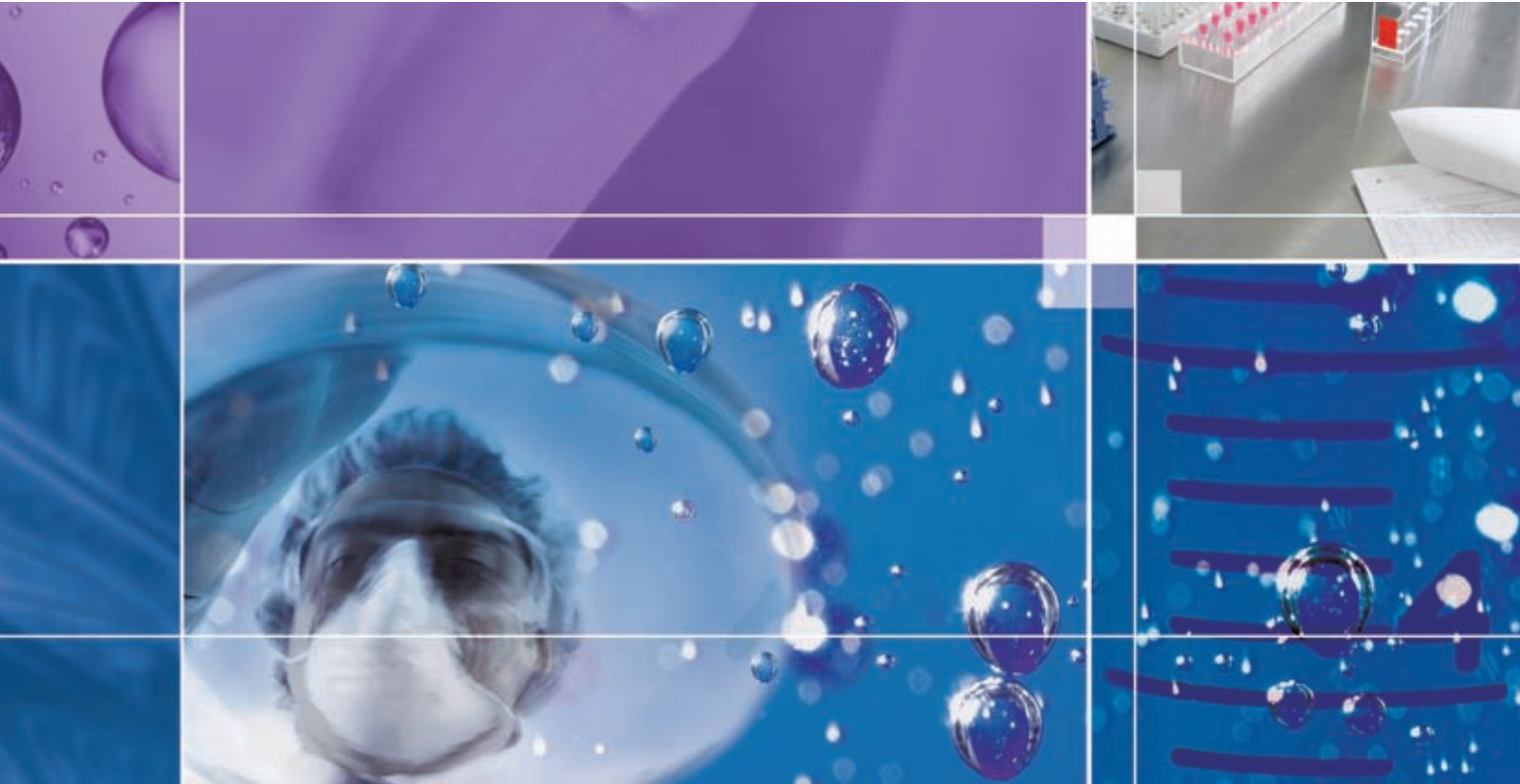# Using Quality Control

The Foundation for a Higher Standard of Patient Care Through Improved Laboratory Performance
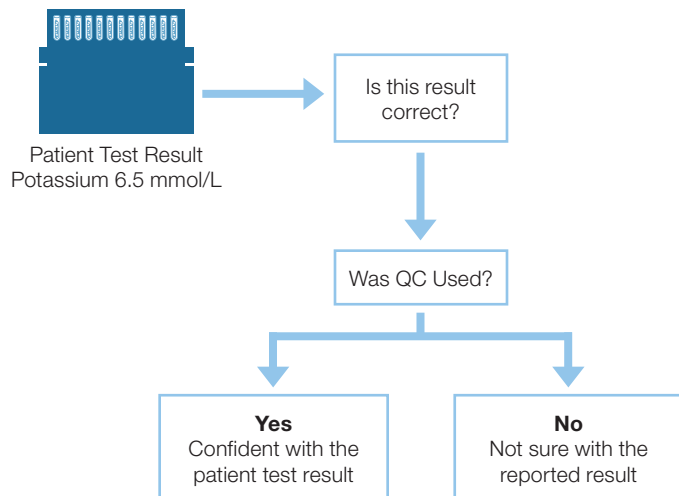
BIO·RAD

Reliable Patient Test Results
Require Daily Quality Control

Without a quality control, how do you have confidence in your patient test results?

Patient test results provided by your laboratory allow health care providers to make critical, and potentially life-saving, diagnostic and therapeutic decisions. Regular quality control testing to confirm the precision of your test systems is the foremost way to provide more confidence that your patient results are correct.

Patient Test Result
Potassium 6.5 mmol/L

Is this result correct?

Was QC Used?

Yes
Confident with the patient test result

No
Not sure with the reported result

Worldwide Standards Call
for Quality Control Practices

Regulations and standards across the world have specific quality control requirements or guidelines. Meeting those applicable requirements is the responsibility of every laboratory.

ISO 15189 (International)

"The laboratory shall design internal quality control systems that verify the attainment of the intended quality of results."

"The quality management system shall include, but not be limited to, internal quality control and participation in organized interlaboratory comparisons such as external quality assessment schemes."

NATA (National Association of Testing Authorities), AS 4633 (ISO 15189), Australia

"The laboratory must have a system of long term monitoring of internal quality control results to assess method performance."

"Controls independent of those produced by the manufacturer of the test or analyzer should be used."

CAP (College of American Pathologists), Chemistry and Toxicology Accreditation Checklist, United States

"Control results must be reviewed before reporting patient/client results. It is implicit in quality control that patient/client test results will not be reported when controls do not yield acceptable results."

"In general, calibrators should not be used as QC materials."

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

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

NABL (National Accreditation Board for Testing & Calibration Laboratories)

"The laboratory shall include a minimum of one level of QC at least once a day." (or more if >25 patient samples are analyzed per day).

CLIA (Clinical Laboratory Improvement Amendments), United States

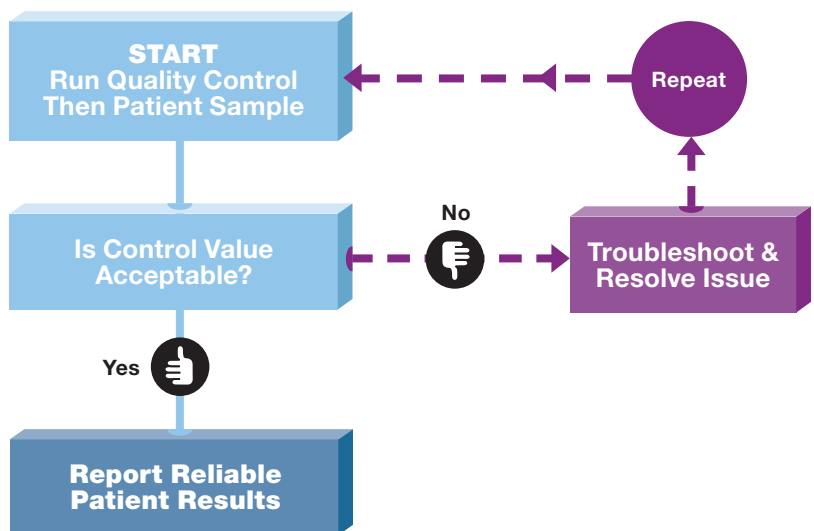"The laboratory must … establish or verify the criteria for acceptability of all control materials."

"Perform control procedures . . . at least once each day patient specimens are assayed . . ."

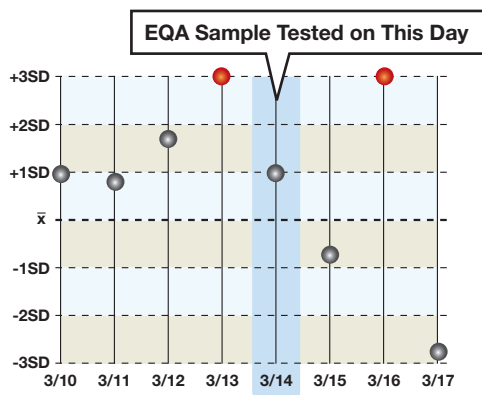# The Starting Point to a Successful Quality Control System

Implementing the use of quality controls on a daily basis in your laboratory is a sound investment in better patient care. A simple, yet effective QC system can help insure that your patient test results are reliable.

START
Run Quality Control
Then Patient Sample

Is Control Value
Acceptable?

Repeat

No

Troubleshoot &
Resolve Issue

Yes

Report Reliable
Patient Results

An External Proficiency Program is Not Enough

Routine use of daily quality controls is the foundation for a higher standard of patient care through improved laboratory performance. External proficiency programs, or external quality assessment (EQA) schemes, also play an essential role in assuring laboratory quality by supporting daily QC, but are not enough when used alone. EQA schemes typically involve testing unknown samples on a monthly or bi-weekly basis, and as such can only provide information about the testing performed on that particular assay run, on that particular day.

EQA Sample Tested on This Day

+3SD							
+2SD							
+1SD							
$\bar{x}$							
-1SD							
-2SD							
-3SD							
3/10	3/11	3/12	3/13	3/14	3/15	3/16	3/17

What about the many tests that are run in between EQA samples? How can the laboratory be sure of these patient test results?

An EQA program provides valuable information that is relevant to a specific moment in time. When used in conjunction with daily controls, the laboratory has a more complete picture of assay performance.

Implementing Daily Quality Control in Your Laboratory

The assayed values printed in a quality control insert are provided as a guide. Due to the many testing variables, a laboratory should always establish their own quality control statistics using their own test system. The most fundamental statistics used by the laboratory are the mean and standard deviation.

These values can be used to decide if a patient result is acceptable and can be reported. Clinical and Laboratory Standards Institute (CLSI) states that, "An initial assessment can be made by measuring a minimum of at least 20 different measurements of control material, for each control level, on separate days."

Step 1: Calculate the Mean [$\bar{x}$]

The mean (or average) provides the best estimate of the analyte's true value for a specific level of control.

To calculate the mean for a specific level of control:

1. Add all values collected for that control
2. Divide the sum of the values by the number of values

Formula:

$$\bar{x} = \sum x_n / n$$

Example:

Data Set = 4.0, 4.1, 4.0, 4.2, 4.1, 4.1, 4.2
Σ = 28.7 mmol/L
n = 7
Mean = 4.1 mmol/L

Where:

Σ = sum
x_n = each value in the data set
n = the number of values in the data set

Step 2: Calculate the Standard Deviation [s]

The standard deviation quantifies how close numerical values are in relation to each other and is used to assess the precision of the test system. Use of a calculator or spreadsheet is highly recommended for calculating a standard deviation.

Formula:

$$s = \sqrt{\frac{\sum(x_n - \bar{x})^2}{n-1}}$$

Example:

Data Set = 4.0, 4.1, 4.0, 4.2, 4.1, 4.1, 4.2
Standard Deviation = 0.082 (or 0.1, rounded)

Where:

s = standard deviation
$\bar{x}$ = mean (average) of the QC values
$\sum(x_n - \bar{x})^2$ = the sum of the squares of differences between individual QC values and the mean
n = the number of values in the data set

Step 3: Establish Decision Limits

Using the mean and standard deviation, the laboratory can establish decision limits. These limits are used to define what is considered an acceptable control result. Decision limits are established at ±1s, 2s and 3s from the mean.

Example:

Data Set = 4.0, 4.1, 4.0, 4.2, 4.1, 4.1, 4.2
Mean = 4.1
Standard Deviation = 0.1

+/- 1s range = 4.0 to 4.2 mmol/L
4.1 − (0.1x1) = 4.0   4.1 + (0.1x1) = 4.2
+/- 2s range = 3.9 to 4.3 mmol/L
4.1 − (0.1x2) = 3.9   4.1 + (0.1x2) = 4.3
+/- 3s range = 3.8 to 4.4 mmol/L
4.1 − (0.1x3) = 3.8   4.1 + (0.1x3) = 4.4

## Step 4: Create a Levey-Jennings Chart

Using the mean and ±3s range, a Levey-Jennings chart is created for each test and each level of control. Daily QC data are plotted on this chart, which allows the laboratory to monitor the precision of their test procedures.
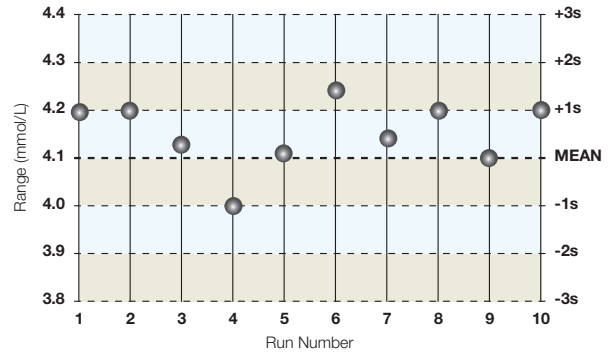

Step 5: Evaluate QC Data

When an analytical process is in control, the QC data will fall in a Gaussian distribution with approximately 99.7% of results falling within the ±3s limits. QC results that are outside the 3s limits are generally considered out of control, and the run should be rejected. QC data greater than 2s, but within the 3s limit does not necessarily indicate that the run must be rejected, as approximately 4% of valid data points will fall between 2s and 3s.

Example Gaussian Distribution Chart
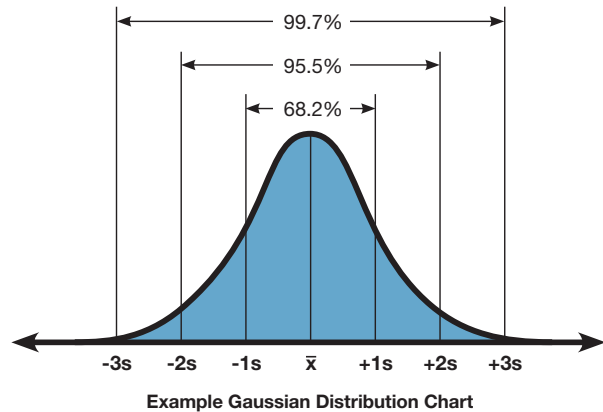
Interlaboratory Comparison Programs Help Improve Laboratory Performance

Comparing your QC results to those of other laboratories using the same instrument or method (peer group) can increase confidence in your patient test results. Participation in an interlaboratory program that provides peer group data for your daily quality controls can offer early awareness of gradual or sudden changes in your test system that may occur between proficiency surveys. In addition, the reports and charts provided in a well established interlaboratory program can significantly ease the task of managing and monitoring your QC data.
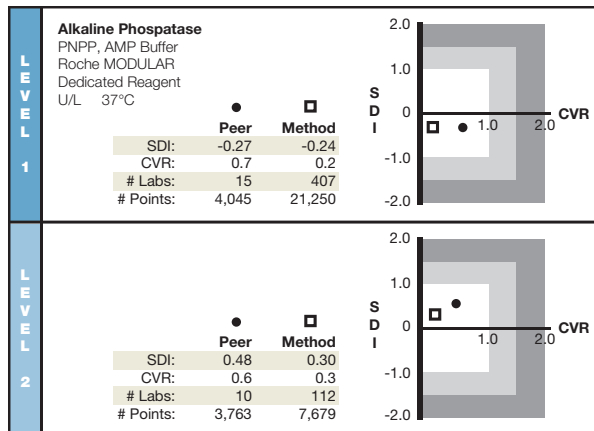
Choosing the Right Quality Control Requires Careful Consideration

Answer a few simple questions to identify the right controls for your laboratory.

- [ ] Is the product similar to patient samples? (i.e. human serum or urine based)
- [ ] Are the analytes at clinically relevant decision levels?
- [ ] Does the control provide an unbiased assessment of the test system? (i.e. control is manufactured independently of the instrument/reagent/calibrator)
- [ ] Is the control multi-analyte to allow for use with many different assays?
- [ ] Is an interlaboratory comparison program available?

- [ ] Does the open vial stability and shelf life allow full use of the product?
- [ ] Is the control appropriate for use on different methods and instruments? (i.e. not optimized for one specific instrument)
- [ ] Does the control manufacturer offer technical support from experienced professionals?
- [ ] Are educational materials and seminar programs available?

About Bio-Rad Laboratories & Our Approach to Quality Control

Get the experience you can count on from the leader in quality control.

With over 50 years of experience and a global network of operations, Bio Rad is recognized as the worldwide leader in providing quality control products and services to medical laboratories.

We earn this recognition by continuously offering innovations in quality control as well as participating in relevant standards committees and working groups throughout the world.

Our team of knowledgeable professionals is with you every step of the way in your journey to improved quality control. We can help you select the right materials, implement QC procedures, and understand the guidelines and regulations that are becoming an integral part of the medical laboratory.

Educational tools, including seminars and QC workbooks, are available to help you learn more about the right way to use quality controls.

BIO·RAD

Bio-Rad Laboratories

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

Clinical Diagnostics Group