Manage Risk More Effectively with Independent Quality Controls

Introduce your lab to an unbiased independent assessment

BIO-RAD

Regulatory Requirements Emphasize the Need for Using Independent Quality Control Material

While guidelines vary, most regulatory organizations recognize that independent quality controls are an important part of an effective laboratory quality control system. There's a good reason these guidelines call for independent controls: instrument manufacturer controls are less sensitive to changes in device performance, and analytical errors could affect a patient sample which in turn may result in harm to the patient.

CLSI

". . . Quality control materials should be different from the calibrator materials to ensure that the QC procedure provides an independent assessment of the measurement procedure's performance in its entirety, including the procedure for calibration of the measurement."

CLSI C24-A3, Statistical Quality Control for Quantitative Measurement Procedures: Principles and Definitions; Approved Guideline—Third Edition, 6.2.1 Relation to Calibrators

CLIA

"For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytical process."

42 CFR Part 493.1256 Medicare, Medicaid, and CLIA Programs; Laboratory Requirements Relating to Quality Systems and Certain Personnel Qualifications; Final Rule

ISO 15189

"Laboratory shall use quality control materials that react to the examining system in a manner as close as possible to patient samples. Use of independent third party control materials should be considered, either instead of, or in addition to, any control materials supplied by the reagent or instrument manufacturer."

ISO 15189:2012. Medical laboratories – requirements for quality and competence. Clause 5.6.2.2 Quality Control Materials

NATA

"Controls independent of those produced by the manufacturer of the test or analyzer should be used. The laboratory must have a system of long-term monitoring of internal quality control results to assess method performance."

NATA (National Association of Testing Authorities) Australia, Interpretation of NPAAC Requirements and ISO 15189, Clause 5.6.2 Internal Quality Control, (ii) and (vi).

Rili-BÄK

"The control samples must be similar as possible to the patient samples being examined. Within the same measuring procedure the control and the calibration materials must not be identical."

Guideline of the German Medical Association on Quality Assurance in Medical Laboratory Examinations (Rili-BÄK). J Lab Med 2015; 31:26-69. Clause B1, 2.1.1 Procedure (5).

QCI

"Medical laboratories shall perform internal quality control. Use of third party human matrix quality control is recommended for all analytes."

Essential Standards for Registration of Medical Testing Laboratories in India, Quality Council of India 3.5.2 Quality Assurance

> *"If you work with manufacturer controls, you will miss a lot of analytical problems that may have an impact on patient results. Moreover, testing independent controls is a requirement of ISO 15189:2012."*
>
> J. M. Gras, MD
> Clinique Saint-Luc
> Bouge, Belgium

Independent Quality Controls

Independent quality controls are an essential part of a quality control system. They provide an independent assessment because they are manufactured independently of the instrument, reagents and calibrators. The majority of independent control materials consist of a human base matrix that helps provide a product that closely mimics a patient sample. Most controls offer a long shelf life which allows the same control lot to be used across multiple reagent lots to monitor long-term reagent performance, and to detect shifts that may occur with new reagents and calibrators.

Instrument Manufacturer Controls

Many instrument manufacturers provide both calibrators and control materials for their own systems. These controls are designed only for use on their test systems. More importantly, they are often manufactured from the same materials as their calibrators. Consequently, the control may mimic the calibrator, making it less sensitive to changes in device performance. This can lead to acceptance of patient test results with analytical errors that could be medically important. Often times, a laboratory using an instrument manufacturer or in-kit control may receive a different control lot with each new reagent lot. This does not provide the laboratory with the benefits of long-term QC monitoring.

"The right QC is about what laboratories should do to ensure that patient results are correct and reliable for their intended use."[1]

For your laboratory, this means controls should be used to monitor analytical errors that may adversely affect the reliability of patient results.

[1]James O. Westgard, "Perspectives on Quality Control, Risk Management, and Analytical Quality Management. Quality Control in the Age of Risk Management", James O. Westgard and Sten Westgard, editors, *Clinics in Laboratory Medicine* Vol 33, no. 1, p. 3 (2013), Elsevier, Philadelphia.

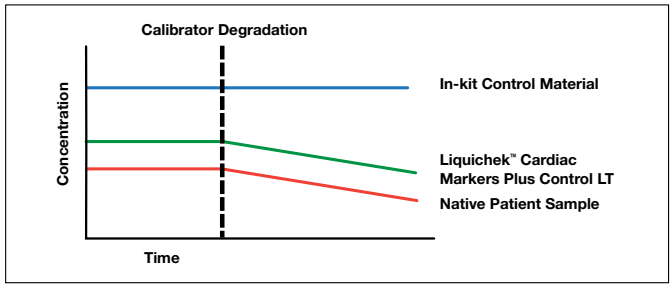
Independent Quality Controls Minimize Medically Important Errors

What errors do instrument controls fail to detect?

Independent quality controls give you greater confidence in your results, because they do not have the same bias as instrument manufacturer controls that may fail to detect errors in calibration or procedures, errors due to faulty equipment or shifts following maintenance.

The following examples demonstrate scenarios where independent quality controls detected errors that instrument manufacturer controls missed, which could have adversely affected the reliability of patient results.

Instrument controls may not detect calibration errors



Scenario:

A laboratory did not realize that their calibrator material had degraded. The in-kit control used was designed to work with the specific instrument, reagent and calibrator and it did not detect the degradation of the calibrator material and patient results were compromised.

Benefit of Independent Quality Control Materials

Liquichek™ Cardiac Markers Plus Control LT is manufactured independently of the test system calibrators and reagents, and closely mimics performance of a patient sample. Therefore, in this situation Liquichek™ Cardiac Markers Plus Control LT would have detected a shift due to degradation of the calibration materials and avoided releasing erroneous patient results.

Instrument controls may not detect procedural errors

Scenario:

A laboratory used the in-kit controls provided by the reagent manufacturer for their APTT testing. The in-kit control values were within the range provided by the reagent manufacturer. A Bio-Rad Lyphochek® Coagulation Control was also run but the results were out of range (high). Investigation of the discrepancy revealed that the laboratory was unaware of a procedure change calling for an adjustment in incubation time recommended by the manufacturer. After changing the procedure to the correct incubation time, the APTT values for the Bio-Rad Lyphochek® Coagulation Control were within the acceptable range.

Benefit of Independent Quality Control Materials

Because the Bio-Rad Lyphochek® Coagulation Control more closely mimics the performance of a patient sample, it detected a procedural error that potentially could have affected patient results. The in-kit controls from the reagent manufacturer did not detect this problem.

"For a truly independent assessment of the test system, it is very important to use controls that are not provided by the instrument manufacturer."

Carol Bartlett
QC Coordinator, USA

Instrument controls may not detect shifts following instrument maintenance

Scenario:

Following a lab's routine preventative maintenance on a specific instrument, the instrument manufacturer controls showed no change and were within the acceptable range. However, the laboratory manager noticed a shift out of range with high values for Triglyceride and Cholesterol for the Bio-Rad Lyphochek® Assayed Chemistry Control. Concern over this shift resulted in additional troubleshooting by the instrument manufacturer's technical specialist. It was found that the slide reading station needed adjustment. Once the adjustments were made, the Bio-Rad control values were again within the acceptable range.

Benefit of Independent Quality Control Materials

The Bio-Rad Lyphochek® Assayed Chemistry Control detected a shift in the recoveries for Triglycerides and Cholesterol that the instrument manufacturer's controls did not detect. This shift could have potentially affected patient results.

Instrument controls may not detect faulty equipment

Scenario:

Results for the instrument manufacturer's intact PTH control were within acceptable limits, however, the Bio-Rad Liquichek™ Specialty Immunoassay Control values were higher than expected. Recalibration and different reagent lots did not resolve the issue. It was only after troubleshooting and replacing the luminometer that the Bio-Rad control fell within the acceptable range.

Benefit of Independent Quality Control Materials

The Bio-Rad Liquichek™ Specialty Immunoassay Control identified a problem with the luminometer that was not detected by the instrument manufacturer's control. If the problem had not been detected, patient results could have been affected.

"I trust Bio-Rad controls because they have not been formulated for only one specific test system."

Lab Manager, France

Partner with the Experts in Quality Control

More laboratories trust Bio-Rad for quality control products than any other manufacturer. You can count on our consistent product quality to help assure reliability of patient results.

A Comprehensive Portfolio of Quality Control Products

Having the right products when you need them is critical to keeping your lab running smoothly and maintaining your quality system. When it comes to quality controls, Bio-Rad offers;

- A comprehensive portfolio of independent quality control material for daily use
- A wide selection of external quality assurance services (EQAS®)
- Unity™ data management solutions to help you manage your QC data
- Access to the world's largest Unity™ peer group comparison program

Customer Support That Provides Answers

Bio-Rad provides comprehensive service, support and consultation to our customers. When you purchase control products from Bio-Rad, you receive the benefit of a full-service Technical Support Department that is:

- Staffed with skilled, friendly teams to handle your inquiries in a prompt, knowledgable, and professional manner
- Focused on providing you with the support and education you need

Educational Programs to Expand Your QC Knowledge

E-learning programs through QCNet™ and a growing library of publications and product documentation, help you to better understand both the technical and regulatory aspects of quality control. We are committed to supporting our customers' needs using a variety of resources, including:

- QCNet™ University, providing premiere, award winning training from experienced trainers on data management and connectivity solutions
- YouTube® channel with over 100 videos related to QC methodologies and laboratory quality
- Downloadable training notes, quick guides and data files on a wide variety of data management and QC topics

EQAS®

An independent, external snapshot of performance in comparison to your peers.

Independent QC

Ongoing, proactive, unbiased QC that identifies errors and trends in a timely manner.

Unity™

QC Data Management tools that help you create a strategy to reduce risk and streamline QC workflow.

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

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