# Optimize quality control across the clinical lab

Best practices and smarter sourcing for clinical measurement success

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# Introduction

**Clinical laboratories are at the very center of modern healthcare. Every diagnosis, treatment decision, and public health response depends on the accuracy of the results they produce. Quality control (QC) is what underpins that accuracy, ensuring patient samples are measured consistently and reliably. When QC breaks down, the consequences are immediate: delayed treatments, wasted resources, misdiagnoses, and loss of patient trust.**

Over the past decade, the role of QC has grown in complexity. Advances in molecular testing, high-throughput platforms, and personalized medicine have expanded laboratory capabilities but also increased the pressure on systems that guarantee quality. During the COVID-19 pandemic, labs faced extraordinary demand surges, shortages of consumables, and the urgent need for validated controls to ensure accuracy at scale. That crisis underscored what many lab managers already knew: that sourcing, maintaining, and applying reliable QC materials is as much a strategic challenge as it is a scientific one.

Today's labs must meet rising regulatory standards and deliver faster turnaround times, often with leaner teams and tighter budgets. This balancing act places enormous pressure

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on lab directors and quality managers to ensure that their QC strategies not only meet current regulatory requirements but are also resilient, scalable, and sustainable.

**Pressures and challenges in sourcing**

Every QC process depends on quality measurement materials. Choosing the right controls and calibrators is not straightforward. Labs must consider technical performance, lot stability, supply reliability, and regulatory compliance, while also managing costs. Each of these factors carries its own risks.

For example, inconsistent lot-to-lot performance can disrupt trending data and complicate long-term quality monitoring. Delays in supply or discontinued products can force labs into emergency revalidations, consuming time and staff effort. Even when materials are available, they may not always align with the exact needs of the assay platforms in use.

The complexity grows further when you consider the range of tests modern labs perform. A single laboratory may run routine chemistry assays, high-sensitivity troponins, molecular tests, and next-generation sequencing, all requiring distinct controls. Coordinating the sourcing and validation of these materials across departments can strain budgets and staff alike. And because laboratory medicine is highly regulated, labs cannot afford to cut corners. Every material must not only work but be demonstrably reliable.

**Meeting challenges through best practices**

The strongest laboratories approach QC proactively. They put systems in place to evaluate materials consistently, qualify vendors carefully, and monitor performance continuously. They also recognize the value of smarter resourcing. Working with partners who provide stable, well-documented, and cross-platform compatible materials reduces the validation burden and safeguards against supply disruptions.

This shift, from transactional buying to strategic partnership, is a best practice in itself. Vendors like LGC Clinical Diagnostics act not just as suppliers but as collaborators, providing the materials, technical support, and regulatory alignment that labs need to maintain confidence in their results. That kind of relationship helps labs stay resilient in the face of growing demands.

**Importance of best practices**

Regulation sets minimum standards. Best practices set a higher bar. They create systems that are efficient, reliable, and adaptable.

Effective QC best practices include:

• Technical rigor: thorough validation, long-term trending, and use of independent controls.

• Operational efficiency: reducing redundant validations and simplifying vendor management.

• Risk management: securing stable supply and planning for contingencies.

• Staff development: training teams to interpret data and solve problems quickly.

• Partnership building: choosing suppliers that align with the lab's priorities.

These practices protect the accuracy of results, preserve credibility, and free up resources. Errors at the testing stage can lead to false positives or false negatives, each with serious consequences. Strong QC practices safeguard against those risks and build trust among clinicians and patients.

Best practices are also dynamic. As automation, informatics, and digital health tools evolve, so must QC strategies. The laboratories that succeed will be those that treat best practices not as a checklist but as a continuous cycle of improvement.

***This eBook is designed to help laboratories navigate these challenges with clarity. It outlines the pressures surrounding QC, highlights the value of best practices, and shows how smarter sourcing and strategic partnerships can help. The following sections include insights from whitepapers, case studies, and product overviews that together provide a roadmap for strengthening QC across the clinical lab.***

**Best practices for clinical labs**

Quality control is more than a regulatory requirement. This best practices whitepaper shows that lasting success begins with culture. When staff are encouraged to report issues and supported through documentation, CAPA, and training, errors are caught early, and improvements endure.

Measurement is also equally important. Tracking a handful of KPIs, turnaround times, repeat test rates, and instrument uptime, helps labs act on data rather than collect it. Mapping workflows and automating repetitive steps reduce error and free staff for critical work.

Independent, third-party controls are highlighted as essential. Unlike in-kit controls, they detect subtle assay drift and enable long-term trending, especially when sourced in large, stable lots. This independence elevates compliance into best practice.

**Diagnostic errors**

This diagnostic errors whitepaper addresses the impact of quality lapses. Errors in ordering, collection, processing, or reporting remain leading causes of patient harm, with most tied to the testing process itself.

Staff shortages, burnout, and rising volumes compound these risks, resulting in missed diagnoses or unnecessary treatments. Solutions include stronger feedback loops, multidisciplinary reviews, and ready-to-use controls that reduce staff burden. Equally important is fostering a culture of education and open communication so teams can maintain high standards under pressure.

**Informatics security comparison**

This informatics whitepaper explores the choice between local on-premises and cloud-based QC systems. On-premises solutions offer direct control but often lag in updates and disaster recovery. Cloud platforms, when managed correctly, provide stronger redundancy and security, though they require careful vendor vetting and configuration.

The paper recommends viewing informatics as part of QC, not just IT. Encryption, access controls, multifactor authentication, audit trails, and exit strategies are essentials. The right choice depends on lab size, IT maturity, and regulatory environment, but the message is clear: security and quality are inseparable.

Together, the three papers outline a framework: to build a culture of quality, use independent controls and stable lots, track meaningful KPIs, streamline workflows, and treat informatics as a quality tool. Best practices evolve as technology and demands change, but labs that view them as a culture of improvement rather than minimum compliance will remain resilient.

**The hidden cost of multi-vendor sourcing**

On the surface, sourcing QC materials from multiple vendors seems like a smart way to diversify supply. In practice, it often introduces hidden costs. Each vendor means different product formats, varying documentation, and multiple validation cycles. Inventory management becomes more complex, and lot-to-lot differences make long-term trending more difficult. Inconsistencies between controls from different suppliers can even mask early signs of assay drift.

There are also operational burdens: staff must be trained on multiple product lines, vendor relationships must be managed separately, and technical support is fragmented. All of these hidden costs add up, potentially outweighing any perceived savings from spreading purchases across suppliers.

**Benefits of streamlining sourcing**

Streamlining to a single strategic supplier can bring clarity and efficiency. With larger lot sizes and consistent materials, labs reduce the frequency of revalidation and simplify trending analysis. Vendor support becomes more responsive when it is concentrated, and supply chain resilience improves when a trusted partner is invested in the lab's long-term success.

Most importantly, consolidation reduces the total cost of ownership. While the unit cost of materials may be similar across vendors, the savings from fewer validations, reduced downtime, and simplified training are significant. Strategic partnerships also open the door to collaborative problem-solving – something that

transactional, multi-vendor sourcing rarely delivers.

## How LGC Clinical Diagnostics can help you meet QC best practices

**Multichem**

The Multichem® range offers consolidated, independent quality controls designed to simplify inventory and reduce cost while covering an exceptionally broad menu of analytes. Flagship products such as Multichem® IA Plus for Immunoassay QC and Multichem® S Plus for Clinical Chemistry QC bring together controls that competitors sell separately into multi-analyte formats. By streamlining multiple controls into one, Multichem improves efficiency, supports robust trending across a wide assay range, and helps laboratories maintain flexibility without sacrificing quality. Learn how PathCare Laboratories, South Africa, has benefitted from using Multichem controls and IAMQC® Peer for QC data management informatics in this case study.

**VALIDATE and AccuTrak**

VALIDATE® and AccuTrak™ kits set the standard for calibration verification and ongoing method performance monitoring. These instrument-specific solutions are ready to use, stable over months, and formulated to cover the full reportable range with minimal dilutions. Whether used at installation, for preventive maintenance, or for troubleshooting, they allow laboratories to confirm assay accuracy, fulfill regulatory requirements, and maintain confidence in instrument performance. By reducing the need for manual preparation and repeat ordering, VALIDATE and AccuTrak free up staff time while ensuring assays meet specifications day after day.

**ACCURUN**

As a leader in low-positive molecular and serology controls, ACCURUN® products are designed to challenge assays at the points where performance matters most, near the clinical decision thresholds. These full-process independent controls mimic patient samples from extraction to detection, helping labs detect subtle performance drifts, lot-to-lot variability, and potential false results. By operating at the lower limits of detection, ACCURUN provides a rigorous safeguard against missed or incorrect calls, giving laboratories greater confidence in both molecular diagnostics and serological testing.

**Detectabuse, Salivabuse and Pregnancy-Skreen**

For toxicology and pregnancy testing, the Biochemical Diagnostics line delivers external controls that provide unbiased verification across multiple methods and devices. Detectabuse® urine controls and Salivabuse® oral fluid controls cover a wide spectrum of drugs, including synthetic THC and nicotine, while remaining DEA exempt and FDA cleared for broad accessibility. Pregnancy-Skreen® liquid controls are compatible with all market test devices, offered in convenient liquid formats that reduce handling and error. Together, these products ensure reliable monitoring of high-impact, point-of-care, and screening assays.

**KOVA Urinalysis Controls**

KOVA® sets the benchmark in urinalysis QC, providing daily, ready-to-use controls that address both macroscopic and microscopic examination. KOVA-Trol®, a human urine–based control with simulated cells, is available in three levels to cover abnormal and normal presentations. KOVA Liqua-Trol® offers liquid controls with added urobilinogen, cutting down on preparation time while maintaining consistency. Both ranges support laboratories in maintaining accuracy across routine urinalysis, one of the most frequently performed diagnostic tests worldwide.

**IAMQC Infinity: Transforming QC Data into Strategic Insight**

IAMQC® Infinity elevates quality control by advancing beyond materials into informatics, delivering a centralized, web-based platform engineered for clinical laboratories. Fully compatible with the Multichem range, Infinity enables automated data capture, harmonized workflows, and real-time performance monitoring – ensuring precision and

consistency across the QC process.

Equipped with intuitive dashboards and built-in configuration tools, IAMQC Infinity simplifies setup and minimizes manual data entry, reducing staff burden and operational costs. Features such as **customizable Westgard rules**, **reagent lot verification**, **two-tier review**, and a **visual traffic light system** provide laboratories with actionable insights at a glance. Its integration with **IAMQC Peer** provides real-time inter-laboratory benchmarking and reporting – empowering labs to validate performance and drive continuous improvement with confidence. As laboratories navigate increasing demands for efficiency, standardization, and regulatory compliance, Infinity serves as a strategic enabler – transforming QC data management into a catalyst for continuous improvement and measurement excellence.

***Explore further practical guidance, evidence from recent whitepapers, and examples of how smarter sourcing strategies can strengthen quality control in the resources below.***

# Featured products

**Explore LGC Clinical Diagnostics' range of Reference Materials & Quality Controls**

## Multichem® Independent Quality Controls
**by LGC Clinical Diagnostics**


The Multichem range offers consolidated, independent quality controls designed to simplify inventory and reduce cost while covering a broad menu of analytes.

## Reference Materials & Quality Controls with ACCURUN®
**by LGC Clinical Diagnostics**


ACCURUN low-positive molecular and serology controls products are designed to challenge assays at the points where performance matters most, near the clinical decision thresholds.

## DETECTABUSE®
**by LGC Clinical Diagnostics**


Detectabuse urine controls cover a wide spectrum of drugs and have been used in drug of abuse testing since 1991.

## Urinalysis Controls with KOVA-Trol®
**by LGC Clinical Diagnostics**


KOVA sets the benchmark in urinalysis QC, providing daily, ready-to-use controls that address both macroscopic and microscopic examination.

## VALIDATE® Calibration Verification & Linearity
**by LGC Clinical Diagnostics**


VALIDATE and AccuTrak kits set the standard for calibration verification and ongoing method performance monitoring.

# Best Practices for Clinical Labs: Strategies for Implementing a Best-in-Class Quality Control System

Clinical testing labs thrive on consistency, predictability, and efficiency. Lab directors endeavor to establish a steady rhythm of receiving samples, running tests, and reporting results accurately. This is how trust is earned and maintained with clinicians. It's also how resources – people, equipment, and budgets – are maximized.

What lab directors worry about most is disruption. Throughput, reproducibility, and reliability are critical, as anything that disrupts the workflow of a lab or introduces uncertainty into results can spell disaster.

Incorporation of a robust quality management system (QMS) is every clinical lab's "insurance policy" against disruption and uncertainty. This paper provides some important considerations when crafting a best-in-class quality control program.

## CREATE A CULTURE OF QUALITY

The first and most important step in assuring top notch clinical lab operations is to create a working environment that supports quality in everything it does. This entails multiple things, as outlined below:

### Encourage employee empowerment

To create a culture of quality, lab staff must be empowered to freely and openly identify and communicate quality issues to lab management. This behavior should actually be encouraged and rewarded. Don't play the blame game – nothing will put a chill into a quality-based culture faster than finger pointing. Yes, staff does need to be held accountable for performance, but mistakes will happen with even the most seasoned lab professional. By encouraging open communication, quality problems are identified and resolved as quickly as possible.

### Foster a continuous improvement mindset

A quality-focused culture is not just about finding problems to fix. It's also about continually improving those lab processes and protocols that are working well. That's why identifying core metrics to track is critical to supporting a continuous improvement mindset. By understanding the lab's overall performance in key areas, everyone knows where there's room for improvement. A suggestion box or some method of collecting staff recommendations on areas to improve is also a good way of keeping the team engaged. Implementation of new processes should be tracked and rewarded to highlight the importance of this mindset and promote engagement.

### Develop strong document control and CAPA processes

Document control is a common deficiency cited in lab inspections. While it goes without saying that lab procedures and protocols need to be documented in detail within standard operating procedure documents (SOPs) so that lab staff can execute protocols reproducibly, a robust document control process goes well beyond this. Stringent tracking and control of document changes and revision history are key to ensure that the most up-to-date protocols are being utilized by lab personnel; "cheat sheets" and other materials created outside of the document control system should not be allowed.

There should also be a well-defined corrective and preventative action (CAPA) procedure that describes how problems will be investigated and what measures will be taken to prevent similar issues in the future. This usually entails a regimented process for root cause analysis along with tracking and verification that effective corrective/preventative measures have been implemented within specified timelines. Proof that effectiveness criteria have been met should be included with all CAPA documentation.

In conjunction with the above, regular internal audits should be scheduled to ensure that all aspects of the QMS (including document control and CAPA processes) are working effectively and being followed by all lab personnel.

## MEASURE, MONITOR, AND IMPROVE

Most clinical labs track some level of metrics, but this is just the first step. To foster a quality-focused culture, there must be a line of sight to improving on current performance levels.

### Identify select key performance indicators and target goals

As with most things in today's world, the amount of data accumulated in short periods of time is tremendous; this is particularly true with large clinical labs utilizing laboratory information systems (LIS). When it comes to metrics, it's important not to get bogged down by information overload, but rather to select a handful of the most critical (and actionable) performance indicators and then track them religiously. Some at the top of the list are the most obvious – test failure/repeat rate, test volume, turnaround time (TAT), cost per test, and equipment efficiency (i.e., uptime). Once you've developed baseline metrics, benchmark your performance to other labs of similar size and function. In what areas is your lab underperforming compared to peers? These are the prime targets for extra focus and stretch goals for improvement. In the spirit of continuous improvement, all core metrics should be accompanied by target goals that improve upon historical trends.

### Make use of visual management techniques

A lean management principle utilized frequently in the corporate world, visual management is actually a simple but effective concept. The idea is to represent key information in visual format to make it quickly and easily understandable and increase the effectiveness of personnel in their respective functions. Think of it as an easily digestible snapshot of the lab's performance.

In the context of clinical lab operations, this may entail a dashboard of simple charts and figures that communicate the status of the key performance indicators. For example, the lab may have a monthly target for testing throughput. Utilizing visual management, this metric could be displayed in a basic bar chart with green representing the number of tests completed month-todate, and red representing the number of tests remaining until the monthly target is achieved. At a glance, lab personnel looking at this chart will immediately be able to identify the gap remaining to achieve the throughput goal for the month and understand if the team is on track to hit that target.

In a similar way, all the critical performance indicators within the lab should be translated into simple, easy-to-understand visuals. These charts can be used to create a comprehensive dashboard and posted on a wall dedicated to metrics tracking.

### Meet regularly with the team to review performance

We've talked about the visual part of visual management above, but equally important is the management piece of the equation – metrics must be monitored and analyzed on a regular basis, with adjustments made when necessary. At minimum, the performance dashboard should be reviewed on a weekly basis. A good practice is to hold team stand-up meetings at regular intervals, in which trends are analyzed and discussed. Monitoring performance is of little use unless there is a commitment to acting on gaps and shortfalls. Using the example above, if the dashboard reveals that throughput is consistently trending downward, what is the root cause? This is where a strong CAPA process comes into play – providing a regimented way to both identify the core issues causing undesirable trends in the metrics and implementing corrective measures before problems get out of hand.

## DISSECT WORKFLOWS TO IDENTIFY INEFFICIENCIES

A lab that doesn't operate at peak efficiency is also one that is prone to quality issues. Not surprisingly, processes that hamper throughput and drain resources also tend to be areas where breakdowns occur and mistakes arise.

### Perform a thorough audit of all primary lab workflows

This first part of the audit is to observe – actually get on the lab floor and carefully watch complete workflows from beginning to end. It should become quickly apparent where the bottlenecks are – specifically, keep an eye out for processes that have extended turnaround time, are heavily manual, or where technician difficulties are greatest. (For example, heavily manual pre-analytic sample processing is often a prime suspect for bottlenecks.)

Once you've identified process trouble spots, begin to build process maps for these portions of the workflow. Work with lab personnel that are responsible for those activities to precisely identify the individual steps in each process. Evaluate each step with team members to determine if there are any that aren't required to complete the process; eliminate those unnecessary steps to increase process efficiency.

Required process steps that may be inefficient should be evaluated for improvements. Are there any approaches that could make those steps simpler, faster, more streamlined? The suggestions below are often good places to start.

### Automate where possible

With advancements in lab instrumentation and technology over the past decade, there is ample opportunity to take advantage of automation options to improve workflow efficiency. Again, an obvious area where this is applicable is pre-analytic processing. Today's automation systems can handle most of these processes without manual intervention, including transfer of the sample to a primary tube and direct delivery to the analytical platform. With respect to another common area ripe for efficiency gains – sample storage – many systems offer onboard storage modules that maintain tested samples at the appropriate temperature and can automatically retrieve them for reflex testing. While automation is a significant investment, it may be well worth it given the efficiency improvements it provides – including minimizing errors and freeing up lab personnel for more value-add activities.

### Implement a robust training program

Regular training – not just for new hires, but continuing education as well – is an important factor in ensuring efficient lab operations over the long-term. In fact, training is a critical component of any robust lab quality system. Despite this, it's often an afterthought in today's busy and demanding clinical lab environments. To implement workflow improvements, training on updated standard operating procedures is a must. But beyond this, regular training opportunities keep skills sharp and boost overall team morale.

## DON'T SKIMP ON QC MAINTENANCE AND MONITORING TOOLS

It's enticing to view expenditures on external QC tools and support – including independently manufactured reference materials and comprehensive preventative maintenance contracts – as luxuries that can be trimmed from tight operating budgets. This is especially true when clinical labs are increasingly viewed as a cost center within most healthcare systems. But the risks of taking this path are considerable.

### Evaluate the true cost of QC failures

Additional investment in QC maintenance and monitoring tools is often the first to be cut (or not included in the budget in the first place) because while the upfront cost is readily apparent, the benefits are hidden and not easily quantified. In the world of quality control, the benefit is preventing failure – test failures, instrument failures, and process failures. In the best-case scenario, these failures sap resources and create immense inefficiencies. Rather than generating reportable results, staff time is diverted to troubleshooting and test repeats. In the worst cases, failures can be catastrophic – inaccurate results are reported to clinicians resulting in poorly informed patient care decisions.

QC failures can snowball, leading to a costly cycle of troubleshooting, downtime, and send outs. This is not to mention the negative impact on the reputations of the lab and associated personnel. In reality, the cost of additional QC, such as independent thirdparty controls, is pennies per test when considered in the context of the average lab's throughput. External QC tools function as an "insurance policy" that mitigates the risk of damaging failure events and are more often than not a worthwhile investment.

### Avoid confusing standard practice with best practice

Clinical labs will often take the approach of adopting the standard practices of peer labs, with a mindset that "most other labs do it this way, so it must be the right way." This assumption also creeps in with CLIA certification, with the thought being that meeting the requirements of CLIA ensures that a lab is already utilizing best practices. Unfortunately, this is often not the case.

The most obvious example here is with regards to the usage of quality control materials. While CLIA does require the use of daily run controls to monitor the accuracy and precision of test systems, it does not specify requirements around the type and design of those controls – meaning in-kit manufacturer's controls are acceptable. Thus, many labs – especially in the United States where CLIA regulations govern lab operations – choose to use assay manufacturer's controls. Why? Well, they're included in the assay kit and don't "cost" anything extra (and meet CLIA requirements).

Globally, it's actually the ISO 15189 guidelines that are considered the gold standard for best practices in quality management in clinical laboratories. In addition to guidance around some topics touched upon earlier in this paper, such as creating a qualityfocused environment geared towards continuous improvement, ISO 15189 also makes it clear that independent third-party controls should be used for quality monitoring of test systems – not manufacturer's controls.

**"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*
*Section 5.6.2.2*
*Medical Laboratories – Requirements for quality and competence*

### Select the right tools for the job

Beyond the obvious conflict in solely depending on materials provided by a test manufacturer to qualify performance of their own test, there are several more technical issues which make reliance on in-kit controls a risky choice.

## 4 REASONS NOT TO RELY ON MANUFACTURER'S CONTROLS ALONE

Given the above shortfalls, manufacturer in-kit controls for daily QC often can't detect several events that can lead to adverse assay performance trends, including: calibrator degradation, faulty equipment, lot-to-lot performance decline, and even more subtle changes at assay limits of detection that could produce inaccurate results.

To catch declining assay performance in advance of a catastrophic failure, follow ISO 15189 guidelines and be sure to utilize independently manufactured external controls.

**1**

Manufacturer controls are often formulated from the same raw materials as the assay calibrators, and thus mimic the calibrators' performance.

**2**

Manufacturer controls are typically high-positive controls, which will not challenge the assay at lower detection limits where the medical decision point lies.

**3**

Manufacturer in-kit control lot changes tend to be frequent, making long-term monitoring of the assay difficult.

**4**

In general, manufacturer's controls are optimized for use with the manufacturer's test system, and thus are less likely to identify assay performance issues.

## WHAT TO LOOK FOR IN THIRD-PARTY CONTROLS

The previous section outlines several reasons why adoption of independent third-party controls is a critical part of a best-in-class quality system. Of similar importance are the characteristics to look for in the third-party controls you choose to incorporate into your daily QC program. In order to get the most of their investment, lab managers and directors should look for controls with certain design features as well as vendors with specific capabilities. Below is a useful checklist to consult when comparing thirdparty controls and vendors:

### Third-Party Control Shopping List

- **Is the control matrix as patient-like as possible?**
  Control materials should mimic authentic patient samples.
- **Are they full-process controls?**
  Controls should be designed to detect errors at every stage of the testing protocol - from sample prep to detection.
- **Are the controls targeted near the clinical decision point?**
  Low positives truly test an assay's performance.
- **Are the controls ready to use?**
  When controls need to be manipulated before use, it can introduce additional error – not to mention workflow delays.
- **Are the controls stable?**
  Material with a long shelf-life helps labs manage inventory and reduce waste.
- **Are the controls available in large lot sizes?**
  An ample supply of control material from a single lot enables labs to perform long-term QC monitoring.
- **Does the vendor have a proven track record of supporting the needs of clinical labs?**
  Vendors should be prepared to meet supply demands and provide technical support when needs fluctuate.

## LGC SERACARE AND YOUR LAB'S QC PROGRAM

In this paper, we discussed some key strategies to build a gold standard QC program to mitigate the risk of failures that can have a catastrophic effect on clinical lab operations. Included in these is the use of well-designed independent controls for daily QC of test systems. Such third-party controls will help your lab detect subtle shifts in assay performance trends, enabling proactive intervention before a failure event occurs.

As you begin your search for a reliable supplier of high-quality external controls, consider LGC SeraCare. LGC SeraCare is one of the most trusted and experienced third-party control vendors in the industry. Since the 1980s, we have supported the diagnostic testing industry with biological materials to develop, validate, and challenge today's most trusted molecular and serological infectious disease assays.

LGC SeraCare is an elite provider of high-quality third-party controls to the clinical laboratory market, with decades of experience designing and manufacturing effective QC monitoring tools. All of our facilities are ISO 13485-certified and comply with cGMP regulations. Our products are completely traceable from sourcing, through processing, to delivery — providing a high level of confidence, quality, and safety.

## ABOUT US

SeraCare offers a comprehensive portfolio of reference materials for oncology and reproductive health, designed and manufactured to meet the precision demanded by NGS assays. The portfolio includes high quality ground-truth RNA, ctDNA and genomic DNA-based reference materials that are NGS platform agnostic for tumor profiling, immuno-oncology, liquid biopsy, NIPT and germline cancer assay workflows. **For more information visit seracare.com**



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# Diagnostic Errors: The Laboratory's Essential Role in Addressing Today's Challenges

"Across all clinical settings, including hospital and clinic-based care, an estimated 795,000 Americans die or are permanently disabled by diagnostic error each year." This includes 371,000 deaths and 424,000 permanent disabilities.[1] These are the findings of a comprehensive national analysis by Johns Hopkins Armstrong Institute Center for Diagnostic Excellence and the Risk Management Foundation of the Harvard Medical Institutions (Burden of serious harms from diagnostic error in the USA).

Laboratories are vital to the diagnostic process, confirming hypotheses and eliminating disparate diagnoses. The Centers for Disease Control (CDC) estimates that 14 billion tests are conducted throughout 320,000 CLIA laboratories in the U.S.[2] Approximately 70% of healthcare decisions regarding diagnosis or treatment involve laboratory testing, and 10% or more of diagnoses aren't finalized until laboratory testing is complete.[3] Yet, consumers rank primary care physicians, pharmacies, and emergency services as the most used healthcare services—greatly misunderstanding the role of laboratory testing in their care.[3]

## ERRORS ACROSS THE TESTING PROCESS

More than 70% of diagnostic errors happen within the testing process, according to an analysis by ECRI, an independent nonprofit patient safety organization.[4] This includes when tests are ordered, samples are collected, tests are processed, results are obtained, and then communicated. Not only do these errors have devastating consequences for patients and their families, but they also cost the U.S. healthcare system an estimated $100 billion annually.[5]

ECRI analyzed 3,014 patient safety adverse events and near-misses reported in 2023 in the US, and 1,011 were related to diagnostic errors. Technical or processing errors (e.g., misuse of equipment, incorrectly processed specimens, unqualified clinician performed test) accounted for 23% of the events.[4] Mixed-up samples, mislabeled specimens, and tests performed on the wrong patient represented 20% of testing errors.[4]

The comprehensive John Hopkins analysis found that most misdiagnoses are due to errors from the treating physicians. This supports an earlier study that identified the "failure to order appropriate diagnostic tests (laboratory tests included) makes up 55% of observed breakdowns in missed and delayed diagnosis in the ambulatory setting and 58% of errors in emergency departments."[6]

## QUALITY CHALLENGES IN THE LAB

A Harris Poll conducted in 2024 for Siemens Healthcare Diagnostics identified the top three challenges laboratory personnel face that significantly impact quality.

- **Limited staff**: Laboratories are not immune to the general worker shortage. However, with vacancy rates between 7% and 11% (up to 25% in some rural locations),[7] laboratories are particularly hard hit.
- **Increased demand**: The number of tests laboratories perform continues growing due to our aging population, increased chronic disease, and the availability of new tests.
- **Lack of automation**: 95% of lab professionals agreed that adopting automated technologies would help them improve patient care, and 89% agree that their laboratory needs automation to keep up with demand.[3]

## INCREASING STAFFING SHORTFALL

Laboratory staffing issues were predicted long before the pandemic impacted hiring. The number of people entering the clinical laboratory field hasn't kept up with the number who are retiring for years, and 28% of laboratory professionals over 50 expect to retire in three to five years.[3]

Approximately 338,000 are now employed, which equals one technologist per 1,000 individuals in the U.S.[8] In 2024, the Bureau of Labor Statistics projected nearly 25,000 openings for clinical and laboratory technologists annually through 2030.[7] Only 5,000 are graduating from academic programs annually. The lack of training programs has fueled this dramatic deficiency. Accredited programs declined from 659 in 1992 to 482 in 2020.[9]

The recent U.S. Laboratory Market Report noted that hospital CEOs nearly unanimously chose the medical and laboratory technician shortage as their organization's top challenge.[10] This is understandable given the effects of this critical staffing shortage.

The Siemens/Harris Poll survey identified several significant impacts of the shortage.

- Hampers ability to provide the highest clinical value
- Increases risks for patients and staff
- Led to lab closings for one or more shifts (5%)
- Caused overworked/burned-out staff to make a low-risk (2%) or high-risk (14%) error

Even with the shortage, organizations can meet turnaround times through overtime, eliminating some non-essential tasks and redistributing resources. All of these factors can cause stress for staff. The vast majority (95%) of laboratory personnel understand they're a critical part of the healthcare system, and 94% believe they positively impact patient outcomes.[3] But, in a severely understaffed industry, 20% of laboratory professionals report feeling burned out, and 9% are considering leaving their workplace or the industry.[3]

## GROWING TESTING DEMAND

Eighty-three percent of lab professionals believe that the demand for laboratory services will sharply or somewhat increase.[3] This isn't surprising when you consider three of the major drivers: our aging population, the incidence of chronic disease (approximately 60% of U.S. adults have at least one[11]), and the introduction of new clinical tests.

New tests are continuously being developed to advance the early detection and diagnosis of disease and improve condition monitoring and outcomes. Roughly 175,000 tests are available, with over 10 new ones added daily (some of which are variations on existing tests).[12] An area that's seen dramatic growth in recent years and greatly impacted testing demand is molecular diagnostics, the foundation of personalized medicine.

## SLOW ADOPTION OF AUTOMATION

Some larger U.S. clinical laboratories have integrated new technologies such as robotics, AI, Machine Learning, and Cloud computing into their operations. While the costs have kept others from adopting automation and AI, the ongoing dearth of laboratory staff will compel more laboratories of all sizes to assess the benefits.

Many manual tasks can be partially or completely automated, improving standardization, organization, efficiency, and quality of testing processes. Human critical thinking can then be devoted to skilled duties, diagnostic activities, and other high-value clinical tasks.

Automation has proven to:

- Shorten time to diagnosis through systems that scale up quickly so more samples can run through an analyzer
- Reduce laboratory errors that occur in sorting and labeling specimens and even tube selection

Repetitive next-generation sequencing (NGS) steps can be automated to reduce the time needed for tasks such as NGS library preparation. AI can search substantial data sets to understand and identify patterns. "Smart instrumentation" (instruments that generate data in addition to their primary purpose) uses built-in diagnostics, self-calibration, and data sorting to handle real-time monitoring, predictive maintenance, and improved data analysis.

With these capabilities and more, it's understandable that the Siemens/Harris Poll found that 41% of those surveyed see AI-integrated tools or technology as the fastest growth area laboratories expect this year.[3] While 52% see automation as a threat to their job, they see the benefits.[3] Having fewer manual tasks or the ability to perform them faster, laboratory staff expect they'd be able to:

- Address unmet patient care challenges or needs (91%)
- Improve patient care (90%)
- Spend time training and mentoring staff (46%).
- Increase quality control troubleshooting (42%)
- Manage the test sample process more efficiently (39%)[3]

The same survey identified the obstacles laboratories face in adopting automation:

- Cybersecurity/IT-related challenges (43%)
- Fear/hassle of changing the laboratory's system(s) (43%)
- Lack of available budgeting/funding (43%)[3]

## OVERCOMING THE CHALLENGES

The enduring shortage of laboratory personnel won't be eliminated overnight. Demand for testing isn't going to lessen and is expected to continue growing well into the future. Incorporating automation into a laboratory requires time for planning, assessment, and funding before implementation. So, what about today? What can be done now to ensure quality doesn't suffer, results are accurate, and the right patient treatment is provided?

### Quality and safety strategies

- Educate providers on laboratory testing
- Provide consultative services
- Initiate feedback loops
- Strengthen testing processes
- Implement multidisciplinary teams to analyze safety events
- Establish a quality culture that encourages staff to report errors and near-misses

### Quality measurement tools

Strategies addressing quality and safety, including those listed above, require qualified personnel to establish and manage. Laboratories feeling the pressure of being short-staffed need easily implemented options, too.

LGC Clinical Diagnostics' independent quality measurement tools offer a streamlined way to gain confidence in patient results. Used with LGC's automated software, this extensive selection of liquid, ready-to-use solutions:

- Support daily quality control needs in clinical biochemistry, molecular testing, serology, next-generation sequencing, urinalysis, and toxicology
- Simplify quality control and calibration verification and linearity data management

These tools help support a culture of quality—an environment that promotes quality throughout the lab by encouraging open communication to identify and resolve quality problems quickly, involving staff in the process, developing a strong, effective document control system, and recognizing and rewarding staff for bringing quality issues to lab management's attention. See LGC's 5 Best Practices for Best-in-class Clinical Lab Quality Control for more details.

## Ongoing industry solutions

Addressing the laboratory staffing shortage amid the growing demand for testing is a priority for U.S. healthcare. This could significantly impact errors. Some proposals recommend lowering the standards for hiring qualified, board-certified, licensed medical lab professionals.[13] This is not a viable solution, as it further compromises the quality of care. However, there are ways the industry can address issues contributing to diagnostic errors.

### Attract people to field

Increasing awareness of science and medical careers can attract more people to choose that professional path. This can be done by engaging with individuals before college and those already in science/medical roles. It can be as simple as career fairs and presentations or more complex, such as internships and mentorships.

For example, Spencerport High School in New York offers a medical laboratory assisting and phlebotomy course through its career and technical education program. In Baltimore, the Johns Hopkins Initiative for Careers in Science and Medicine provides biomedical research opportunities for high school students. Boston Children's Hospital internship program connects high school students with hospitals and laboratories. In late 2024, Bloomberg Philanthropies announced a $250 million healthcare-focused initiative with high schools in 17 urban and rural areas across the U.S.

Other initiatives launched in 2024 designed to increase the number of qualified laboratory professionals include the Loyola University Chicago Medical Laboratory Science summer immersion program for college students and graduates and Indiana University School of Medicine's expansion of its Bachelor of Science Medical Laboratory Scientist Program to the Evansville campus.

The CDC's OneLab and OneLab VR programs are designed "to build capacity and establish a sustainable learning community that equips the laboratory workforce and testing community with the essential tools and resources to improve public health and patient outcomes." The programs include free resources, training scenarios, and a 50,000-square-foot virtual facility.[14]

### Retain staff

An obvious way to retain staff is to offer laboratory professionals compensation commensurate with education and experience. Other practices that lead to job satisfaction and reduce stress and burnout are continuing education opportunities, flexible scheduling, using assistants for pre- and post-analytical tasks, and providing resources and support that create a positive team environment.

### Expand automation

Scott Wallask wrote in Lab Manager, "There is no army of new medical laboratory scientists coming to the rescue for short-staffed clinical laboratories. Instead, lab leaders in these organizations must pursue a combination of cost-savings, workflow efficiencies, and helpful technology." Automation can provide greater control and flexibility, but introducing technology requires staff oversight.

The decision to introduce automation begins with existing processes and workflows. It's critical that they are already efficient and streamlined. Another preliminary step is to analyze current and future needs. Taking incremental steps often leads to greater success. Initiate automation for one process, assess and adjust as necessary, and ensure staff supports the effort before expanding to another.[15]

### Seek out collaboration

Clinical laboratories do more than generate results; they impact outcomes. As such, visibility for laboratory leadership, particularly with the C-suite, supports interactions with ordering providers to establish evidence-based decision-making for correct test ordering and to ensure they understand the proper use of testing and the significance of the results.

Laboratory scientists are essential healthcare professionals who perform complex laboratory tests to diagnose and treat patients. The data these experts produce and interpret provides insights that influence disease prevention, treatment, and projection. Producing accurate test results establishes trust for the continuum of care that follows, making it incumbent on all who are part of the diagnostic process to contribute to the solutions for the challenges.

LGC Clinical Diagnostics supports the diagnostic testing industry with biological materials to develop, validate, and challenge today's most trusted molecular and serological infectious disease assays. We are an elite provider of high-quality third-party controls for the clinical laboratory market, with decades of experience designing and manufacturing effective quality control monitoring tools.

**Learn more about how we can improve your ability to report accurate patient results.**

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- Biophysics Research for Baltimore Teens

# Security Comparison: Local Server-Based vs. Cloud-Based Informatics Software for Hospital QC Labs

LGC CLINICAL DIAGNOSTICS

Science for a Safer World

## EXECUTIVE SUMMARY

This white paper provides a comprehensive analysis of the security differences between local server-based and cloud-based informatics software, with a specific focus on applications for hospital quality control laboratories. The healthcare industry faces unique security challenges due to stringent regulatory requirements and the sensitive nature of patient data. As hospitals increasingly consider cloud migration for their informatics systems, IT professionals must understand the evolving security landscape to make informed decisions. This analysis reveals that modern cloud-based informatics solutions can offer security capabilities equal to or exceeding traditional on-premises deployments when properly implemented, though each approach presents distinct advantages and challenges that must be carefully evaluated within the context of specific organizational requirements.

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# Security Comparison: Local Server-Based vs. Cloud-Based Informatics Software for Hospital QC Labs

This white paper provides a comprehensive analysis of the security differences between local server-based and cloud-based informatics software, with a specific focus on applications for hospital quality control laboratories. The healthcare industry faces unique security challenges due to stringent regulatory requirements and the sensitive nature of patient data. As hospitals increasingly consider cloud migration for their informatics systems, IT professionals must understand the evolving security landscape to make informed decisions. This analysis reveals that modern cloud-based informatics solutions can offer security capabilities equal to or exceeding traditional on-premises deployments when properly implemented, though each approach presents distinct advantages and challenges that must be carefully evaluated within the context of specific organizational requirements.

## THE EVOLVING LANDSCAPE OF LABORATORY INFORMATICS

Laboratory Information Management Systems (LIMS) and other informatics solutions are essential tools for hospital quality control laboratories, managing everything from sample tracking to data analysis and reporting. Traditionally, these systems were deployed exclusively on local servers under the direct control of the organization's IT department. However, the emergence of cloud computing has created new deployment options with different security implications. The LIMS market is projected to grow from $2.1 billion in 2024 to $3.8 billion by 2029, with a compound annual growth rate of 12.9%, indicating the increasing significance of these systems in laboratory operations.[1]

As hospitals consider migrating from traditional on-premises implementations to cloud-based alternatives, security remains a primary concern. This white paper examines the security characteristics of both deployment models to provide IT professionals with a framework for evaluating whether cloud-based informatics software is appropriate for hospital QC laboratories.

## UNDERSTANDING DEPLOYMENT MODELS

Before diving into security comparisons, it's important to clarify the different deployment models available for laboratory informatics software:

### On-Premises (Local Server-Based)

Traditional on-premises deployments involve purchasing software licenses (often called "pay-per-license" or PPL) and installing the application on servers located within and managed by the organization. Major LIMS vendors in this space include LabVantage, Bio-Rad Unity, LabWare, SampleManager, and STARLIMS.[2] This approach has historically been the standard for hospital environments.

### Cloud-Based Deployments

Cloud-based deployments typically fall into three categories:

**1. Infrastructure as a Service (IaaS):** The hardware infrastructure is managed by the provider, but the organization is responsible for installing, configuring, and maintaining the virtual machines, networking, the application itself, including security update.

**2. Platform as a Service (PaaS):** Delivers hardware and software to application developers over the internet. An example might be a database, where the cloud provider manages and provides security patching and maintenance, allowing the developers to focus on design and development.[2]

**3. Software as a Service (SaaS):** A fully managed service provided by a vendor. The organization accesses the software through a web browser or dedicated application, with the provider taking responsibility for updates, patches, and maintenance.[2,3]

| | You own and operate your full lab | You rent a lab shell and bring your own systems & staff | You rent a lab with some systems & tools | You use a full-service diagnostic platform |
|---|---|---|---|---|
| **Closed Terminology** | **On-Premise** | **IaaS** | **PaaS** | **SaaS** |
| **Regulatory Compliance** | You | Shared | Shared | Vendor |
| **Result Reporting** | You | You | Shared | Vendor |
| **Test Methods/Protocols** | You | You | You | Vendor |
| **Lab Technicians** | You | You | Vendor | Vendor |
| **Supplies & Reagents** | You | You | Vendor | Vendor |
| **Workstations (benchtop computers, devices)** | You | You | Vendor | Vendor |
| **IT Infrastructure (LIS, Servers)** | You | You | Vendor | Vendor |
| **Lab Equipment** | You | Vendor | Vendor | Vendor |
| **Facility & Power** | You | Vendor | Vendor | Vendor |
| **Summary** | **Fully self-managed** | **Rented lab, bring-your-own tools** | **Rented lab with tools, you define tests** | **End-to-end testing service you just use** |

The advantages of moving higher in the stack with the hyperscale providers (AWS, Azure, Google) is that they invest billions in both tooling and resources to protect their environments and have significantly sized teams monitoring 24x7. Day to day the service teams are consistently upgrading and staying on top of security updates and maintenance of the underlying PaaS and SaaS offerings with specialists in their field.

## SECURITY COMPARISON: ON-PREMISES VS. CLOUD-BASED SOLUTIONS

### Security Advantages of On-Premises Deployments

**1. Direct Control**
On-premises deployments provide organizations with complete control over their security infrastructure. IT departments can directly implement and manage security policies, access controls, firewalls, monitoring and other protective measures according to specific organizational requirements.[4]

**2. Physical Security Management**
With on-site servers, the organization maintains direct control over physical access to the hardware where sensitive data resides. This can be particularly reassuring for healthcare organizations that must adhere to strict data protection regulations.[4]

**3. Network Isolation**
Local server deployments can be configured to operate on isolated networks, potentially limiting exposure to external threats. For particularly sensitive operations, systems can be completely air-gapped from the internet.[4]

**4. Customization Flexibility**
On-premises solutions offer greater flexibility for customizing security configurations to meet specific compliance requirements, which can be particularly valuable in highly regulated healthcare environments.[4]

## Security Challenges of On-Premises Deployments

**1. Resource Dependencies**
Maintaining robust security for on-premises systems requires dedicated IT security expertise, which can strain hospital resources. Without adequate staffing and expertise, security may be compromised due to improperly configured systems or delayed security patches.[2]

**2. Update Management**
Security effectiveness depends heavily on regular updates and patches. Hospitals often face challenges implementing these updates promptly due to operational constraints and limited IT resources, potentially leaving systems vulnerable to known security issues.[2,3]

**3. Disaster Recovery Complexity**
Implementing comprehensive disaster recovery for on-premises systems requires significant investment in redundant infrastructure and backup solutions, which may exceed the capabilities of many hospital IT departments.[2]

**4. Uneven Security Implementation**
The security advantages often cited to support on-premises installations – such as more control over servers and firewalls – can become disadvantages when organizations lack specialized security expertise or resources to implement best practices consistently.[3] A typical on-premise deployment will be a variety of security vendor products "bolted" together. This can be hard to manage and the skill level to be experts in all of the products difficult to attain, leaving room for misconfiguration and vulnerabilities.

## Security Advantages of Cloud-Based Solutions

**1. Specialized Security Expertise**
Cloud providers typically employ dedicated security teams with specialized expertise that exceeds what most individual hospitals can maintain internally. These teams are focused exclusively on maintaining security across their infrastructure.[2]

**2. Automated Security Updates**
Cloud solutions, particularly SaaS implementations, automatically apply security patches and updates without requiring action from hospital IT staff. This ensures systems remain protected against known vulnerabilities without diverting internal resources.[2,3]

**3. Advanced Threat Detection**
Major cloud providers implement sophisticated threat detection and prevention systems that can identify and respond to potential security incidents in real-time and more effectively than most on-premises security solutions. These systems benefit from visibility across numerous customers, improving threat intelligence.[4]

**4. Robust Infrastructure Security**
Cloud providers typically implement physical and digital security measures exceeding what individual hospitals can achieve, including state-of-the-art data centers with multiple layers of physical security, redundant systems, and comprehensive disaster recovery capabilities.[2] Underlying components are inhouse proprietary products making them less vulnerable to attack.

**5. Distributed Architecture Benefits**
Cloud providers' distributed architectures can offer improved resilience against certain types of attacks, such as distributed denial of service (DDoS) attacks, compared to typical on-premises deployments.[4]

**6. Data Residency Considerations**
Healthcare organizations must ensure that patient data is stored and processed in compliance with applicable regulations, which may include requirements for data to remain within specific geographic boundaries.[4] This is easier to achieve with hyperscale providers as they have many regions to choose from, and recently we have seen the creation of sovereign clouds (European Sovereign Clouds) to address these concerns.

### Security Challenges of Cloud-Based Systems

**1. Reduced Direct Control**
Organizations must rely on cloud providers' security practices rather than implementing all security measures directly, which can create concerns about visibility and control, particularly in highly regulated environments.[4]

**2. Misconfigurations**
There are lots of examples where inexperienced cloud users have left openings to their environment through misconfiguration. This is the most common cause of data loss, but those same configuration mistakes can happen on premise as well. This is a lack of training and knowledge in the required security tooling.

**3. Multi-Tenant Security Concerns**
In multi-tenant cloud environments, organizations share underlying infrastructure with other customers, creating theoretical risks of data leakage between tenants if isolation mechanisms fail.[4].

**4. Internet Dependency**
Cloud-based systems require reliable internet connectivity, introducing potential vulnerabilities to internet-based attacks and service disruptions if network connectivity is compromised.[2]

## KEY SECURITY CONSIDERATIONS FOR HOSPITAL QC LABS

### Regulatory Compliance

Hospital quality control laboratories operate under strict regulatory frameworks, including HIPAA for patient data protection. Any informatics solution must demonstrate compliance with these regulations if storing patient data.[4] Hyperscale providers accreditations across a wide range of regulatory frameworks is unmatched – HIPPA, SOC1/2/3, ISO27001, which provides a solid foundation for product development.

**On-Premises Approach**
With on-premises systems, the organization retains complete responsibility for implementing and documenting compliance measures. This provides direct control but also places the full compliance burden on the hospital's IT and security teams.[4] These are typically point in time audits with an element of real time reporting.

**Cloud Approach**
Modern cloud providers increasingly offer compliance-focused solutions specifically designed for healthcare environments. These often include built-in tools for maintaining compliance in real-time and can simplify the compliance documentation process.[4] However, it remains essential to verify that any cloud provider has appropriate compliance certifications and can support the hospital's specific regulatory requirements.

### Data Security and Privacy

QC labs handle sensitive information that must be protected from unauthorized access or disclosure.

**On-Premises Approach**
Traditional approaches rely on perimeter-based security models with firewalls, network segmentation, and access controls managed by internal IT teams. This provides customizable protection but depends entirely on the organization's security implementation quality.[4]

**Cloud Approach**
Cloud providers implement defense-in-depth security strategies, typically including encryption both in transit and at rest, sophisticated identity management, and continuous monitoring for security threats. These measures are often more advanced than what many hospitals implement internally.[2,3]

### Business Continuity and Disaster Recovery

Laboratory operations are critical to patient care, making system availability and disaster recovery essential considerations.

**On-Premises Approach**
Robust disaster recovery for on-premises systems requires significant investment in redundant infrastructure, backup solutions, and recovery procedures. Many hospital IT departments struggle to implement and maintain comprehensive disaster recovery capabilities due to resource constraints.[2]

**Cloud Approach**
Cloud providers build redundancy and disaster recovery capabilities into their core infrastructure, typically providing geographic distribution of data, automated backups, and rapid recovery options that exceed what most hospitals can implement internally.[2,3]

### Integration Security

Laboratory informatics systems must securely integrate with other hospital systems while maintaining appropriate security boundaries.

**On-Premises Approach**
Integration between on-premises systems typically occurs within the hospital's network perimeter, potentially simplifying security but often requiring custom integration development and ongoing maintenance.[2]

**Cloud Approach**
Modern cloud-based informatics solutions typically offer secure API-based integration capabilities, often with pre-built connectors for common healthcare systems. These integrations implement industry-standard security protocols but require careful configuration to maintain appropriate access controls.[2,3]

## EVALUATING CLOUD SOLUTIONS FOR HEALTHCARE ENVIRONMENTS

When assessing cloud-based informatics solutions for hospital QC labs, IT professionals should consider the following security-specific evaluation criteria:

### 1. Healthcare-Specific Compliance Certifications

Verify that the cloud provider maintains current certifications relevant to healthcare, such SOC 2 Type II reports, and ISO 27001 certification. These third-party validations provide assurance of the provider's security practices.[3,4]

### 2. Data Protection Capabilities

Evaluate the solution's encryption implementation, including encryption at rest and in transit, key management practices, and data isolation mechanisms. Cloud solutions should offer encryption capabilities meeting or exceeding industry standards.[4]

### 3. Access Control and Authentication

Assess support for role-based access control, multi-factor authentication, single sign-on integration, and detailed audit logging. These capabilities are essential for maintaining appropriate access restrictions in healthcare environments.[2,3]

### 4. Contractual Protections

Review service level agreements (SLAs) and contracts for explicit security commitments, including breach notification procedures, data handling requirements, and compliance support obligations. These contractual protections provide important recourse in case of security incidents.[4]

### 5. Vendor Security Practices

Investigate the provider's security team resources, vulnerability management processes, penetration testing schedule, and incident response capabilities. A transparent provider will share information about these practices to demonstrate their security commitment.[2,3]

### 6. Exit Strategy

Consider how data would be securely migrated if you needed to change providers in the future. Cloud solutions should offer clear data export capabilities and migration support to prevent vendor lock-in.[2]

## MAKING THE RIGHT CHOICE FOR YOUR HOSPITAL QC LAB

The security landscape for informatics software has evolved significantly, challenging the traditional assumption that on-premises deployments are inherently more secure than cloud alternatives. For hospital QC laboratories, both deployment models offer viable approaches to securing sensitive data, each with distinct advantages and limitations.

The historical security advantages of on-premises solutions-direct control, customization flexibility, and physical access management-remain relevant but must be weighed against the significant expertise and resource requirements needed to implement these advantages effectively. Many hospitals struggle to maintain the specialized security resources required for optimal on-premises security, potentially creating vulnerabilities despite the theoretical benefits of direct control.

Conversely, cloud-based informatics solutions have matured substantially, offering sophisticated security capabilities that often exceed what individual hospitals can implement independently. Modern cloud providers leverage specialized security expertise, economies of scale, and continuous improvement processes to deliver robust security protections specifically designed for highly regulated environments like healthcare.

For many hospital QC laboratories, cloud-based informatics solutions now represent the more secure option, particularly when internal IT security resources are limited. By transferring complex security implementation responsibilities to specialized providers with dedicated expertise, hospitals can often achieve higher security levels while reducing internal resource demands.

However, this determination is not universal and must consider the specific circumstances of each hospital, including existing security capabilities, regulatory requirements, integration needs, and risk tolerance. A careful evaluation using the criteria outlined in this white paper will help IT professionals determine whether cloud-based or on-premises informatics software best meets their hospital's unique security requirements.

The key conclusion for IT professionals is that modern cloud-based informatics solutions can provide security capabilities equal to or exceeding traditional on-premises deployments when properly implemented and configured. The critical factors are not the deployment model itself, but rather the specific security implementations, the resources available for ongoing security management, and the alignment between the chosen solution and the hospital's particular requirements.

As healthcare continues to evolve, cloud-based solutions increasingly offer compelling security advantages for hospital QC laboratories, provided they are selected with appropriate due diligence and implemented with careful attention to healthcare-specific security requirements.

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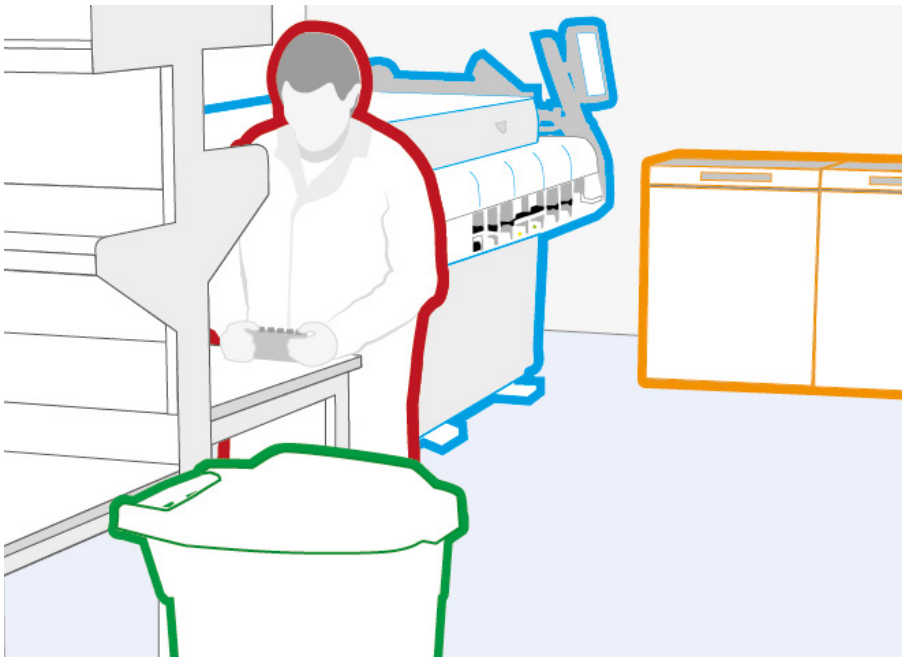
# Multichem® independent quality control (QC) allows you to simplify your inventory, reduce your costs, and improve efficiencies



**REDUCE**
**DEAD VOLUME WASTE**

**REDUCE**
**STORAGE SPACE**

**REDUCE**
**HANDLING REQUIREMENTS**

**REDUCE**
**CONSUMABLE WASTE**

## Multichem Flagship Products

Our two flagship products, Multichem IA Plus and Multichem S Plus, contain more than 190 tests combined.

Technopath Clinical Diagnostics is one of the largest manufacturers of liquid-ready quality controls globally in compliance with the highest quality standards. Multichem is our class leading independent test-consolidated QC product range. With an extensive list of analytes included in our Multichem product range - quality, choice and flexibility is guaranteed for all customers.

**Multichem IA Plus**
Combines our competitors separate Immunoassay, Cardiac Marker, Tumor Marker, and Specialty IA controls into one tri-level control.


**Multichem S Plus**
Combines our competitors separate Serum Chemistry, Immunology, Lipids, and TDM controls into one tri-level control.

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# Multichem® Independent QC Portfolio

## Including KOVA Urinalysis QC & Biochemical Diagnostics DOA Analysis

Multichem **A1c**

Multichem **AE**

Multichem **AMH**

Multichem **CSF**

Multichem **D-Dimer**

Multichem **hsTn**

Multichem **NB**

Multichem **IA Plus**

Multichem **IA Speciality**

Multichem **P**

Multichem **S Plus**

Multichem **U**

Multichem **WBT**

Multichem **ID-B**
**ID-SeroNeg**

Multichem **ID-COVID19 G**
**ID-COVID19 Neg**


KOVA **Urinalysis**

Biochemical Diagnostics **DOA Analysis**

# Enhancing Laboratory Efficiencies through...

### CONSOLIDATION

Fewer QC products required to cover your core laboratory control needs, leading to increased operational efficiencies, and reduced waste.

### INFORMATICS

Cloud-based daily QC management/reporting and real-time, interlaboratory peer review software.

### QUALITY

Independent, liquid frozen, human based controls with analytes targeted at clinical decision points supporting clinician quality goals.

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# Customer Testimonial

PathCare

**ORGANISATION / HEALTH SYSTEM:** PathCare Laboratories, South Africa.

**ABOUT PATHCARE:** PathCare comprises of 104 laboratories in total; one core lab and nine regional laboratories.

**INSTRUMENTS:** 196 instruments in total comprising of 69 x Alinity i, 77 x Alinity c, 22 x ARCHITECT i1000, 2 x ARCHITECT i2000, 25 x ARCHITECT c4000 and 1 x ARCHITECT c8000. The PathCare core laboratory in Cape Town has four Alinity c and six Alinity i instruments.

**NUMBER OF TESTS:** Daily average at main lab on Abbott platform: 7,856 for chemistry and 3,525 for endocrinology.

**PRODUCTS IN USE:** Multichem® IA Plus, Multichem S Plus, Multichem U, Multichem P, Multichem A1c, Multichem AE, Multichem WBT; IAMQC® Peer for QC data management.

**TESTIMONIAL PROVIDED BY: Yolanda Veerajoo,** PathCare National QA Coordinator: Quality Assurance Division. Yolanda is a qualified Medical Technologist with a Bachelor of Technology: Clinical Pathology and has more than 10 years of experience in the field.

*"The IAMQC peer reports have proven to be very useful and have become a vital component of our QC review procedures."*

**Yolanda Veerajoo**
QA Coordinator: Quality Assurance Division


**What are the most important points for you in working with Technopath?**

The IAMQC Peer website has had the most important impact on the lab. We were able to design the QC module based on the automated IAMQC reports. Our monthly review procedure using the IAMQC Bias Report enables to work in a much leaner way, which is efficient and time saving.

**Tell us about how you run up new quality controls?**

When we start with a new lot of QC, we run the old lot and new lot in parallel for 3 days. This is to ensure that biases on the new lot are not system related but rather QC related. Initially, we consider the peer mean as a target value until we have at least 20 QC data points per level and thereafter switch to our running mean.

**What rules do you follow in running quality controls?**

We follow Westgard Rules, including warning rules and violation alerts. In terms of specification for analytical goals, we refer to EFLM, RCPA, Westgard and CLIA. QC management is done via our middleware, AlinIQ AMS or Meditech.

**What advantages have you seen with the Technopath barcoded QC?**

Smaller QC vials, which can be loaded onto the instrument is new for us and is definitely welcomed by the laboratory staff. We find that running the QC directly from the vial saves us time as we no longer need to aliquot the product. We have also noted a subsequent reduction in errors, where previously QC levels could have been swapped around.

**Is there anything you would highlight as uniquely valuable in the Technopath system?**

The automated Reagent Lot Report in IAMQC is a unique competitive feature. If we observe shifts, we refer to the Reagent Lot Report to assess the mean. We then assess if the shift it clinically acceptable by comparing it to the acceptable %Bias. The IAMQC peer reports have proven to be very useful and have become a vital component of our QC review procedures.

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# Product Brochure

## Calibration Verification and/or Linearity Test Products for Clinical Analyzers

Validate® AccuTrak™


Calibration Verification, performed at regular intervals, confirms that your clinical analyzer is performing to the manufacturer's claims, ensuring reliable and consistent patient test results.

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# Market Leader in Calibration Verification

**INSTALLATION**

VALIDATE® and AccuTrak™ products are used to perform verification of new instruments and assays. These instrument-specific kits are used by clinical laboratories to ensure instrument and assay specifications are being met, maintaining reliable and consistent patient results.

**MAINTENANCE & TROUBLESHOOTING**

VALIDATE® and AccuTrak™ products are multi-use with extended open-vial stability. Having the same solutions available over several months and multiple uses affords the laboratory an invaluable tool when verifying and monitoring a method's performance.

## Easy

VALIDATE® and AccuTrak™ test kits use human-sourced raw materials, where available, and require no reconstitution.

Liquid, ready-to-use solutions are supplied in multi-use dropper bottles for easy dispensing.

Order once per year with extended open-vial stability and additional material for troubleshooting.

## Fast

VALIDATE® and AccuTrak™ test kits increase productivity, reducing the need for sample preparation and manual dilutions.

VALIDATE® levels 1 - 5 are prepared according to CLSI's EP06 guideline. AccuTrak™ is prepared as individual levels across the reportable range.

Fulfill CLIA, CAP, ISO 15189, COLA, JCAHO, JCI and other accreditation and regulatory requirements.

## Efficient

Together with the MSDRx® Infinity software, VALIDATE® and AccuTrak™ provides a comprehensive calibration verification assessment.

Instrument-specific configurations maximize range coverage and minimize dilutions.

Use for installation, preventative maintenance and troubleshooting of reagents, QC and calibrations.

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# AccuTrak™ and VALIDATE®

**AccuTrak™**

AccuTrak™ **Calibration Verification Panels** are designed to provide independent levels across the assay's reportable range. These panels are intended exclusively for **calibration verification** and are **not suitable for linearity assessments.**

**VALIDATE®**

In contrast, VALIDATE® **Calibration Verification and Linearity products** are manufactured using an **equal-delta format**, which creates a defined relationship between levels. This format supports both **calibration verification** and **linearity assessment**.

Both AccuTrak™ and VALIDATE® products are **liquid, ready-to-use**, and compatible with MSDRx Infinity® - LGC's cloud-based data reduction software that enables peer group analysis.


| AccuTrak™ | VALIDATE® |
|---|---|
| For calibration verification and reportable range verification | For linearity, calibration verification, and reportable range verification |
| Single analyte | Single or multi-analyte |
| Liquid, ready-to-use | Liquid, ready-to-use |
| Good for multiple uses and have extended open-vial stability | Good for multiple uses and have extended open-vial stability |
| Configurations tailor-made to analytical instrument platforms | Configurations tailor-made to analytical instrument platforms |
| Levels are prepared individually across the reportable range | Levels 1-5 are prepared according to CLSI's EP06-A guidelines |
| Data reduction software and peer group comparison through MSDRx Infinity | Data reduction software and peer group comparison through MSDRx Infinity |

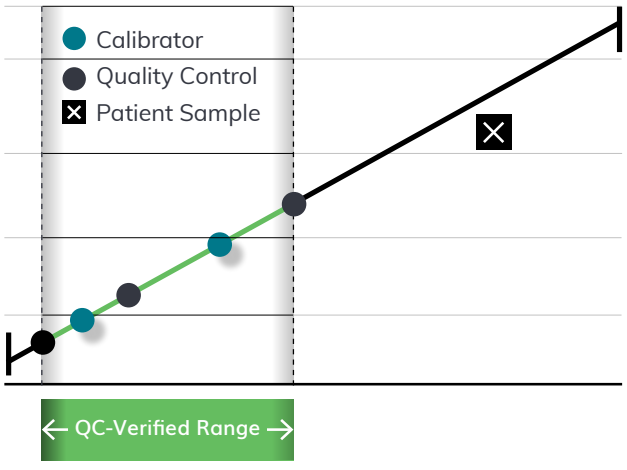
LGC CLINICAL DIAGNOSTICS



# Comparison of Recovered Value vs. Concentration

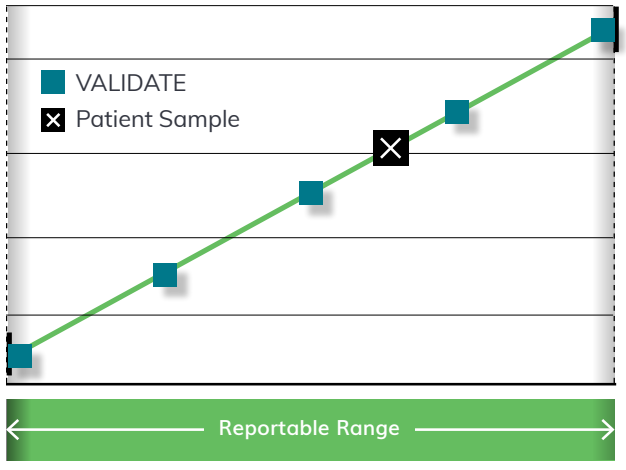
Assaying materials in the same manner as patient samples, using VALIDATE® and AccuTrak™, confirms that an instrument, kit or test system has remained stable throughout the reportable range. Therefore, laboratories can expand beyond the routine quality control range with confidence.

**ROUTINE QUALITY CONTROL**




- ❗ Upper and lower limits unchallenged
- ❗ Assay linearity unknown
- ❗ Unknown patient result outside of QC limits

**VALIDATE® CALIBRATION VERIFICATION**




- ☑ Limits challenged and monitored
- ☑ Assay linearity established
- ☑ Patient result within verified range

The laboratory cannot ensure that the response curve is linear beyond the limits of the calibrator and controls. When a patient sample result falls outside this range, there is reduced confidence that the result is valid. VALIDATE® challenges the extremes of the reportable range. Assaying five levels, using the equal-delta protocol described in CLSI EP06, verifies a linear response. AccuTrak™ products are manufactured as individual levels across the reportable range to assist in calibration verification. Patient samples are reported with increased confidence.

*NOTE: AccuTrak™ Products are only intended for use in calibration verification and reportable range verification.

# Configurations Tailor-Made to Analytical Instrument Platforms

**CLINICAL CHEMISTRY & IMMUNOASSAY ANALYZERS**

- Abbott Laboratories
- Beckman Coulter
- QuidelOrtho
- Polymedco
- Roche Diagnostics
- Siemens Healthineers
- Tosoh Bioscience

**HEMOSTASIS ANALYZERS**

- Diagnostica Stago
- Instrumentation Laboratory
- Siemens Healthineers

maine standards

# Calibration Verification Products

The following VALIDATE® and AccuTrak™ products offer in excess of 170+ analytes, formulated into standard groupings. Visit **mainestandards.com** website to see Typical Recovered Values (TRV) and lot-specific information in Product Inserts (PIs).

**VALIDATE® PRODUCTS** **AccuTrak™ PRODUCTS**

## GENERAL CHEMISTRY

### GC1*

Albumin
Blood Urea Nitrogen
Calcium
Chloride
Cholesterol
Creatinine
Glucose
Lactate
Lithium
Magnesium
Phosphorus
Potassium
Sodium
Total Protein
Triglycerides
Uric Acid**

*1100ab and 1100ro are not CE-approved

**Uric Acid is only available for 1100vt

### GC2

Ammonia
Carbon Dioxide
Ethyl Alcohol
Total Iron
Uric Acid**

**Uric Acid is not available for 1200vt

### GC3*

Alanine Aminotransferase
Alkaline Phosphatase
Amylase
Aspartate Aminotransferase
Creatine Kinase
Gamma-Glutamyltransferase
Lactate Dehydrogenase
Lipase

*1300ab not CE-approved

### GC4

Conjugated Bilirubin
Direct Bilirubin
Total Bilirubin

## IRON BINDING CAPACITY

### IBC

Total Iron Binding Capacity
Unsaturated Iron Binding Capacity

## LIPOPROTEINS

### LP

High Density Lipoprotein
Low Density Lipoprotein

### LP2

Apolipoprotein A1
Apolipoprotein B

## ACTH

### ACTH

Adrenocorticotropic Hormone

## ANEMIA

### Anemia

Ferritin
Folate
Vitamin B12

### Ferritin

Ferritin

### Folate RBC*

Folate RBC

*Not CE-approved

## BODY FLUIDS

### Body Fluids

Albumin
Amylase
Cerebrospinal Fluid Total Protein
Cholesterol
Creatinine
Glucose
Lactate
Lactate Dehydrogenase
Total Protein
Triglycerides
Urea Nitrogen

### Body Fluids 2

Calcium
Chloride
Potassium
Sodium
Total Bilirubin
Uric Acid

### Body Fluids 3

Cancer Antigen 19-9
Carcinoembryonic Antigen

## BONE

### B-CTx*

Beta-CrossLaps

*Not CE-approved

### OCN*

N-MID Osteocalcin

*Not CE-approved

### PTH

Parathyroid Hormone

### VIT D*

Vitamin D

*506ro not CE-approved

maine standards

# Calibration Verification Products (continued)

## CARDIAC CE

### CM1

Creatine Kinase-MB
Myoglobin

### CM2*

Brain Natriuretic Peptide
High Sensitivity C-Reactive Protein
N-Terminal Prohormone of BNP
Troponin I

*402pf, 402re, and 402vt are not CE-approved

### CM3

Homocysteine
Lipoprotein (a)

### HIGH SENSITIVE TROPONIN

High Sensitivity Troponin T
High Sensitivity Troponin I

## DIABETES CE

### Diabetes*

Cystatin C
Beta-Hydroxybutyrate
C-Peptide
Insulin
Fructosamine

*Not CE-approved

### HbA1c

% Glycohemoglobin A1c

## FERTILITY CE

### Fertility 1

Follicle-stimulating Hormone
Human Chorionic Gonadotropin
Luteinizing Hormone
Prolactin
Testosterone

### Fertility 2*

Alpha-fetoprotein
Androstenedione
Dehydroepiandrosterone Sulfate
Estradiol
Progesterone

*504re not CE-approved

### Fertility 3

Anti-Müllerian Hormone
Sex Hormone-binding Globulin

### Fertility 4*

Placental Growth Factor

*Not CE-approved

## FERTILITY II

### sFlt-1

Soluble fms-like Tyrosine Kinase-1

## HORMONE

### GH

Human Growth Hormone
Insulin-Like Growth Factor-1

### GH2

Insulin-Like Growth Factor Binding Protein-3

## HEMOSTASIS CE

### D-DIMER

D-Dimer

### FIBRINOGEN

Fibrinogen

### HEPARIN

Heparin Anti-Xa

## IMMUNOSUPPRESSANTS CE

### ISx

Cyclosporine
Sirolimus
Tacrolimus

## OSMOLALITY CE

### OSMO

Serum Osmolality
Urine Osmolality

## POC CE

### WBG

Glucose

## RHEUMATOID ARTHRITIS

### Anti-CCP

Cyclic Citrullinated Peptides IgG Antibody

## SARS-CoV-2 IgG CE

### SARS-CoV-2 IgG

SARS-CoV-2 IgG Antibody



# Calibration Verification Products (continued)

## SEPSIS

### IL-6
Interleukin-6

### PCT
Procalcitonin

## SEROLOGY

### aHBs
Hepatitis B Surface IgG Antibody

### Rubella IgG
Rubella IgG Antibody

### Toxoplasma IgG
*Toxoplasma gondii* IgG Antibody

## SERUM PROTEINS

### SP1
Alpha-1 Antitrypsin
Complement C3
Complement C4
Immunoglobulin A
Immunoglobulin G
Immunoglobulin M
Transferrin

### SP2
Albumin
C-Reactive Protein
Ceruloplasmin
Haptoglobin
Prealbumin
Rheumatoid Factor

### SP3
Alpha-1-Acid Glycoprotein
Antistreptolysin O
B2-Microglobulin
Immunoglobulin E

## THERAPEUTIC DRUGS

### MTX*
Methotrexate
*Not CE-approved

### TDM1*
Acetaminophen
Amikacin
Carbamazepine
Digoxin
Gentamicin
Lidocaine
N-Acetylprocainamide
Phenobarbital
Phenytoin
Primidone
Procainamide
Quinidine
Salicylate
Theophylline
Tobramycin
Valproic Acid
Vancomycin
*301ab, 301au, and 301bc are not CE-approved

## THYROID

### THY*
Cortisol
Free Triiodothyronine
Free Thyroxine
Thyroid Stimulating Hormone
Total Triiodothyronine
Total Thyroxine
*901ab and 901re not CE-approved

### THY2*
Thyroglobulin
T-Uptake
*Not CE-approved

### CT*
Calcitonin
*Not CE-approved

## THYROID II

### aTG
Anti-Thyroglobulin

### aTPO
Anti-Thyroid Peroxidase

## TUMOR MARKERS

### PSA*
Free Prostate-Specific Antigen
Total Free Prostate-Specific Antigen
*Not CE-approved

### Tumor Markers
Cancer Antigen 15-3
Cancer Antigen 19-9
Cancer Antigen 125
Carcinoembryonic Antigen

### Tumor Markers 2*
Cytokeratin 19 Fragment
Human Epididymal Protein 4
*Not CE-approved

## URINE CHEMISTRY

### UC1*
Chloride
Ethyl Alcohol
Glucose
Potassium
Sodium
Total Protein
Urea Nitrogen
Uric Acid
*701re not CE-approved

### UC4*
Calcium
Cortisol
Creatinine
Magnesium
Phosphorus
*704ro not CE-approved

### UC5
Amylase
Micro-Albumin
Pancreatic Amylase

### UC6
Micro-Albumin
Creatinine

# Data Submission

MSDRx INFINITY

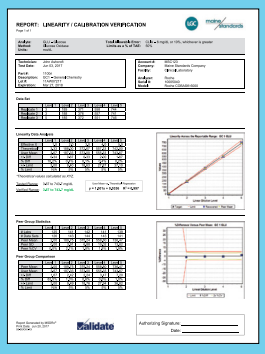
Maine Standards' Data Reduction Program puts the power of analysis at your fingertips. This free statistical software delivers real-time analysis of your calibration verification and linearity test results.

### LINEARITY ASSESSMENT

Instant results. Easily and quickly perform linear regression analysis, including slope (proportional error), y-intercept (constant error), $R^2$ and view an X-Y graph.

### PEER GROUP ANALYSIS

Take peer group analysis to a new level by using VALIDATE®, AccuTrak™, and MSDRx® Infinity. Compare your data to Peer Means at each level across the entire range. Supplying vital information to troubleshoot your assay and evaluate specific methods as part of routine accreditation events with anytime, online access to peer recoveries.



## Reports

MSDRx® Infinity provides clear, concise, easily understood and explained statistical analyses and graphic presentations. You, your colleagues, your inspectors and your auditors can assess your laboratory performance quickly and with little interpretation.

CE marked kits. Check with international distributors for specific product availability.

DEA Registered Facility for the manufacture of controlled substances.

US FDA Registered Facility. Complies with Quality System Regulation (QSR).

ISO 13485:2016 Accredited Quality Management System (QMS).

CE EC REP

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AccuTrak™

Validate®

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MKT-00618 Rev. 33

LGC CLINICAL DIAGNOSTICS

Science for a Safer World

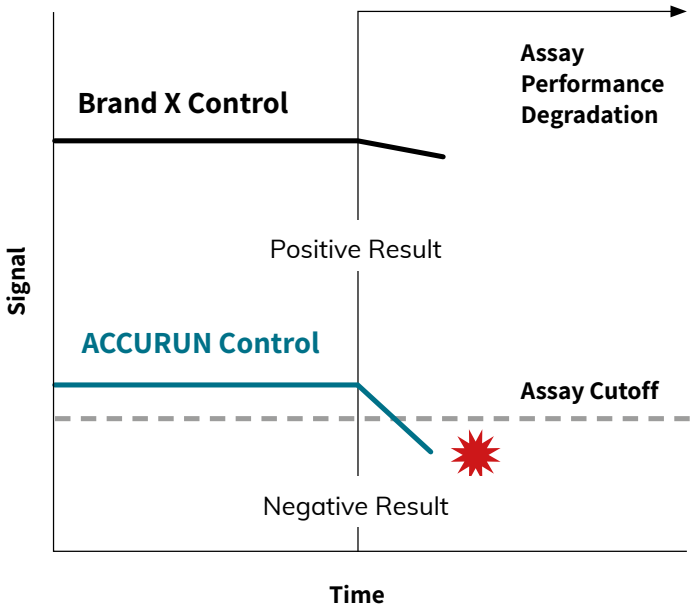
# ACCURUN®

**The leader in low-positive molecular controls for infectious disease testing**

## INTRODUCTION

**Monitor all aspects of your molecular testing program with full-process independent controls that truly challenge assay performance. ACCURUN molecular controls mimic patient samples and enable evaluation of the entire testing process, from extraction through detection. As a leader in low-positive controls, we provide the tools to challenge your molecular assay near the limit of detection, enabling superior monitoring of overall assay performance and lot-to-lot variability.**

Specially formulated to exhibit weak reactivity in true patient-like matrices to pressure-test assay performance near critical clinical decision points, ACCURUN controls offer sensitive detection of subtle shifts in testing trends and mitigate the risk of reporting false results.




| | | |
|---|---|---|
| **CLINICALLY RELEVANT RANGES**<br>Weakly reactive, low-positive controls that challenge an assay's performance at critical decision points | **PATIENT-LIKE MATRICES**<br>Human sourced to mimic authentic patient samples encountered in a daily testing environment | **FULL PROCESS CONTROLS**<br>Whole virus/organism controls designed to detect failures at every stage of the testing protocol |
| **LOT-TO-LOT CONSISTENCY**<br>Produced in large lot sizes under cGMP and ISO 13485 conditions for long-term QC monitoring | **EXTENDED SHELF LIFE**<br>Stable for at least 18 months from date of manufacture | **EASE OF USE**<br>Controls are offered in ready-to-use format in convenient pack sizes |

## ABOUT US

SeraCare offers a comprehensive portfolio of reference materials for oncology and reproductive health, designed and manufactured to meet the precision demanded by NGS assays. The portfolio includes high quality ground-truth RNA, ctDNA and genomic DNA-based reference materials that are NGS platform agnostic for tumor profiling, immuno-oncology, liquid biopsy, NIPT and germline cancer assay workflows. **For more information visit seracare.com**

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LGC CLINICAL DIAGNOSTICS

ACCURUN®

| | PRODUCT NAME | HBV DNA | HCV RNA | HIV-1 RNA | CMV DNA | CT/NG Nucleic Acid | HPV Type 16 DNA | HPV Type 18 DNA | *C. difficile* | Babesia microti | Cystic Fibrosis | SARS-CoV-2 | RSV | Influenza A/B | Internal Control | COMPLIANCE | STORAGE |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| POSITIVE MOLECULAR CONTROLS AND REFERENCE MATERIAL | ACCURUN 305 Series 100 | | ● | | | | | | | | | | | | | CE-IVD, US-IVD, CA-IVD | |
| | ACCURUN 305 Series 150 | | ● | | | | | | | | | | | | | CE-IVD, US-IVD, CA-IVD | |
| | ACCURUN 305 Series 300 | | ● | | | | | | | | | | | | | CE-IVD, US-IVD, CA-IVD | |
| | ACCURUN 305 Series 400 | | ● | | | | | | | | | | | | | CE-IVD, US-IVD, CA-IVD | |
| | ACCURUN 315 Series 150 | | | ● | | | | | | | | | | | | CE-IVD, US-IVD, CA-IVD | |
| | ACCURUN 315 Series 200 | | | ● | | | | | | | | | | | | CE-IVD, US-IVD, CA-IVD | |
| | ACCURUN 315 Series 400 | | | ● | | | | | | | | | | | | CE-IVD, US-IVD, CA-IVD | |
| | ACCURUN 325 Series 200 | ● | | | | | | | | | | | | | | CE-IVD, US-IVD, CA-IVD | |
| | ACCURUN 325 Series 700 | ● | | | | | | | | | | | | | | CE-IVD, US-IVD, CA-IVD | |
| | ACCURUN 342 Series 100 | | | | | ● | | | | | | | | | | CE-IVD, US-IVD, CA-IVD | |
| | ACCURUN 342 Series 700 | | | | | ● | | | | | | | | | | CE-IVD, US-IVD, CA-IVD | |
| | ACCURUN 345 Series 150 | ● | ● | ● | | | | | | | | | | | | CE-IVD, US-IVD, CA-IVD | |
| | ACCURUN 372 Series 400 | | | | | | ● | | | | | | | | | CE-IVD, US-IVD, CA-IVD | |
| | ACCURUN 372 Series 600 | | | | | | ● | | | | | | | | | CE-IVD, US-IVD, CA-IVD | |
| | ACCURUN 378 Series 5000 | | | | | | ● | | | | | | | | | CE-IVD, US-IVD, CA-IVD | |
| | ACCURUN 381 | | | | | | ● | ● | | | | | | | | CE-IVD, US-IVD, CA-IVD | |
| | ACCURUN 501 | | | | | | | | ● | | | | | | | CE-IVD, US-IVD, CA-IVD | |
| | ACCURUN Babesia | | | | | | | | | ● | | | | | | US-IVD | |
| | ACCURUN 350 CMV DNA | | | | ● | | | | | | | | | | | CE-IVD, US-IVD | |
| | ACCURUN MS2 | | | | | | | | | | | | | ● | | RUO | |
| | ACCURUN 644 | | | | | | | | | ● | | | | | | RUO | |
| | ACCURUN 676 | | | | | | | | | ● | | | | | | RUO | |
| POSITIVE SWAB CONTROLS | ACCURUN Swab SARS-CoV-2 Reference Material Kit | | | | | | | | | | ● | | | | | RUO | |
| | ACCURUN Swab RSV Reference Material Kit | | | | | | | | | | | ● | | | | RUO | |
| | ACCURUN Swab Flu A/B Reference Material Kit | | | | | | | | | | | | ● | | | RUO | |
| NEGATIVE CONTROLS | ACCURUN 803 | ● | ● | ● | | | | | | | | | | | | CE-IVD, US-IVD, CA-IVD | |
| | ACCURUN 841 | | | | | ● | | | | | | | | | | CE-IVD, US-IVD | |
| | ACCURUN 872 | | | | | | ● | ● | | | | | | | | CE-IVD, US-IVD | |
| | ACCURUN 873 | | | | | | ● | ● | | | | | | | | CE-IVD, US-IVD, CA-IVD | |

CE Conformité Européene  IVD For *In Vitro* Diagnostic Use  RUO For Research Use Only  2 °C – 8 °C  -20 °C  -70 °C

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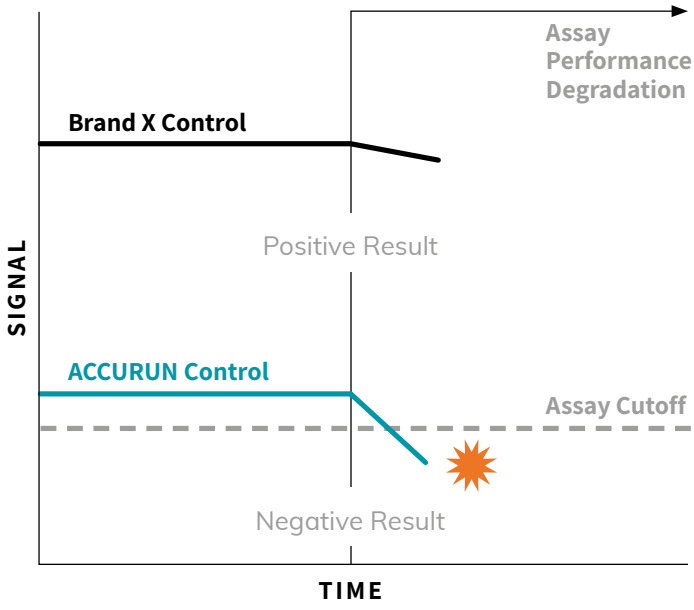
LGC CLINICAL DIAGNOSTICS

# ACCURUN®

## The Leader in Low-Positive Serology Controls for Infectious Disease Testing

The truest test of an assay's performance is at the lower limits of detection, near the clinical decision point – the boundary between a positive and negative result. This is where even a modest degradation in performance can produce the catastrophic consequence of a false patient result. Unfortunately, many manufacturers' in-kit controls and third-party commercial controls are not designed to detect subtle performance changes at these lower detection limits.

Avoid false-positives and false-negatives with ACCURUN independent serological controls for your assay. Our controls help monitor and troubleshoot test methods to isolate system errors in your laboratory. As a leader in lower limit-of-detection controls, we provide the tools to challenge your assay closer to the assay cut-off, giving confidence in your serology test results.




### LOW-POSITIVE CONTROLS

Specifically designed to be weakly reactive, low-positive controls, ACCURUN truly challenges an assays' performance at critical decision points.

### PATIENT-LIKE MATRICES

ACCURUN controls are human sourced to mimic authentic patient samples, as encountered in a daily testing environment.

### THIRD-PARTY/INDEPENDENT

ACCURUN controls are designed to deliver an independent and unbiased assessment of performance.

### LOT TO LOT CONSISTENCY

ACCURUN is produced in large lot sizes under cGMP and ISO 13485 conditions to ensure availability of bulk of a single lot for long-term QC monitoring.

### EXTENDED SHELF LIFE AND OPEN VIAL STABILITY

ACCURUN serology controls are stable for at least 18 months from date of manufacture and stable for at least 60 days once opened.

### EASE OF USE

Controls are offered in refrigerated, ready-to-use liquid format, enabling streamlined lab workflows.

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TO LEARN MORE OR ORDER ACCURUN SEROLOGY CONTROLS

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MKT-00669 Rev. 3