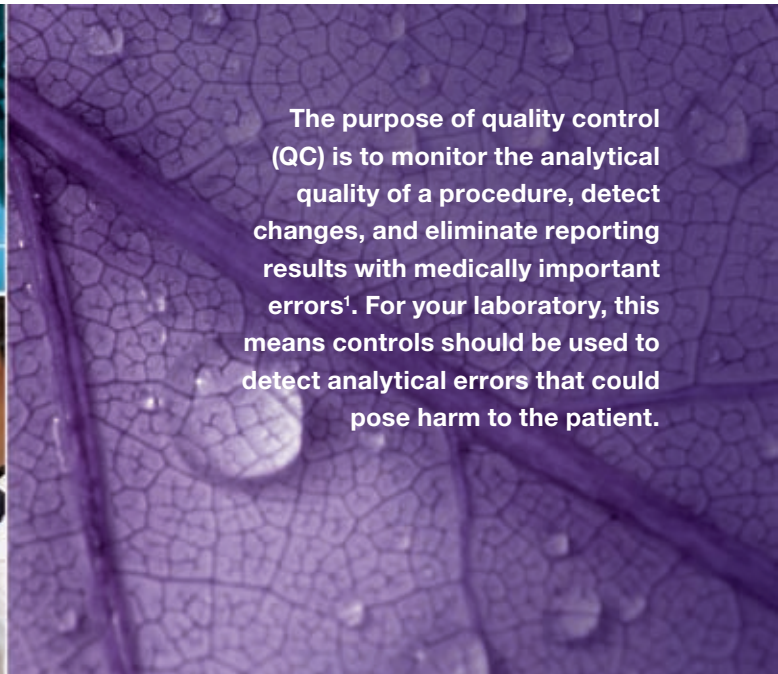




Discover the Importance of Third Party Quality Control

Introduce Your Laboratory to an Independent Assessment





The purpose of quality control (QC) is to monitor the analytical quality of a procedure, detect changes, and eliminate reporting results with medically important errors¹. For your laboratory, this means controls should be used to detect analytical errors that could pose harm to the patient.

Third Party Controls



Instrument Manufacturer Controls

The term “third party” is used to describe a quality control product that helps provide an independent assessment of a diagnostic device or method, and is not optimized for any specific instrument or reagent system. Third party controls are manufactured independently of the test system calibrators and reagents. Such controls generally begin with a human base matrix that helps provide a product more similar to a patient sample. Third party controls with a longer shelf life allow use of the same control lot over multiple changes in reagents and calibrators, giving the laboratory the ability to detect shifts that may occur with new reagents or calibrators.

Many instrument manufacturers provide both calibrators and control materials for their own systems. These controls are designed for use only on their own test systems, but more importantly, they are often manufactured from the same materials as the 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 error 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.

A control with a long shelf life allows for long-term QC monitoring across different reagent lots and saves time and money due to fewer lot crossovers.

	Year 1	Year 2	Year 3
Instrument Manufacturer Reagent	Lot 1	Lot 2	Lot 3
Instrument Manufacturer Control	Lot 1	Lot 2	Lot 3
Third Party Control	Lot 1		

¹ Westgard JO, Barry PL. Cost-Effective Quality Control: Managing the Quality and Productivity of Analytical Processes



Regulatory Requirements Emphasize the Need for Using Third Party Quality Controls

The following are a few examples of regulatory standards and guidelines from around the world.

“. . . 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

“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) AS 4633 (ISO 15189), Australia, 5.6.1 Internal Quality Control

“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

“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

“The use of controls independent of those produced by the manufacturer of the test or analyzer is preferable”

Laboratory Accreditation Scheme of Malaysia 5.6.1 Quality Control



“If you wanted to make sure that the divisions on your ruler are correct, would you check it against another ruler made by the same manufacturer? For an unbiased assessment, you would choose a ruler from a different manufacturer.”

Dr. Richard Pang, China

Detecting Procedural Errors A True Laboratory Situation

What Happened?

1. The laboratory used in-kit controls provided by the reagent manufacturer for their APTT testing. The values for these in-kit controls were found to be within the insert range provided by the reagent manufacturer.
2. Bio-Rad Lyphochek® Coagulation Control was also run, and the results were out of range (high).
3. Further investigations revealed that the laboratory was unaware of a procedural change calling for an adjustment in incubation time recommended by the manufacturer.
4. After changing the procedure and correcting the incubation time, the APTT values for the Bio-Rad Lyphochek® Coagulation Control were then within the acceptable range.

Conclusion

The Bio-Rad Lyphochek® Coagulation Control detected a problem that led to the discovery of a procedural error that potentially could have affected patient test results. The in-kit controls from the reagent manufacturer did not detect this problem.

Detecting Shifts Following Instrument Maintenance

A True Laboratory Situation

What Happened?

1. Following routine preventive maintenance on their instrument, results for the instrument manufacturer's controls appeared to show no change, and were within the expected range.
2. The laboratory manager noticed a shift in Triglyceride and Cholesterol values for the Bio-Rad Lyphochek® Assayed Chemistry Control, causing them to be out of range on the high side.
3. After additional troubleshooting, the technical specialist from the instrument manufacturer determined that the slide reading station needed adjustment.
4. Following adjustment of the slide reading station, the Bio-Rad controls were within acceptable range again.

Conclusion

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

Detecting Faulty Equipment

A True Laboratory Situation

What Happened?

1. Results for the instrument manufacturer's intact PTH control were within acceptable limits.
2. The results for intact PTH in Bio-Rad Liquichek™ Specialty Immunoassay Control were higher than expected.
3. Recalibrating and trying different reagent lots did not resolve the issue.
4. After further investigations, the luminometer was replaced, and results for the Bio-Rad control then agreed with the expected values.

Conclusion

The instrument manufacturer's control did not identify any system problem. If a third party control (Bio-Rad Liquichek™ Specialty Immunoassay Control) had not been tested, the problem with the luminometer could have gone on undetected – potentially affecting patient test results.

Bio-Rad is Your Trusted Partner For Third Party QC



Discover a comprehensive range of over 300 third party quality controls, including controls for daily use and a wide selection of External Quality Assurance Services (EQAS) programs from the #1 choice in independent, unbiased products.

Other Products & Services

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Easy-to-use software tools and services to help you monitor and manage your QC data, including the world's largest peer group comparison program.

Customer Service

Our team of well trained professionals will attend to your inquiries in a prompt and knowledgeable manner.

Education

Bio-Rad provides many opportunities to attend seminars and participate in basic to advanced level educational programs.

Learn more online at
thirdpartyQC.bio-rad.com



What Customers Say About Bio-Rad QC

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

Lab Manager, France

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

*Carol Bartlett
QC Coordinator, USA*

"The instrument manufacturer's controls are usually less sensitive to QC problems, and now we always try to work with third party controls."

*Ekaterina Hasyanova
Manager, QC Group,
Russia*

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For further information, please contact your local Bio-Rad office or learn more online at thirdpartyQC.bio-rad.com

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