Bio-Rad Mission: Control™

Take the Guesswork out of Your QC Strategy

Bio-Rad Mission: Control™ is the first objective risk management software to help laboratories identify the best QC rules and the right QC frequency to develop a scientifically sound Quality Control Plan that delivers reliable test results to best fit a laboratory's risk tolerance.

- Calculates the risk of reporting an incorrect patient result
  - Incorporates easy-to-use risk metrics
  - Focuses on patient health
- Emphasizes the most critical tests
- Provides the lowest Cost of Quality by detecting errors early and minimizing False Rejection Rate
- Improves operational effectiveness and regulatory compliance
- Intuitive and user friendly web based application with clear outputs
- Optimizes laboratory analytical performance by adjusting key parameters
  - QC Method (CV, bias and time between failures)
  - Quality Specifications (total allowable error and patient harm)
  - QC Strategy (QC rules and frequency interval)
- Helps develop a QC Plan consistent with the guidelines defined by CLSI EP23-A, ISO 14971 and ISO 15189

BIO-RAD

Find out what your peers are saying about Bio-Rad Mission: Control™

Dr. Jeremie Gras

Clinical Biology Laboratory – Clinique Saint-Luc, Bouge, Belgium

"Bio-Rad Mission: Control™ helped us determine a QC frequency that is scientifically justified. In our laboratory, we are devoted to producing quality results that help clinical decisions and guarantee patient safety. However, until recently, QC frequency was based on arbitrary decisions – even when using risk acceptability matrices like the ones that are recommended in CLSI EP23.

The use of Bio-Rad Mission: Control™ allowed us to determine the patient risk indexes of E(Nuf) and E(Nuc), in order to determine which QC frequency will minimize the expected number of unacceptable results that are final or that can be corrected. Using Bio-Rad Mission: Control™ allows us to define a QC frequency that is specific for each test, and which is based on indexes that are published in peer-reviewed literature. This helps in reducing the number of incorrect results that are final (which could lead to inappropriate medical actions); but it also helps us to reduce the number of unacceptable results that can be corrected (a process which takes time and costs money because the patient samples have to be retested once that the QC failure is discovered).

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–Dr. Jeremie Gras

Dr. Guillaume Lefèvre

Hôpital Tenon – Paris

"I had the opportunity to evaluate Bio-Rad Mission: Control™ a new software Bio-Rad developed with the aim to mitigate the risk of generating incorrect patient results. Quality Control plays a major role in biological laboratory practices especially when the lab is involved in ISO 15189 accreditation and must define the expected quality for a test, verify that the observed quality is meeting expectations, and participate in interlaboratory comparisons.

For a lab, QC interpretation is a mandatory step in a labs daily activity, with time and money spent to reach an efficient and correct result. One of the goals of QC interpretation is to detect analytical errors that could lead to false patient results and/or clinical misinterpretations as soon as possible. Fortunately, most of our existing QC procedures limit these occurrences through the use of Westgard Rules, and different concepts such as total allowable error, bias and imprecision.

On one hand each lab must define precisely for a test the interval of QC and the rules to be used for QC interpretation. On the other hand that each test has its own characteristics due to imprecision, bias and total error, application to clinical chemistry of sigma metrics demonstrated that it is possible to adapt for each test its own QC rules.

I deem that one of the main questions linked to QC is its frequency, or the interval between two QC runs. This frequency is generally fixed for most labs today (for example 12 h or 24 h) and is mostly at the same frequency for all analysis or sub-groups of analysis. As more frequent QC evaluations are run, we lower the average number of unacceptable patient results when an error occurs. But, most of the time, convenient organization, spending, or implementation of norms are the main reason for using the same QC frequency, without questioning its use. I was positively surprised to see that all these analytical concepts about imprecision of tests and six sigma metrics, together with the interval of QC and the expected rate of unacceptable patient's results, are used in Bio-Rad Mission: Control™ software. Labs can use this as a QC integrated tool. I think in the future this software could be helpful within all laboratories to (re)define QC rules, frequency of QC, and the QC levels to use to finally increase even more the quality of patient results."

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Dr. Guillaume Lefèvre

Dra. Carmen Perich Alsina

Quality Director, Clinical Laboratory
Hospital Vall d'Hebron–Barcelona, Spain

"The Vall d'Hebron Hospital clinical laboratory where I work, provides coverage for admitted hospital patients (over 1100 beds), external and emergency consultations, as well as the majority of primary care patients for the city of Barcelona, which corresponds to 4,000 patients a day.

I validated the new Bio-Rad software called Mission: Control™ and I found it easy to use, even if it may require professional skill for to interpret key indexes. After evaluating the program, I discovered important advantages that the software offered, such as the possibility to decrease the likelihood of reporting incorrect results, therefore improving patient safety. It has been always controversial to decide whether to increase QC samples or retest many more patient samples when a failure occurs; Bio-Rad Mission: Control™ seems to help in finding the right balance.

I found it interesting to see the inclusion of the new QC rule: Repeat 1:2s, as it is the first option used in daily practice in our laboratory. When current QC strategy is not sufficient, the program gives options such as increasing the number of QC samples, modifying the Total Error allowable, and changing the rules. I also have some opinions to share with the aim to improve the adoption of this statistical tool.

The concept is easy to understand, but training from Bio-Rad is advisable to correctly apply Bio-Rad Mission: Control™ and interpret the results.

In the case of our laboratory, the main utility of using this program is to determine what QC rules and QC frequency are the most suitable to adopt in order to ensure, with a certain probability, that our lab will produce only the minimum acceptable number of patient results with unacceptable error. This is especially important in instruments performing a large number of patient samples and tests, such as core laboratory analyzers."

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Dr. Carmen Perich Alsina

Dr. Pilar Fernandez-Calle, MD, PhD

Quality Director, Department of Laboratory Medicine
Hospital Universitario–La Paz, Madrid, Spain

Hospital Universitario La Paz
Hospital de Cantoblanco
Hospital Carlos III
SaludMadrid
Comunidad de Madrid

"La Paz University Hospital in Madrid, Spain is a tertiary hospital with 1,200 beds and a high degree of specialization, including some Departments of National Reference such as Neonatology, Children Nephrology and Burn Unit. The Laboratory Department is organized in two main locations related to the type of activity: Emergency Laboratory (600-700 patients/day) and Core laboratory (around 4000 patients/day) together with specific laboratories where more specialized knowledge areas and complex technology are present. Quality Assurance is a cornerstone of our laboratory, and the interchangeability of patients results is one of our most important concerns. Currently we are changing our QC policy from a traditional approach to a patient risk management strategic approach (CLSI EP23-A).

In this sense we find the Bio-Rad Mission: Control™ software to be a very useful tool for this transition. In our opinion the new software is user friendly, easy to manage, and is intuitive. On the other hand, it gives a lot of useful information providing interesting data about risk that laboratories assume when applying a particular QC strategy. An interesting fact is that a personalized QC strategy can be designed measurand to measurand based on the risk the laboratory decides to assume, the clinical relevance of each magnitude, and how its interpretation could be critical to the clinical decision making, and ultimately to patient. This tool also offers the possibility to consider and calculate patient risk as a unique laboratory statistic, independently of how many instruments are simultaneously used to determine a particular measurand. Some considerations for future improvements include the possibility of introducing current systematic error (lot to lot variation, calibration effect. . .), and displaying the risk calculations in real time.

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–Dr. Pilar Fernandez-Calle, MD, PhD

Nathalie Durgniat

Head of Unilabs Lausanne–
FAMH Specialist in Laboratory Medicine, Clinical Chemistry
Lausanne, Switzerland

"We are a private lab belonging to the Unilabs chain which works in close association with a private hospital open 24 hours a day, 7 days a week. For each method we have defined our quality goals in the form of Total Allowable Error. The internal quality controls allow us to assure the quality of our results daily compared to the goals we've defined. Periodically, we evaluate the capability of our methods to initiate corrective or preventive actions when the performance is not optimal. Bio-Rad presented us the new software, Bio-Rad Mission: Control™. First, this new tool allowed us to estimate, based on the current QC strategy and activity of our lab, the number of patient results potentially wrong when our instruments malfunction. The advantage of this new approach is to be more focused on our patients.

Secondly, this new software can allow us to establish a new QC strategy by reversing the process. As lab manager I had to fix, consciously, the maximum number of wrong patient results for each test performed in my lab. Previously no tool was available to help my lab to mitigate the risk of generating bad results. Based on the trial carried out, Bio-Rad Mission: Control™ demonstrated to be effective in assessing the level of patient risk for selected analytes, and determining the best QC strategy to adopt based upon the goal to put patient care at the center of my lab activities."

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–Nathalie Durgniat

Dott. Romolo M. Dorizzi

Direttore Dipartimento Anatomia Patologica, Medicina Trasfusionale e di Laboratorio
Direttore U.O. Patologia Clinica (Corelab) -Laboratorio Unico, AUSL della Romagna
Direttore Programma di Patologia Clinica di AVR
Responsabile f.f. LRR Cesena

"In my high throughput Core Lab (more than 50,000 reportable tests/day) I had the opportunity to evaluate a new software intended to design QC around the patient and not simply the analyzer. This is in-line with my lab commitment to strive to obtain strict and continuous control of the quality of the results. The Bio-Rad Mission: Control™ software is an innovative tool for enabling my laboratory to tailor the rules and the frequency of the controls to minimize the risk of delivering inaccurate results improving the safety of the patients."

Francesca Occhipinti
Daniel Tumiatti

Responsible for Clinical Quality Control
Azienda Sanitaria dell'Alto Adige, Laboratorio Centrale di Patologia Clinica
Bolzano, Italy

"We had the opportunity to evaluate and test Bio-Rad Mission: Control™. The program helps laboratories determine the best frequency for running internal QC materials and to assess the clinical risk associated with each test. This approach optimizes the relationship between cost and quality. For instance, Bio-Rad Mission: Control™ helped us, in the case of albumin, to identify a problem with high imprecision and overall low sigma performance that was affecting our patient results. Based on the risk assessment in Bio-Rad Mission: Control™, we changed the frequency of calibration and greatly improved our imprecision and sigma score for albumin."

QC Consulting

Working with Bio-Rad QC specialists, your laboratory can develop a better understanding of QC design with a managed risk approach to quality control. The more you know about risk-based QC, the sooner you can implement QC rules and adjust QC frequency to improve operational efficiencies.

- Gain expert insight into risk-based quality control using objective evaluations for the analytical phase of laboratory testing
- Leverage QC knowledge base to help you design appropriate QC plans to minimize risk and improve operational efficiency
- Learn how to utilize Bio-Rad Mission: Control™ to include an analytical assessment in your IQCP plan

Bio-Rad Mission: Control™ software helps laboratories identify the proper QC rules and the right QC frequency to develop a customized quality control plan to deliver reliable test results.

Ordering Information

Cat #	Bio-Rad Mission: Control™
11000002	Annual Subscription
11000005	Subscription and Consultation (10 hours)

To get started, contact your Bio-Rad sales representative, or visit www.qcnet.com/missioncontrol

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For further information, please contact the Bio-Rad office nearest you or visit our website at www.qcnet.com/missioncontrol

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