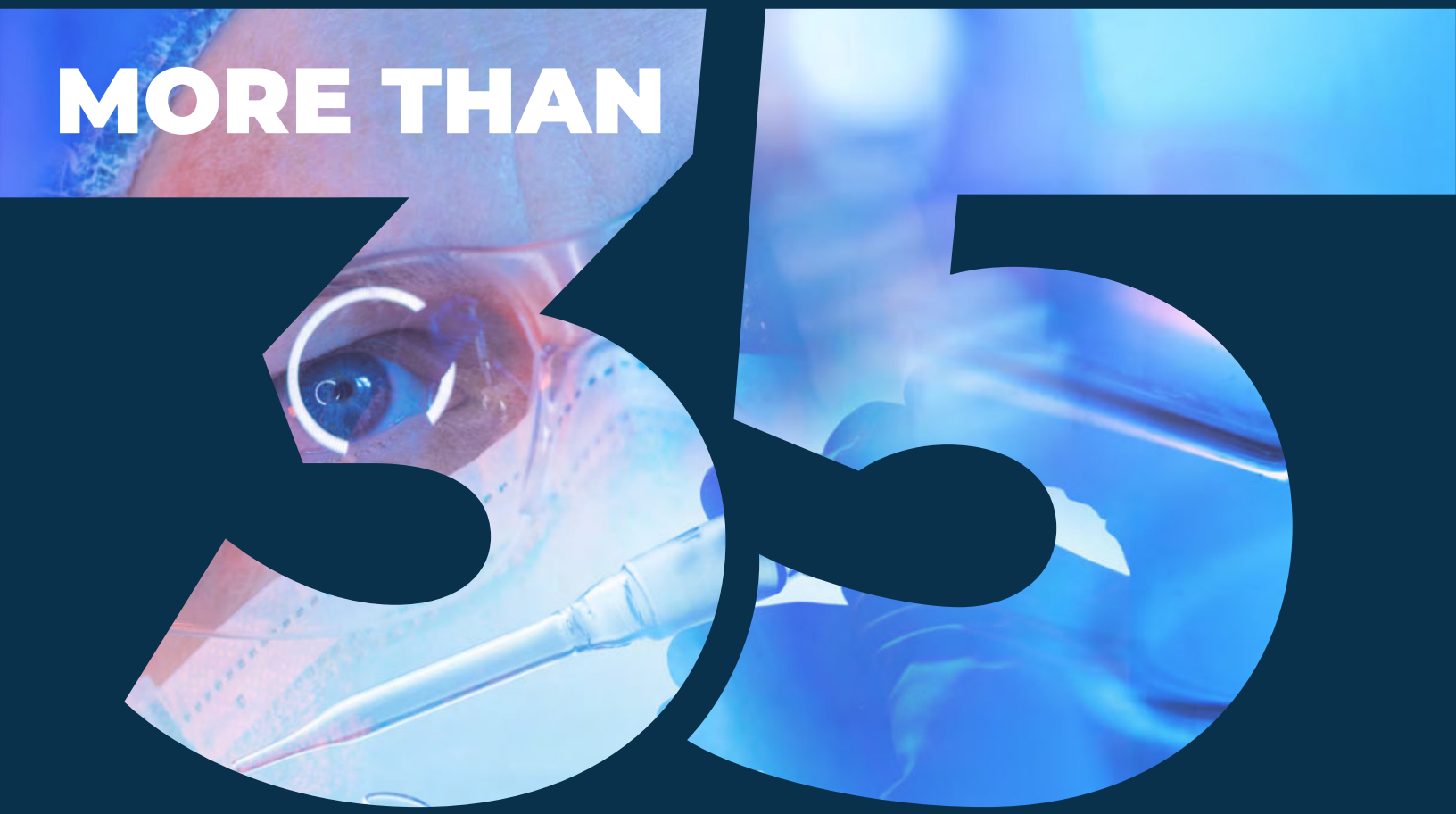
COLA'S Spring Edition 2025

inSIGHTS



MORE THAN 35 YEARS

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COLA™
COMMISSION ON LABORATORY ACCREDITATION

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LETTER FROM THE CHAIR

SPRING EDITION 2025

Any organization that exists for longer than 30 years is certain to have undergone changes and transitions that shape its impact on the industry it serves. I have the honor of having worked with COLA for more than ten years, first as a member of the Board of Directors appointed by the American Academy of Family Physicians (AAFP) and, since 2023, as the Board Chair. During those years I worked closely with COLA's leadership, I watched the organization dedicate itself to laboratory quality and earn CLIA deemed status through every renewal cycle thanks to their unwavering commitment to upholding the highest of standards.

Leadership itself has also changed at COLA; the Board had the important task of selecting a new CEO in 2018, and Nancy Stratton has proven many times over that the Board's ultimate choice was the right one for COLA. Under her guidance, the organization earned deemed status for Pathology, navigated significant changes to the CLIA regulations and weathered a global pandemic that tested the laboratory workforce.

Through it all, COLA's commitment to education has been a meaningful focal point for the organization. GiveBack365 is a national program that supports laboratory science through scholarships and outreach events at high schools and colleges. COLA also collaborates closely with other industry leaders within the Workforce Action Alliance to develop meaningful approaches to alleviating the workforce shortages affecting the laboratory field.

COLA has recently rebranded to better reflect the accreditation and educational services provided to laboratories across the country to ensure that they are able to meet high standards of quality and safety. Commission On Laboratory Accreditation is an organization confident in its identity and mission within the healthcare community and is ready to grow towards what the future brings.

Keith Davis, MD, FAAFP
Chair, COLA Board of Directors

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Letters From Past Board Chairs

I am proud to have served on the COLA Board of Directors for the last 14 years, and to have served as Board Chair, but my tenure is small change compared to the 35 years that COLA and its vanguard publication, inSights, have been fulfilling our mission: "Promoting Health and Safety through Accreditation and Education." I serve on the Board as a representative of the American College of Physicians (ACP), the largest medical specialty organization in the world, representing primary care internists and medicine sub-specialists. My own professional experience and work in the ACP provide both insight and appreciation for COLA and inSights' achievement in championing laboratory medicine.

Initially trained in internal medicine and hematology, I began my life-long career in academic medicine as the director of transfusion medicine at the Temple University School of Medicine. Admittedly much more comfortable with complex clinical transfusion decisions than identifying obscure antibodies, I was fortunate to work alongside a superb blood bank supervisor who filled those gaps, taught me and facilitated my involvement in the American Association of Blood Banks. While my career shifted toward medical education and my practice shifted toward primary care, I never gave up my appreciation for laboratory safety and quality. I grew more aware of the importance of enhancing communication between laboratory professionals and clinicians and ensuring that the laboratory strives to be cost effective and patient centered as well as precise, accurate and reliable.

My collaboration with remarkable laboratory professionals thrives at COLA. I am wowed by the scope of our work, maintaining timely awareness of the regulatory environment and late breaking opportunities to further enhance laboratory safety while reaching out to laboratories all over the country with an unwavering focus on education and collegiality that furthers success in our accreditation role. After all, patients' lives hang in the balance!

Congratulations to the staff at COLA, to the laboratories we serve and to inSights, for chronicling the spirit and the mission of COLA over the years.

Richard S. Eisenstaedt, MD, MACP
Past Chair, COLA Board of Directors

Letters From Past Board Chairs

As a newly elected member of the American Medical Association Board of trustees, I was assigned to be one of three AMA representatives on the board of COLA. Since I had spent the first 16 years of my private practice in a group of 5 physicians with a laboratory in our office, I certainly was aware of COLA, but did not realize how much more COLA was than a name on a certificate of accreditation.

The first thing that I learned was COLA's approach to the certification/recertification process was designed to be constructive and educational, not punitive. While you still had to meet all the requirements, COLA made a lot of effort to be sure that you were successful, all the way down to an open, fair and thorough Appeals Committee process. The board, management and staff worked very hard to make sure COLA truly lived up to its mission statement "Promoting Health and Safety Through Accreditation and Education."

During my 11-year tenure on the board, culminating in serving as board chair, I was privileged to get to know not only my colleagues on the board, but also all of the COLA management and most of the staff. I was there during difficult times, including the COVID pandemic and some difficult staff transitions, but also participated in the hiring of a new CEO and the exploration of and expansion into new areas where COLA could better the laboratory community. I can honestly say that my board service was one of the highlights of my career and I know that physicians and laboratories are in a better place because of COLA.

I am thankful for the privilege of serving!

William Kobler, MD
Past Chair, COLA Board of Directors

Letters From Past Board Chairs

I am honored to have had the opportunity to serve on COLA's Board of Directors for 20 years, including 4 years as Board Chair. From the vantage point of my role on the Board, I have watched as laboratory accreditation and education have upheld quality standards and adapted to new technologies to support a national effort to reduce the impact of HIV.

During the 1980s and 1990s as I delivered HIV care in rural Kansas, the increasing availability and sophistication of laboratory testing for HIV and AIDS meant that HIV care could begin to shift from hospice and palliative care into meaningful treatment, and eventually to prevention. Since that time, diagnostics have continued to evolve; rapid point-of-care testing, viral load monitoring and genetic testing have improved patient access to high quality care and prevented countless new HIV infections. The laboratory truly is key to management of HIV diagnosis and care, as is comprehensive clinical and patient education about the disease and the benefits of early detection and medication compliance.

I am grateful to have worked with so many dedicated laboratory professionals over the course of my medical career and to have had a chance to lead COLA's Board of Directors in supporting the organization's mission.

Donna E. Sweet, MD, MACP
Past Chair, COLA Board of Directors

Letters From Past Board Chairs

I am honored to have served on the COLA Board for over 20 years, including two terms as Board Chair, and more recently to lead the in-person COLA Laboratory Director certification course. This course is so vital because it gives physicians with no laboratory experience or training the tools to effectively direct a laboratory – and to make it a high-quality laboratory that best serves patients. It is even more important now that CMS requires it of ALL non-pathologist individuals who wish to direct a laboratory, moderate or high complexity.

The laboratory director, like the leader of any group or organization, is key to the success of the laboratory. They set the tone for the laboratory's employees, and if they are absent, especially without a seasoned laboratorian on staff, the laboratory is essentially rudderless. But, as stated in one of my favorite quotes from Vince Lombardi, the historic football coach of the Green Bay Packers, "the dictionary is the only place where success comes before work." For a non-laboratory-trained physician to be a successful laboratory director, it does take a modicum of work. Part of that is learning enough about laboratory science to effectively communicate your expectations to as well as communicate with your laboratory staff.

COLA's online Laboratory Director certification course covers the material very well, but in my opinion the in-person course is even more valuable, offering opportunities to network with other physicians as well as learn from the discussion and dialogue that occurs naturally during the course. During my 20 plus years of experience teaching laboratory directors in these courses, many attendees who had previously completed an online course expressed to me just how much more they gained from attending the in-person course. I would encourage any laboratory director, particularly those whose laboratory is struggling to meet regulatory requirements, to attend the in-person course as it will undoubtedly take your ability to direct a laboratory up a notch or two.

I've mentioned the importance of the laboratory director to the laboratory – let's consider briefly the importance of the laboratory to the physician office – another passion of mine. I can't imagine not having had a laboratory in my office during my 35-year career as a family physician. The ability to have an accurate result quickly serves both the physician AND the patient. How much better to have the result the same day, often within hours—if not minutes—for the patient. Questions about test results can be answered in person rather than via phone or online portal message, and can save the patient a second visit to receive results. I could go on and on about the benefits of an in-office laboratory but won't since I'm speaking to the choir.

That said, I would encourage those of you who agree with me to tout the benefits from your perspective to your colleagues and organized medicine, as many no longer have this benefit or even know what it was like, but could and should. Some say that it just isn't feasible anymore – too hard to find staff, to put up with the regulatory requirements, to maintain quality and to make it work financially. While all are certainly issues and require some work, they can be managed by an effective laboratory director to the benefit of your patients and partners.

Verlin K. Janzen, MD, FAAFP
Past Chair, COLA Board of Directors

COLA
Clinical Laboratory Accreditation

NOTES FROM ACCREDITATION

Kathy Wilson, HT(ASCP)QLS

Kathy Wilson joined COLA in December of 2021 as Director of Pathology Accreditation. She is an ASCP certified Histotechnologist with the ASCP Qualification in Safety. She has over 45 years total experience in the laboratory, across multiple disciplines. Prior to joining COLA, Ms. Wilson was the Anatomic Pathology Operations Manager, Safety Officer and Committee Chair for a large reference laboratory, both local and regional operations, based in Austin, Texas. In addition, she managed multiple hospital frozen section and satellite laboratory locations. Ms. Wilson has managed multiple laboratory set-up, remodels, and build-out projects.

CELEBRATING THREE YEARS OF ONGOING DEEMED STATUS FOR PATHOLOGY!

In February of 2022, COLA was granted deemed status from CMS to accredit the specialty of pathology including histopathology, oral pathology and cytology. Types of pathology laboratories enrolling vary from limited service to full-service test menus to include interpretation only, frozen section and dermatology Mohs frozen section, full-service histopathology and cytology.

COLA's enrolled laboratories have commented on how consistent, thorough and fair the survey process is and love the fact that they have ongoing support from enrollment through the entire survey cycle. I look forward to working with even more pathology laboratories in the years ahead!

COLA
Clinical Laboratory Accreditation

NOTES FROM ACCREDITATION

Eamon Tiffany, BSN, MLS(ASCP)

Prior to joining COLA in 2017, Eamon Tiffany, MT (ASCP), BSN, 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.

In July of 2022 and in December of 2023 CMS published the most significant changes to CLIA requirements since the inception of CLIA '88, with the most impactful of these changes relating to proficiency testing and personnel. As an accrediting organization, we were contacted by many laboratories after the changes were published, seeking guidance on the interpretation of the new and revised CLIA requirements as well as for preparation to meet the requirements prior to their

effective dates at the end of December 2024 and the beginning of 2025.

The new proficiency testing requirements, with the addition of 29 regulated analytes, will allow for another level of accuracy assurance for patient results based on requiring participation in approved proficiency testing programs for pivotal analytes such as HgbA1c and Troponin. Laboratories initiating new testing going forward will need to maintain close contact with their proficiency testing provider and accreditation or regulatory organization to ensure compliance with enrolling in the appropriate proficiency testing modules.

There are additional significant changes to the PT regulations:

1. Laboratories that perform both automated and manual WBC differentials must now enroll in PT for both methods.

2. The passing score for antibody screening PT has been changed from 80% to 100%.

3. There are changes to Microbiology subspecialty PT modules. Laboratories must perform PT to the same level that they perform for patient testing for each subspecialty. Contact your PT provider if you need guidance on available PT modules for Microbiology.

4. For several analytes, the criteria for acceptable PT performance have been updated.

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The revised and new personnel CLIA requirements will require laboratories to intensify their focus on reviewing qualification documentation for all staff members seeking CLIA-defined positions, particularly with documents to support experience listed in resumes or CVs. Even though some degrees in some fields are no longer accepted to qualify individuals, other pathways are available to qualify for laboratory positions in the new CLIA requirements, which involve algorithms based on post-secondary education coursework.

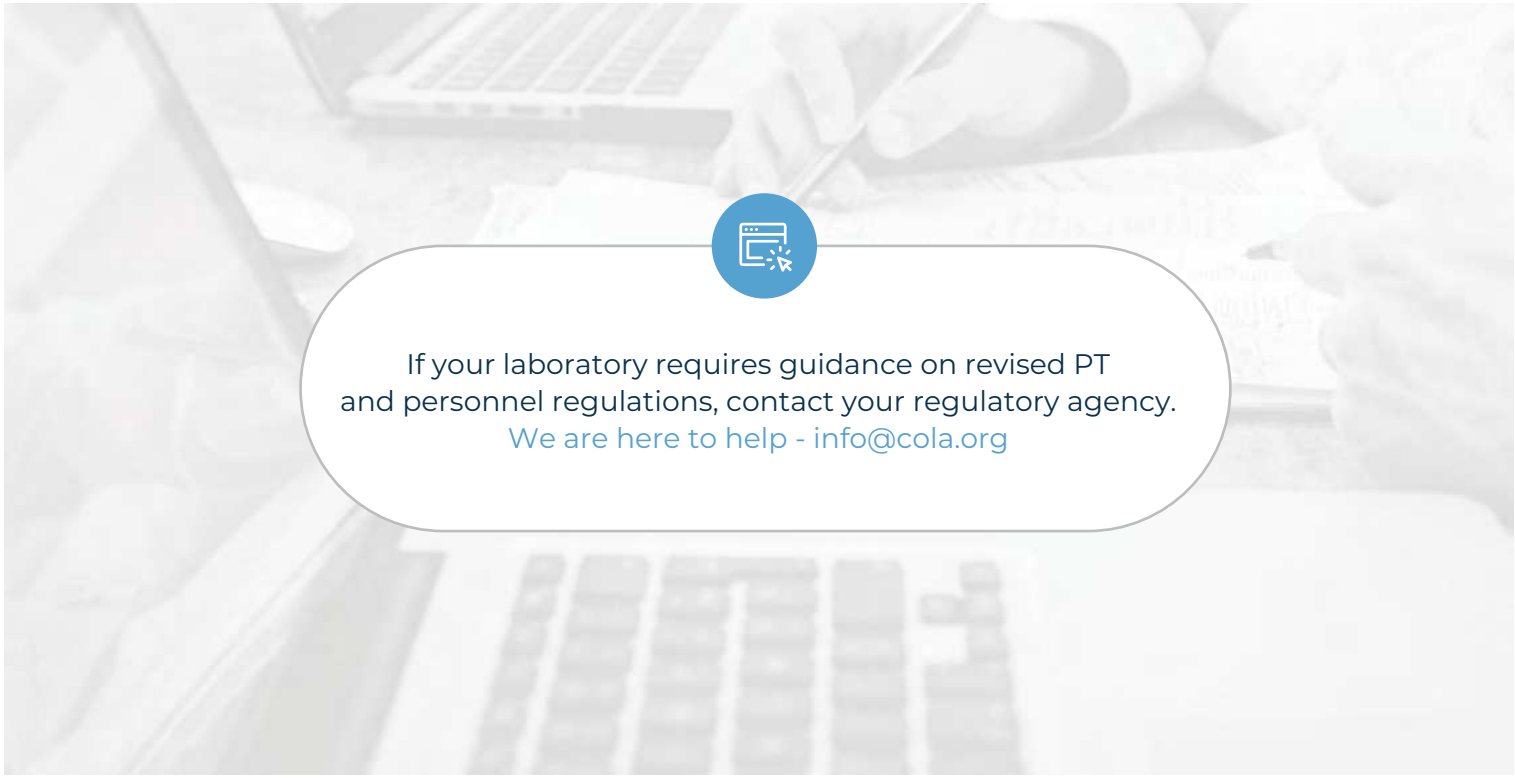
The position of laboratory director has been greatly impacted, for example:

- New requirements include the completion of 20 credit hours of laboratory director responsibility education for non-board-certified pathologists
- Documented onsite visits to the laboratory, at least every six months, with no less than four months between visits, are required
- Non-pathologist physician directors of moderate complexity laboratories must now complete BOTH the 20 CE laboratory director education AND a minimum of one year experience directing or supervising non-waived testing
- COLA, and other laboratory accrediting organizations, has been tasked by CMS with the review of laboratory director qualifications, and we will continue to support laboratories in identifying qualified applicants to comply with the new and revised CLIA requirements as well as with other positions in the laboratory

In addition, there are changes to other CLIA-required positions, including:

- With the required four years of experience, Associate degree level Medical Laboratory Technicians can serve as Technical Consultant for moderate complexity laboratories
- The requirements for the position of Technical Supervisor for the specialty of Immunohematology is now aligned with the requirements for Technical Supervisor for other specialties and subspecialties

This position can now be filled by individuals with Bachelor's, Master's or doctoral degrees and the required experience.



If your laboratory requires guidance on revised PT and personnel regulations, contact your regulatory agency.
We are here to help - info@cola.org

WELCOME TO OUR NEW DIRECTOR OF CLINICAL ACCREDITATION

Kim Ogren, BS, MLS(ASCP)CM

Kim Ogren joined COLA as a Laboratory Surveyor in October 2015. She has conducted surveys in a variety of laboratory settings, including Physician Office laboratories, small rural hospitals and large reference and hospital laboratories. Her areas of expertise include Survey experience includes core laboratory, microbiology, LCMS, transfusion medicine and molecular PCR.

Kim was promoted to Surveys Team Leader in February 2022. In this role, she provided consultation and support to Surveyors on accreditation matters, addressed their inquiries and offered mentorship. Her additional responsibilities included assisting in the training of new Surveyors, reviewing regulatory guidelines, developing training materials and participating in the recruitment and hiring of new Surveyors.

In July 2024, Kim advanced to the position of Surveys Team Manager, where she continued to make a significant impact on the Surveyor team. Her duties in this role included monitoring and reporting surveying metrics, approving strategies to improve survey scheduling and tracking on-time rates and collaborating with laboratories on post-survey questions to improve the survey process.

Prior to joining COLA in 2015, Kim Ogren worked at M Health Fairview where she spent her time working in the core laboratory, transfusion services and the Infectious Disease Diagnostic Laboratory (IDDL).

Kim earned her Bachelor of Science degree at Minnesota State University Mankato in Microbiology and went on to graduate from the Clinical Laboratory Science program through Fairview Health Services to earn her MT ASCP certification.

Kim is thrilled to step into this new role as Director of Clinical Accreditation and is eager to contribute to COLA's ongoing success and growth. She looks forward to utilizing her experience and skills to improve Surveyor operations and uphold COLA's high standards of quality and efficiency relating to the on-site survey process. Kim is particularly excited about collaborating with the talented team at COLA to drive innovative solutions that will enhance COLA's capabilities and the services it provides to laboratories. She believes that, together, they can achieve remarkable outcomes that will significantly impact COLA's laboratory accreditation program.

Advances in Laboratory Medicine

By: Jennifer MacCormack, MLS (ASCP)[CM]

Jennifer MacCormack is an experienced science and medical writer with a background in clinical laboratory testing, medical & health science and regulatory oversight. She received her Bachelor of Science in Physiology from McGill University.

COLA has been accrediting laboratories for more than 30 years, and our Surveyors and technical staff have adapted along the way as laboratory technology advanced.

Many areas of laboratory science have seen significant shifts in techniques and technology, which have improved workflows, turnaround time and the quality of laboratory results. All of this is ultimately having a positive effect on the laboratory workforce and on patient care.

Laboratory Automation and Robotics

Advances in laboratory automation and robotics, especially the advent of fully-automated track systems, have improved laboratory efficiency and throughput by streamlining workflows. In laboratories performing a large volume of routine clinical chemistry and hematology testing, automation can dramatically reduce turnaround time. Where fully-automated robotic track systems have been implemented, specimens can be loaded on a rack as they are received in the laboratory and then may not ever be touched again by human hands. Scanning and accessioning, centrifuging, instrument loading and transfer to refrigerated storage are all handled by the automated track.

Even smaller laboratories can benefit from automation, as instrument advances include more and more automated and robotic elements. In hematology, for example, slide-makers and automated stainers take on much of the hands-on work and allow for higher throughput. Some chemistry analyzers have a cap-piercing system, so that tubes can be loaded directly on board without being uncapped. This improves both efficiency and safety.

There is also an underappreciated ergonomic benefit to automation: simple and repetitive tasks, such as labeling, pipetting, uncapping and aliquoting can now be handled by robotic systems, greatly reducing the risks of repetitive stress injury.

Next-Generation Sequencing (NGS)

Gene sequencing is the key to diagnosis of many hereditary diseases and rare genetic disorders and has become indispensable to the field of oncology as it can identify specific mutations for targeted gene-based therapies. It is also of great importance to public health as it can track the mutation of pathogens as they spread and help to track down sources of outbreaks.

Next-Generation Sequencing (NGS) technology allows for much more rapid and comprehensive genetic analysis than previous methods, such as Sanger sequencing. Instead of performing many different genetic tests to look for each possible mutation in a specimen, NGS allows for the sequencing of many genes – even a whole genome – in a short period of time. Its high sensitivity allows for it to be used on specimens where only a small fraction of tumor DNA may be present – for example, in liquid biopsy and the analysis of cell-free DNA for cancer screening and management.

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Mass Spectrometry (MS) for Clinical Diagnostics

Mass spectrometry has many applications, from detecting environmental contaminants to radio-isotope dating, and has been used in research laboratories for decades. With high specificity and sensitivity in both detecting and quantifying molecules, it is now considered routine in the medical laboratory. It is commonly used for confirming positive immunoassay drug screen results, but it is also routinely used for endocrinology testing and newborn screening for disorders of metabolism.

As reference libraries of molecular compounds grow more comprehensive, mass spectrometry has even found its way into the microbiology laboratory. Matrix-assisted laser desorption/ionization – time of flight mass spectrometry (MALDI-TOF MS) can be used to identify bacteria based on the species-specific protein profiles detected in a specimen. With a quicker turnaround time than traditional culture methods, MALDI-TOF MS systems are an attractive option for high-throughput microbiology laboratories.

Digitization and Artificial Intelligence in Pathology

Traditional pathology relies on meticulous examination of prepared slides under a microscope. This is a time-consuming process requiring highly trained and experienced personnel. Advances in data storage and transfer and in digital imaging technology have made it possible to review high-resolution images of histological slides remotely. This can be done via review of static images or via live image streaming. Live streaming requires either a robotic system for remote manipulation of the slide, or trained personnel on-site to move the slide and highlight areas of interest for the remote pathologist to review.

Telepathology is often used to provide immediate remote specimen evaluations in cases requiring an intraoperative consultation (i.e., frozen section) and in rapid on-site evaluation (ROSE) of fine needle aspirations (FNAs).

Artificial intelligence algorithms are increasingly used to streamline pathology by being trained on massive data sets of digital histology images to detect cellular changes associated with cancer.

Because they can process data very rapidly, AI systems have the potential for decreasing turnaround times for pathology results;

however, their accuracy relies on the quality of the data sets on which they have been trained.

Advances in Point-of-Care Testing

Demand has increased for simple and high-quality point-of-care (POC) tests that can be performed at the bedside and deliver results during the patient encounter. POC testing has greatly expanded the scope of emergency care and urgent care, where immediate results can be critical to treatment.

POC testing related to infectious diseases, including sexually-transmitted infections, eliminates the need to have the patient go elsewhere for laboratory testing, wait for results, and return for treatment. Having the testing at the point of care allows for immediate treatment, which can in turn reduce the spread of those infections and improve population health.

POC testing can bring healthcare to where it's needed, such as rural areas or other areas where many are uninsured or underinsured and lack consistent access to healthcare. Portable handheld devices are used in mobile laboratories and health fairs, making diagnosis and management of infectious or chronic diseases more accessible to populations who face barriers to comprehensive medical care.

Home testing has also expanded, with more FDA-approved tests available over the counter for patients to have a greater role in their own healthcare. In particular, the COVID-19 pandemic spurred the development of rapid antigen tests for detection of SARS-CoV2, allowing patients to self-monitor and isolate as necessary to protect public health. More recently, some of the manufacturers of at-home SARS-CoV2 antigen tests have developed at-home tests for influenza.

The laboratory will continue to innovate, as biomedical research leads to the development and adoption of new tests and techniques to detect biomarkers for more diseases and conditions, such as Alzheimer's disease, traumatic brain injury, autoimmune disorders and cancer. Technology is always innovating, as well. The future of laboratory medicine is likely to see a greater number of tests performed on smaller specimen volumes as well as more tests developed for the POC setting and for home use. Flexibility and a commitment to ongoing learning will be key to laboratory professionals' success as the laboratory continues to change around us.

inSights with Kathryn Connolly,

MLS(ASCP), CPA(ASQ)

By: Jennifer MacCormack, MLS (ASCP)[CM]

Jennifer MacCormack is an experienced science and medical writer with a background in clinical laboratory testing, medical & health science, and regulatory oversight. She received her Bachelor of Science in Physiology from McGill University.

The world of laboratory accreditation has come a long way over the last 30 years, and COLA has had to remain agile and innovative to stay ahead of changes in the industry.

Kathryn Connolly, COLA's Director of Quality Systems & IT Liaison, has been with COLA since 1994 and has been an integral part of dozens of transformative projects over the course of her career. As she nears her much-deserved retirement, inSights invited Kathryn to discuss her experiences as one of COLA's longest-serving employees.

Kathryn first joined COLA as a Surveyor, shortly after the young organization received deemed authority by CMS to survey laboratories for compliance. A well-rounded "tech-of-all-trades," she used her previous experience in hospital laboratories, pediatric laboratories, public health and laboratory management to help laboratories of all kinds achieve compliance and improve quality.

Accreditation in the '90s

In the early days of COLA accreditation, the work was analog. "We didn't have cell phones and laptops back then," explains Kathryn. "We received a paper file with the information for each laboratory we were visiting on a tour, and we used paper maps and travel agents to figure out our driving routes, flights and hotels." Completed survey documentation was mailed back to COLA's headquarters in Maryland to be reviewed by others on the technical team who would then type up a report and mail it to the laboratory.

Proficiency testing results were also all on paper at that time. COLA headquarters would receive copies of every PT event for every laboratory, which had to be manually organized, reviewed and filed. A digital upgrade was needed to improve efficiency, and Kathryn, who by that time had moved into a role on the Proficiency Testing team, was tapped to lead the project.

"We had to develop a whole software system for PT monitoring," Kathryn said. "For handling all that data and tracking which laboratories needed to cease testing for repeated issues." Kathryn says that despite being new to developing requirements for computer systems, it came naturally to her and she learned quickly on the job.

"I would sit with the IT development team and they would explain what they were trying to do. And I would listen and see things maybe they hadn't thought about. Gaps in the plan, possible unintended outcomes."

Those investigative skills were put to good use as COLA grew and developed new systems and processes. Kathryn was deeply involved in many of COLA's big steps forward, such as the launch of the COLAcentral customer portal and its later upgrade; changes to the survey scheduling system and other internal software; and the addition of the Pathology specialty to COLA's accreditation portfolio.

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Focus on Quality

In 2003, the International Organization for Standardization published a set of international standards that specify requirements for quality in medical laboratories. Called ISO 15189, the new standards were soon being discussed as a possible replacement to the CLIA regulations. COLA asked Kathryn to explore ISO 15189 for possible implementation. She traveled to Asia to perform ISO 15189 surveys and learn more about the standards and their possible impact on accreditation in the United States. In this role, she also represented COLA on several Clinical and Laboratory Standards Institute (CLSI) committees, developing new standards and editing existing ones to align with changes in the field. Through the work with CLSI, Kathryn made connections that inspired her to pursue qualifications in quality auditing.

After taking a series of courses in quality auditing, Kathryn earned her ASQ certification and then continued her studies to achieve a qualification as an ISO 9001 audit team leader. COLA leadership decided to pursue ISO 9001 certification as a means of monitoring and improving quality within the organization.

At that time, the Maryland Department of Economic Development was funding training for small businesses to help them achieve ISO 9001 certification. Kathryn attended the training and developed policies and procedures for COLA's different departments that aligned with ISO 9001 requirements. "It made sense to have these internal quality standards for the organization," says Kathryn. "We were responsible for laboratory quality, holding laboratories to accreditation standards and the CLIA regulations. So having an eye on our own quality, and holding ourselves to high standards, helped us to do better." COLA earned ISO 9001 certification in 2011; it was the first laboratory accreditor in the United States to make that commitment to quality and achieve that certification.

As part of COLA's ongoing ISO 9001 certification, the organization undergoes regular external audits.

To monitor and maintain quality in between those audits, COLA's internal audit team reviews processes and documentation to ensure ongoing compliance with the standards. The audit team, led by Kathryn, comprises several COLA employees from different departments, who receive thorough training on the ISO standards and the steps involved in auditing.

What Lies Ahead

What are Kathryn's thoughts on the future of laboratory medicine and quality? "Technology is advancing quickly," she states. Artificial intelligence, data analysis and data security are areas where she expects to see big changes in the next decade in the laboratory world. "We have all this data and the capacity to analyze it and use it in different ways, not only for patient care but for laboratory quality as well." There is also an opportunity for technology to allow more ongoing quality assessment by external auditors like COLA, as opposed to a visit every two years, she explains. "All this data is generated in the laboratory – quality control, proficiency testing, digital temperature readings and so on. There's a real opportunity to have more regular check-ins using remote access to systems and keep a better eye on quality along the way."

Data security, too, is likely to become a more urgent concern. Kathryn believes that more organizations will pursue data security certifications such as System and Organization Controls 2 (SOC2) certification. Developed by the American Institute of Certified Public Accountants (AICPA) the SOC2 standards cover customer data management.

Of primary concern are the concepts of security, availability, processing integrity, confidentiality and privacy. While few laboratories are currently SOC2 certified, Kathryn believes the idea may gain momentum as AI tools are integrated into more software and more organizations are targeted by cyber attacks.

"If I am exchanging data with an organization, a certification like that means I can be confident that the data is being handled properly and that lowers the risk of any privacy concerns."

With her retirement on the horizon, Kathryn has some advice for new laboratorians just getting started in the field. "Be curious. Always be curious. Ask: why do we do things a certain way? What's the importance of doing this? Always ask questions and to try to understand how something works or why it works – and what happens if it doesn't." A growth mindset and openness to opportunity have contributed to Kathryn's success at COLA, and the success of the projects she has worked on.

"Just say yes to every opportunity you can. Where you end up might be far from where you start but you'll learn so much."

Seven Laboratory Best Practices to Make Your Operation More Efficient

By: Bryan Firestone

Bryan founded a consulting company in 2003 that quickly grew and was re-branded as U.S. HealthTek in 2013. He has over 30 years of experience in the clinical and environmental laboratory space, holding the position of Chief Information Officer for American Medical Laboratories, TestAmerica Laboratories, Solstas Lab Partners, Healthscape Data and Drugscan. Before founding U.S. HealthTek, he held senior management positions at National Health Laboratories, LabCorp, Quest Diagnostics, and Clinical Pathology Laboratories. In addition, he has several years of experience managing and automating a semi-conductor reliability testing lab for United Technologies.

If I were to tell you that we are in turbulent times, you would likely remind me that with our industry, it's never calm sailing. And you'd be right.

We are always adjusting, reinventing, reinvigorating and capitalizing on the opportunities change can bring.

One thing we can agree on: the need for ultimate efficiency is no longer a lofty goal, it's a necessity. So here are seven key action items to help us all get there. Every one of these is worthy of an article on its own (if not a series of articles), but here we simply wanted to start the discussion. For more in-depth examinations on these and other topics, go to our website USHealthTek.com and look under Resources.

1 Upgrade Your LIMS/LIS

Laboratory information management systems (LIMS) and laboratory information systems (LIS) are prevalent, but what I'm noticing is a "set it and forget it" mentality that can hinder productivity. Just because it doesn't cause any problems doesn't mean it is efficient or inexpensive. Know that there are newer LIMS out there that are more flexible and more efficient, have better management reporting and perhaps most critically in these times, are more cost effective.

A frequent situation I see is a system that has over time become overburdened to the point of being slow and less trustworthy.

But there are usually a number of other issues that need to be addressed as well. So know that there are a number of tools, services and personnel that can and should be called upon to re-evaluate and vastly improve your LIMS/LIS and upgrade your system. And tell this to your CFO: it's a matter of protecting your investment, too. So, whether the system is new or existing, a support structure is critical to the success of any laboratory software application. A proactive approach will ensure that your team achieves the highest level of success in return on investment (ROI) and predictable total cost of ownership.

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2 Commit to Reducing Staff Turnover

It's been five years since the start of the pandemic, but there are still reverberations that are likely never going to dissipate, and one is staff turnover. This is always a challenge in our business, with the cost and disruption being much higher than what it takes to keep your current employees content and fulfilled.

Too often I see managers caught up thinking only of their customers and clients, neglecting the importance of building a strong, experienced staff – and retaining it.

According to LinkedIn, an average of 10.9 percent of employees across all industries leave their organizations each year.

In hospitals and laboratories, that number is likely between the high teens and 30 percent. But there are things we can do to minimize turnover and build a corporate culture that makes for a more effective, efficient work environment.

The top three are:

- Salaries must be competitive
- Benefits must be a source of comfort, not stress
- Satisfied employees are on a path with goals, so career mapping is a great tool

Be an "employee whisperer" and have your ear to the ground to better understand and react to what your staff is experiencing. Of course, it's the right thing to do – but it also pays off in the long run.

3 Embrace The Cloud

We are moving more clients to cloud-based technology every year, but there is still skepticism. I get it. But cloud advantages far outweigh the concerns because of the technology and security the cloud offers. Just know this: it has to be done with a trusted partner who can make sure it's done right.

With the cloud, the laboratory is able to avoid the expensive maintenance of an onsite system. We've been especially successful moving laboratories to the cloud because of our expertise, which allows us to make sure that it's done right. Another development in this area is that, in addition to the big three services (AWS, Microsoft, and Google), there are smaller private cloud data centers popping up.

However you ascend, the problems and security concerns with an old in-house system are too risky, believe me.

4 Shore Up Your Network Operations Center (NOC) for 365/24/7 Monitoring

As I was coming up through my career and becoming responsible for larger and larger IT laboratory departments, the proactive monitoring of hardware and servers was crucial. Back then, it was also complicated and expensive. But the good news is that it doesn't have to be. Many improvements and cost-saving measures have been developed in this industry over the years, and yet this problem has just been exacerbated, due to more and more complicated technology. If you're a small- or mid-sized laboratory, use a custom-built service that is a blend of advanced technology with a team of experts to monitor what's happening in real time – but at the fraction of the cost of a traditional NOC.

5 Update Your Electronic Medical Record (EMR) Systems

You don't have to tell me what the challenges of medical data translations are – I know them well. Risky. Expensive. Takes too long.

Yet it's an inevitable part of the fabric of today's medical laboratory and must be done to be competitive.

- Understand the what and the why. The first step is to make sure you work with a team that is going to ask you the important questions that will clarify what you're doing, and why you're doing it.
- Minimize disruption. It typically takes three to six months to recover from an EMR move, depending on the size and complexity of the laboratory. Anticipate the problems and minimize them.
- Work with an experienced team. You want people who have previous real laboratory experience, and who come to the table with different perspectives to ensure a smooth execution.

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6 Prepare for the Artificial Intelligence (AI) Revolution (and Organize and Own Your Data)

We've been inundated with stories about AI. Understanding it, and what it means to the healthcare industry, is imperative to being ready for the future. We at U.S. HealthTek have been on the forefront of this from the beginning, already using it successfully in many instances for a greater good in terms of both efficiency and profitability.

Here are key things to know:

- AI is not "one thing." There are many aspects to it, and it can operate on many levels. This is key to understanding how it can be leveraged to a specific healthcare organization's advantage. Narrow AI, also known as Weak AI, is a branch of AI that performs specific tasks in a narrowly defined field and is void of general cognitive ability. Generative AI, or GenAI, which we've been hearing a lot about lately, is a type of Narrow AI. This is what is already all around us now, but especially for this industry, it needs specific guidance from qualified professionals to be effective.

- Prep properly for AI systems. We need to prepare, as the prerequisites for initiating AI are complicated.

There are procedures that must be put into place.

When implementing a system, compile your data, centralize it and get placed on the right platforms operationally to allow AI to work and crunch that data so that it's primed for success.

- AI is taught using data. This data is information that already exists in cyberspace, and it matters how we tap and use that data. You don't want to just plug into "all" of it; a company may have four or five different "use" cases from each main department, and customer service is certainly one of them. In that case, we want to be able to pull data more quickly for customers asking basic questions and thus use AI to free up staff. In doing this, we can learn where most of our "pain" points are, and what customers are asking based on AI activity.

Beyond that, we want to better mine the data we have.

A simple example of this is knowing which clients are the most loyal to your business, and which services are especially popular and profitable. Those are just two use cases where you need data compiled in a specific way, but we can use language models to ask those questions, and to translate that into accurate information.

- Make sure you own your own data. I'm continually amazed at laboratory organizations that don't read the fine print and partner with a consultant who not just manages their data, but owns it. There is a clear advantage to this partnership as opposed to relying on a third-party vendor who "manages" your data and also ends up owning it.

More professionals in the industry have become aware of how valuable this data is.

7 Work With Properly Certified (SOC 2 and HIPAA) Partners

A few years ago, we committed to achieving SOC2 and HIPAA certification, the "gold standards" for the IT and health care industries. This is just one example of an organization's commitment to security and compliance by safeguarding customer and patient health information.

It is increasingly important that we all do this.

- System and Organization Controls (SOC) is a set of auditing standards that determines the security, availability, processing integrity, confidentiality and privacy of an organization's systems. SOC2 is a type of reporting that focuses on availability, security, processing integrity, confidentiality and privacy, i.e. the five Trust Services Criteria. It's downright surprising that it's not mandatory for industry organizations – it should be.

- The Health Insurance Portability and Accountability Act (HIPAA) is a federal law that sets standards for Protected Health Information (PHI) and how it should not be disclosed to anyone other than the patient and the patient's authorized representatives. There is overlap between SOC2 and HIPAA, though their objectives are different. Combined, they offer the highest assurances and confidence to protect sensitive information.

- The certification process is long and challenging, but it has allowed us to make all our clients feel confident in our abilities. This is now an extra layer that will ensure current and future clients that their data is safe and secure to the highest level.

Final Thoughts

As the expression goes, "if you're not moving forward, you're falling behind." We can't do all the things we want – or even should – all the time, but what can we do? My challenge to you is think about not just what you need to make it through this year, but what building blocks can you put in place for the long game?

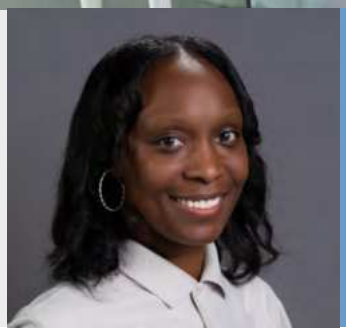
About U.S. HealthTek

U.S. HealthTek is an IT consulting company focused specifically on the needs of the healthcare industry, offering solutions for personnel support, interoperability, data mapping, project management, and custom software builds among other products and services. Bryan Firestone founded the company in 2003. He has over 30 years of experience in the clinical and environmental laboratory space, holding the position of Chief Information Officer for American Medical Laboratories, TestAmerica Laboratories, Solstas Lab Partners, Healthscape Data, and Drugscan. For more go to USHealthTek.com.

PERSPECTIVES:

Understanding Proficiency Testing

By: Maurica Price BS, H(ASCP)^{CM}



Maurica Price currently serves as a Regulatory Technical Advisor at COLA. In her role, she leads as the Proficiency Testing (PT) Specialist, supporting laboratories across the country with a strong focus on quality and compliance. Passionate about advocacy and awareness for the laboratory profession, Maurica is actively involved in student-enrichment initiatives and is a proud member of the Workforce Action Alliance. Through her work with COLA's GiveBack365 program, she helps support the next generation of laboratorians—offering scholarships and engaging in meaningful service within the communities COLA serves.
With a strong commitment to advocacy and outreach, Maurica brings both expertise and enthusiasm to every opportunity to connect and collaborate.

What should I do once I receive my graded PT results?

When your PT results arrive, document the date received and submit the results to the laboratory director or qualified designee for review.

1

Review for results that are not graded or given 100% due to lack of consensus or lack of a peer group. These results should be compared with the information provided by the PT program in the Data Summary Report. The laboratory must perform a self-evaluation of those results and document their findings. Take appropriate corrective action if required.

2

Review for results that are given a passing score of less than 100%. The laboratory should perform a self-evaluation of those results and document their findings. Take appropriate corrective action if required.

3

Review for unacceptable results. The laboratory should investigate the failures and document the outcome of the investigation and corrective action taken.

What is considered unsatisfactory performance?

If your laboratory fails a single testing event, it receives a performance score of "unsatisfactory" for that analyte, subspecialty or specialty.

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What should I do once I receive my graded PT results?

Laboratories that demonstrate "repeat unsuccessful" or second unsuccessful PT performance over 12 PT events for the same regulated analyte, subspecialty or specialty are directed to cease testing the regulated analyte, subspecialty or specialty for a minimum of six months.

What are the patterns of performance that would lead to a cease testing order?

Below are some of the patterns that will result in cease testing.

FAIL	FAIL	FAIL									
FAIL	PASS	FAIL	FAIL								
FAIL	FAIL	PASS	FAIL								
FAIL	PASS	FAIL	PASS	FAIL							
PASS	FAIL	PASS	FAIL	PASS	PASS	PASS	PASS	PASS	PASS	FAIL	FAIL

Do these patterns also hold true for specialties and subspecialities in which a laboratory performs testing?

Yes. For analytes in the same subspecialty and specialty, the scores are averaged to obtain an overall subspecialty and specialty score. A laboratory may be ceased at the analyte, subspecialty or specialty level.

How do I avoid having to cease testing for unsuccessful PT?

If the laboratory meets the requirements for cease testing, (repeat unsuccessful PT results within 12 PT events) it cannot be avoided. Cease testing for a full six months may be avoided if your laboratory immediately notifies its regulatory agency and ceases testing voluntarily before a cease testing order is received. In this case, you must still pass two consecutive PT events before resuming testing. Alternatively, the laboratory may opt to delete the test or perform the test under waived complexity, if available.

When should I cease testing?

Immediately when notified by your regulatory agency that you meet the cease testing requirements. Alternatively, the laboratory may voluntarily cease testing at any time by notifying their regulatory agency of the decision before a cease testing order has been issued.

How do I reinstate my laboratory?

For regulated analytes, the laboratory must adhere to the six-month cease mandate (unless you follow the exception described above) and demonstrate satisfactory performance for two consecutive PT testing events. Graded off-schedule PT may be used for reinstatement purposes.

You should always investigate and resolve any PT failures, even for "unregulated" analytes. Depending on the circumstances, your regulatory agency may or may not apply cease testing to unregulated analytes in the same manner as for regulated analytes. Contact your regulatory agency for further information regarding cease testing and reinstatement requirements for unregulated analytes.

How CLIA Affected Changes in the Clinical Chemistry Laboratory

By: Melinda Cottman BS, MLS(ASCP)

Melinda is a COLA Surveyor with over 30 years of experience in the clinical laboratory. She started her career in the Hematology/Coagulation department at Hahnemann University of Philadelphia, PA. She has also worked as a generalist, traveling Clinical Laboratory Scientist and Lead Chemistry Clinical Laboratory Scientist.

Laboratory testing dates back to the 18th century. The period between the 1890s and 1920s saw an increase in the development of diagnostic tests and the study of pathology because of increased interest in scientifically diagnosing and managing diseases. By 1926, the American College of Surgeons required that every hospital have a clinical laboratory. Clinical chemistry at that time included many manual processes that were complex and prone to human error.

With the 1950s came automated technologies that allowed centralized clinical laboratories to perform larger numbers of tests at a low cost with a reduction of human error.

The first automated clinical chemistry analyzer, the AutoAnanlyzer, manufactured by the Technicon Corporation, was invented by Leonard Skaggs in 1957. It used a special flow technique named continuous flow analysis (CFA). Soon afterwards, in 1959, Hans Baruch introduced the world to a device called the Robot Chemist. The Robot Chemist was the first commercially available discrete analyzer that produced results with a digital printout.

This was groundbreaking, considering that at the time in the United States there were not many computers in use.

With the emergence of new techniques and technology, clinical laboratories grew rapidly. However, without regulation and oversight, dangerous quality issues began to come to light. The Clinical Laboratory Improvement Amendments (CLIA) were enacted into law in 1967 in response to concerns about quality. CLIA 67 set regulations for laboratory standards but only covered independent and hospital laboratories. It did not regulate all laboratories performing PAP smear testing and this led to “PAP mills” that produced erroneous and life-threatening results.

A 1987 Wall Street Journal article highlighted scandals involving some commercial laboratories that inaccurately analyzed PAP smears, leading to the deaths of several women from undetected cervical cancer. Congress made changes to the CLIA regulations to ensure the accuracy and reliability of all laboratories testing human specimens for diagnosis and management of disease. This legislation, known as “CLIA 88,” was signed by President Reagan in 1988 and implemented with comprehensive regulations in 1992.

CLIA oversight is currently managed by the Centers for Medicare and Medicaid Services (CMS) within the Department of Health and Human Services (HHS). The Commission on Office Laboratory Accreditation, now known as Commission On Laboratory Accreditation (COLA) was established in 1988 to help physician office laboratories stay in compliance with CLIA 88. In 1993 COLA was granted CLIA-deemed status as an Accreditation Organization, allowing them to perform compliance surveys in the place of the state CLIA agencies. Since that time, COLA has grown beyond their original physician office niche and uses accreditation and educational support to help laboratories of all kinds improve their processes and better serve patients and their communities.

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The regulations enacted through CLIA helped steer the invention of instruments and processes that would help to improve accuracy and quality in patient care.

For example, point-of-care testing (POCT) emerged in the 1970's with the introduction of the glucometer and rapid pregnancy tests. The growth of POCT since then has increased the accessibility of clinical chemistry testing in urgent care, emergency rooms and physician office laboratories. These devices allow patient testing to occur at the patient's bedside using a minimal amount of specimen and are often easier to use than large laboratory analyzers. While POC tests do not always have the specificity of standard laboratory tests, they do have a benefit of rapid turnaround time in urgent and emergent situations.

They are also generally less costly than larger instruments, which makes them more accessible to smaller laboratories and physician offices who provide care in underserved or rural areas.

The emerging technologies in the clinical chemistry laboratory used today were inspired by the regulations formed by CLIA 67 and CLIA 88. Manual processes are being performed less frequently in the laboratory, as tests and analyzers gain new capabilities. The preanalytical process of positive patient identification has improved with the use of barcode scanners and computer systems, lessening the risk of human mislabeling errors. Some laboratories use software to look at patients' data and determine moving averages; the laboratory can then use this data as another form of quality control. Today we have automation lines that connect several instruments, centrifuges and refrigerators, which reduces the frequency of repetitive tasks that testing personnel must perform.

This prevents ergonomic injury while improving efficiency and result turnaround times.

Continuous improvement in quality and safety of testing personnel in the clinical chemistry laboratory are the basis of CLIA's creation in 1967.

Those issues are still important in the laboratory today, as new technology continues to evolve and the field struggles with a workforce shortage.

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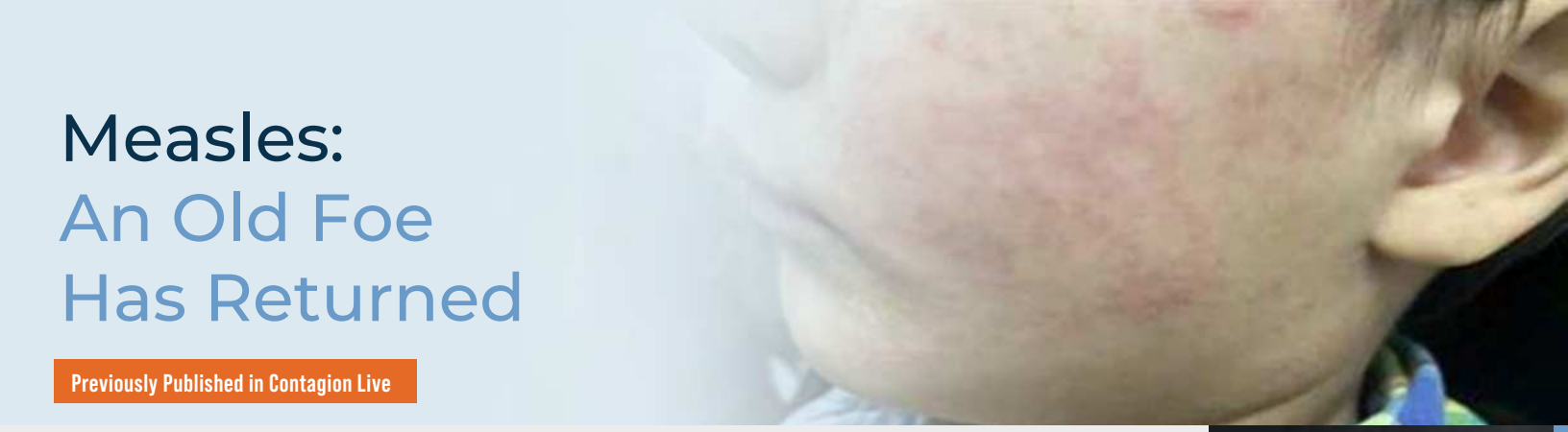
Measles: An Old Foe Has Returned



Previously Published in Contagion Live

By: Rodney Rohde PhD, SV, SM, MB(ASCP), FACSc

Rodney E. Rohde, PhD is a Regents' Professor, Texas State University System, University Distinguished Professor and Chair for the Medical Laboratory Science (MLS) Program in the College of Health Professions at Texas State University. He also serves as Associate Director for the Translational Health Research Center. Dr. Rohde is a Global Fellow, Fellow of the Association of Clinical Scientists, and Honorary Professor of International studies. He is an ASCP board-certified Specialist in Virology, Microbiology and Molecular Biology. He spent a decade as a public health microbiologist and molecular epidemiologist with the Texas Department of State Health Services (DSHS) Bureau of Laboratories and Zoonosis Control Division prior to his academic career, including two terms as a CDC Visiting Scientist. Dr. Rohde served as Associate Dean for Research in the College of Health Professions for nine years (2011-20). Dr. Rohde has published 100+ research articles and abstracts, two books and is a highly sought keynote presenter with over 100 international, national, and state conference presentations.

As of March 7, 2025, Texas is experiencing a significant measles outbreak, with 198 confirmed cases across more than 9 counties, primarily in the South Plains region.

This marks the state's largest outbreak in 30 years. Tragically, an unvaccinated school-aged child has died-the first measles-related death in the US since 2015. The outbreak has predominantly affected unvaccinated children aged 5 to 17. Approximately 23 patients have been hospitalized due to complications. The outbreak's spread has been linked to declining vaccination rates, particularly in communities with higher exemption rates. The outbreak is ongoing, and data will be updated each Tuesday and Friday.

Nationally, the Centers for Disease Control and Prevention (CDC) reported 222 measles cases in 2025, with 93% associated with outbreaks. In 2024, there were 285 cases, with 69% linked to outbreaks. Health officials strongly recommend ensuring vaccinations are up to date to prevent further spread of the disease. The measles, mumps, and rubella (MMR) vaccine is highly effective, with 2 doses providing 97% immunity against measles.

What is Measles?

Most medical experts acknowledge that measles may be the most contagious known infectious disease in humans. It is estimated that an infected carrier can transmit the measles virus to 12 to 18 others, an epidemiological concept known as the basic reproduction number (RO). This RO assumes others are susceptible to the disease and have no existing immunity towards it. This translates to a staggering estimate that nine out of ten unimmunized individuals who are in contact with an infected person will be infected. Central to its infectivity is that the virus can linger in the air for up to two hours after the infected patient leaves a room. Thus, direct contact with or facing an infected person is not necessary for the virus to propagate; a susceptible person simply needs to be in the same room that an infected person was previously in recently.

Measles virus is a member of the genus Morbillivirus of the family Paramyxoviridae and exhibits a typical incubation period averaging 10-14days from exposure to onset of initial symptoms. The first set of symptoms to occur are typically high-grade fever (>102°F or> 39°C), sinus congestion, cough, myalgia, conjunctivitis, and small spots with white or bluish white centers on an erythematous base appearing on the buccal mucosa (Koplik spots). Measles initially infects the respiratory tract and then finds its way into lymph nodes, setting off a chain of events resulting in the typical body rash ~2 weeks after exposure.

This red, blotchy (maculopapular) rash usually begins on the face, becomes generalized, and lasts 4-7 days.

Common measles complications include diarrhea (8%), middle ear infection (7%-9%), and pneumonia (1%-6%). Encephalitis, which can result in permanent brain damage, occurs in about 1 per 1,000-2,000 cases of measles. The risk for serious complications or death is highest for children aged ≤5 years, adults aged ≥20 years, and in populations with poor nutritional status or that lack access to health care.

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Subacute sclerosing panencephalitis (SSPE) is a progressive neurologic disorder caused by measles virus that usually presents 5-10 years after recovery from the initial primary measles virus infection. SSPE manifests as mental and motor deterioration, which can progress to coma and death. SSPE affects approximately 1 out of every 5,000 measles cases; rates are higher among children <5 years of age.

Measles Diagnostics

Usually, infection by the measles virus can be diagnosed based on the typical signs and symptoms, especially with the observation of Koplik's spots, and known exposure to an infected person.The CDC and other experts strongly recommend laboratory confirmation. A nasopharyngeal swab, throat swab, or urine specimen, as well as a blood specimen, can be collected from all patients with clinical features indicative of measles. Nasopharyngeal or throat swabs are preferred over urine specimens. Like any good medical laboratory professional will tell a healthcare provider or others, the accuracy of any strong laboratory medicine test begins with the accurate collection of the correct specimen.

For a measles infection, specimens are acquired from throat, nasal, or urine specimens. A laboratory confirmation can be made via detection of measles IgM antibodies in blood or virus RNA by a reverse transcription polymerase chain reaction (RT-PCR) assay. RT-PCR is particularly useful to confirm inconclusive IgM antibody results.

If blood can't be utilized, then saliva can also be used for salivary measles-specific IgG or IgA testing.

The oral fluid based IgG or IgA method is not a preferred method, as saliva contains many other fluids and proteins that may make it difficult to collect samples and detect measles antibodies.

Also, our antibody repertoire evolves since the time of virus exposure. The antibody IgM is the first type of antibody produced against a newly encountered pathogen, in this case, measles virus.

The immune system then refines its own antibodies towards measles, eventually producing high affinity IgG and IgA antibodies. It usually takes approximately 1 week before IgG and IgA appear to a newly encountered virus in the absence of pre-existing immunity. Therefore, salivary IgG and IgA detection methods suffer from sensitivity issues since they are only beginning production after infection.

When testing, it's always important to consider the geographic regions with low measles prevalence due to high vaccination rates. For example, routine serological methods such as IgM detection may have a reduced positive predictive value and require confirmation by other methods. Direct detection via viral culture (less common) or of viral genomic material using RT-PCR methodologies can play an important role for laboratory confirmation of acute infections. Importantly, genotyping viruses can provide useful molecular epidemiological data for differentiating vaccine from wild-type strains, linking cases and outbreaks, and tracking geographic spread and elimination.

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The Ongoing Outbreak

With the highly contagious nature of the measles virus, additional cases are likely to occur in the outbreak area and the surrounding communities. The Texas Department of State Health Services is working with local health departments to investigate the outbreak. The CDC Epidemic Intelligence Service (EIS). is now collaborating on the ground in Texas to assist with the outbreak. The partnership, called Epi-Aid, involves EIS officers who provide on-site support for 1 to 3 weeks to help quickly control health threats while led by local authorities. Of the 198 cases, 80 are unvaccinated, and 113 have an unknown vaccination status.

Five patients had received at least one dose of the measles, mumps, and rubella (MMR) vaccine.

In neighboring Lea County, New Mexico, the number of measles cases remained at 30, according to the latest update from the New Mexico Department of Health. For ongoing, up to-date information about the outbreak, visit the Texas DSHS Measles Outbreak website. On March 6, 2025, the New Mexico Department of Health confirmed that an unvaccinated adult from Lea County had died from measles.

As of March 6, 2025, the CDC reports that a total of 222 measles cases were reported by 12 jurisdictions: Alaska, California, Florida, Georgia, Kentucky, New Jersey, New Mexico, New York City, Pennsylvania, Rhode Island, Texas, and Washington. There have been 3 outbreaks (defined as 3 or more related cases) reported in 2025, and 93% of cases (207 of 222) are outbreak-associated. For comparison, 16 outbreaks were reported during 2024 and 69% of cases (198 of 285) were outbreak-associated. Of those 222 cases, the vaccine status is reported: Unvaccinated or Unknown: 94%; 1 MMR dose: 4%; and 2 MMR doses: 2%. Approximately 17% (38 of 222) of cases were hospitalized.

Guidance: MMR vaccine and Immunity

The measles, mumps, and rubella vaccine (MMR) is often considered one of the gold standards in immunizations.

The efficacy for protection against each of the three diseases is well over 86% after completion of the 2-dose series;

specifically for measles, it is ~97% effective. Part of the reason that the vaccine is highly effective against measles is that the virus has adapted and fine-tuned itself to human-to-human transmission since the 10th - 11th century, and antibody and Tcell targets on the virus are fairly evolutionarily stagnant at this point. A great contrast to this would be SARS-CoV-2, which has spawned numerous variants since its emergence in 2019 to adapt itself to its new human host. This is the primary reason that COVID-19 vaccines are continuously updated.

Another reason that the MMR vaccine has had great success against measles is that humans are the only known host of the virus. Contrast that to influenza, which infects birds, pigs, humans, rodents, horses, and others. A broad host range for influenza virus allows it to continuously remodel itself, hence the need for updated vaccines.

For measles, the problem is that not everyone is vaccinated. Since this virus is so contagious, it relies on at least 95% of a community to be vaccinated to prevent a community outbreak.

In the US, about 91% of U.S. children ages 19-35 months have been vaccinated.

However, coverage in some communities like the current west Texas outbreak, is much lower, putting them at greatest risk.

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Final Thoughts

Measles was officially eliminated from the United States in 2000, meaning there is no measles spreading within the country, and new cases are only found when someone contracts measles abroad and returns to the country.

Achieving measles elimination status in the United States was a historic public health achievement.

However, as long as there are pockets of low vaccination coverage throughout the US, we will continue seeing sporadic outbreaks of measles virus. Now, the threat of a large-scale state-wide outbreak in Texas remains low thanks to the relatively high vaccine uptake rates in higher density regions like San Antonio and Austin. Unfortunately, over the past decade or so the public trust in medical and research expertise has eroded due to several complex factors. For example, strong immunization programs undermine themselves: When vaccination rates are high, the disease goes away. As a result, people no longer view the disease as a threat and may choose to not receive a vaccine.

Simply put, the success of vaccination has created, ironically, a public that doesn't always see the critical importance of continuing the vaccine recommendations by medical experts. The COVID-19 pandemic certainly created societal disruptions, and those impacts will continue to be felt in the misinformation, disinformation, and social media echo chambers that have resulted.

The burst of measles virus cases in the Texas outbreak is not a surprise to many in public health. It is likely the most contagious human infectious agent known. It is also preventable. For decades, the United States has kept this virus at bay through high vaccination uptake. However, these vaccine uptake rates are not the same across all regions. This can be due to several factors, but the distrust in vaccinations and public health that has been fomented for years is not an innocent party here. The time has long passed for local, state, and federal leaders to address the factors that have led to this preventable outbreak.

Old foes will gain ground or re-emerge if we do nothing, but this does not need to happen.

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Interview with Daniel Dees,

DCLS, CC (NRCC), MLS(ASCP)

Daniel Dees is currently acting as the interim medical director for clinical hematology and flow cytometry at Brigham and Women's Hospital in Boston, MA. Daniel is a seasoned laboratory professional with 16 years of experience performing, supervising and directing high complexity laboratory testing. Holding a relatively new Doctorate in Clinical Laboratory Science (DCLS) from the University of Texas Medical Branch, Daniel has been heavily involved in advocacy for the advancement of the clinical laboratory profession. He is one of the first DCLS to become board-certified through the National Registry of Certified Chemists (NRCC) qualifying him as a high complexity laboratory director.

What made you decide to pursue a Doctor of Clinical Laboratory Science (DCLS) degree?

I started in the laboratory when I joined the military in 2008. Initially I had no idea what the clinical laboratory field was or what it entailed but through my experience I learned quickly that I enjoyed the work and wanted to stay in that field long term. I utilized military benefits to get my MLT certification, then my MLS, and then a Master's degree. I thought I would top out there, but I came across an article published by ASCLS about the DCLS degree and it really was exactly what I wanted to do. The flexibility of the degree and the endpoint was where I wanted to go with my career.

Can you elaborate on how the DCLS was exactly what you wanted? What opportunities did it open up that the Master's degree didn't?

CMS recently acknowledged DCLS as qualified for high complexity medical laboratory directorship.

As far as education goes, the curriculum for the DCLS was similar to the MLS curriculum only more in depth and more focus towards the clinical side. So you're learning what these laboratory values reflect clinically in a patient, and how to interpret those results in context, for example in the presence of different medications or different disease states. So you can really help the clinical team and guide them in result interpretation or the additional ordering of other tests. The curriculum helps to bridge that knowledge gap that sometimes exists between the laboratory and the clinical teams.

What sort of work do you do, day-to-day, in your current role?

I'm currently the medical director for clinical hematology and flow cytometry in the mass General Brigham System, specifically at Brigham and Women's Hospital. Right now we're working on consolidating some of our more specialized testing. Massachusetts General Hospital and Brigham and Women's Hospital both have decades of proven, excellent patient care, but they both have their own different ways of practicing sometimes and that tends to trickle down into the laboratory. My role is to come up with processes that fit both sites.

I routinely interact with the hematology groups, the pharmacy groups, frontline patient care teams and pathology groups, including the laboratory teams, on both sites to help solidify processes that will get them information in the most efficient way.

Can you tell me more about the best and worst parts of the job?

The best part is easy, right? It's making sure we get those frontline health care providers the best possible information available to guide care for patients. I've always known that I've wanted to be in healthcare and to help patients, but I really found my niche behind the scenes in making sure that they have the information available to make those decisions when they're in front of the patient. That part really hasn't changed, no matter what level I'm on. It's just nice now as the medical director to be able to interact more with those teams and understand their needs better.

The worst part is similar to the struggle on every level of the laboratory: staffing challenges, technological barriers and the ever-shrinking budget. The administrative pressure to continue to do more with less, that's really the most challenging part day-to-day.

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Do you feel like having this DCLS degree gives your words more impact when you're advocating for the laboratory and its needs?

Absolutely. Having the terminal degree for this career field gives us a seat at that proverbial table and allows us to have a voice in administration and in the C-Suite that we normally may not have gotten otherwise. It's still a relatively new degree and with that comes the pressures of proving yourself with every conversation; you must make sure that you are the subject matter expert on what you're talking about.

The credentials do help tremendously, I think, but you must still put in that work on the back end to support what you're saying.

On that note, what is something you wish more people—both within the laboratory field and outside of it—understood about the DCLS degree?

On the pathology side, I stress every chance I get that DCLS individuals are in no way being developed to replace pathologists in their role. We're here to support them and the laboratory as a whole. The pathology field is facing staffing challenges just like ours, with the pool of qualified pathologists shrinking every year as the demand is going up. Our degree is a support system for pathologists, helping to make sure the laboratory is still getting what they need.

On the clinical side, I really wish more of the clinical teams understood how much value the laboratory can add, especially in those more complex cases. I do my best to advertise myself as often as possible, and some clinicians are getting more comfortable reaching out to me for help interpreting test results or deciding if additional testing might be needed to confirm clinical suspicions. However, I wish more of the clinical teams knew that we were a resource that's available.

What was the DCLS program like? Can you tell us about the coursework involved, what kind of work needs to be put in to earn that degree?

The full-time program at the University of Texas Medical Branch in Galveston is about 3 years, but I have some colleagues who took a part time option to extend it to 4 or 5 years. The first 2 years are heavy didactic courses like advanced hematology and advanced microbiology, and we're really learning how to correlate laboratory results with a clinical disease state or in the presence of certain medications. We have a couple of pharmacology classes that we go through as well to better understand medications and their effect on the body and thus the laboratory testing.

During those two years, you also start your clinical rotations. The first rotation was in a diagnostic management team: combining clinical and laboratory professionals to help interpret more complex cases. We were primarily focused on coagulation and transfusion services when I was there. For the other three rotations I was with clinical teams on the floor seeing patients.

I would arrive with the medical students and residents. We would prepare rounds for the day for the attending physician and then we would round on each patient and discuss their cases. What laboratory tests were ordered? How should we interpret those? What should we order next?

So that gave me a really nice view on what happens on that side and the challenges that they face that sometimes frustrate us on the laboratory side. Sometimes it's just that we're speaking different languages, so it's nice to get a little bit of fluency in their language as well. I don't think we understand sometimes that they just don't get much education on the laboratory side in medical school. I can help ease frustration and help them understand why we can't do something, and that's such a valuable experience.

Do you think that the DCLS degree is going to have a big impact on the laboratory field long term?

I really think it has potential to increase retention within our field by allowing more room for professional growth. Before this, if you wanted to get your doctorate in a clinical laboratory, you would need to either go the PhD route, or you would need to go more towards the clinical side, maybe going for the PA or MD/DO route.

The DCLS gives us the ability to stay directly within our field and have a terminal degree. Now that CMS officially determined DCLS to be qualified for high complexity laboratory director, I believe it opens the door for laboratory professionals to help better support the pathology departments that they're in while being able to combine those operational skills and clinical knowledge into the role.

What advice would you have for someone who is reading this and considering whether maybe a DCLS degree would be a good choice for them?

As with any doctorate degree, you want to make sure it's something that you're really passionate about. It's not easy by any means, no matter where you're at in life. Even though this program is developed to be able to be done while you're working, it is another full-time commitment. You need to be passionate about the work that the laboratory does for patients and be willing to advocate at every level. That's a responsibility that comes with a newer degree.

And really don't be afraid to get outside your comfort zone because as an MLS we're all generalists first. We've had at least some exposure to all areas of the laboratory. With that baseline knowledge, don't be afraid to jump in and learn a new department if the opportunity arises. It really is worth it.

Business Continuity and Quality Management

By: Kathryn Connolly MLS(ASCP), CPA(ASQ)

Kathryn Connolly is the Director of Quality Systems for COLA. She is responsible for the development, implementation and continual improvement of COLA's internal quality management system in accordance with ISO 9001 requirements. Ms. Connolly is certified as a Quality Auditor and Lean Facilitator. She is an active member of the American Society for Quality, and serves as COLA's Delegate to Clinical Laboratory Standards Institute (CLSI).

The last five years held special challenges for laboratories, from the COVID-19 pandemic to staff shortages, data breaches and significant natural disasters. Some laboratories survived while others ceased their operations temporarily or permanently. Have you ever wondered if you are doing all you can to help your laboratory weather the next storm?

You can put your quality management program to work creating a business continuity plan to ensure you're as prepared as you can be.

Quality management is not a new concept for laboratories.

The **Clinical Laboratory Improvement Amendments** (CLIA) of 1988 sets minimum requirements for a "quality system" that is focused on general, preanalytic, analytic and postanalytic activities. To meet those requirements, laboratories have implemented a variety of checks and balances, including audits, to ensure that their total testing process delivers quality results. But what about the administrative functions necessary to sustain a laboratory during a crisis? The same principles used to control the total testing process can be applied to any aspect of a business, and doing so provides a solid footing for business continuity.

I like the definition of business continuity offered by Cisco Systems Inc: "Developing a process-driven approach to maintaining operations in the event of an unplanned disruption." A process-based approach, such as "Plan – Do – Check – Act," is a key principle of quality management. It can be applied to achieving organizational goals, addressing risks and opportunities, defining and documenting operations as well as personnel management. Business continuity enables the laboratory to pivot when external or internal crises occur.

Developing a business continuity plan requires the involvement of leadership and a team approach just like other quality management activities, and includes:

1. Identifying Critical Business Functions
2. Analyzing Risks and Their Potential Impacts
3. Assigning Key Responsibilities
4. Documenting the Continuity Plan
5. Testing the Continuity Plan
6. Making Adjustments

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1 Identifying Critical Business Functions

Which critical laboratory activities cannot be stopped during an emergency or can only be down a very short time? These are activities for which you will need back-up systems or processes in place. During an emergency, you may consider different means of freeing up laboratory resources to focus on what is truly critical. This could include limiting the type of testing offered during a crisis or emergency, adjusting expected turnaround times or even transferring some services to another location or facility.

Assess laboratory activities and assign them to categories based on how long the laboratory can operate with that function offline, whether it is minutes, hours or days. Starting with the most critical activities, identify the minimum resources required to perform each activity. Include all types of resources: staff, environment, documentation, equipment, supplies and utilities.

This provides a good foundation for formulating specific back-up plans.

2 Analyzing Risks and Potential Impacts

A key part of planning is considering risks or threats. Risk management involves a systematic approach to recognizing, evaluating and mitigating risks. It is essential for laboratories to prepare for unexpected circumstances that can disrupt laboratory services.

Create a list of events that are likely to create a need to implement your business continuity plan. What is the probability of occurrence of each event? How will a given event affect the critical functions in the laboratory?

This will enable you to prioritize which scenarios to address first.

3 Assigning Key Responsibilities

Personnel management is critical to maintaining laboratory operations. This includes more than testing personnel; other roles such as receptionists, couriers, accessioning staff, supervisory personnel, custodial staff, procurement and inventory staff, information technology staff and personnel responsible for billing and coding may also be needed to maintain adequate services.

After identifying the minimum staffing levels required to maintain operations, assess the minimum requirements necessary for coverage of critical functions. Consider different ways to meet those needs, whether that involves cross training, pulling staff from other areas or locations or even outsourcing some tasks. Establish plans to communicate how to fill key roles, define responsibilities and ensure competency.

4 Documenting the Plan

A business continuity plan and its associated materials must be accessible to those who will need to implement it. Access to both electronic and hardcopy versions is best. When you need to implement the plan, you will find out just how effective your documentation is. Having key staff confused and unsure how to proceed in an emergency can take a crisis from bad to worse.

Define succession plans for key roles that must be filled. Identify critical laboratory functions, the individuals with the knowledge to perform them, the amount of time those functions can be down and any special instructions required for bringing them back up. Maintain lists of critical vendors including account numbers, contact names, phone numbers and email addresses. Maintain equipment lists and ensure that laboratory procedures and related materials will be accessible in the event of a crisis. It is especially important for back-up staff to re-familiarize themselves with processes and procedures when stepping in to assist in areas that are not part of their day-to-day responsibilities.

Lastly, don't forget about any information systems or data management systems. Ensuring service continuity requires data system protections, downtime procedures and recovery procedures.

5 Testing the Plan

Once the plan is created, review and discuss it with staff responsible for its implementation.

If possible, create drills to test individual components of the plan.

Remember the Boy Scouts & Girl Scouts motto "be prepared." The old Girl Scouts handbook reminds us that "willingness to serve is not enough; you must know how to do the job well, even in an emergency."

6 Making Adjustments

As practice drills are conducted or events happen that require implementation of the laboratory's business continuity plan, reserve time afterward to reflect on and learn from the experience. What went according to plan?

What surprises came up and how effectively did the team respond?

Collecting this information and using it to adjust the plan itself and associated training can help to improve your plan and better prepare your team for unexpected scenarios.

Quality management is a process-based approach that teaches us to examine risks and develop contingency plans for events with a high probability of occurrence. It relies on collecting and examining facts and data in the process of decision making. The challenges we've faced in the laboratory field over the past few years have given us opportunities to look back, evaluate our successes and discover areas for improvement, so that we can adjust our contingency plans before the next crisis.

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ABOUT COLA:

COLA, Inc. is a physician-directed organization whose purpose is to promote health and safety through accreditation and educational programs. In 1993, COLA was granted deemed status by CMS to provide laboratory accreditation. As a leading laboratory accreditor in the United States, COLA operates its laboratory accreditation program in accordance with a quality management system certified to ISO 9001. This means we offer our customers a unique, standardized program and staff dedicated to satisfaction and laboratory quality. Our Surveyors and Technical Advisors are guided by a coaching approach and uncomplicated quality engineered processes. Laboratories of all types and sizes are evaluated and mentored to produce the highest quality laboratory services and meet CLIA regulations.

COLA's Board of Directors consists of representatives from three founding member organizations: the American Medical Association (AMA), American Academy of Family Physicians (AAFP) and the American College of Physicians (ACP).

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