Instrumentation Laboratory

GEM® Premier™ 3000 with iQM™

Frequently Asked Questions

The following Frequently Asked Questions concerning Intelligent Quality Management (iQM) on the GEM Premier 300 were received from customers. We posed these questions to Dr. James Westgard and Dr. Sharon Ehrmeyer, renowned experts in the field of Quality Control.

***James Westgard**, Ph.D., is a Professor in the Department of Pathology and Laboratory Medicine at the University of Wisconsin Medical School and Faculty Director of Quality Management Services for the Clinical Laboratories at the University of Wisconsin Hospital and Clinics. He teaches in the Clinical Laboratory Science Program and is codirector of a new Internet program that offers a Graduate Certificate in Laboratory Quality Management. He is also president of Westgard QC, Inc., a small business that provides tools, technology, and training for laboratory quality management. He earned a BA degree in chemistry from Concordia College in Moorhead, MN, and Master's and Ph.D. degrees in analytical chemistry from the University of Wisconsin-Madison. His interest in quality control began in 1976-77 when he was on sabbatical leave at Uppsala University in Sweden. This work led to the development of a multi-rule control procedure, often referred to as "Westgard Rules." He has published many articles, chapters, and books on statistical QC and laboratory quality management and also provides extensive educational and training materials via the Internet at www.westgard.com*

***Sharon Ehrmeyer**, Ph.D., MT (ASCP), is a Professor of Pathology and Laboratory Medicine and Director of the Clinical Laboratory Science/Medical Technology Program at the University of Wisconsin Medical School in Madison, Wisconsin. Dr. Ehrmeyer currently is the secretary of the AACC's Critical and POCT Division, a member of ASCP's Board of Governors, and the section editor of the Regulatory Affairs column in "Point of Care," the journal of near-patient testing and technology. Her interests focus on laboratory quality issues including the impact of laboratory regulations on laboratory practices and POCT. She has written numerous book chapters and journal articles and has presented these interests nationally and internationally.*

Instrumentation Laboratory

GEM® Premier™ 3000 with iQM™

Frequently Asked Questions

Question: How do the New CLIA Regulations stating that 'Calibration material cannot be used for QC' work for iQM?

Specifically, § 493.1256 (d) (9) states:
When using calibration material as a control material, use calibration material from a different lot number than that used to establish a cut-off value or to calibrate the system.

Answer from Dr. Westgard:

iQM makes use of a series of external solutions, called "Calibration Verification Products," to initially validate the performance of a new cartridge, then employs a series of internal "Process Control Solutions" for the ongoing monitoring and adjustments over the lifetime of a cartridge. These Process Control Solutions are used to monitor sensor performance and look for changes in the analytical system. The traditional calibration and control functions are carried out by the combination of the thousands of measurements on these Process Control Solutions and the advanced iQM software that measures any changes, makes any necessary adjustments for sensor drift and slope, and identifies abnormal or unusual changes (outside of defined statistical drift limits) to trigger QC flags and corrective actions.

The idea that a calibration material cannot be used for QC dates back to the early generations of automated analyzers, such as the continuous flow analyzers that were popular in the 60s and 70s. Those analytical systems were subject to many variables and changes associated with daily operation and individual operators. It is important to recognize that many of the provisions encoded in the CLIA regulations are based on past generations of analytical systems and may not be appropriate for new technology. The GEM Premier 3000 is a closed system in which nothing can be changed by the operator, making many of those past problems and the practices that addressed them not applicable. The computer capabilities in this new analyzer make it possible to do things differently – and better.

iQM is new and more advanced QC technology. It has been reviewed by the FDA, who approved IL's product claim stating that iQM replaces the use of traditional external controls. CLIA originally contained a provision to require all manufacturers to validate their QC procedures and obtain clearance from FDA. This requirement was eliminated in the Final CLIA Rule of 2003, but manufacturers can still submit a claim for QC, and if their data supports that claim, they can obtain approval for that claim from the FDA. That is the route IL pursued for iQM, making it the first new QC technology approved as a replacement for traditional external controls.

Instrumentation Laboratory

GEM® Premier™ 3000 with iQM™

Frequently Asked Questions

Question: CLIA states in Section 93.1256 (7) "over time, rotate control material testing among all operators who perform the test." How can this be accomplished with iQM?

Answer from Dr. Westgard:

With iQM, the Process Control Solutions are measured in a regular pattern with defined time intervals for analysis. All operators are subject to the same QC under iQM and, furthermore, the operators have no influence on the QC results. In that context, the Process Control Solutions will automatically be rotated among all operators. This is actually the intent of the CLIA rule – that QC monitor all operators.

Question: How is the requirement for "Peer Review" met with iQM?

Answer from Dr. Ehrmeyer:

This is NOT a CLIA requirement.

Section **493.1236(2)(c), Evaluation of proficiency testing performance,** of the CLIA regulations states that at least twice annually, the laboratory must verify the accuracy of all analytes tested.

One mechanism to accomplish this is through mandated, regulatory proficiency testing for blood gases and electrolytes that occurs three times each year. Acceptable or passing performance in proficiency testing by achieving similar results to those in the laboratory's PT peer-grading group is tantamount to demonstrating accuracy.

Instrumentation Laboratory

GEM® Premier™ 3000 with iQM™

Frequently Asked Questions

Question: Are the Delta Charts a good replacement for Levey-Jennings? Are mean values and SD statistics available?

Answer from Dr. Ehrmeyer:

Although there is no specific CLIA requirement to plot QC data, plotting the results has become an accepted way to view the distribution of data. With a traditional Levey-Jennings chart, typically only a few data points are plotted each day. Over the course of several weeks, the GEM Premier 3000 with iQM generates thousands of QC data points, making it impractical to plot on a Levey-Jennings chart. Delta charts provide a means to include all these data points and display the entire distribution. This is actually better than using a traditional Levey-Jennings chart. With iQM, mean and SD statistics are automatically calculated and always available.

Instrumentation Laboratory

GEM® Premier™ 3000 with iQM™

Frequently Asked Questions

Question: How does the GEM Premier 3000 with iQM check the entire analytical range (Low, Normal, High)?

Answer from Dr. Ehrmeyer:

With iQM, the GEM Premier 3000 automatically analyzes different levels of Process Control Solutions daily. Blood gases and pH are assessed with 3-levels and electrolytes, glucose and lactate are evaluated using 2-levels. These Process Control Solutions are equivalent to the traditional practice of analyzing 3-levels of QC solutions for blood gases and 2-levels for the remaining analytes over a 24-hour period.

The control ranges of acceptability of the GEM Premier 3000 are optimized to assure accuracy and precision of the analytical process throughout the analytical measurement range. Unlike the infrequent analysis of QC (every 8 hours) with traditional blood gas systems, the high frequency of QC analysis of the GEM Premier 3000 reduces the time to error detection from hours to minutes.

Instrumentation Laboratory

GEM® Premier™ 3000 with iQM™

Frequently Asked Questions

Question: How can I detect changes in the GEM Premier 3000 at the extreme ends of the calibration curves?

Answer from Dr. Ehrmeyer:

IL offers Performance Verification Product (PVP), designed for this purpose and for verifying the reportable range of the instrument. For test sites that routinely perform testing on patients with more extreme values, additional liquid controls at selected levels can be purchased and analyzed.

Question: Don't ALL manufacturers' analyzers do what the GEM Premier 3000 does?

Answer from Dr. Westgard:

There may be similarities in the measurement technology, but I am not aware of any other manufacturer who has developed a completely automated QC process and obtained FDA clearance for the claim that "it replaces the use of traditional external QC materials." iQM is unique in that respect and sets a new standard for other manufacturers to achieve.