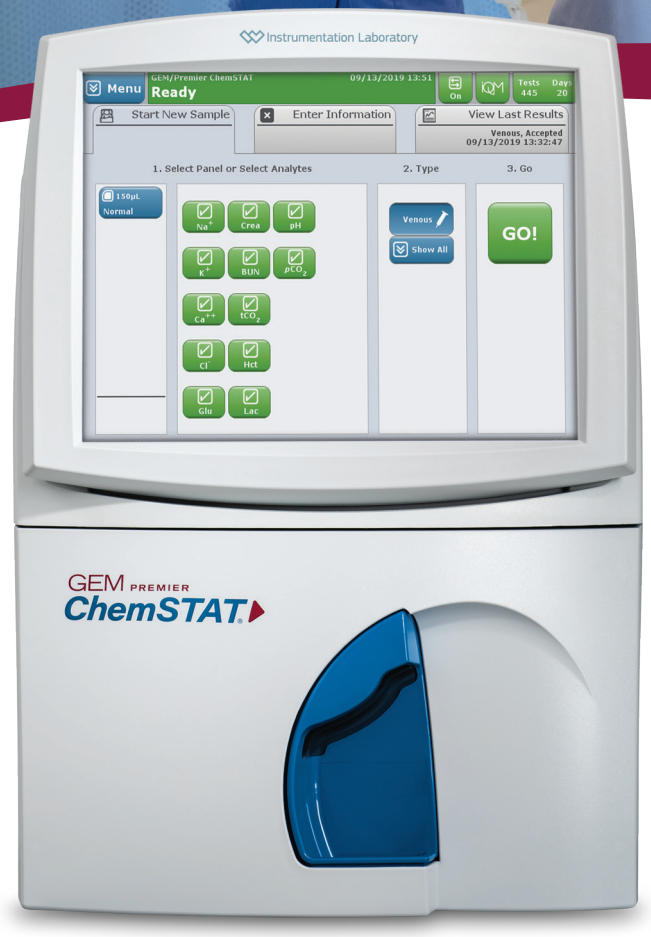
GEM PREMIER ChemSTAT®



INTRODUCING

Basic Metabolic Panel.

STAT.

werfen

GEM PREMIER ChemSTAT®

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^+	K^+	Ca^{++}	Cl^-	Glu	Crea	BUN	tCO_2	Hct	Lac	pH	pCO_2
BMP	✓	✓	✓	✓	✓	✓	✓	✓	✓			
BMP Plus	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

Calculated parameters

AG	$HCO_3^{-(m)}$	BUN/Crea ratio	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.

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Crea (Creatinine), BUN (Blood Urea Nitrogen), AG (Anion Gap), HCO_3 (Bicarbonate), 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.

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% 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]

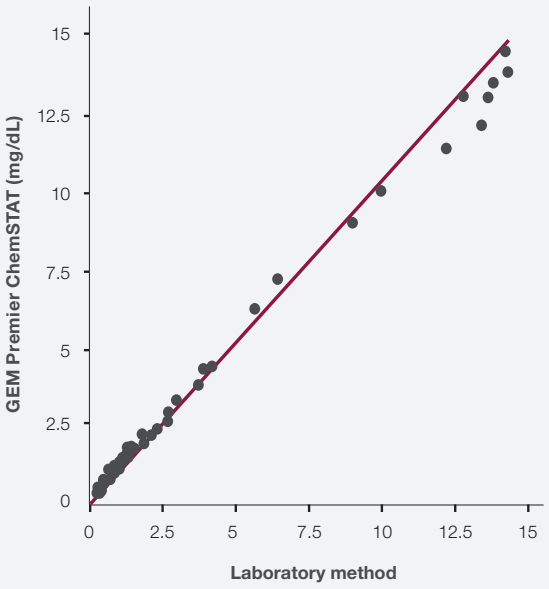
- Claims more lives than breast cancer, prostate cancer and human immunodeficiency virus combined[8]
- Surviving Sepsis Campaign International Guidelines recommend that hospitals have a performance-improvement program for sepsis, including sepsis screening for acutely ill, high-risk patients[9]
- On-demand 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 the US annually, with 2–10% mortality[11–13]
- POC BMP testing allows initiation of fluid/electrolyte replacement and insulin therapy in the 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*



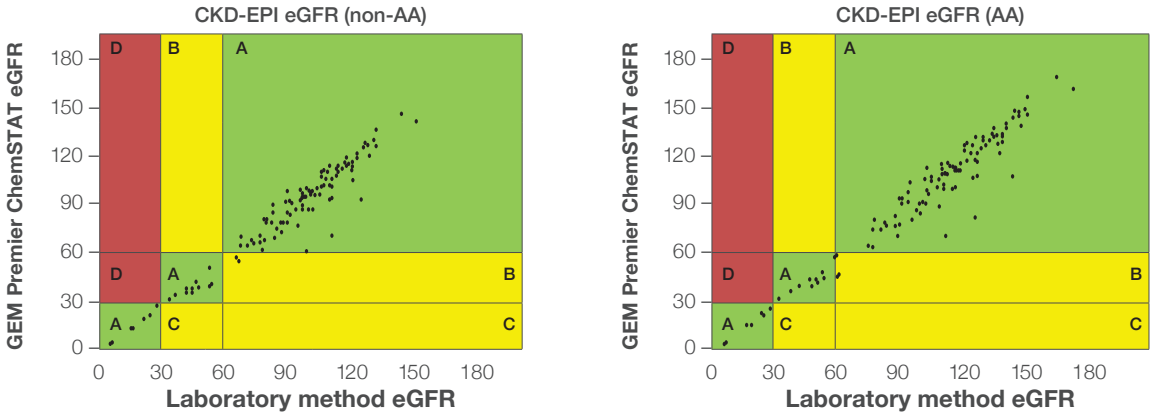
* Isotope dilution, mass spectrometry (IDMS)-traceable, enzymatic assay.

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.

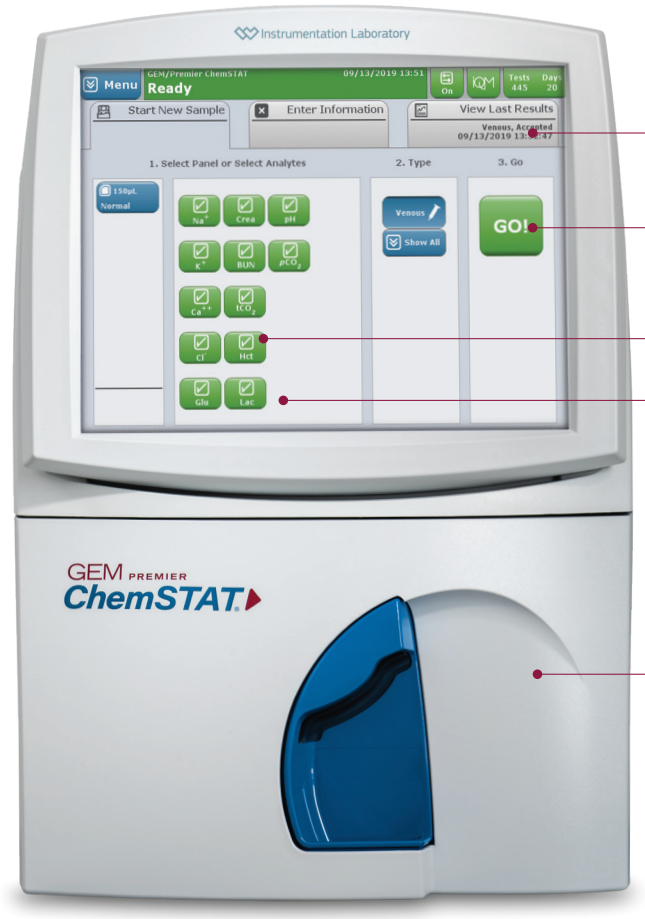
Real-time quality assurance

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

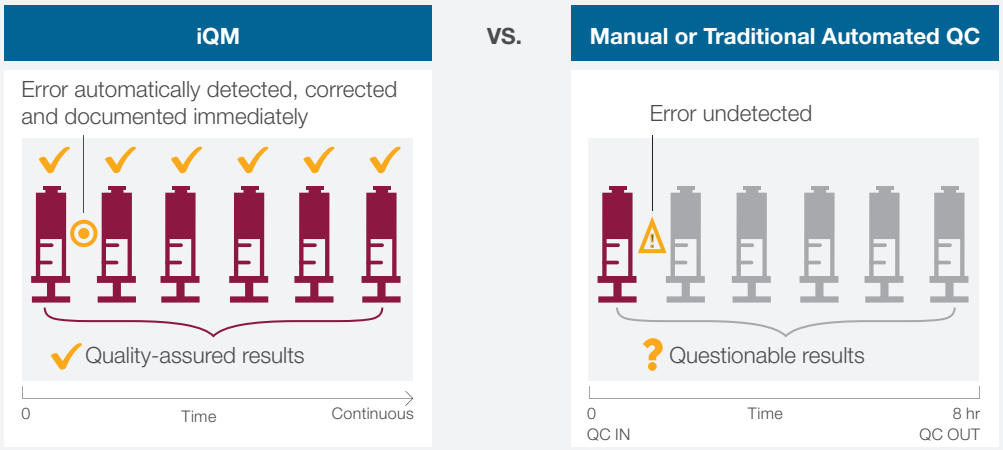
BMP Plus menu option, including Lac, pH, pCO_2

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

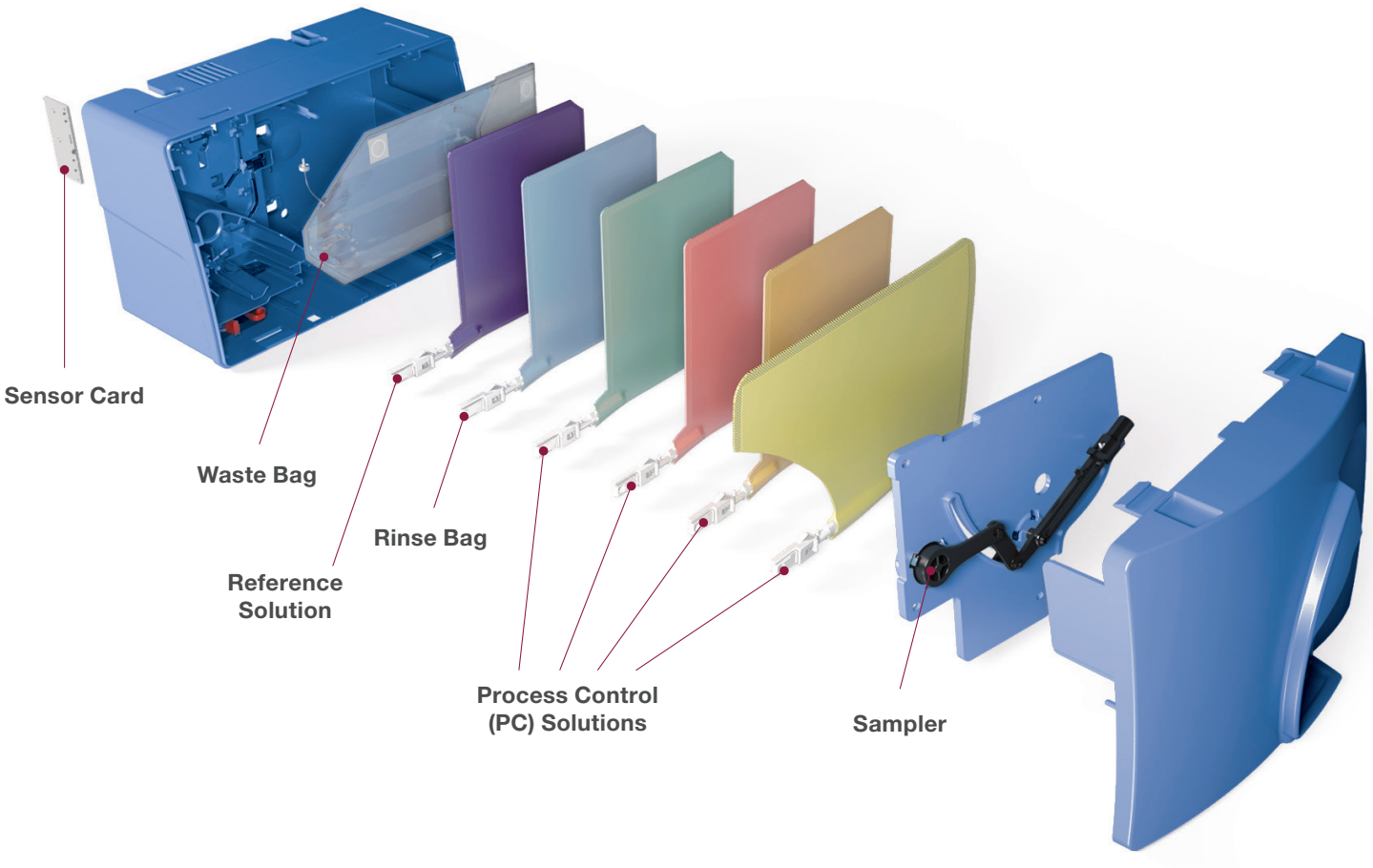
- All-in-one, multi-use GEM PAK includes all testing components (sensors, sampler, tubing, solutions and waste bag)
- No liquids or biohazardous materials enter analyzer; thus, no maintenance or troubleshooting required
- Only one GEM PAK to inventory and manage

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 500
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

GEM PREMIER ChemSTAT®

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^+, 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 ratio	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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