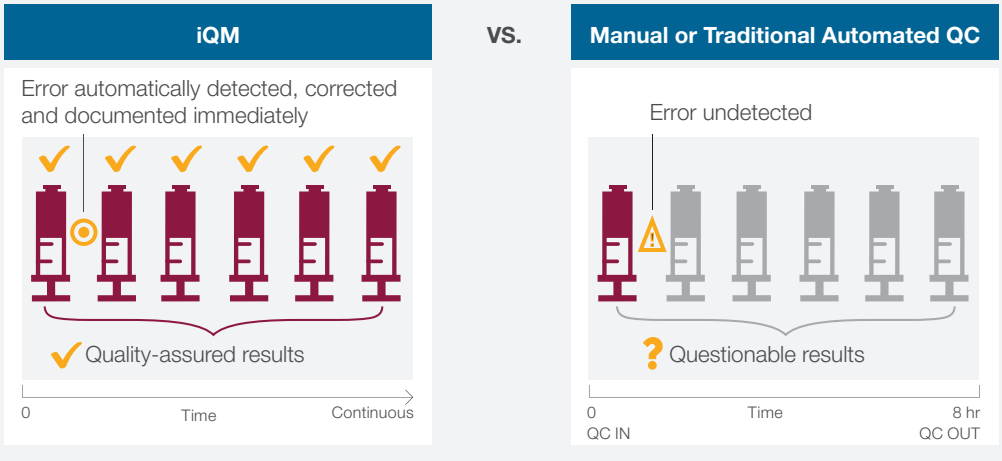
BMP Plus menu option, including Lac, pH, $pCO_2$

**All-in-one, multi-use GEM PAK**

75-, 150-, 300-, 450-test configurations

Just replace every 21 days

## Continuous quality management vs. traditional QC




**All results from 8-hour period require review**

# GEM PAK saves time and reduces risk

**Automates the most labor- and skill-intensive processes.**

## No maintenance or manual troubleshooting

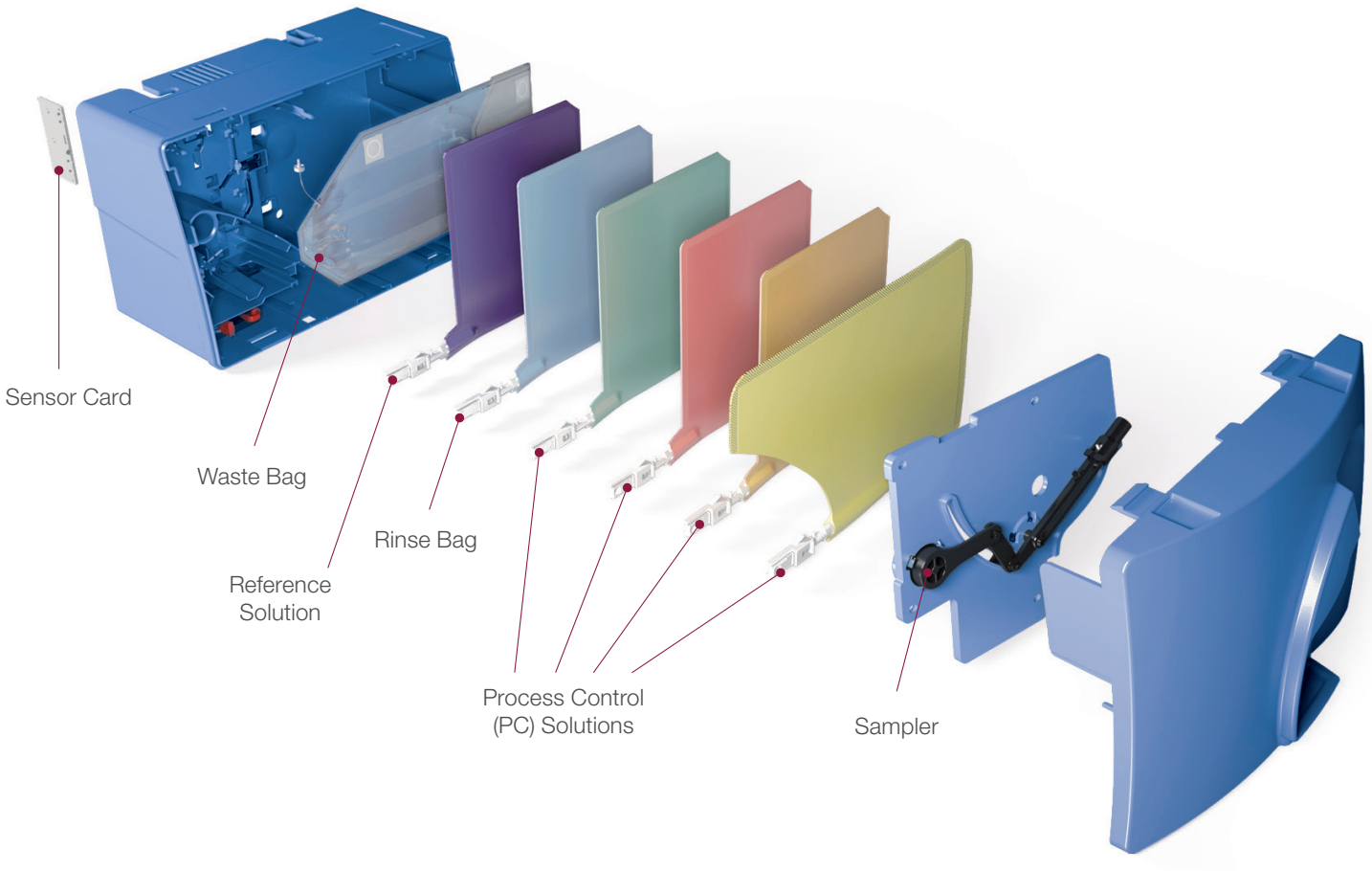
- All-in-one, multi-use GEM PAK includes all testing components (sensors, sampler, tubing, solutions and waste bag)
- No liquids or biohazardous material enter analyzer; thus, no maintenance or troubleshooting required
- Only one GEM PAK to inventory and manage

## Ensures patient and operator safety

- All analytical components are self-contained, limiting biohazard exposure for patient and operator

## Ultimate simplicity

- Room-temperature storage; no refrigeration required
- Replaced every 21 days
- Ideal for high- and low-volume testing needs
- With iQM, no hands-on corrective actions or manual documentation required
- Easy, front-loading




**Reduces inventory, maintenance and handling requirements for greater efficiency**

# GEMweb Plus 500 Custom Connectivity

**Customizable connectivity and automated functionality for complete control of analyzers, operators and data oversight.**

GEMweb® Plus 500
CUSTOM CONNECTIVITY

## Simplifies point-of-care testing

- Simple web access from any browser
- Optimized interface for access from computer, tablet device or directly from GEM Premier ChemSTAT Systems
- Easy, at-a-glance dashboard
- Real-time remote control: full access to analyzer configuration without testing interruption
- Total automated control of operators with multi-level authorization and traceability of users, actions and competence

## Centralizes point-of-care testing

- Single, unified database to access patient samples and historical results
- Data connection to iQM
- Customizable to multiple connection types, including patient monitors, HIS/LIS and ADT
- Open connectivity, including select non-IL analyzers*

* Contact your local Werfen representative for information on non-IL device connection details and availability.



Simple, intuitive dashboard, accessible from any analyzer, computer or tablet.

**Combines control of information, analyzers and operators into one intuitive management system**

NEW GEM PREMIER ChemSTAT™

# Lab-quality results, on-demand, for rapid triage and management

## Sample Volume

150 µL to obtain $Na^+$, $K^+$, $Ca^{++}$, $Cl^-$, Glu, Lac, Hct, Crea, BUN, $tCO_2$, pH, $pCO_2$

## Sample Type

Lithium-heparinized whole blood

## Time to Results

All test results: 70 seconds

## GEM PAK Test Capacity

75, 150, 300 and 450 tests

## GEM PAK Onboard Use-Life

21 days

## GEM PAK Shelf-Life

5 months

## Storage Conditions

Room temperature: 15°C (59°F)–25°C (77°F)

## Measurement Methodology

***Amperometric:*** Glu, Lac, Crea

***Potentiometric:*** $Na^+$, $K^+$, $Ca^{++}$, $Cl^-$, BUN, $tCO_2$, pH, $pCO_2$

***Conductivity:*** Hct

## Interface Protocols

ASTM or HL7 enables data transmission to a laboratory, hospital or third-party information management system.

## Measurable Range

| *Analyte* | *Unit* | *Measurable Range** |
|---|---|---|
| $Na^+$ | mmol/L | 92–200 |
| $K^+$ | mmol/L | 0.3–19.6 |
| $Ca^{++}$ | mmol/L | 0.05–4.27 |
| $Cl^-$ | mmol/L | 36–177 |
| Glu | mg/dL | 3–749 |
| Lac | mmol/L | 0.2–17.8 |
| Hct | % | 13–74 |
| Crea | mg/dL | 0.10–16.40 |
| BUN | mg/dL | 2.4–122.0 |
| $tCO_2$ | mmol/L | 3.6–51.3 |
| pH | pH | 6.76–8.06 |
| $pCO_2$ | mmHg | 3–125 |

* The measurable range for a parameter is the range established through linearity and limit of quantification testing.

## Derived (Calculated) Parameters

| | |
|---|---|
| AG | tHb(c) |
| $HCO_3^{-(m)}$ | $Ca^{++}$(7.4) |
| BUN/Crea | Osm |
| BEecf | eGFR (MDRD)† |
| BE(B) | eGFR (CKD-EPI)† |

† Two eGFR results are provided by the analyzer if the Crea result, age, gender and ethnicity are available: $eGFR_{AA}$ (MDRD and CKD-EPI) for African Americans (AA) and eGFR (MDRD or CKD-EPI) for non-AA.

## Calibration Valuation Product (CVP)

GEM Premier ChemSTAT CVP ampoules must be run to activate the GEM PAK prior to patient testing.

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