



INTRODUCING

Basic
Metabolic Panel.
STAT.

NEWGEM 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	BE _{ecf}	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), HCO₃ (Bicarbonate), BUN/Crea (BUN/Creatinine ratio), BE_{ecf} (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.

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% incidence⁵
- Accurate testing may improve clinical decisions when balancing benefits of radiocontrast-enhanced imaging vs. AKI risk⁶
- Rapid and accurate measurement of Creatinine levels, together with eGFR values, can help prevent CIN⁷

Sepsis and Septic Shock [Lytes, Lac, pH, pCO₂]

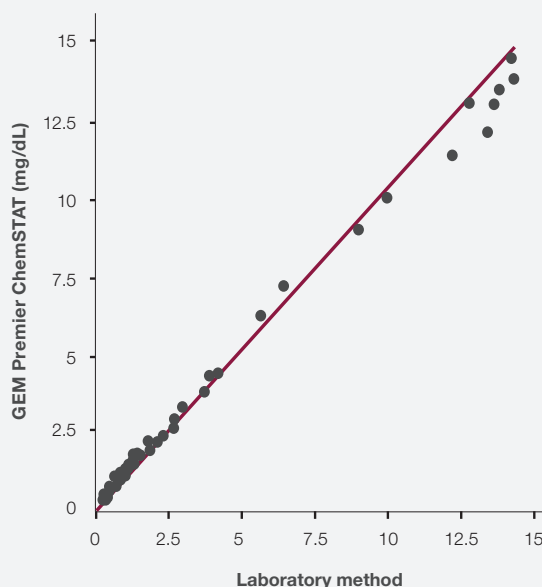
- Claims more lives than breast cancer, prostate cancer and human immunodeficiency virus combined⁸
- Surviving Sepsis Campaign International Guidelines recommend that hospitals have a performance-improvement program for sepsis, including sepsis screening for acutely ill, high-risk patients⁹
- On-demand POC lactate testing can rapidly guide protocolized, quantitative resuscitation and management of sepsis¹⁰

Diabetic Ketoacidosis (DKA) [Glu, pH, HCO₃]

- Accounts for >110,000 hospitalizations in US annually, with 2–10% mortality¹¹⁻¹³
- POC BMP testing allows initiation of fluid/electrolyte replacement and insulin therapy in ED, leading to improved patient outcomes¹⁴
- Integration of clinical findings with venous blood gas results can safely guide management decisions¹⁵

Rapid lab-quality Creatinine results in the ED¹⁶

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



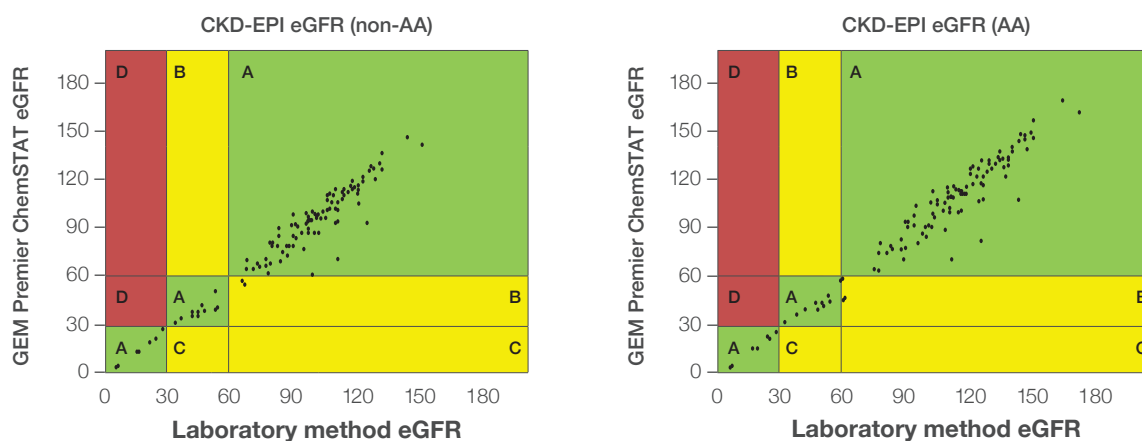
* Isotope dilution, mass spectrometry (IDMS)-traceable, enzymatic assay.

Lab-quality Creatinine at the POC

Creatinine and eGFR¹⁷

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



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

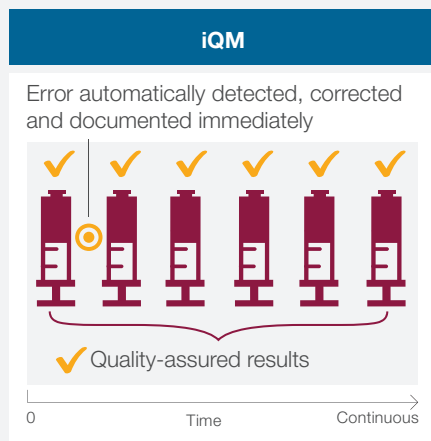
**All-in-one, multi-use
GEM PAK**

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

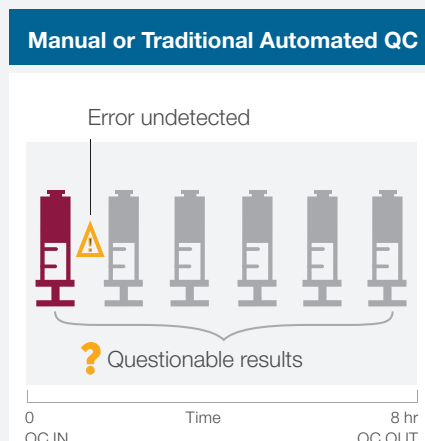
Just replace every 21 days



Continuous quality management vs. traditional QC



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

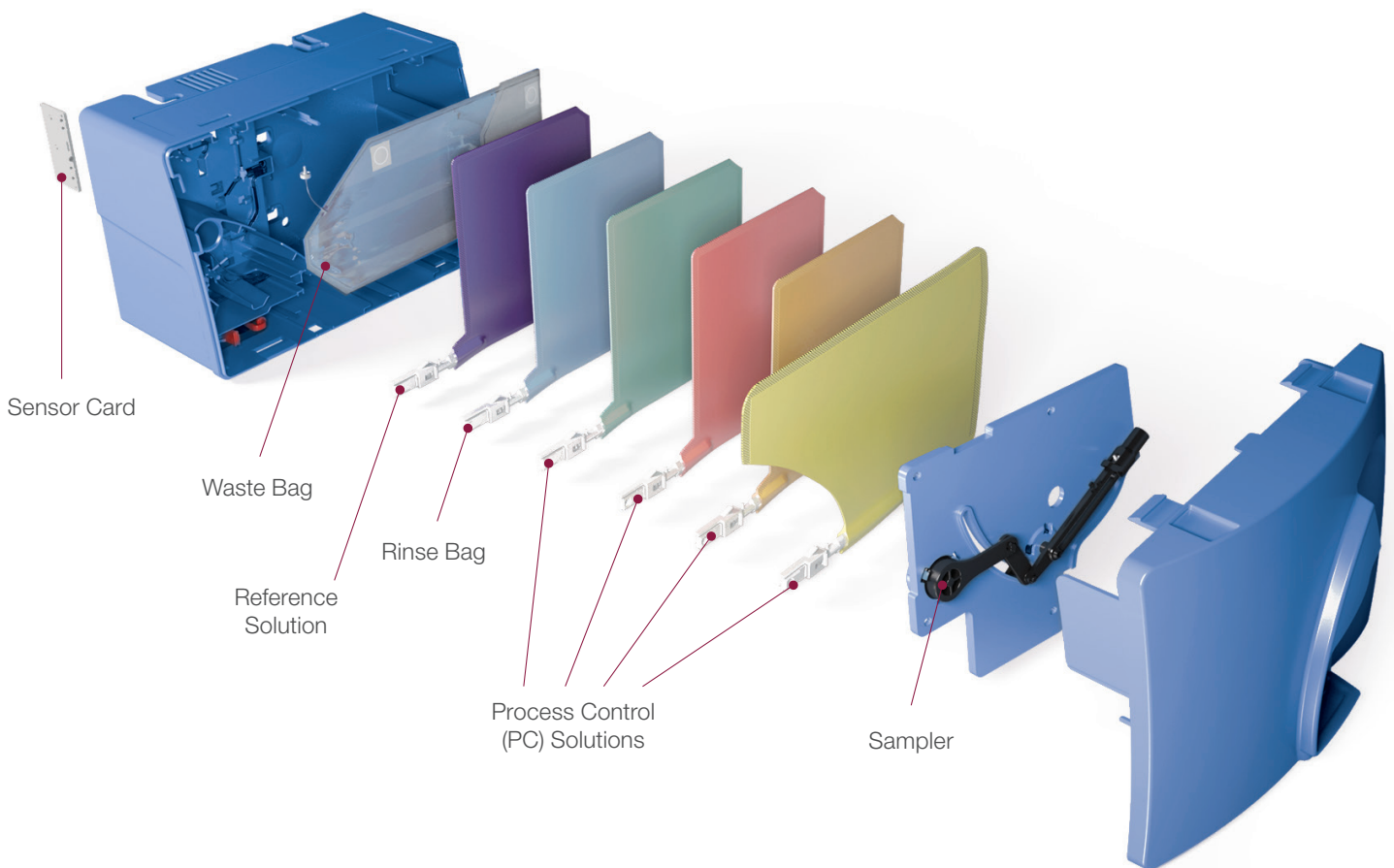
- All-in-one, multi-use GEM PAK includes all testing components (sensors, sampler, tubing, solutions and waste bag)
- No liquids or biohazardous material enter analyzer; thus, no maintenance or troubleshooting required
- Only one GEM PAK to inventory and manage

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[®] Plus⁵⁰⁰
CUSTOM CONNECTIVITY

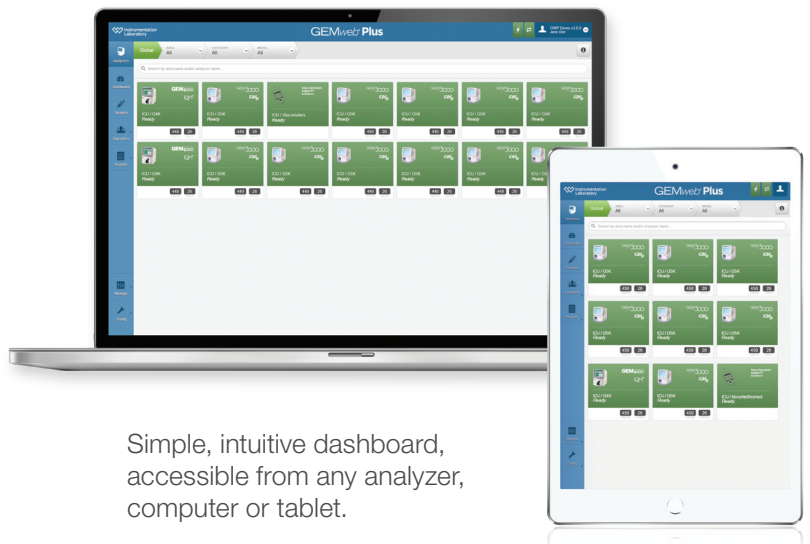
Simplifies point-of-care testing

- 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

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, tCO₂, pH, pCO₂

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, tCO₂, pH, pCO₂

Conductivity: Hct

Interface Protocols

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

Calibration Valuation Product (CVP)

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

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.

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