COLA'S SPRING 2026

inSights

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LETTER FROM THE CHAIR

Spring 2026

Spring is a season of renewal, and this edition of inSights arrives at a moment when the laboratory community has much to reflect on and much to look forward to. At the center of this issue is a topic that defines the collective mission within the Clinical Lab 2.0 movement: how we can deepen collaboration between laboratories and healthcare providers to help the patients we serve. Alongside this theme, our authors examine the global standards framework that makes quality measurable and comparable across borders. The International Organization for Standardization, whose very name reflects a commitment to equivalence, provides the scaffolding upon which laboratories everywhere can build credibility, consistency and clinical trust. Understanding how ISO standards shape laboratory practice is essential reading for any leader seeking to strengthen quality principles in the laboratory.

This edition also reminds us that the future of laboratory medicine is being shaped at every level — including among the very youngest. We are proud to feature the inspiring "STEM to STAT" initiative, which brings laboratory science to life for elementary-age children through The ABCs of Laboratory Medicine, a richly illustrated debut that introduces the next generation to the language of diagnostics. Building a workforce capable of sustaining quality and advancing collaboration begins long before the first shift in a clinical lab. And speaking of foundations — spring is also an ideal moment to tend to the operational ones. Our practical feature on laboratory spring cleaning offers timely guidance on decluttering records, streamlining documentation and ensuring your workspace is organized and compliance ready. Together, the articles in this issue weave a single thread: quality is not a destination but a continuous practice, cultivated at every level from the laboratory bench to the boardroom and from the classroom to the clinic.

Mary J. McDonald, MD, MPH
Chair, COLA Board of Directors

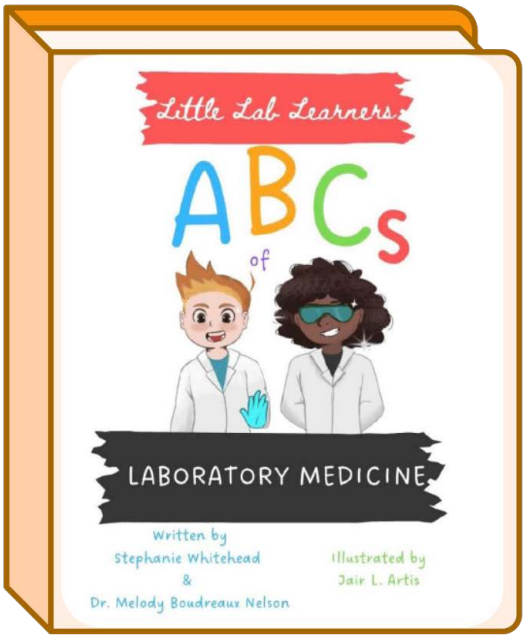
New Book Alert: The ABC's of Laboratory Medicine

By: Jennifer MacCormack MLS (ASCP)

Jennifer MacCormack is an experienced science and medical writer with a background in clinical laboratory testing, medical & health science.

Introduction

Some of the most transformative ideas don't emerge in isolation — they are born at the intersection of shared passion, cross-disciplinary dialogue and the kind of serendipitous connection that only happens when laboratory science professionals dare to show up, engage and be consistent in their commitment to laboratory and patients. Professional development and networking are often framed as career tools, but their true power runs deeper: they create the conditions for collaboration, spark curiosity and plant seeds that can grow into movements. That is precisely what happened for two laboratory science professionals whose repeated encounters on the conference circuit evolved into a partnership — and ultimately, a bold vision for the future of the field.



As their paths crossed multiple times at laboratory industry events and conferences beginning in 2020, Melody Nelson, DCLS, CC(NRCC), MS, MLS(ASCP) and Stephanie Whitehead, MBA, MPH, MLS(ASCP) found ways to collaborate on papers, present at international conferences and serve on laboratory workforce committees. As they pursued professional development and advocated for the laboratory profession, they heard from workforce development teams supporting ambassador programs and student events — at high schools and colleges, where many young people have already begun to form ideas about their future. What if, they thought, laboratory professionals tried to reach kids even younger, to nurture their inherent curiosity and give them a foundation of what laboratory science is about?

With an alignment of values and vision, Nelson and Whitehead, along with their colleague Aaron Odegard, developed a concept for an educational project they call “STEM to STAT,” which they hope to develop into a series of books and supporting learning materials for children at the elementary school level. The first book to grow out of this idea, The ABCs of Laboratory Medicine, takes young readers from “A is for Antibodies” to “Z is for Zone of Inhibition,” stopping to define a whole alphabet of laboratory science terms along the way. Every page features colorful laboratory imagery and a diverse cast of little laboratorians, illustrated by Jair L. Artis.

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Why did they decide to create an "ABCs" book instead of a more in-depth storybook? "There's a real gap in elementary exposure," says Nelson. At that age, "they're already talking about what they want to be when they grow up. That's the time to show them cool things that they could be." Whitehead agrees. While the laboratory industry is improving outreach towards students in high school and middle school, she sees an opportunity to establish foundational laboratory concepts with emerging readers at the preschool and elementary school level.

"Research shows that children start having ideas about formation of their careers between elementary and middle school," she explains. "The earlier we can add [laboratory science] as a possible career choice into their lives, and make it normal, it creates this pipeline."

A lot of thought went into the language choices for the book. Both parents and authors understand that a children's book's success often depends on how easily it can be read aloud. They emphasized accessibility for those who are new to laboratory science terms. "Can a parent who's non-medical read the book to them?" asks Nelson. "Will it be a painful process?" They also took great care selecting examples for each letter, ensuring that readers get a glimpse of all the different areas and specialties of the laboratory. "It's about sparking curiosity. It's about filling that gap with early learners and normalizing that language," explains Whitehead.

The book's official launch date was March 2, 2026, chosen specifically to coincide with Read Across America Day. The book was available for a pre-sale period; more than 200 copies were sold, far exceeding the authors' goal of 50. Much of the interest during the pre-sale period came from within the laboratory industry: laboratory scientists excited to have a book to share with their own children about their career, or to bring to career day events as they engage in their own outreach efforts.

"The reception has been really encouraging and affirming," says Whitehead. "People have sent us videos of their children flipping through the book and smiling." They have received inquiries from schools and library systems and are hoping that this proof of concept opens a door for an entire book series dedicated to different aspects of laboratory science. "We think about our legacy," says Nelson. "When we're not here anymore, what will people say about what we've done for our field?" They encourage other laboratorians to lean into their own talents and interests to create more visibility for the profession, and use their passions to draw others in. It's common for laboratorians to stay behind the scenes, but it's being seen that will get people interested in what we do. "It's time," says Whitehead, "for people to start knowing who we each individually are."

The ABCs of Laboratory Medicine, written by Melody Nelson, DCLS, CC(NRCC), MS, MLS(ASCP) and Stephanie Whitehead, MBA, MPH, MLS(ASCP) and illustrated by Jair L. Artis, is available in hardcover and paperback at https://stem-to-stat.myshopify.com/

Melody Boudreaux Nelson, DCLS, CC(NRCC), MS, MLS is an Assistant Clinical Professor in the Department of Pathology and Laboratory Medicine at the University of Kansas Medical Center. She serves as the Assistant Director of the Core Laboratory with a focus on Clinical Chemistry and the Section Director of Point of Care services at the University of Kansas Health System. Dr. Nelson holds board certification in Clinical Chemistry through the National Registry of Certified Chemists. She also is a certified High Value Healthcare Professional through the International Consortium for Health Outcomes Measurement.

Stephanie Whitehead, MBA, MPH, MLS(ASCP) is an accomplished executive laboratory leader recognized for her warm and approachable demeanor. With extensive experience in both hospital administration and laboratory operations, she combines expertise in conflict resolution, team building, and customer-focused service. A skilled multitasker and punctual problem solver, Stephanie consistently plays a key role in delivering immediate, impactful solutions while contributing to the long-term success of her organization.

The Clinical Lab 2.0 Movement: A Report from the Project Santa Fe Foundation

CLINICAL LAB 2.0
A PROJECT SANTA FE FOUNDATION INITIATIVE

By James M. Crawford, MD PhD, FCAP, FASCP and Khosrow Shotorbani, MBA, MLS(ASCP)

Dr. James Crawford is chair emeritus of the department of pathology and laboratory medicine at Northwell Health and the Donald and Barbara Zucker School of Medicine at Hofstra/Northwell. From 2009-2023, he served as department chair, and as Senior Vice President for Laboratory Services, and led Northwell Health Laboratories, a major non-profit integrated regional laboratory network serving the Northwell Health system.

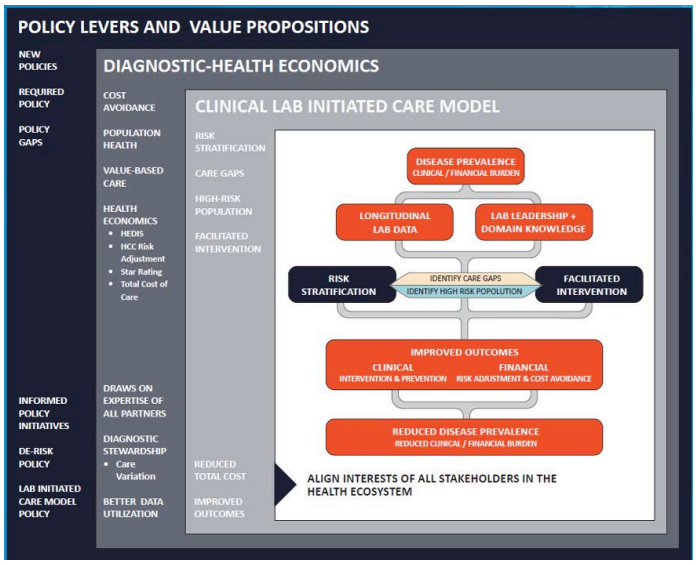
Khosrow Shotorbani is the founder and The CEO of new established Lab 2.0 Strategic Services, LLC. He is a member of Project Santa Fe lab 2.0 industry advocate. As a former President and Chief Executive Officer at TriCore Reference Laboratories, Shotorbani oversaw the corporate direction and strategy of TriCore, focusing on leadership and innovation, as well as operations, growth, and the financial health of the company.

Founded in 2017 and formalized as a nonprofit organization in June 2019, the Project Santa Fe Foundation (PSFF) is a coalition of laboratory leaders dedicated to transforming clinical laboratory services through its Clinical Lab 2.0 movement (CL2.0). Our mission is to challenge the traditional volume-driven laboratory testing model by exploring disruptive value-based paradigms and alternative business models that elevate the role of diagnostic services in future healthcare. This is a global movement, in that the opportunities are in all international settings, bounded only by the national healthcare policies affecting valuation and payment for healthcare.

The pillars of the CL2.0 movement are:

- Leadership: outside of the four walls of the laboratory
- Clinical Lab 2.0 Standards: measuring what matters, with objective key results (OKR)
- Evidence Building: establishing a robust evidence base to support the business case for the integrative, proactive role of diagnostic laboratory services in health care
- Collaboration: partnership with industry stakeholders to guide policy, disseminate knowledge and scale Clinical Lab 2.0 practices
- Population Health Focus: using longitudinal laboratory data to improve time-to-diagnosis, optimize therapeutic decisions, proactively manage chronic conditions and manage risk for intercurrent acute events. Expanding the clinical laboratory's influence on the entirety of the healthcare spend, not just the 2.5%ascribed to laboratory expense.

Figure 1 provides an overview of the CL2.0 model.



Clinical Laboratory Initiated Care Model:

The clinical laboratory plays a central role in identifying disease within populations: the combination of longitudinal laboratory data and the domain knowledge, leadership and expertise of laboratory professionals help ensure that the clinical burden of disease is recognized. This permits identification of individuals at high risk of disease and identification of gaps in their health care. Laboratory-informed risk stratification can trigger clinical program design to ensure intervention in patient management. The outcome measures must include both clinical and financial outcomes; only with both can the value contribution of the clinical laboratory be identified and attributed. The ultimate goal is reduced prevalence of disease in the populations at risk, as measured both by reduced clinical disease burden and reduced total costs for care of these populations.

Diagnostic-Health Economics:

Improved economics include cost avoidance for intercurrent health events and improved health of the population. In the U.S., the metrics include the Value-Based Care metrics of Healthcare Effectiveness Data and Information Set (HEDIS); risk adjustment on the basis of Hierarchical Condition Categories (HCC); Medicare Star Ratings, as administered by the Centers for Medicare & Medicaid Services (CMS); and improved total costs of care, as reflected in Per Member Per Month (PMPM) costs.

Policy Levers and Value Propositions:

The challenge is that current health care policy does not recognize the clinical laboratory contribution to value-based care. Laboratories are reimbursed only for the resulting of laboratory tests, not for contributing strategically to the health outcomes of populations. The CL2.0 movement advocates for new policies that will empower clinical laboratories to be active contributors and hopefully leaders in strategic design and implementation of health care programming that will achieve both improved clinical and economic outcomes of the populations we serve. This should include recognition of laboratory-initiated care models.

The activities of the CL2.0 movement are:

Annual Workshops:

Since 2016, PSFF's Clinical Lab 2.0 Public Workshop convenes healthcare and laboratory executives to discuss convergence of pathology, population health, AI and value-based care.

Annual Colloquia:

Since 2016, PSFF also has convened invitation-only annual colloquia, conducted under The Chatham House Rule, to encourage deep and extensive discussions among leaders in the clinical laboratory and in vitro diagnostics industry.

Demonstration Projects:

Multi-institutional initiatives benchmark how laboratories can close care gaps, stratify risk and drive outcomes, particularly for high-prevalence conditions like diabetes or chronic kidney disease.

Industry Engagement:

Key partnerships in support of the CL2.0 mission include leading partners across the in vitro diagnostics industry.

From 2017 to 2023, the CL2.0 movement was based predominantly on the leadership and activities of the entities reflected in the board of directors **(Table 1)**.

Table 1: Entities Represented on the PSFF Board of Directors

Institution	Board Member
Northwell Health	James M. Crawford, MD PhD
Geisinger Health System	Myra L. Wilkerson, MD
Robert Larner MD College of Medicine, University of Vermont	Mark K. Fung, MD PhD
North Shore/Endeavor Health	Karen L. Kaul, MD PhD
University of Pittsburgh School of Medicine	Octavia M. Peck Palmer, PhD
Henry Ford Health System	Richard J. Zarbo, MD DMD
COLA	Nancy Stratton, MBA
Lab 2.0 Strategic Services, LLC	Khosrow Shotorbani, MBA, MLS (ASCP)

In 2024, a major step was taken in formation of committees to drive innovation in four domains: education and certification; business and alternative payment models; demonstration projects; and informatics and artificial intelligence **(Table 2).**

Table 2: Committees of the CL2.0 Movement

Committee	Co-Chairs
Education and Certification	Hassan Aziz, PhD, FACSs, MLS (ASCP) Peter Hu, PhD, FACSc, FASAHP Yasmen Simonian, PhD, MLS(ASCP), FACSc, FASAHP
Business-Alternative Payment Model	Lena Chaihorsky Julie Cooper, MA, FACHE
Multi-Institutional Demonstration Projects	Aya Haghamad, PharmD Yachana Kataria, PhD Kathy Swanson, MS, RPh, PSFF Staff Liaison
Pathology Informatics-Artificial Intelligence	Amjad Azizi Ulysses Balis, MD, FCAP, FASCP
Policy	Ralph Hall, JD Jennifer Houlihan, MSP
Industry Coalition	James G. Donnelly, PhD, MBA, DABCC, FADLM, FCACB Jack Redding, MBA

This year, 2026, two further committees have been commissioned: policy and the CL2.0 industry coalition. The engagement of a broad coalition of laboratory leaders through these committees is a powerful driving force for advancing the mission of CL2.0. The committee products will include protocols and standards for pursuing CL2.0 within your own institutional settings, with vignettes to illustrate how CL2.0 can play out in specific examples.

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Lastly, the ten-year journey of CL2.0 has made clear a number of principles by which clinical laboratories can increase their contributions to the regional populations they serve, while simultaneously being recognized for those contributions **(Table 3)**.

Table 3: Principles for CL2.0 Success

Criterion	Comment
Selection of Disease Condition*	The condition should be an important health problem; There should be a recognizable latent or early symptomatic stage; The natural history of the condition, including development from latent to declared disease, should be adequately understood.
Setting*	Facilities for diagnosis and treatment should be available.
Diagnosis*	There should be a suitable test for diagnosis; The test should be acceptable to the population; The test findings should be part of a longitudinal care process.
Treatment*	There should be an accepted intervention for treatment of patients diagnosed with the condition.
Cost-effectiveness*	The cost of case finding (including diagnosis and treatment of patients diagnosed) should be economically balanced in relation to possible expenditure on medical care as a whole.
Opportunity	There should be gaps between the laboratory's ability to identify a potential disease condition, and the actual rate of condition diagnosis in a population at risk
Prioritization	There is realistic feasibility for realized improvement in population health status on the basis of the proposed initiative. In addition, the CL2.0 project must matter to stakeholders (e.g., health care providers; health system CEO, COO, CFO, CQO, CMO, CNO, etc.; payers; civic stakeholders; patient advocacy stakeholders).
Health Care Team and Coalition Building	Laboratory should be part of and potentially lead the multidisciplinary, interprofessional team required to conduct the project.
Funding	These activities are not resourced by the laboratory cost-per-test revenue cycle; either funding for the coalition effort will need to include resourcing of the laboratory contribution or the laboratory will need to pilot the resourcing as part of reputation-building.
Metrics	The quantitative data to inform population status before and after intervention needs to be established before project initiation and should be accrued prospectively.
Valuation	The project metrics should be linked to the metrics of value-based care.
Outcomes	Clinical and economic outcomes must be realized, not imputed.
Attribution	The clinical laboratory's causal contribution to program initiation and deployment, and hence outcomes, must be established at the outset of the project.
Reputation	The laboratory should be forthright in stating its causal contribution to successful project outcomes.

Abbreviations: CEO, chief executive officer; CFO, chief financial officer; CMO, chief medical officer; CNO, chief nursing officer; COO, chief operating officer; CQO, chief quality officer.
*From Gines P, et al., Hepatology 2022; 75:213-218. DOI: 10.1002/jep.32163.

Examples of successful outcomes of CL2.0 projects are given in **Table 4,** each of which has had significant reputational value for the clinical laboratories involved.

Table 4: Illustrative CL2.0 Demonstration Projects

Topic	Intervention	Outcomes
Acute Kidney Injury (AKI)[1]	Laboratory-triggered identification of AKI upon or during hospital admission	Improved diagnosis of AKI, ensuring proactive management
Blood Bottle Fill Volume[2]	Full inoculum of blood in bottle, especially for blood draws performed in emergency departments	Identification of bacteremia on admission rather than on 2nd blood draw; earlier antibiotic adjustment
Prenatal care of diabetes[3]	Identification of gaps in diabetes care during pregnancy	Reduced neonatal intensive care admissions for newborn children
COVID-19 laboratory response[4]	Health system deployment of SARS-CoV-2 diagnostic testing	Ability to keep health facilities open, and to protect the healthcare workforce
Chronic Kidney Disease (CKD)[5]	Laboratory-triggered identification of undiagnosed CKD Stages 3 and 4	Real world evidence to support health system strategic programming for early diagnosis of CKD

Citations: (1) Kothari T, et al., *Acad Pathol* 2018; DOI: 10.1177/2374289518816502; (2) Khare R et al., *Clin Infect Dis* 2019 March 14; pii.ciz198; doi: 10.1093/cid/ciz198; (3) VanNess R, et al., *Am J Managed Care* 2021 Feb; 27(2): 60-65. doi: 10.37765/ajmc.2021.88582; (4) Kaul K, et al. *Acad Pathol* 2021; DOI: 10.1177/23742895211010253; (5) Fung M, et al., *BMC Nephrology,* 6 Dec 2024; 25:447. DOI: 10.1186/s12882-024-03869-4.

We welcome your involvement in the CL2.0 movement. This is made possible through sending a message through the CL2.0 website (https://cl2lab.org).

This could include participation on one of the committees, initiation of a demonstration project in your own practice setting, advocacy or other activities as you are able. The future is before us.

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The Origins and Global Impact of ISO: Setting the Standard for Quality and Safety Worldwide

By: Eamon Tiffany BSN, MLS(ASCP)

Prior to joining COLA in 2017, Eamon Tiffany was a General Supervisor at the University of Maryland Medical Center Midtown Campus for 14 years, overseeing the Core Laboratory, Transfusion Services, and Microbiology sections. He previously held the position of Senior Operations Manager at COLA, where he managed and supported surveyors and developed policies and process improvement strategies for the Accreditation Division. He currently serves as COLA's Director of Standards, Regulations and Policies.

The International Organization for Standardization is commonly referred to as ISO. The letters ISO are not an acronym; they are derived from the Greek word “isos,” meaning equal, which relates to the organization's overall goal to ensure a standard level of quality and safety across a wide array of industry sectors on a global scale. ISO was formed in 1947 by a group of technical experts from 25 countries in fields such as manufacturing, shipbuilding, food production and laboratory equipment. The first standard developed by ISO was released in 1951 and addressed a reference temperature for conducting industrial measurements. Currently, there are 25,000 ISO standards, and representatives from 175 countries are participating in the continued development and revision of standards..

Until 2003, medical laboratories throughout the world were assessed to the ISO standards 9001 and 17025. These standards relate to quality management systems and testing and calibrations, respectively, and apply to a variety of types of laboratories. ISO and medical laboratories conforming to those standards recognized the need for a new standard consisting of more specific requirements which would address the unique operations of a medical laboratory in delivering safe, accurate and efficient patient care, as well as ensuring the safety of laboratory personnel. As a result, the first edition of the ISO 15189 Standard was published in 2003. This standard combined the elements of the ISO 9001 Standard in terms of a focus on maintaining a high level of quality in all phases of testing and the ISO 17025 Standard, related to requirements for the performance of patient testing, oversight of equipment used in testing patient specimens and competence of laboratory personnel. The current version of the standard, ISO 15189 Standard:2022, is the third edition since its inception.

The ISO 15189 Standard has been adopted internationally into the regulations of over 60 countries for the oversight of medical laboratories. In the U.S., we are accustomed to laboratories complying with CLIA regulations, but some laboratories within this country choose to adhere to both the CLIA regulations and the ISO 15189 Standard, most often in situations where those laboratories are accepting patient specimens from other countries for testing.

The ISO 15189 Standard differs from CLIA regulations in that it focuses on a laboratory’s processes for patient testing, utilizing instruments and assessing the competence of laboratory personnel. This is in contrast with an emphasis on procedures which require specific elements, as is seen in the CLIA regulations. The structure of the requirements in the ISO 15189 Standard allows for a wider range of means for a laboratory to meet those requirements. As a result, assessments to determine conformity related to the requirements’ intent require a broader approach than a typical CLIA survey. The ISO 15189 Standard:2022 version also places responsibility on a laboratory to identify and mitigate any risks to its delivery of patient testing results and related operations.

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The terminology associated with the standard differs from CLIA regulations as well. For example, whereas CLIA requirements refer to as a "survey," the standard uses the term "assessment." Also in the standard, the term "assessor" is used to describe the individual performing the assessment, "accreditation body" is the entity accrediting a laboratory, and "conformity assessment body" is the laboratory being assessed. Generally, the assessment cycle for a laboratory to be accredited to the ISO 15189 Standard occurs over three years, with a reapproval assessment on the third year and two annual surveillance assessments in the intervening years. The reapproval assessment involves assessing full conformity with all requirements in the standards, while the surveillance assessment may focus on particular areas, such as the competency of staff or proficiency testing. In addition, the history of non-conformities of the particular laboratory will guide assessors in determining areas of focus.

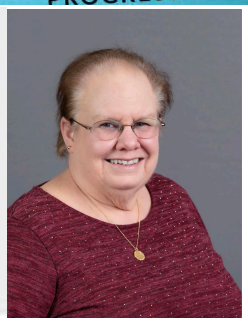
COLA has developed its ISO 15189 Program through careful research and development, and we are in a great position to provide accreditation services to laboratories abroad, as well as within the U.S. In pursuit of strengthening our program, we received an Associate Membership from the Inter-American Accreditation Cooperation (IAAC) in September of 2025. The IAAC provides recognition of accreditation bodies, such as COLA, that are able to provide ISO accreditation services in accordance with its standards. The IAAC recognizes and supports accreditation bodies throughout North and South America. This recognition for COLA is a step in achieving global recognition with the Global Accreditation Cooperation (GAC), which will enhance our ability to accredit laboratories to the ISO 15189 Standard globally.

Our staff of Surveyors who are trained as Assessors in the ISO 15189 Program, bring a vast amount of knowledge and experience from surveying to the CLIA requirements, which is easily translatable to performing assessments to the ISO 15189 Standard. As an accreditation body, COLA itself conforms to a separate ISO standard: ISO 17011. This standard contains requirements for accreditation bodies to provide consistent, high-quality services in the oversight of their accredited laboratories. In addition, COLA has been certified to ISO 9001, Quality Management System Requirements, since 2011.

COLA is excited to take this next step with our ISO 15189 Program in becoming a global brand with accreditation services, allowing laboratories to deliver the best care possible for their patients.

Quality Assessment: Optimizing Collaboration Between Laboratories and Healthcare Providers

By Anita Coleman BS, MLS(ASCP)



Anita Coleman began her laboratory career in 1973 as a Medical Laboratory Technician at Oscar B. Hunter Laboratory in Washington, DC, gaining foundational experience in Serology and Coagulation. She also served as a clinical instructor for Medical Technologist students from American University. Anita earned her Bachelor of Science in Medical Technology from George Washington University in 1993.
In 2001, she joined COLA as a Technical Advisor for the Southeast region and was promoted in 2008 to Technical Support Specialist, a role in which she works closely with laboratories needing additional guidance to achieve regulatory compliance — ensuring they can deliver accurate, safe results for their patients.

The relationship between healthcare providers and medical laboratories is crucial for effective patient care. Medical laboratory professionals perform a wide range of testing that assists providers in diagnosing and monitoring medical conditions and they collaborate closely with those healthcare providers to ensure accurate and timely results.

Facets of the relationship between healthcare providers and laboratories include:

1) Consultation on test selection
   - Laboratory directors and clinical consultants are available to advise healthcare providers in determining the most appropriate test(s) to order based on a patient's symptoms and medical history
2) Interpretation of results
   - Laboratory professionals do not only perform testing; they can provide additional context or insights to assist healthcare providers in understanding the performance characteristics of tests and implications for patient care
   - The laboratory's clinical consultant assists providers with interpretation of results
3) Communication
   - Effective communication supports successful collaboration, ensuring that healthcare providers and laboratory professionals are operating with the same information and working toward the same goals
4) Technology
   - Advances in technology, such as electronic health records, telemedicine and patient portals facilitate communication and streamline exchange of information between medical laboratory professionals, healthcare providers and patients

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Collaboration between providers and the laboratory is essential for making informed decisions about patient care and improving diagnostic accuracy. An important means of producing accurate and timely results to ensure patient safety and patient care is for laboratories to have an effective quality assessment (QA) plan. The QA plan addresses the total laboratory process, from the time the order is placed, to specimen collection and arrival in the laboratory, to the moment results are reported to an appropriate healthcare provider.

Quality assessment monitors accuracy, reliability and validity of a laboratory's testing results. Key components of a laboratory's QA plan include documentation control, record management, training and competency management along with analyzer calibration and maintenance. Risk management, root cause analysis and problem solving are also important components of a comprehensive QA plan. Regular QA activities also contribute to survey readiness and help to manage any concerns or complaints from healthcare providers or patients.

CLIA regulations and COLA accreditation criteria address specific QA requirements, stating that laboratories must establish and follow written policies and procedures for a comprehensive QA program that is designed to monitor and evaluate the ongoing and overall quality of the total testing process. It involves determining specific quality goals, deciding whether those goals have been achieved and implementing corrective action plans if the goals have not been met. A QA plan includes auditing the effectiveness of written policies and procedures in achieving the necessary level of quality and encompasses all phases of testing and general administration of the laboratory.

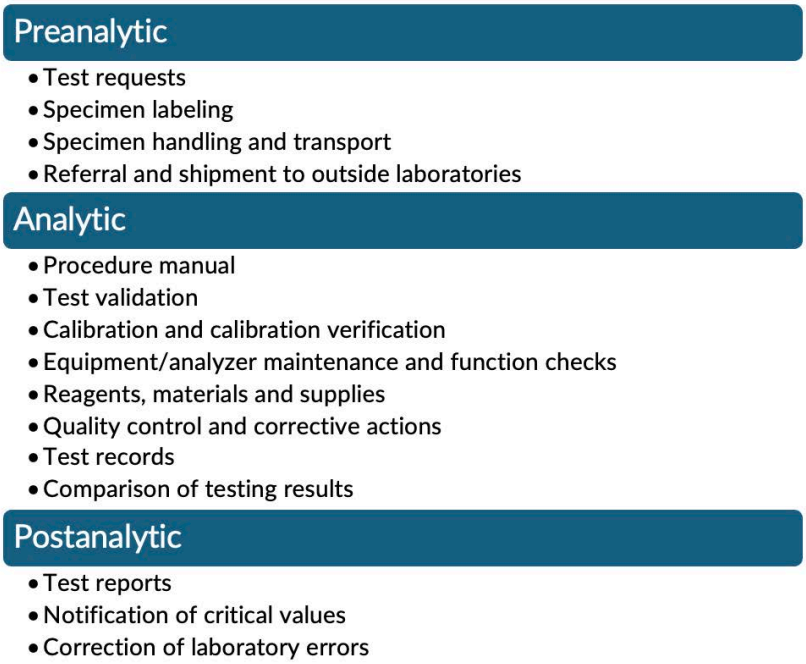

Figure 1

Every quality system in a laboratory must be thoroughly evaluated over the course of each year. QA plans should cover the entire testing process as well as more general laboratory processes including confidentiality of patient information, specimen identification and integrity, communication and complaints, personnel competency assessments, proficiency testing (PT) and/or split-specimen testing
(SST).

All phases of testing must be addressed in quality assessment reviews: preanalytic, analytic and postanalytic.
Figure 1 includes examples of targets for regular QA review in all areas of the testing process. Regular and thorough assessment of all these processes is essential for maintaining quality and compliance with regulatory requirements.

The goal of any quality system is to obtain testing results that are reliable, relevant and reproducible. A quality assessment program is an ongoing, comprehensive program that aims to uncover gaps in quality and areas for improvement. For example, a thorough review of Quality Control (QC) data can identify potential test system problems before they affect patient results. When a follow-up review reveals that the corrective action succeeded in preventing further issues, the laboratory can be confident that their QC procedures are working better after the intervention. A comprehensive QA plan works the same way: monitor for non-confirming events, identify the root cause, implement corrective actions and then re-review for effectiveness.

Effective and well managed QA is crucial for informed collaborative decision-making in healthcare. It assists in identifying and preventing errors, maintaining compliance with requirements and improving the credibility of laboratory data. Working with a laboratory whose QA systems are thorough allows healthcare providers to be confident that any results coming from the laboratory are reliable and they can be certain of their diagnosis and treatment plan for their patients.

Out With the Old, In With the Organized: A Spring Cleaning Guide for Clinical Laboratories

By: Jennifer MacCormack, MLS (ASCP)

Jennifer MacCormack is an experienced science and medical writer with a background in clinical laboratory testing, medical & health science.

Spring is a common time for cleaning up and refreshing. It's worth taking some time to give your laboratory a once-over to declutter and tidy things so you can work in a more organized space and be prepared for compliance visits. Many laboratories err on the side of keeping more paperwork than they need to, because record-keeping is so important for regulatory compliance. But keeping too much, or having it stored haphazardly, makes it harder to find items you need.

Review Records and References

Check shelves, workstations and drawers for publications and reference books that have been collected over the years and determine whether any have outlived their usefulness. A user manual for an instrument the laboratory got rid of over two years ago? A laboratory magazine featuring the newest hematology technology of 2003? It might be time to retire those to the recycling bin. If any out-of-date reference book needs to go, make a note to research an appropriate replacement so that it can be purchased. Cleanup also applies to job aids and quick reference guides kept at the bench. If they are too old or have been beaten up and stained from regular use, think about replacing them.

Review the requirements for record retention and make sure that you aren't keeping records for longer than necessary. Most types of records must be retained for at least two years, but laboratories performing immunohematology or pathology testing will need to keep things longer. Some states and some accreditation organizations may have additional requirements, and the most stringent of those must be met. COLA-accredited laboratories can refer to the Postanalytic section of the Accreditation Manual for more details about retention times for different specialties and types of documents. Keeping documents long past the required retention time can clutter up your space and make it more difficult to find records when you need to refer back to something. If you use off-site storage for older documents, that is a cost that adds up.

Clean up Personnel Files

Everyone working in the laboratory needs to have a personnel file containing documentation showing they're qualified for the roles that they fill. This includes copies of diplomas or transcripts to show they have completed the required level of education. If anyone earned a degree outside of the United States, they also need a document showing that their educational credentials have been assessed for equivalency to US education, and, if applicable, a translation of any documents that are not written in English. They also need documentation supporting their years of experience working in the laboratory. This may include evidence of hands-on bench work or supervisory work, depending on the specific role.

The recent updates to the CLIA regulations emphasized the importance of having third-party confirmation of work experience; that is, documents other than a person's own CV or resume. Some examples of this include job descriptions for positions previously held, and statements from employers or supervisors describing the person's roles and responsibilities. Many people are likely missing those third-party verifications of experience, and a review of personnel files will show which individuals should work on acquiring that documentation.

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Even if it's not needed for their current role in the laboratory, the absence of that documentation may get in the way of their career progress as they look to move into supervisory roles.

Job descriptions also need a regular refresh as people are trained in new areas and on new instruments and tests that are brought on board. Especially because these job descriptions can be used as supporting documentation for a person's experience, it is very helpful for them to be detailed. If possible, revise job descriptions to include information about what tests a person performs, including instrument names, test names, and the tests' complexity and laboratory specialty under which they are classified.

Check Expiration Dates

Most laboratories schedule a monthly walkthrough to review expiration dates on kits and products so that no old items linger on shelves past their expiration dates. However, it is easy to miss outdated items that are stored outside of the main laboratory area. If your laboratory has a phlebotomy area or serves a clinic with patient examination rooms, be sure to do a thorough sweep of those areas to confirm that any specimen collection materials present are in date. Look for expired swabs, tubes and urine cups. Replace the supplies as needed.

Take inventory of items in your laboratory that may not have expiration dates but nonetheless have a limited useful lifespan. For example, centrifuge balance tubes, squirt bottles and pipettes. Are they deteriorating? Are the markings or labels on them still legible? Look through safety supplies, too. If spill kits or first aid kits have been used, be sure to replenish necessary supplies. If your laboratory uses saline eyewash bottles instead of a built-in eyewash station or sink adapter, check the expiration dates – because they are very rarely used, they are often missed during a walkthrough.

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