QC Education

Laboratory Quality Control Materials

QC Workbook Series

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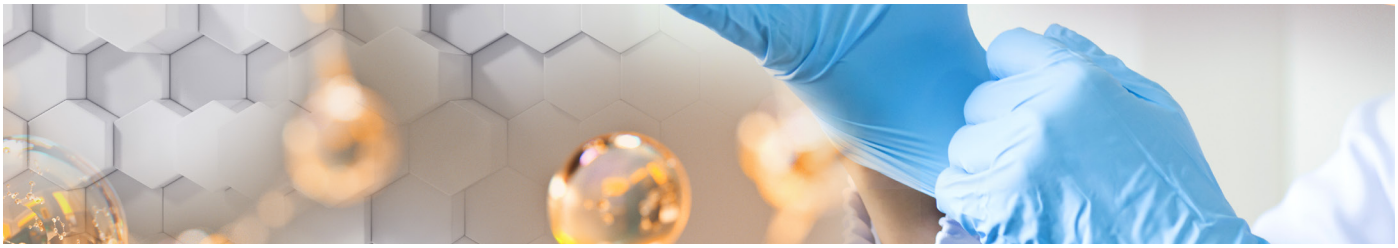
How to Use This Workbook

This booklet is part of an educational series offered by Bio-Rad, designed to improve your knowledge of Quality Control (QC) materials. The workbook contains educational content as well as practice evaluation exercises.

A Certificate of Completion will be made available to you after successful completion of a short exam. Please see page 17 for details and link to the exam.

Bio-Rad proudly supports laboratory professionals and the commitment to achieving a higher standard of quality for improved patient test results. We are dedicated to the ongoing development of educational materials to support each laboratory's quality journey.



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Introduction

Achieving quality in the medical laboratory requires the use of many tools. These include procedure manuals, maintenance schedules, calibrations, a quality assurance program, training, continuing education, competency assessments, and quality control materials.

Important parts of quality control in the medical laboratory are identification of proper quality control materials, and the statistical process, used to monitor and evaluate the analytical process. The goal of quality control materials in the laboratory is to have products that are used in the same manner as patient samples so that they can help assure that the test systems are functioning appropriately and producing high quality patient results.

In this workbook, the background and use of different types of quality control materials are explained.

What Will You Learn?

- To differentiate between open-vial stability and shelf-life stability
- To differentiate between liquid and lyophilized quality control materials
- To understand the criteria to consider when selecting quality control material
- To differentiate between independent and dependent quality control materials
- To choose and/or recommend control materials based on shelf life, open-vial stability, clinically relevant decision levels and an interlaboratory comparison program

Background

Quality control data are produced by testing quality control materials in the same manner as patient samples. QC materials are available in various concentrations.

The most common concentrations used in medical laboratory testing are a normal concentration for the analyte of interest and abnormal high and/or low concentrations.

Typically, laboratories test both normal and abnormal concentrations of control materials each day. For qualitative molecular tests, negative and positive controls are tested at a frequency consistent with compliance requirements. For quantitative molecular tests, negative, low positive, and high positive controls are tested with each patient run.

The Quality System

A robust quality system permeates all laboratory activities – from the point of the test order and patient reception to the analytical bench, ending with the test result report to the caregiver. Laboratories should implement a quality control plan which defines and monitors all aspects of testing based on the potential errors identified during the risk assessment, including the following parameters:

- Frequency of quality control
- Criteria for acceptance performance (e.g., instrument calibration, reagents, and quality control)
- Specimen quality
- Instrument maintenance and function checks
- Training and competency of testing personnel

There are three phases of the testing process: pre-analytical, analytical and post-analytical.

- The pre-analytical phase covers test ordering, specimen collection, accessioning of the collected patient specimen, transportation, processing of the specimen
- The analytical phase covers performing the test on the processed sample
- The post analytical phase covers the review and interpretation of the results, reporting the results (including report content), and the retention and disposal of patient specimens

The laboratory can implement a variety of systems and processes to assure that quality is maintained throughout all three phases of the testing process. One of the most important parts of the overall laboratory quality system is the *Quality Control Procedure*.

The Quality Control Procedure consists of the following:

- Quality control materials
- Statistical process control
- Retrospective review of data

QC results are used to evaluate whether a test system (including instruments and assay reagents) is operating within pre-defined specifications, inferring that patient test results are reliable.

In this workbook, focus is given to the background, types, selection, and use of quality control materials.

Types of QC Materials

Quality control material is designed to be similar to patient sample ideally made from human serum, whole blood, plasma, urine, spinal fluid, or other body fluids. A large amount of laboratory data that is used in calculation of laboratory statistics comes from the routine testing of quality control materials. There are also other types of quality controls, which are surrogate controls, such as electronic signals, glass filters, or reference cassettes that are mostly used in point of care testing devices. These typically evaluate the photometric, electronic, and computational component of the test system. Electronic quality controls do not evaluate chemical reactions, sample, and reagent performance.

Independent and Dependent Quality Controls

Dependent controls are control materials developed and formulated to be run on specific test systems. These may be made by the test system manufacturer (sometimes called “first party controls”) or contracted out to another company (sometimes called “second party controls”). The use of dependent controls is defined in the package insert for the test kit and its description of use of these "in-kit" controls must be followed by the laboratory.

Independent controls are control materials developed without direction or aid from the manufacturer of the test system. The QC formulation of these QC materials is developed entirely by an independent company and typically can work on multiple test systems and across any reagent lots. These controls are frequently called “third party controls.”

Independent controls may pick up errors that go undetected by dependent control materials. Dependent controls are often designed and manufactured based on the specific test method, this means these dependent controls might be based on the calibration materials or reagents used in the test system. This dependency might prevent the dependent control from detecting specific errors like material degradation or reagent linked changes. As a result, independent control materials may be suited to mimic how a patient sample interacts with the test system and provide an unbiased assessment.

Independent control manufacturers typically use human sources for the analytes in control materials. They are often made from human materials such as serum, plasma, whole blood and urine.

Guidelines

The value of using third party independent quality controls is emphasized by different guidelines. Below are three examples of guidance related to the use of independent quality controls:

ISO 15189: "Use of third-party internal quality control material should be considered, either as an alternative to, or in addition to, control material supplied by the reagent or instrument manufacturer."[1]

CLSI C24: "QC materials should be different from the calibrator materials to ensure that the QC results provide an independent assessment of the measurement procedure's performance in its entirety, including the procedure for calibration."[2]

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."[3]

Note: In addition to commercially purchased QC, a quality control material could also be made by the laboratory itself, referred to as "laboratory developed/home brewed QC". This type of QC material could be less stable over a longer timeframe. Potential challenges in making in-house QC are obtaining adequate patient samples to make the QC, the time involved to produce and standardize the material, and difficulty in achieving high lot-to-lot consistency.

Self-Test

Determine if the following quality control materials are dependent or independent.

- **Test system manufacturer "A" made their own quality control materials to run on their test system**

  Click for answer — **Dependent**

- **Company "B" is developing a quality control product with its own formulation that can work on multiple manufacturers' test system platforms**

  Click for answer — **Independent**

- **Test system manufacturer "C" is contracting out the manufacturing of quality control materials according to a provided formulation that will be run on its own test system platforms**

  Click for answer — **Dependent**

[1]ISO 15189. Medical laboratories - Requirements for quality and competence. Geneva, Switzerland: International Organization for Standardization; 2022.ISO 15189:2022. Subclause 7.3.7.2.
[2]CLSI (Clinical Laboratory Standards Institute) C24-A4, Statistical Quality Control for Quantitative Measurement Procedures: Principles and Definitions; Approved Guideline - Fourth Edition 5.2.5 Relation to Calibrators.
[3]AS 4633 (ISO 15189) Field Application Document - Supplementary Requirements for accreditation in the field of Medical Testing, NATA, July 2009.

Liquid, Lyophilized

Quality control materials could be in a liquid or lyophilized (freeze-dried) state. Lyophilized controls have good stability and shelf life, but need to be reconstituted prior to use. Since this is a manual process, it is time-consuming and could be error-prone if performed inconsistently. For liquid controls, no reconstitution is necessary, but are often frozen and need consistent temperature control. The choice between liquid or lyophilized quality controls lies within the laboratory. Some laboratories prefer liquid controls because they are convenient and merely require a thaw and no reconstitution.

Composition, Concentration

A quality control product may contain one or more analytes. For example, a general chemistry control can contain any number of chemistry analytes including, for example, potassium, glucose, albumin, and calcium. Most laboratories prefer to have as many analytes as possible in each control material for convenience to reduce the number of controls that need to be tested. However, control materials should contain the analytes of greatest interest to the laboratory. When selecting a QC material, different aspects can be taken into consideration. It is important to find the right choice for specific needs and for balancing the different variables. As an example, it can be convenient to have 120 analytes in one QC product vial, but when only using 20 analytes out of 120 in a laboratory, the 120-analyte approach may not be cost efficient. As another example, a health system with multiple chemistry platforms across their laboratories may find it advantageous to buy a chemistry QC material with many analytes that meets the needs of their health system. For certain labs, it may be more appropriate to have a less consolidated product. The individual situation of the laboratory will determine which will be the right choice for the specific needs.

When choosing control materials for the laboratory, the menu of analytes and the estimated concentration for each analyte are essential and important considerations. Control materials can come in three concentrations: normal, abnormally high, and abnormally low (or negative, low positive, and high positive controls for quantitative molecular tests). Some control materials have normal and abnormal concentration (or negative and positive). It is important that each analyte be at a clinically important or relevant concentration, (i.e., at the medical decision point) whenever possible.

It may be difficult to find all analytes at relevant concentrations. The purchase decision should be made on a product that most closely meets the laboratory's needs. Some quality control materials are delivered in ready-to-use tubes with barcodes. These can be directly loaded on the platform and will automatically be recognized (for type and lot number) by the instrument. Manual handling steps (program control information, labelling, pipetting and aliquoting) are significantly reduced, which lowers the risk of errors.

Quantitative, Semi-Quantitative, and Qualitative Tests

The type of quality control that will be used is also dependent on the type of test that is run in the laboratory. There are different types of tests: quantitative, semi-quantitative and qualitative tests.

Most controls contain analytes that can be measured as a quantity, and reported numerically, such as 100 mg/dL (100 milligrams per deciliter) for a chemistry analyte. Control materials formulated in this way can be used for quantitative tests.

Semi-quantitative methods are tests that yield an approximation of the quantity and report results as a range of measurement, such as 10-50 mIU/L (milli-International Units per liter). Some manufacturers produce control materials specifically for these semi-quantitative methods.

Qualitative tests give a result that is more descriptive, with an indication of whether an analyte is present or not; or if a test is positive or negative. For some qualitative assays, the data can be represented quantitatively, such as Ct values, signal/cutoff, etc. When this is the case, QC data can be managed with the same approach as quantitative results in the data management software.

Self-Test

Determine if the following tests are quantitative, semi-quantitative or qualitative.

- Pregnancy test of human chorionic gonadotrophin (HCG) in the patient's urine (positive / negative) — Click for answer — **Qualitative**
- +1 +2 +3 +4 indication (interval scale) of hemolysis interference — Click for answer — **Semi-quantitative**
- Glucose measurement in blood (mg/dl) — Click for answer — **Quantitative**
- Potassium in serum (mmol/l) — Click for answer — **Quantitative**
- Detected or not detected COVID-19 (SARS-CoV-2) antibody test saliva (detected / not detected) — Click for answer — **Qualitative**

Selection of QC Materials

Many different quality control materials are available for laboratories. Choosing the right quality control product requires careful consideration. It may be tempting to purchase the least expensive product. Unfortunately, the cheaper alternative may exhibit significant limitations, such as a short shelf life or open-vial stability. A reduced open-vial stability can result in unnecessary waste if the laboratory cannot use all the material before it expires. Other materials may not be sufficiently like patient specimens (e.g., serum or urine). This can cause problems with some test systems because these materials do not interact with the test system in the same manner as a patient specimen.

This chapter features descriptions of factors that can be taken into consideration when selecting a quality control material, including open-vial stability, shelf life, pricing/volume, matrix, medically relevant decision levels, interlaboratory comparison programs and data management.

Open-Vial Stability

When purchasing a quality control product, it is important to know the approximate volume of the control to be used each day to determine the open-vial stability requirements. Open-vial stability refers to the amount of time, after being opened, that the QC remains stable, and analytes do not degrade. For example, consider a general chemistry control material that can be purchased in 10 mL vials. Laboratories that use 10 mL or more per day would be less concerned with open-vial stability for this product. But for those laboratories that use a lower volume of control (1 mL/day for example), open-vial stability becomes an important issue.

Quality control open-vial stability should match or exceed the laboratory's normal usage rate to avoid waste. For example, a laboratory that purchases a quality control product that offers only a five-day open-vial stability, when the lab's usage rate would require 10 days to fully use the product, will waste 50% of the product. Consequently, if a laboratory paid $0.18/mL for the product, the actual cost based on usage becomes twice that or $0.36/mL. A more cost-efficient option would be to purchase a quality control product that offers a 10-day open-vial stability for all analytes, even though it may be a higher price. In this example, quality control material with the same analytes and a 10-day open vial stability, at the higher price of $0.28/mL is a better value.

Interlaboratory Comparison Programs and Data Management

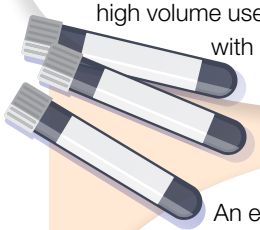
Participation in an interlaboratory quality control comparison program is highly recommended. In such programs, laboratories anonymously submit QC results for different assay/platform combinations. This allows participating laboratories to compare their QC results with peer labs using the same test systems. One of the easiest methods to assess trueness and imprecision is to compare the within-laboratory method means and standard deviations with other laboratories (peer group) using the same instrument and method. Confirmation that the QC manufacturer provides an interlaboratory comparison program and the number of laboratories that use the program are important factors to consider when selecting and purchasing QC materials. Without such programs, the laboratory becomes a statistical island and has no means to regularly verify the reliability of its work in reference to other laboratories.

Easy access to QC data management software can help achieve greater efficiency, allowing laboratories to identify trends and make corrections before results are compromised. More specifically, this will help with data review and run validation and provide access to advanced charts and reports for data analysis. Access to a QC software package is an additional factor to consider when making the decision about which type of QC material to choose.

Selection criteria based on laboratory type

Reference Lab

As a reference lab with 4 high throughput analyzers, we prefer quality control materials that are consolidated, with a significant amount of analytes. Open-vial stability is not so important to us, as we have high volume use. The shelf life is important to us – with a long shelf life we limit crossover costs.



An easy-to-use data management QC software, that gives specific access to all team members (each with their own log-in), is important to us. As an accredited lab it is important for us to follow and track all steps of our QC process. We also create greater efficiency. Interlaboratory comparison program also helps us to compare to our peers around the globe. We prefer QC materials where no reconstitution is necessary and ideally in barcoded tubes, as the instrument has QC onboard storage.

Small Lab

We are a small lab, with one analyzer. The open-vial stability is an important factor when choosing a quality control material. As we are using a limited amount of QC each day, we try to optimize the usage of the complete vial over multiple days. For our menu of tests, we try to minimize the amount of separate QC material vials by choosing consolidated products.

The data management software helps us to identify trends and make corrections if appropriate. It is important to us to compare to the interlaboratory group to evaluate our performance.

Shelf Life

Another important factor to take into consideration when buying quality control materials is shelf life. Shelf life in this context refers to the expiration date of the unopened product. A long shelf life provides the ability to measure performance over a long time, including reagent and calibrator lot changes. A longer shelf-life results in fewer QC lot change studies that need to be performed. Fewer crossover studies also, ultimately result in a lower cost.

Pricing/Volume

For quality control products, the pricing can be based on various factors. Specific pricing models can be dependent on the volume within the individual vials, or the specific number of vials included in a box. Higher vial fill volumes can be less expensive but can run the risk of less optimal usage and waste. It is recommended to have an idea of the cost of the quality control product per mL and use this information when comparing QC materials.

Matrix

The primary purpose of a control material is to evaluate a testing procedure's ability to perform as expected and to confirm that the patient test results are suitable for use in providing medical care. When choosing a quality control material, it is important to choose a product that matches the matrix of the patient sample as closely as possible. The matrix is the substance that contains the measuring analytes. If a chemistry analyzer tests glucose on both serum and urine samples, QC material for each of these matrices should be used.

Self-Test

Open-vial stability and price/volume

Evaluate the different quality control products that are available, and choose the optimal product for the individual laboratories.

Quality Control Product A

Vial size: 10 mL
Open-vial stability: 5 days
Price:

Quality Control Product B

Vial size: 20 mL
Open-vial stability: 10 days
Price:

Quality Control Product C

Vial size: 10 mL
Open-vial stability: 10 days
Price:

Which quality control product to choose?

Laboratory X

Usage: 1 mL/day

Product C

Click for answer

Laboratory Y

Usage: 2 mL/day

Product B

Click for answer

Laboratory Z

Usage: 3 mL/day

Product B

Click for answer

Medically Relevant Decision Levels

It is important that the analyte concentration of quality control materials be at clinically relevant levels.

As an example, assume a laboratory's objective is to purchase a trilevel (three level) quality control that allows the lab to "control" (evaluate) the method curve for low thyroid stimulating hormone (TSH) (<3.0 µIU/mL), normal TSH (between 3.0 µIU/mL and 10 µIU/mL) and abnormal high TSH (>10 µIU/mL). The lab's instrument has a reportable range up to 50 µIU/mL.

A quality control vendor offers an immunoassay control with three levels:

- Low Level (1.03 - 1.23 µIU/mL)
- Normal Level (7.5 - 9.6 µIU/mL)
- High Abnormal Level (27.9 - 34.5 µIU/mL)

This product meets the laboratory's diagnostic criteria. It contains three distinct levels at the decision limits used by the laboratory.

A second vendor also offers a trilevel product, but for a reduced price:

- Low Level (3.0 - 5.0 µIU/mL)
- Normal Level (8.0 - 10.0 µIU/mL)
- High Abnormal Level (45 - 55 µIU/mL)

In this case, the less expensive product does not cover low TSH because the level is higher than the laboratory decision limit. Furthermore, it does not provide adequate control on the high end of the curve because the level for the high control may exceed the reportable range.. The price is lower, but the product provides less value.

Note: It is often difficult to find a perfect quality control product for every instrument, kit or method available. When deciding on a quality control vendor, assess the entire test menu of the instrument or department. As an example, assume the immunoassay instrument used in a laboratory has a test menu that includes about 50 different hormones and therapeutic drugs. One quality control product which may be more expensive provides trilevel diagnostic utility for 45 analytes. A less expensive product may provide true trilevel utility for only 30 of the 50 analytes of the test menu. It may be not cost-effective to buy the less expensive quality control that has fewer analytes, as other materials will need to be purchased or made in-house to cover the missing analytes.

Other Considerations When Choosing a Quality Control Product

While the pricing and appropriateness of analyte concentrations are important, the quality control product purchase decision should also take into consideration the value of other value-added services such as QC technical and educational support provided by the manufacturer. Another important evaluation to consider is checking whether the manufacturer has ISO (or other) certifications to indicate consistency in the observance of quality standards.

Handling of QC Materials

In this chapter, key points and suggestions on the usage and handling of control materials are described. Country regulations and/or local guidance documents, product inserts and instructions for use can provide more specific background and guidance.

Processing Steps

Control materials are tested along with patient samples and should undergo all pre-treatments (if any) just like a patient sample. For example, if a patient sample goes through an extraction process, the control material should also go through the same process as well, if possible. (Note: It may not be possible in every case to find a control material that can undergo a specific pre-treatment process, but it is important for the laboratory to make that determination and use materials that can mimic the patient sample processing as much as possible).

Product Inserts

Product inserts for control materials provide a variety of important information. Printed paper inserts may be shipped with the product, but most manufacturers today have moved product inserts to an online, digital format. Product inserts are used to publish claims associated with each lot number of the control material. Claims typically include:

- The stability for specific analytes after reconstitution or thaw
- The expiration date (shelf life)
- The open-vial stability of the product
- Instructions for reconstitution or thawing
- For quantitative products, an estimate of the mean for each analyte along with a range of acceptable means if it is an assayed control

The published means and ranges are derived by replicate analyses and are specific for each control lot. The published insert ranges are +/-2s or +/-3s range, unless specified by the manufacturer. Typically, they are derived from a variety of sources (such as clinical laboratories or instrument manufacturers) to determine the values (along with the manufacturer's value assignment, if any) and therefore represent interlaboratory, not intralaboratory, performance.

It is recommended that each laboratory establish its own acceptable ranges and use those provided only as guides. Laboratory-established ranges may vary from those listed in the package insert during the life of a QC product. Variations over time and between laboratories may be caused by differences in laboratory technique, instrumentation, reagent lots and calibrator lots or by the manufacturer's test modifications.

Reconstitution

Always follow the manufacturer instructions for reconstitution of the control material. If reconstitution requires the use of a calibrated volumetric pipette to deliver a specific amount of diluent, using a non-calibrated pipette is unacceptable. Use care and caution when mixing a control to dissolve the lyophilized pellet into a solution. Specific reconstitution procedures are contained in the Instructions for Use (IFU) of each specific quality control product.

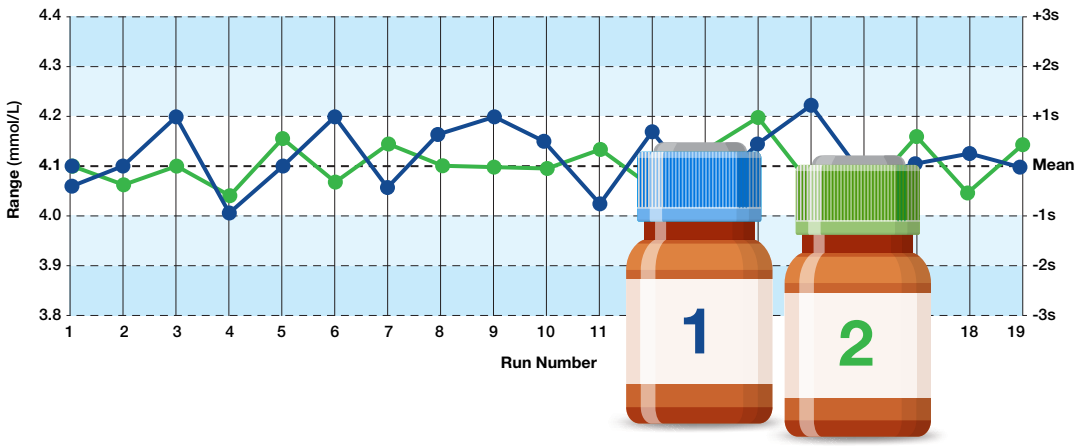
Levels

The medical decision point should determine whether to test the abnormal high or low control. If the decision point is at a low level, the abnormal low control should be tested. If the decision point is at an elevated level, the abnormal high control should be tested. Normal control is always tested because most patient results fall within the normal range. For quantitative molecular tests, negative, low positive, and high positive controls are tested with each patient run.

Many guidelines recommend running two levels of control for each day of patient testing. It's common to run a normal and abnormal level (or positive/negative for qualitative tests). Some laboratories may for some tests routinely test an abnormal low control and an abnormal high control, assuming that if the low and high controls are in control then the normal range will be in control as well. This assumption may work for some linear methods, but it is not recommended for all analytes. Two levels may not be sufficient for non-linear methods. Non-linear methods often require three controls to cover the full measurement range. Most immunoassay and toxicology tests have these curves, and they might need a three-level control.

Control material corresponding to abnormal values should be tested based on the patient test results produced. If a lab routinely tests an abnormal high control but does not test a low control and the batch of patient samples being tested has one or more low results, then a low abnormal control should be tested as well.

It is recommended that laboratories use a minimum of two levels of QC.



Storage and Handling

The quality control product IFU will also contain information regarding appropriate storage and handling procedures. Before a laboratory decides to aliquot and freeze quality control material, the product insert should be reviewed to ensure the manufacturer states that this is acceptable. Some refrigerated and even frozen materials may not remain stable when frozen or thawed and re-frozen. To eliminate temperature fluctuation during long storage, avoid using a frost-free freezer.

If the control product is to be kept refrigerated after thawing or reconstitution, do not allow the material to remain at room temperature by sitting too long on the workbench and never use a control product past its expiration date.

Frequency

While the frequency of testing quality controls is an important decision to make, it rarely is part of the criteria for selection of QC materials, except as it relates to volume needed. Regional guidelines and/or government regulations may provide guidance on QC use and frequency. As with any regulations or guidelines, the requirements are regularly reviewed and often updated. Laboratories should periodically review the applicable documents to ensure they remain in compliance and are following current guidance.

Training

The use and handling of QC materials is an important activity that has a direct impact on the analytical performance of the laboratory. Therefore, all the steps involved – from preparation, use, analysis, review, follow up and storage of quality control materials – should be followed very meticulously. All the individual steps should be noted in operating procedures.

Continuing education is an important part of maintaining laboratory quality. A good QC provider can be a source of education and training on QC theory and good lab practices.

Guidelines/Standards

There are country/regional specific guidelines as well as international standards and guidelines that are not discussed in this workbook. These guidelines are typically published by standards development organizations, local bodies, and professional societies and organizations. Depending on a lab's local situation, it is important to take these additional guidelines into consideration.

Final Examination

When you are ready, click on the link below to take the final exam. A certificate of completion will be awarded to anyone who scores 70% or higher. To receive P.A.C.E. credits, please fill out the survey.

Link to Final Examination

Bio-Rad Laboratories is approved as a provider of continuing education in the clinical laboratory sciences by the P.A.C.E. Program through the American Society of Clinical Laboratory Science. This basic to intermediate self instructional course is approved for 2 contact hours. This course is also approved for California clinical licensees under the P.A.C.E. California Accrediting Agency License No. 0001.

Medical Laboratory Vocabulary

Because official scientific definitions are often sourced to international standards, they can often be complicated and potentially confusing for an introductory workbook. The following collection of glossary terms are defined here in layperson's terms.

A

Aliquot
A specific amount of material that has been removed (usually by a pipette) from a larger quantity of that material.

Analyte
Commonly used term to identify the component of a patient specimen that is being detected in a medical laboratory test.

C

Calibration
Process where the response that is obtained is compared with or adjusted to the known response of a specimen.

Concentration
The amount or quantity of a substance contained within a matrix.

CLSI
Clinical Laboratory Standards Institute.

Control Materials
See Quality Control Materials.

Crossover Studies
The process utilized when a new lot of quality control material is put into use. The material is tested alongside the quality control materials currently in use. One example would be when the values for a new lot number used in statistical process control are verified by being compared with the current lot.

Ct Value
Cycle threshold value is the number of cycles required for the fluorescent signal to exceed background levels in a real time polymerase chain reaction (PCR).

H

Hemolysis
Interference factor that occurs when the red blood cells rupture and release their contents into surrounding fluid. As a result, hemolysis causes a reddish hue in the plasma, serum and may cause false results in some tests.

I

Interlaboratory
Between multiple laboratories.

Interlaboratory Comparison Programs
Program methodology is used to assess reliability and imprecision through comparison with other laboratories (peer group) using the same instrument and method.

ISO
International Organization for Standardization.

ISO 15189
International standard of practice for medical laboratories: requirements for quality and competence.

L

Levels of Control

Another way to refer to control materials of different concentrations.

Lyophilize(d)
A process used to freeze-dry quality control materials. Lyophilized materials require reconstitution before they can be used.

M

Matrix

A substance that contains other constituents. For example, a human matrix such as serum or plasma contains elements such as calcium and potassium as well as proteins such as thyroglobulin.

N

NATA

National Association of Testing Authorities (Australia).

P

Peer group

A group that shares common characteristics. For statistical process control, a peer group consists of laboratories that use the same instrument, reagent, method and units of measure for a particular test.

Photometry

Measurement of light absorbed, used to determine the amount of an analyte in a test solution.

Plasma

Clear (if separated) yellowish circulatory fluid of the blood (contains anticoagulant) that carries water, salts and enzymes.

Q

QC Data Management Software

Software tools that help to review data, identify trends and provide charts and reports for data analysis.

Quality Control (QC)

A process that uses materials of known value, reaction or performance along with preset parameters (often statistical in nature) to monitor the reliability of medical laboratory testing.

Quality Control Materials

Liquid or freeze-dried (lyophilized) materials that are tested alongside patient samples to verify that the system analytical performance meets expectations and that results for patient samples are suitable for intended use.

R

Reagent

A substance is added to a system, causing a chemical reaction, often used to indicate the presence of another analyte.

S

Statistical Process Control (SPC)

A process that uses basic statistics such as mean and standard deviation to construct a framework for monitoring the quality of laboratory testing.

Serum

Clear part of the blood (when blood cells and clotting proteins have been removed).

T

Test System

Includes the instrument, reagents, calibrators, sampling mechanism, measurement modules etc.

TSH

Thyroid Stimulating Hormone.

V

Vial

Small container, often made of glass, used for holding liquid.

W

Whole Blood

Whole blood contains white blood cells, red blood cells, and platelets suspended in blood plasma.

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