



## ***The Intelligent Analyzer.***

Assuring quality before, during and after sample analysis—for improved patient care.



# Improving patient care Now that's intelligent

With the GEM Premier 5000 system:\*

- ▶ iQM2 provides **real-time assurance**
- ▶ All-in-one, multi-use GEM PAK offers **advanced simplicity**
- ▶ GEMweb® Plus 500 Custom Connectivity allows **complete management**

In the lab and at the point of care

\*Not available in all countries.



# care and efficiency. ent.

## Real-time quality assurance, everywhere

New iQM2 with IntraSpec<sup>™</sup> technology provides intelligent analyzing—automated quality assurance with every sample, continuously and in real time, unlike traditional (auto or manual) quality control (QC) offerings.

### Real-time detection

iQM2 performs continuous checks—**before, during** and **after** every sample.

### Immediate, automatic correction

### Automatic documentation

## Advanced simplicity, anywhere

- Self-contained GEM PAKs
- Available in different menu and test-volume configurations
- Allow ultimate flexibility for the needs of specific units (e.g., ICU, NICU, CVOR, ED)
- **31-days<sup>†</sup>** use-life and **require no refrigeration**

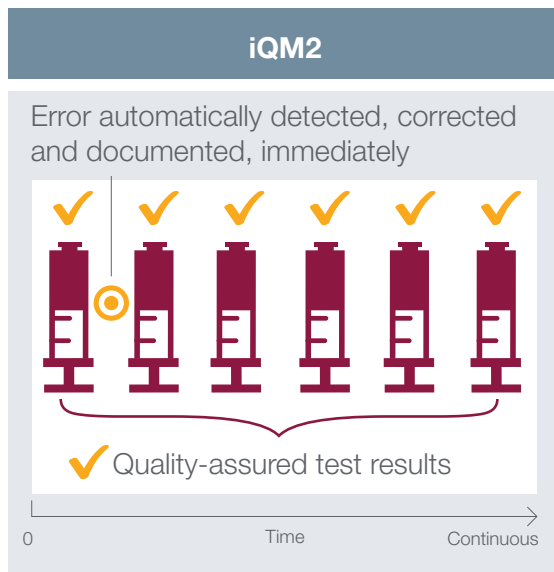
<sup>†</sup>21-day onboard use-life for 600-test PAK.



30 different GEM PAK configurations available.

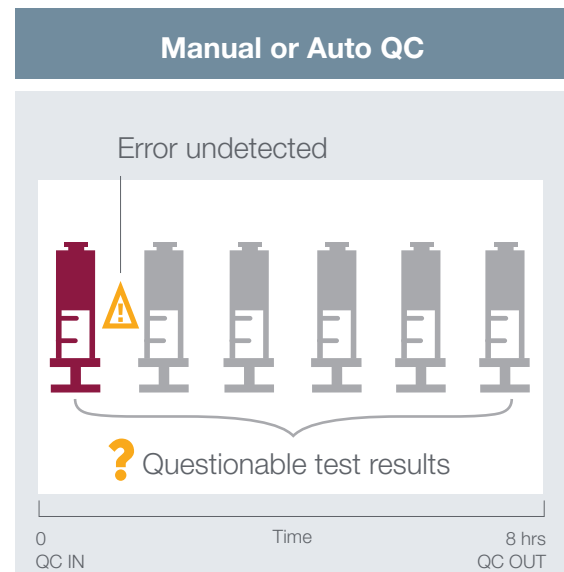
## iQM2: Real-time detection, correction and documentation

- Error detection reduced from hours to minutes
- A complete picture of quality for each and every sample
- Designed to mitigate risks in all phases of testing, from pre-analytical through post-analytical



**iQM2 assures quality continuously**

VS.



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

**Reduces error detection time from hours to minutes<sup>1,2</sup> and detects transient sample-specific errors that traditional QC methods miss.**

|                                 | pH         | pO <sub>2</sub> | pCO <sub>2</sub> | Na <sup>+</sup> | K <sup>+</sup> | Ca <sup>++</sup> | Cl <sup>-</sup> | Glu         | Lac      | Hct      | tHb      | tBili    |
|---------------------------------|------------|-----------------|------------------|-----------------|----------------|------------------|-----------------|-------------|----------|----------|----------|----------|
| <b>iQM2* (mins)</b>             | <b>2</b>   | <b>2</b>        | <b>2</b>         | <b>4.1</b>      | <b>2</b>       | <b>2</b>         | <b>2</b>        | <b>16.8</b> | <b>2</b> | <b>2</b> | <b>2</b> | <b>2</b> |
| Traditional QC (manual or auto) | ← ≥8 hrs → |                 |                  |                 |                |                  |                 |             |          |          |          |          |

Statistical presentation of an average error detection time with 95% confidence.

### Automated, real-time assurance helps ensure accurate results with every sample

- Provides caregivers more time at the bedside
- Fast and quality-assured test results allow for immediate patient management decisions
- Eliminates unnecessary retesting, for higher patient and staff satisfaction

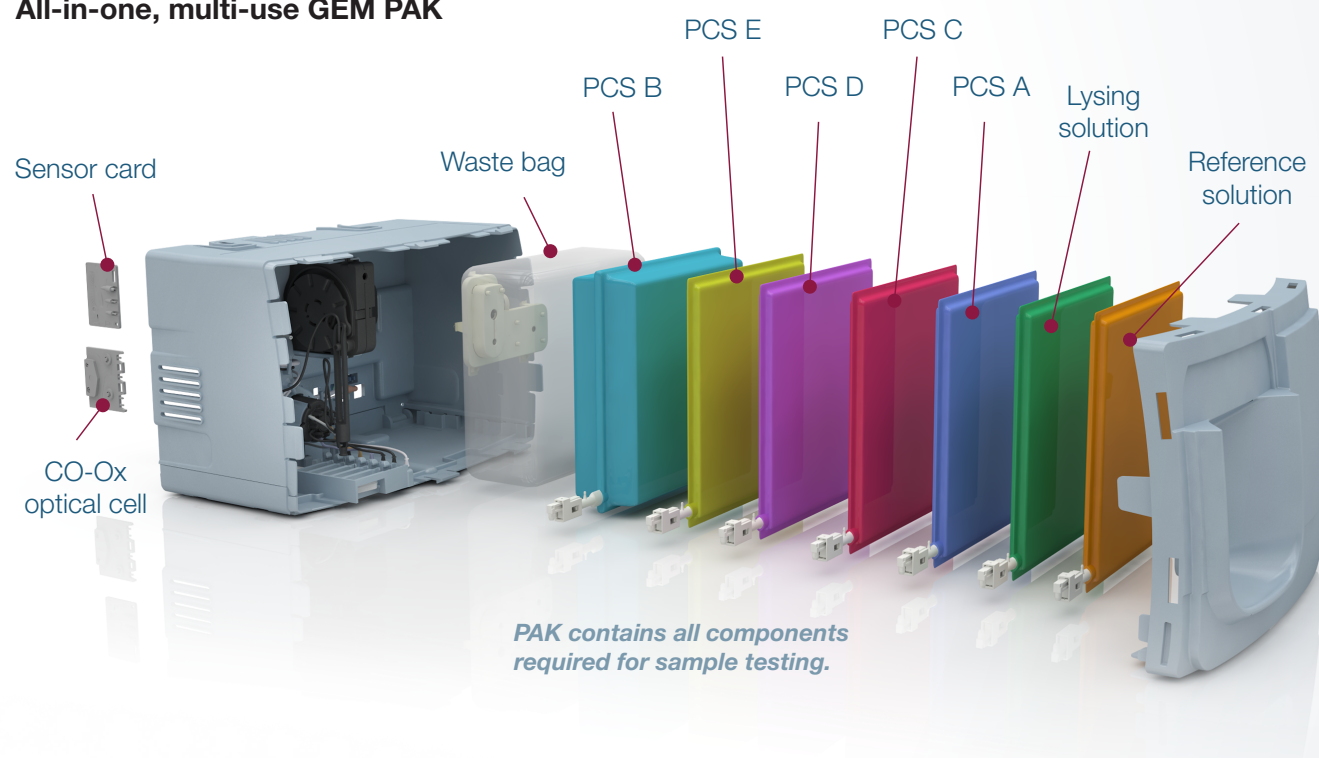
\*Together with James Westgard, PhD, Instrumentation Laboratory established the methodology for optimizing high probability of error detection and low probability of false rejection of drift limits. Method performance, in terms of mean and Standard Deviation, of measured Process Control Solutions (PCS) values were obtained from the data of 276 GEM PAK cartridges used in Proof-of-Performance and external studies for the GEM Premier 5000 analyzer.



## How is it possible?

- **iQM2 functions within a stable, closed analytical system**
  - Eliminates outside variables
  - Ensures errors are known and limited
- **Identifies errors through patented Pattern Recognition software**
  - Pattern Recognition is at the heart of iQM2 functionality
  - Possible only with a stable, closed analytical system to which the user cannot introduce change
- **Analyzes 5 levels of PCSs continuously to confirm sensor and PAK performance**

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



### Continuous monitoring through 5 PCSs at Medical Decision Levels (MDL)

- PCSs are traceable to Clinical & Laboratory Standards Institute (CLSI) and National Institute of Standards and Technology (NIST) primary standards
- Each PCS follows the same pathway as a patient sample and serves a specific function in the iQM2 process
- Established target values monitor MDLs and ensure accuracy of results
- Monitoring MDLs is essential to ensure accuracy in clinical decisions, particularly in critically ill patients (e.g., lactate MDL align with recommended values for treatment of sepsis)

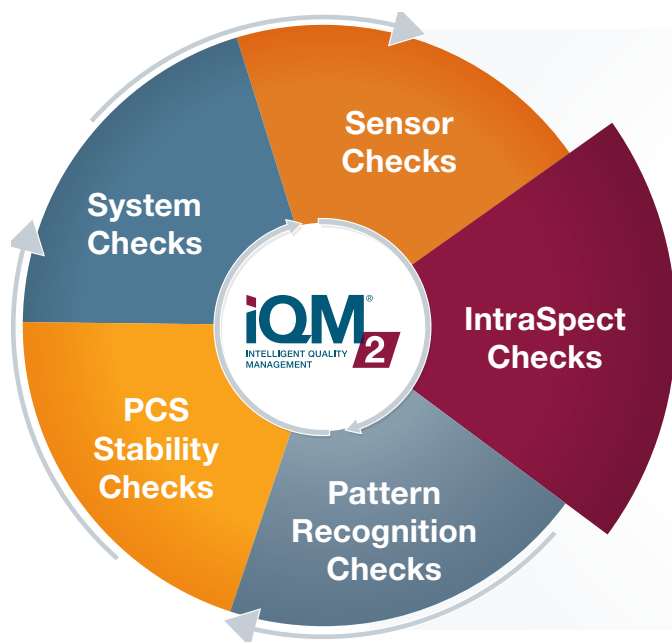
# Only iQM2 assures the integrity of every sample in real time

**The only continuous quality management system that checks sample integrity before, during and after every sample analysis.**

- Features patented Pattern Recognition technology in a single-cartridge, stable, closed system
- Auto-detects transient errors during sample analysis that other QC methods could miss
- Auto-documents all errors and corrections
- Generates operator- and sample quality-specific reports to help managers proactively support quality improvement initiatives\*

\*Available through GEMweb Plus 500 Custom Connectivity.

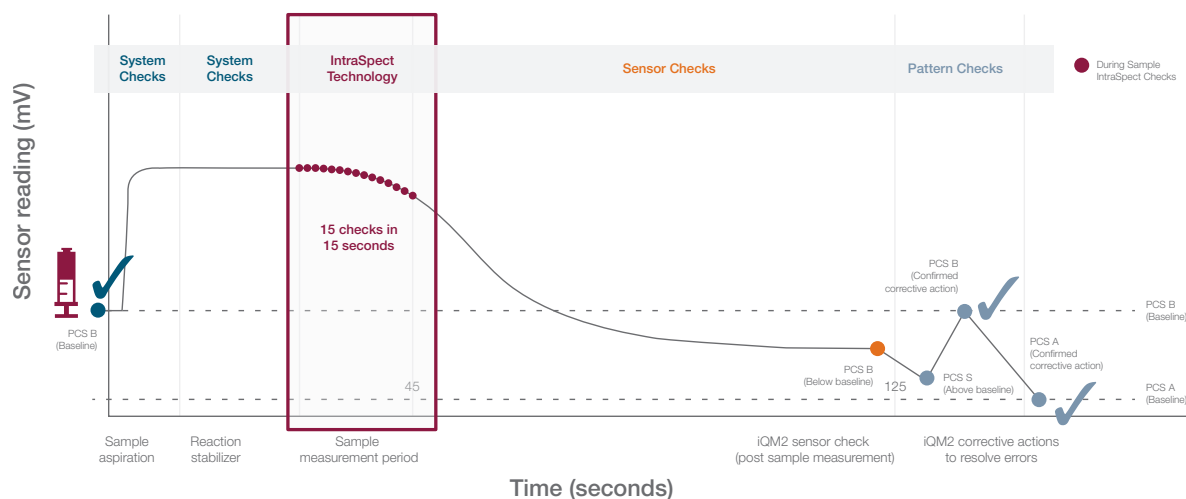
**Only iQM2 conducts a continuous cycle of 5 quality checks—more than any other blood gas system**



## Only iQM2 has IntraSpect technology

Detects sample-specific errors during sample measurement that traditional QC methods could miss (e.g., micro-clots, micro-bubbles, interferences). If missed, these errors may affect current or future sample integrity.

**Quality management with every second of analysis: iQM2 in real time**



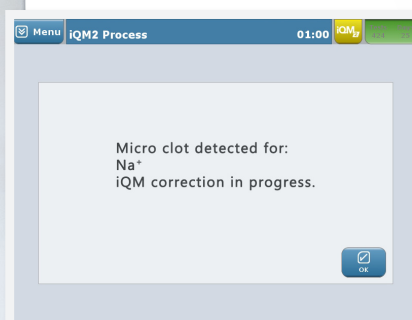
# Only iQM2 offers complete automation of sample quality management

Performs auto-detection, -correction and -documentation, plus sample-handling reports, tailored training programs and certification—uniquely improve quality and management.\*

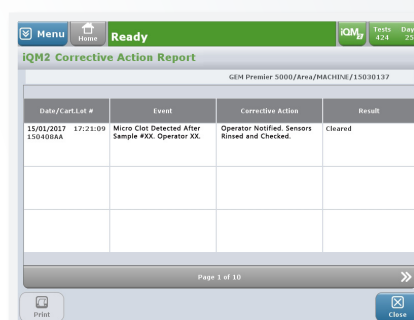
\*Reports available through GEMweb Plus 500 Custom Connectivity.



**1** Real-time error detection



**2** Real-time auto-detection and -correction of transient errors



**3** Auto-documentation of corrective actions applied

|                       |                                  |        |          |
|-----------------------|----------------------------------|--------|----------|
| Operator ID           | Z10                              |        |          |
| Last Name, First Name | Bachelder, Vanesa                |        |          |
| Event Rate            | 4 events for 224 samples (1.79%) |        |          |
| Event                 | Analysis Date/Time               | Area   | Analyzer |
| ⚡ Micro Clot Detected | 06/25/2019 14:47:30              | CVOR 1 | G5000 1  |
|                       | 06/25/2019 14:13:32              | CVOR 1 | G5000 1  |
| ⚡ Absorbance Error    | 06/26/2019 14:37:11              | OR 2   | AACC-5   |
|                       | 06/13/2019 14:57:46              | OR 2   | AACC-5   |

|                       |                                  |        |          |
|-----------------------|----------------------------------|--------|----------|
| Operator ID           | z34                              |        |          |
| Last Name, First Name | Wadleigh, Oleta                  |        |          |
| Event Rate            | 4 events for 228 samples (1.75%) |        |          |
| Event                 | Analysis Date/Time               | Area   | Analyzer |
| ⚡ Micro Clot Detected | 06/28/2019 14:36:06              | CVOR 1 | G5000 1  |
|                       | 06/28/2019 13:46:38              | CVOR 1 | G5000 1  |
|                       | 06/28/2019 13:42:32              | CVOR 1 | G5000 1  |
|                       | 06/28/2019 13:38:54              | CVOR 1 | G5000 1  |

**Sample handling reports traceable to operator or clinical setting**

(from GEMweb Plus 500 Custom Connectivity)

## FDA-cleared technology

*"iQM2 manages the quality control process, replacing external quality control."*

— US Food and Drug Administration

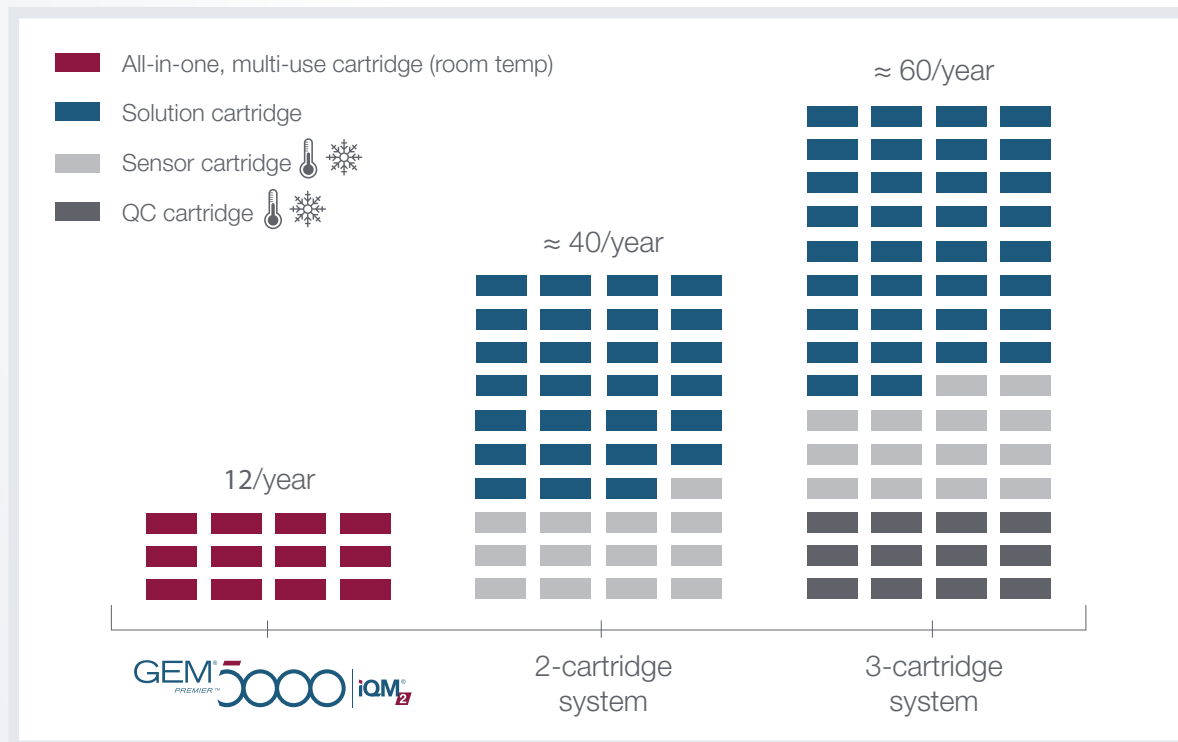


# GEM PAK: Advanced simplicity at every point of care

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

- **Zero maintenance—just replace the disposable, all-in-one, multi-use PAK monthly; no additional cartridge-handling required**
  - Includes all testing components: sensors, CO-Ox optical cell, lysing solution, PCSs, tubing, waste bag and sampler
  - Only 1 PAK to inventory and manage
  - No hands-on troubleshooting or corrective actions required
- **Ensures patient and operator safety**
  - All components are self-contained, limiting operator biohazard exposure
  - No blood enters the analyzer, limiting infection exposure for patient and operator
- **Ultimate simplicity—no special requirements**
  - Easy front-loading
  - Room-temperature storage; no refrigeration required
  - Replaced every 31 days—only 12 PAKs per year\*
  - Ideal for high- and low-volume testing

## Annual Cartridge Utilization Comparison†



\*Assumes constant test volume of 450 samples/month or less.

†Based on 1 analyzer with annual sample volume  $\approx$  4,800 and QC requirement of 3 times/day. Data on file, IL.

❄️ \* Requires refrigeration.

**GEM PAK contains all analytical and quality control components.**



## Management and compliance simplified

GEMweb Plus 500 Custom Connectivity provides customizable connectivity and automated functionality for complete control of analyzers, operators and data oversight.



*Simple, intuitive dashboard, accessible from any analyzer, PC or tablet.*

### Simplify POCT

- Simple web access from any browser
- Optimized interface for access from analyzer and tablet devices
- 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

### Centralize POCT

- Single unified database to access patient samples and historical results
- Data connection to iQM on GEM Premier 3500/4000 and GEM Premier ChemSTAT™ systems
- Data connection to iQM2 on GEM Premier 5000 systems
- Customizable to multiple connection types, including patient monitors, HIS/LIS and ADT
- Open connectivity, including select non-IL analyzers†

# What's different about the GEM Premier 5000 system?

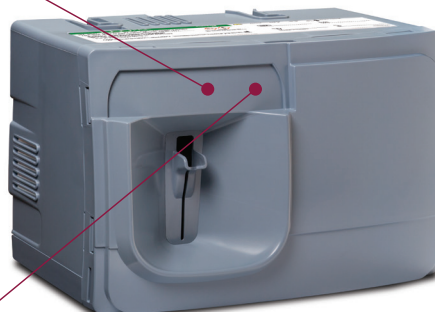
## Advanced Simplicity *outside*



**iQM<sup>2</sup> with IntraSpect technology**  
Provides a complete picture of quality for each sample

## Real-Time Assurance *inside*

**AutoPAK Validation**  
Standardizes time-to-ready state





## Improve patient care *and* efficiency

### Improved patient care

- Rapid, quality-assured test results with every sample, not just every 8 hours
- Identifies and reduces risks associated with testing processes before, during and after every sample
- Prevents the reporting of erroneous results
- Enables staff to spend less time maintaining/troubleshooting and more time at the patient's bedside



Ask your IL representative for a customized time, resource and savings calculation.

### Improved efficiency

- Automates analyzer and operator management
- Manages quality in self-contained GEM PAKs
- Eliminates outside variability
- Eliminates maintenance
- Menu- and volume-specific GEM PAKs allow customization tailored to unit needs
- Allows system-wide control from any analyzer or PC
- Keeps documentation just a click away

**A complete solution for improved patient care and efficiency.**



GEM<sup>®</sup> 5000  
PREMIER™

iQM<sup>®</sup>  
2

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

## Technical Specifications

### Quantitative Measured Analytes

| Analyte           | Unit   |
|-------------------|--------|
| pH                | n/a    |
| pCO <sub>2</sub>  | mmHg   |
| pO <sub>2</sub>   | mmHg   |
| Na <sup>+</sup>   | mmol/L |
| K <sup>+</sup>    | mmol/L |
| Ca <sup>++</sup>  | mmol/L |
| Cl <sup>-</sup>   | mmol/L |
| Glu               | mg/dL  |
| Lac               | mmol/L |
| Hct               | %      |
| tHb               | g/dL   |
| O <sub>2</sub> Hb | %      |
| COHb              | %      |
| MetHb             | %      |
| HHb               | %      |
| tBili             | mg/dL  |
| sO <sub>2</sub> * | %      |

\*sO<sub>2</sub> = O<sub>2</sub>Hb/O<sub>2</sub>Hb+HHb.

### Derived (Calculated) Parameters

|                        |                     |                                    |                                       |
|------------------------|---------------------|------------------------------------|---------------------------------------|
| BE(B)                  | pAO <sub>2</sub>    | O <sub>2</sub> ct                  | RI                                    |
| BE(ecf)                | CaO <sub>2</sub>    | HCO <sub>3</sub> <sup>-</sup> std  | CcO <sub>2</sub>                      |
| tHb(c)                 | CvO <sub>2</sub>    | TCO <sub>2</sub>                   | a-vDO <sub>2</sub>                    |
| Ca <sup>++</sup> (7.4) | p <sub>50</sub>     | HCO <sub>3</sub> <sup>-</sup> (c)  | Q <sub>sp</sub> /Q <sub>t</sub> (est) |
| Anion gap (AG)         | O <sub>2</sub> cap  | A-aDO <sub>2</sub>                 | Q <sub>sp</sub> /Q <sub>t</sub>       |
| P/F ratio              | sO <sub>2</sub> (c) | paO <sub>2</sub> /pAO <sub>2</sub> | Hct(c)                                |

### Flexible Customization

Test volumes: 75, 150, 300, 450, 600<sup>†</sup>

#### Menu

Blood Gas, Hct, tHb, O<sub>2</sub>Hb, HHb, COHb, MetHb, sO<sub>2</sub>, tBili<sup>‡</sup>

Blood Gas, Electrolytes, Hct, tHb, O<sub>2</sub>Hb, HHb, COHb, MetHb, sO<sub>2</sub>, tBili<sup>‡</sup>

Blood Gas, Electrolytes, Glu, Lac, Hct, tHb, O<sub>2</sub>Hb, HHb, COHb, MetHb, sO<sub>2</sub>, tBili<sup>‡</sup>

<sup>†</sup> Onboard use-life is 31-days, except 600-test PAK, which is 21-days.

<sup>‡</sup> PAKs available with or without tBili.

**Real-time assurance and advanced simplicity. Now that's intelligent.**

1. Westgard JO, *et al.* Validation of iQM active process control technology. *Point Care*. 2003;2:1–7.
2. Toffaletti JG, *et al.* Validation of a quality assessment of blood gas and electrolyte testing. *Clin Chim Acta*. 2007;382:65–70.

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