

**INTRODUCING**

# Basic Metabolic Panel. **STAT.**



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

The 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 <sup>+</sup>	K <sup>+</sup>	Ca <sup>++</sup>	Cl <sup>-</sup>	Glu	Crea	BUN	tCO <sub>2</sub>	Hct	Lac	pH	pCO <sub>2</sub>
BMP	✓	✓	✓	✓	✓	✓	✓	✓	✓			
BMP Plus	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

### Calculated parameters

AG	HCO <sub>3</sub> <sup>-</sup> (m)	BUN/Crea ratio	BE <sub>ecf</sub>	BE(B)
tHb(c)	Ca <sup>++</sup> (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<sub>AA</sub> (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<sub>AA</sub> (CKD-EPI) for AA and eGFR (CKD-EPI) for non-AA.

Crea (Creatinine), BUN (Blood Urea Nitrogen), AG (Anion Gap), HCO<sub>3</sub> (Bicarbonate), BE<sub>ecf</sub> (Base Excess of Extracellular Fluid [*in vivo*]), BE(B) (Base Excess of Blood [*in vitro*]), tHb(c) (Calculated Total Hemoglobin), Ca<sup>++</sup> (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.





# 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:<sup>1-4</sup>

- 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.

## 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<sup>5</sup>
- Accurate testing may improve clinical decisions when balancing benefits of radiocontrast-enhanced imaging vs. AKI risk<sup>6</sup>
- Rapid and accurate measurement of Creatinine levels, together with eGFR values, can help prevent CIN<sup>7</sup>

### Sepsis and Septic Shock [Lytes, Lac, pH, pCO<sub>2</sub>]

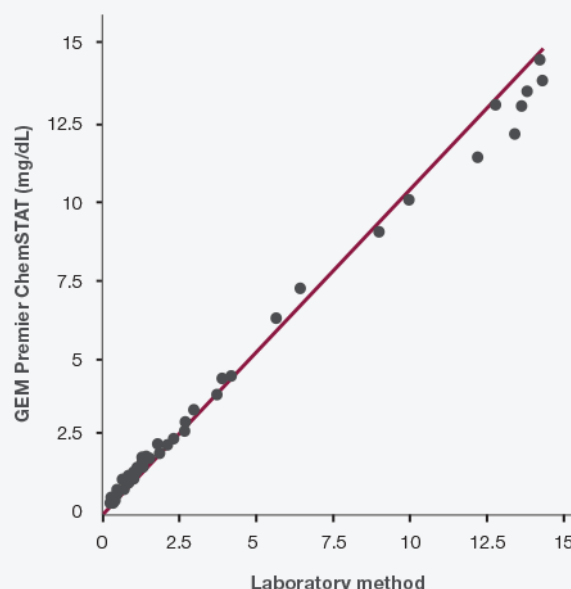
- Claims more lives than breast cancer, prostate cancer and human immunodeficiency virus combined<sup>8</sup>
- Surviving Sepsis Campaign International Guidelines recommend that hospitals have a performance-improvement program for sepsis, including sepsis screening for acutely ill, high-risk patients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

### Diabetic Ketoacidosis (DKA) [Glu, pH, HCO<sub>3</sub>]

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

## Rapid lab-quality Creatinine results in the ED<sup>16</sup>

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



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

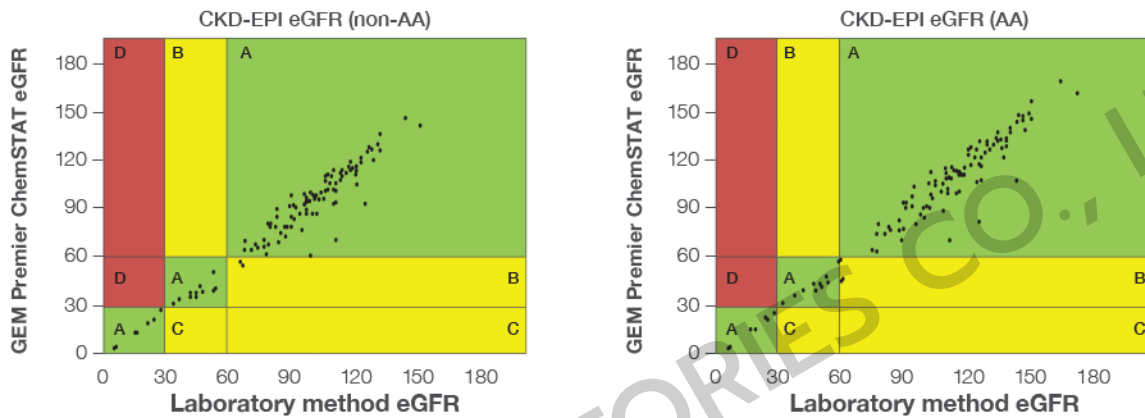


# Lab-quality Creatinine at the POC

## Creatinine and eGFR<sup>17</sup>

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<sup>16</sup>), 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
<b>Zone A</b>	Correct risk classification—appropriate management	116 (98.3%)	116 (98.3%)
<b>Zone B</b>	Incorrectly classified, but no implication for clinical management	2 (1.7%)	2 (1.7%)
<b>Zone C</b>	Incorrect classification, potential for unnecessary prophylaxis or withholding of contrast	0	0
<b>Zone D</b>	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

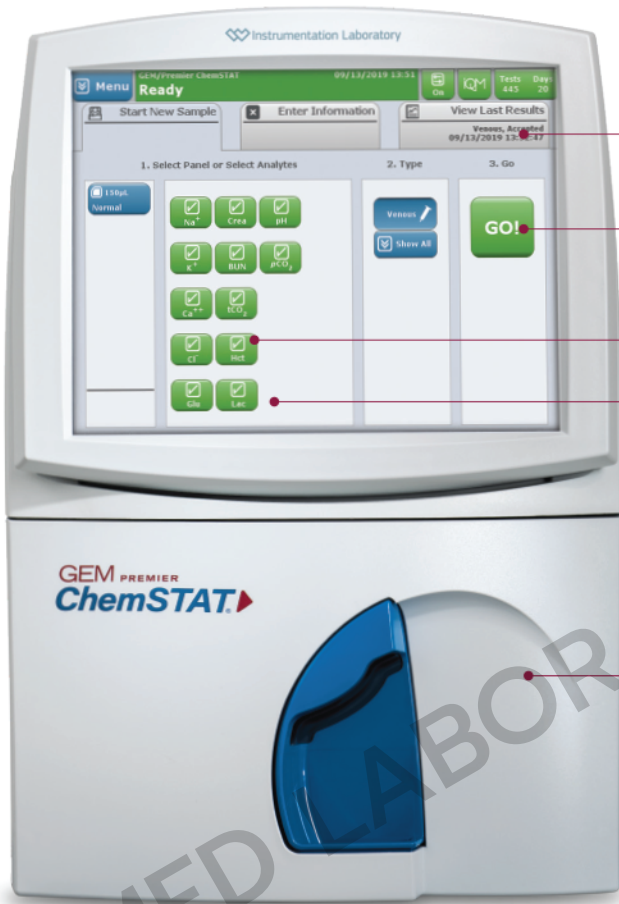


Exclusive to GEM Premier systems, iQM is an active quality management program designed to provide continuous monitoring of the analytical process with real-time, automatic error detection, correction, and documentation of all corrective actions, replacing the use of traditional external quality control.

- 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<sub>2</sub>

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

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

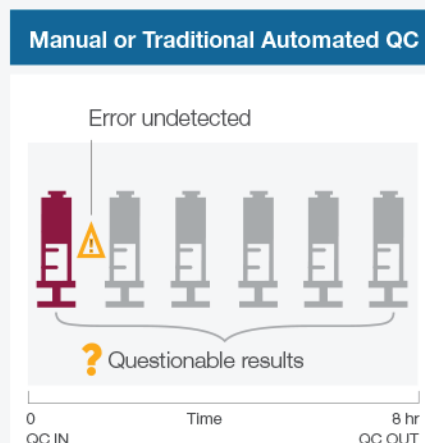
Just replace every 21 days



### Continuous quality management vs. traditional QC



vs.



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

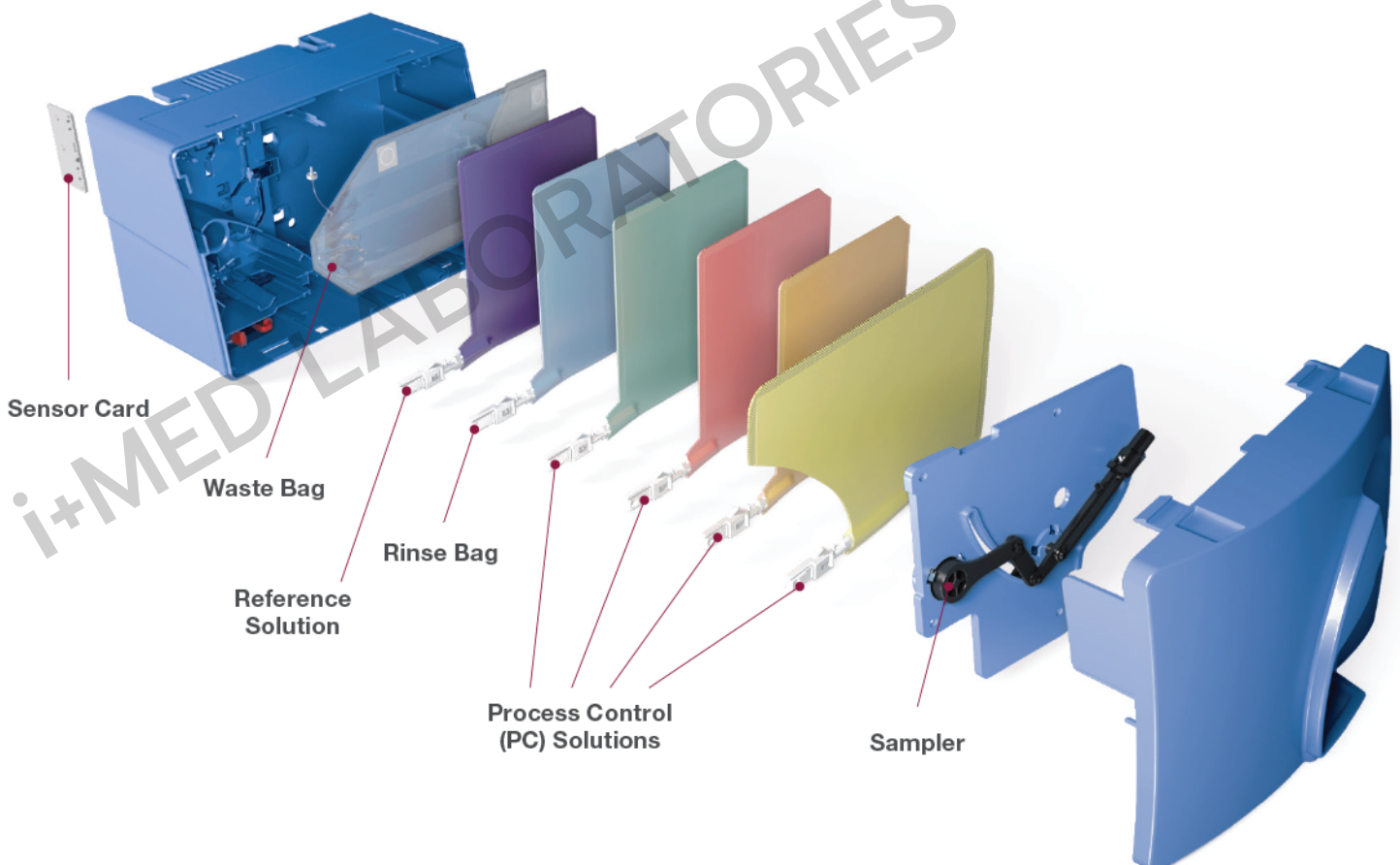
- All-in-one, multi-use GEM PAK includes all testing components (sensors, sampler, tubing, solutions and waste bag)
- No liquids or biohazardous materials enter analyzer; thus, no maintenance or troubleshooting required
- Only one GEM PAK to inventory and manage

## 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
- Replace 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**





# Customizable connectivity and automated functionality

**GEMweb® Plus<sup>500</sup>**  
CUSTOM CONNECTIVITY

For comprehensive management of analyzers, operators and data oversight.

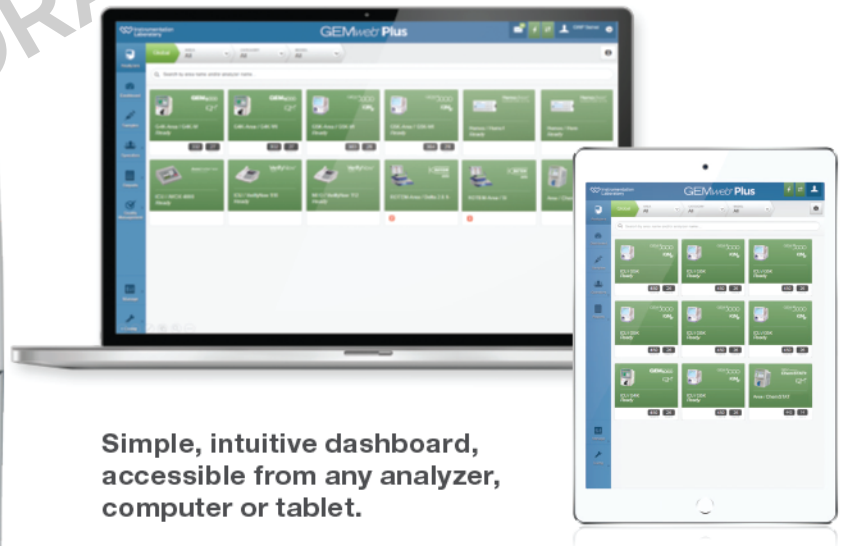
## Simplifies POCT

- 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 management of analyzer configuration without testing interruption
- Total automated management of operators with multi-level authorization and traceability of users, actions and competence

## Centralizes POCT

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

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



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

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



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

## Dimensions and Weight

### Analyzer

H: 46.88 cm (18.5 in), W: 33.19 cm (13.1 in) D: 41.48 cm (16.3 in), Wt: 19.1 kg (42.1 lbs)

### GEM PAK

H: 16.73 cm (6.6 in), W: 25.93 cm (10.2 in) D: 19.31 cm (7.6 in), Wt: 3.6 kg (8.5 lbs)

## Sample Volume

150 µL to obtain Na<sup>+</sup>, K<sup>+</sup>, Ca<sup>++</sup>, Cl<sup>-</sup>, Glu, Lac, Hct, Crea, BUN, tCO<sub>2</sub>, pH, pCO<sub>2</sub>

## 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<sup>+</sup>, K<sup>+</sup>, Ca<sup>++</sup>, Cl<sup>-</sup>, BUN, tCO<sub>2</sub>, pH, pCO<sub>2</sub>

**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 <sup>+</sup>	mmol/L	92–200
K <sup>+</sup>	mmol/L	0.3–19.6
Ca <sup>++</sup>	mmol/L	0.05–4.27
Cl <sup>-</sup>	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 <sub>2</sub>	mmol/L	3.6–51.3
pH	pH	6.76–8.06
pCO <sub>2</sub>	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 <sub>3</sub> <sup>-m</sup>	Ca <sup>++</sup> (7.4)
BUN/Crea ratio	Osm
BEecf	eGFR (MDRD) <sup>†</sup>
BE(B)	eGFR (CKD-EPI) <sup>†</sup>

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

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