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MEDICAL LABORATORY OBSERVER

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The Peer-Reviewed Management Source for Lab Professionals since 1969

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LAB INNOVATOR

Tony F. Freeman, BS, HT(ASCP)
Laboratory Specialist
with the Accreditation Commission
for Health Care (ACHC)

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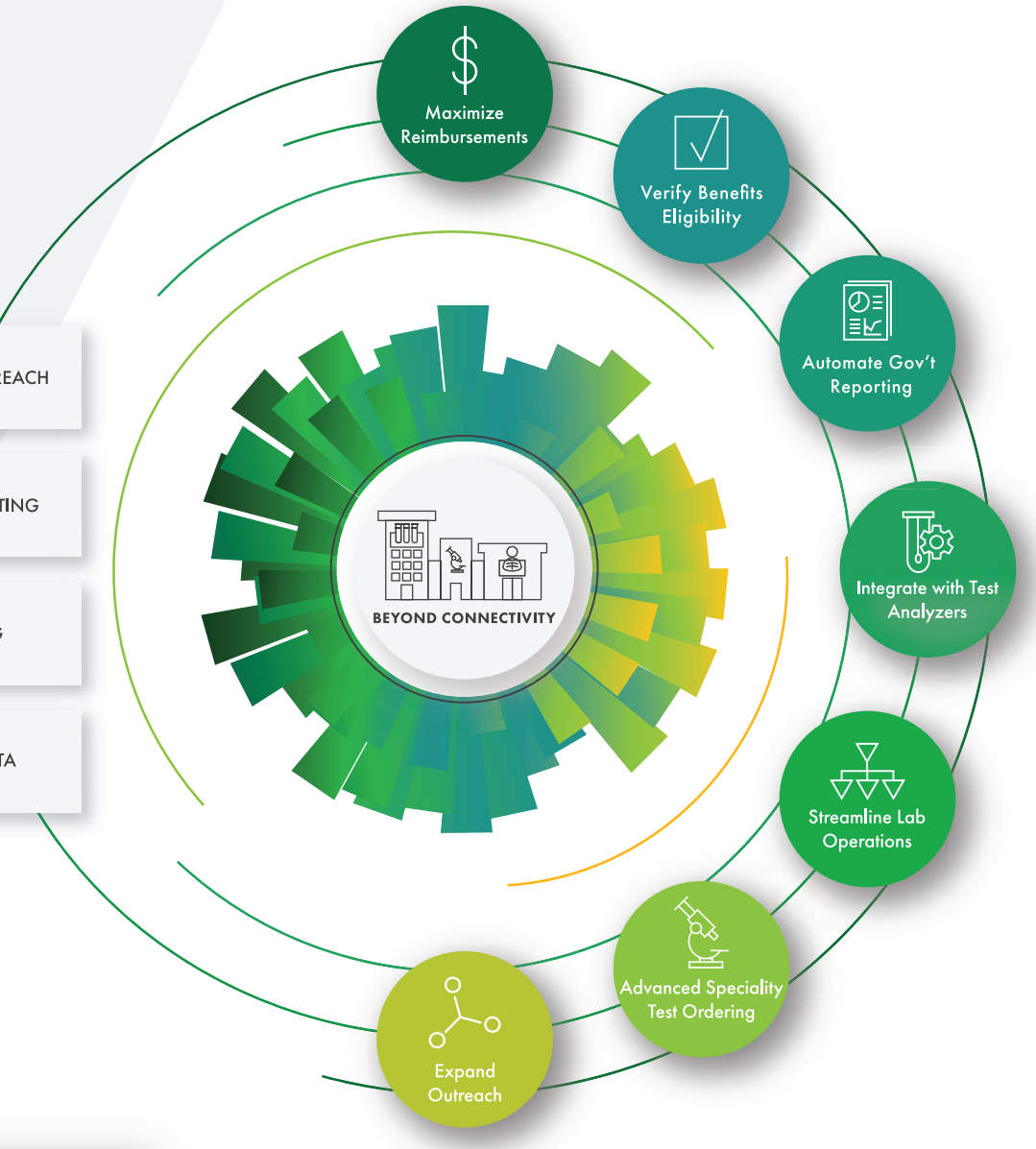

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Clinical or medical? Technologist or scientist?

By Christina Wichmann

By Christina Wichmann
Editor in Chief

Writing this year's Salary Survey allowed me to dive a little deeper into the world of the medical laboratory professional. The information gathered from the survey (article on page 22) is based on 436 respondents. This year's composite medical lab professional is female, between 56–65 years old, and holds a salaried, management position in a hospital lab. She has been in the lab profession for more than 30 years and has worked for her current employer over 30 years.

While analyzing the data from the Salary Survey on the certifications respondents hold and the organizations the certifications are from, I became very interested in what looked like very similar certifications with slight naming differences. I wanted to have a better understanding of the differences and started doing some research. I already had an understanding of the difference between a medical laboratory scientist and a medical laboratory technician, and I had some understanding of the differences between a technologist and a technician. But I wasn't actually sure what the differences might be between certifications such as medical laboratory scientist, clinical laboratory scientist, medical laboratory technician, medical technologist, and clinical laboratory technologist — which were identified certifications in the Salary Survey.

The MLO Salary Survey is mostly the same questions each year; this is to allow comparisons in the data/feedback from one year to the next. In taking the closer look at the certification section, I noticed a couple things that will probably need to be changed for next year. For one, we ask if anyone's certification is from National Certification Agency for Medical Laboratory Personnel (NCA). Although 49 respondents said "yes," I discovered this agency was unified with the American Society for Clinical Pathology (ASCP) Board of Registry (BOR) in 2009. Maybe we shouldn't ask if a certification is from NCA anymore. NCA had used the designations Clinical Laboratory Scientist and Clinical Laboratory Technician. But under the single certification agency (ASCP BOR), the professional designations became Medical Laboratory Scientist and Medical Laboratory Technician.

I came across an interesting white paper on the ASCP website: "Promoting the medical laboratory science profession through standardized titles."[1] The problem statement of that paper identified lack of industrywide standardization in the title of certified baccalaureate-educated laboratory personnel as confusing and undermining both professional identity of practitioners as well as public understanding of the profession. In addition, another certifying body, the American Medical Technologists (AMT), has transitioned its Medical Technologist designation to Medical Laboratory Scientist this year. Its certifications include Medical Laboratory Scientist, Medical Laboratory Technician, and Medical Laboratory Assistant.

All of this made me think we should be more aware at MLO in using these updated, standardized terms.

I welcome your comments and questions — please send them to me at cwichmann@mlo-online.com.

REFERENCES

1. ASCP.org. Accessed April 4, 2023. https://www.ascp.org/content/docs/default-source/boc-pdfs/about_boc/promote_mls_standardized_titles.pdf.

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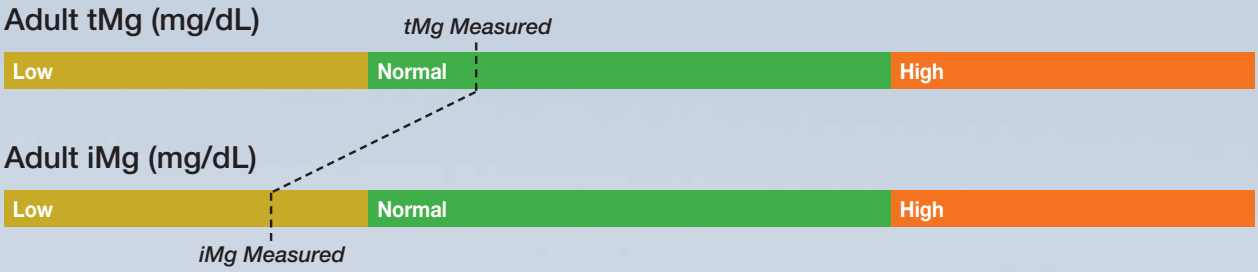
ICU Patient Studies Show Critical Importance of Ionized Magnesium

Patients Undergoing Continuous Renal Replacement Therapy (CRRT)

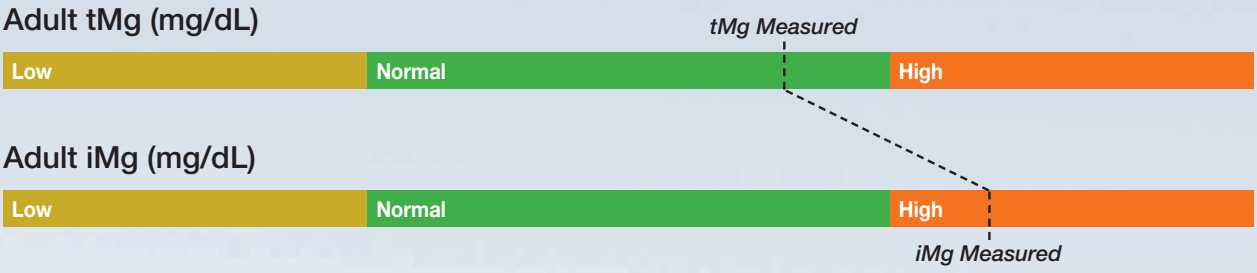
Hutten et. al.[1] found that patients receiving CRRT with citrate anticoagulation had normal tMg levels, but low iMg levels. This is due to magnesium ions being bound by citrate, and the citrate-magnesium complex being measured as tMg. These patients are actually hypomagnesemic but would not be recognized as such if only tMg were measured.



1.Hutten et al., Ionized and not total magnesium as a discriminating biomarker for hypomagnesaemia in continuous venovenous haemofiltration patients. *Nephrol Dial Transplant*, 2021.

Surgical ICU Patients

Yeh et. al.[2] found that 21% of tMg tests which were reported as normal were hypermagnesemic based on iMg. This exposes patients to potential risks associated with undetected hypermagnesemia, including prolonged days on the ventilator, muscle weakness, QT prolongation, and cardiac arrhythmia. In addition, there were many patients with low tMg and normal iMg, which led to unnecessary Mg supplementation and repeat blood draws.



2.Yeh, et al. Total and ionized magnesium testing in the surgical intensive care unit - Opportunities for improved laboratory and pharmacy utilization. *J Crit Care*, 2017, 42, 147-151.

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Fast Facts

In a recent multisite survey of more than 8,000 patients who accessed their test results via an online patient portal account, researchers at Beth Israel Deaconess Medical Center (BIDMC) and colleagues found that users overwhelmingly supported receiving the results immediately, even if their provider had not yet reviewed them. The findings, published in *JAMA Network Open*, showed only a small subset of patients reported experiencing additional worry after receiving abnormal test results. In addition, pre-counseling by the healthcare team before tests were ordered was linked to reduced worry among patients with abnormal results

Of the 8,139 survey respondents:

80%

reported reviewing at least one test result in the past month.

57%

reported normal findings.

90%

of respondents with normal results indicated they would prefer receiving their result via the patient portal when asked about their preferences for contacts about future test results.

96%

indicated a preference for receiving results through the patient portal as soon as they are available, even if their provider had not yet reviewed them.

8%<

reported being more worried after viewing test results.

17% versus 5%

respondents who viewed not normal results were more likely to report being more worried, or much more worried, than those reporting normal results.

Source: https://www.bidmc.org/about-bidmc/news/2023/03/survey-shows-patients-prefer-immediate-access-to-test-results#:

NIH researchers discover new autoinflammatory disease, suggest target for potential treatments

Scientists have identified an autoinflammatory disease caused by mutations in the LYN gene, an important regulator of immune responses in health and disease.

Named Lyn kinase-associated vasculopathy and liver fibrosis (LAVLI), the identification sheds light on how genes linked to certain illnesses can potentially be targets for treatment by repurposing existing drugs. The research, published in *Nature Communications*, was led by Adriana A. de Jesus, M.D. Ph.D., and Raphaela Goldbach-Mansky, M.D., M.H.S. of the Translational Autoinflammatory Diseases Section of the Laboratory of Clinical Immunology and Microbiology at the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health.

LAVLI was first discovered in a pediatric patient through genetic testing, which detected a mutation in LYN, the gene that encodes the Lyn kinase protein. Two additional, unrelated pediatric patients were later discovered to have two more mutations in the same gene. All three patients developed diseases linked to the LYN genetic mutation shortly after birth. Two patients developed liver fibrosis—excessive amounts of scar tissue caused by inflammation and repeated liver damage—in the first year of life. All three patients had perinatal onset of neutrophilic cutaneous small vessel vasculitis. This is an immune disorder characterized by inflammation from high numbers of neutrophils—white blood cells of the immune system—that can damage small blood vessels. The study revealed Lyn kinase was always active and unable to shut down in the three patients with the LYN mutation, which increased neutrophil migration, altered inflammatory signals and activated scar and fibrosis-inducing liver cells. The results of this study suggest that Lyn kinase may be a potential therapeutic target for drugs that treat forms of non-syndromic small vessel vasculitis and other types of inflammation-induced liver fibrosis.

NIH-supported trial shows artificial pancreas improves blood glucose control in young children

Artificial pancreas technology improved blood glucose control in young children between ages 2 and 5 with type 1 diabetes, according to the results of the Pediatric Artificial Pancreas (PEDAP) Trial, a 13-week randomized controlled trial conducted at three pediatric diabetes centers across the United States. The study was funded by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), part of the National Institutes of Health, and results were published in the *New England Journal of Medicine*.

The artificial pancreas, also known as closed-loop control, is an "all-in-one" diabetes management system that tracks blood glucose levels using a continuous glucose monitor (CGM) and automatically delivers insulin when needed using an insulin pump. The system replaces reliance on testing by fingerstick or CGM with delivery of insulin by multiple daily injections or a pump controlled by the patient or caregiver.

The trial enrolled 102 participants between ages 2 and 5, a particularly challenging population when it comes to glycemic control, and randomly assigned them to either the artificial pancreas group or the standard care comparison group. The artificial pancreas group received training on how to use the study device — an insulin pump programmed with Control-IQ insulin dosing technology — and a CGM. The standard care group continued to use their pre-study method of blood glucose management and were trained to use the study CGM.

During the 13 weeks, participants in the artificial pancreas group spent 12% more time — approximately three hours per day — within their target blood glucose range compared to the standard care group. The greatest difference in blood glucose control was seen at nighttime, between 10 p.m. and 6 a.m., with artificial pancreas participants spending 18% more time in range than the standard care group. Nighttime control is especially challenging to maintain in children with type 1 diabetes.

Additional measurements of blood glucose control also improved, similar to findings seen in previous artificial pancreas trials in older children and adults.

The study also assessed the safety of using the artificial pancreas device in young children. Similar numbers of severe hypoglycemia occurred among both study groups. One instance of diabetic ketoacidosis occurred in the artificial pancreas group due to a problem with the insulin pump tubing called infusion set failure.

Genetic causes of three previously unexplained rare diseases identified

Using a new computational approach they developed to analyze large genetic datasets from rare disease cohorts, researchers at the Icahn School of Medicine at Mount Sinai and colleagues have discovered previously unknown genetic causes of three rare conditions: primary lymphedema (characterized by tissue swelling), thoracic aortic aneurysm disease, and congenital deafness. The work was done in collaboration with colleagues at the University of Bristol, UK; KU Leuven, Belgium; the University of Tokyo; the University of Maryland; Imperial College London, and others from around the world.

An enhanced understanding of the functions of the genes involved in these and other disorders could pave the way for the development of treatments. The findings were published in the March 16 online issue of *Nature Medicine*.

The investigators studied a collection of 269 rare disease classes using data from 77,539 participants in the 100,000 Genomes Project, one of the largest datasets of phenotyped and whole-genome-sequenced rare disease patients. The researchers identified 260 associations between genes and rare disease classes, including 19 associations previously absent from the literature. Through an international academic collaboration, the authors validated the three most plausible novel associations by identifying additional cases in other countries and through experimental and bioinformatic approaches.

FDA approves first over-the-counter naloxone nasal spray

The U.S. Food and Drug Administration approved Narcan, 4 milligram (mg) naloxone hydrochloride nasal spray for over-the-counter (OTC), nonprescription, use – the first naloxone product approved for use without a prescription. Naloxone is a medication that rapidly reverses the effects of opioid overdose and is the standard treatment for opioid overdose.

The timeline for availability and price of this OTC product is determined by the manufacturer. The FDA will work with all stakeholders to help facilitate the continued availability of naloxone nasal spray products during the time needed to implement the Narcan switch from prescription to OTC status, which may take months. Other formulations and dosages of naloxone will remain available by prescription only.

The FDA granted the OTC approval of Narcan to Emergent BioSolutions.

SAGE updates COVID-19 vaccination guidance

Following its 20-23 March meeting, the World Health Organization's Strategic Advisory Group of Experts on Immunization (SAGE) revised the roadmap for prioritizing the use of COVID-19 vaccines, to reflect the impact of Omicron and high population-level immunity due to infection and vaccination.

The roadmap newly considers the cost-effectiveness of COVID-19 vaccination for those at lower risk – namely healthy children and adolescents – compared to other health interventions. The roadmap also includes revised recommendations on additional booster doses and the spacing of boosters. The current COVID-19 vaccines' reduction of post-COVID conditions is also considered but the evidence on the extent of their impact is inconsistent.

The revised roadmap outlines three priority-use groups for COVID-19 vaccination: high, medium, and low. These priority groups are principally based on risk of severe disease and death, and consider vaccine performance, cost-effectiveness, programmatic factors and community acceptance.

The high priority group includes older adults; younger adults with significant comorbidities (e.g. diabetes and heart disease); people with immunocompromising conditions (e.g. people living with HIV and transplant recipients), including children aged 6 months and older; pregnant persons; and frontline health workers.

For the high priority group, SAGE recommends an additional booster of either 6 or 12 months after the last dose, with the timeframe depending on factors such as age and immunocompromising conditions. All the COVID-19 vaccine recommendations are time-limited, applying for the current epidemiological scenario only, and so the additional booster recommendations should not be seen as for continued annual COVID-19 vaccine boosters. The aim is to serve countries planning for the near- to mid-term.

The medium priority group includes healthy adults – usually under the age of 50-60 – without comorbidities and children and adolescents with comorbidities. SAGE recommends primary series and first booster doses for the medium priority group. Although additional boosters are safe for this group, SAGE does not routinely recommend them, given the comparatively low public health returns.

The low priority group includes healthy children and adolescents aged 6 months to 17 years. Primary and booster doses are safe and effective in children and adolescents. However, considering the low burden of disease, SAGE urges countries considering vaccination of this age group to base their decisions on contextual factors, such as the disease burden, cost effectiveness, and other health or programmatic priorities and opportunity costs.

Other meeting highlights include:

- Polio
- Regional reports on measles
- Status of new tuberculosis vaccines
- Malaria
- Identifying priority pathogens for new vaccines

Electronic CLIA certificate rollout

On March 22, 2023, the Centers for Medicare & Medicaid Services will start sending electronic certificates to laboratories that opt on their CLIA application (Form CMS-116) to receive email notifications. These laboratories will be emailed a link to their CLIA certificate, which they can print in hard copy. Generally, new certificates will be emailed approximately 30 days prior to the expiration of the current certificate.

A welcome email was sent out on February 8, 2023 to all labs that opted to receive email notifications. If you have not received a welcome email, you have either not opted to get email notifications or your email address needs to be updated. To update an email address or opt to get email notifications, laboratories must give written notification to the State Agency where they're located. Federal jurisdiction laboratories should contact their CMS Location.

Laboratories will also keep getting paper certificates until further notice.

Laboratory quality – a comprehensive look

By Nancy Ross MS, MT(ASCP)cmp, CQIA (ASQ), CLC (AMT), CQM/OE (ASQ); Irwin Z. Rothenberg; Graham K. Mafela, MLS (ASCP), MBA

The concept and definitions of quality in laboratory medicine have been steadily evolving throughout the second half of the twentieth century right up to the present day. Originally focused on the analytical phase of testing, quality was defined primarily by measurements of the accuracy, precision, and reproducibility of test results, determined by performing quality control (QC) on the testing process. Professional as well as governmental standards of acceptable performance were originally based on this paradigm.

However, in recent years, the concept of quality monitoring for laboratory testing has evolved to encompass the total testing process, also known as TTP. Beginning with test ordering and ending with result reporting, TTP encompasses the pre-analytical, analytical, and post-analytical phases of testing. Monitoring this entire process is the basis of quality assurance (QA).[1] QA is thus defined as the overall monitoring program that ensures that the final test results reported by the laboratory are as correct and timely as possible; with QC being one component of a program that includes standards for specimen collection, instrument maintenance, environmental monitoring, personnel training, competency and safety, data management, and record keeping.

Today, the concept of quality laboratory service continues to evolve enabled by rapid advances in digital technology, new service delivery models, the decentralization of patient contact, and the ability to meet the demands of non-physician patient test ordering and reporting.

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LEARNING OBJECTIVES

Upon completion of this article, the reader will be able to:

1. Discuss the original focus of laboratory quality.
2. Describe the evolution of how quality monitoring is changing.
3. Differentiate between quality control and quality assurance.
4. List the steps of a complete quality management system (QMS).

Quality management

Quality control is designed to detect and correct deficiencies in a laboratory's internal analytical process prior to the release of patient test results in order to ensure the quality of the work reported by the laboratory. Quality control is a measure of precision, or how well the measurement system reproduces the same result over time and under varying operating conditions. Laboratory quality control material is usually run at the beginning of each shift, after an instrument is serviced, when reagent lots are changed, after calibration, and whenever patient results seem inappropriate. The effectiveness of quality control is assessed on a per test basis.[2]

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Quality assurance is a more broadly focused ongoing program for auditing all of an organization's processes and systems; it involves setting quality goals, deciding whether or not these goals have been achieved, and implementing corrective action if these goals have not been reached. It includes auditing the effectiveness of policies and procedures and encompasses all phases of testing and general administration. There are no limits for quality assessment audits as these go well beyond the more test-specific focus of quality control.[2]

The CLIA regulations address specific quality assurance requirements. The Code of Federal Regulations (42 CFR 493) states that laboratories "must establish and follow written policies and procedures for a comprehensive quality assurance program that is designed to monitor and evaluate the ongoing and overall quality of the total testing process." The QA program must accomplish the following:

- Assess the effectiveness of the lab's policies and procedures
- Identify and correct problems
- Ensure the accurate, reliable, and prompt reporting of test results
- Ensure the adequacy and competency of the staff

The changing landscape for quality management

While the management skills needed to lead a laboratory that provides quality patient care are well understood, the defining components of quality care itself are not static. Whether discussing the traditional issues of test accuracy, turnaround time, specimen acquisition, or result reporting, the operating environment around these activities is changing, including new testing and data technology and the way tests are performed and reported; new treatment protocols requiring new tests; physician needs for immediate digital access; legislation regarding laboratory fees and CLIA regulations; patient expectations; labor shortages; and changing demographics that will affect future demand for laboratory services. Additional changes include technological advances that have led to an increasingly visible and active role of the laboratory within healthcare delivery systems, the rapid decentralization of laboratory testing that has led to the rise of point-of-care testing (POCT) and retail medicine, as well as remote wearable technology allowing accurate mobile test monitoring. These developments place added responsibilities on the central laboratory to ensure that the quality of testing is maintained.

Thus, the requirements to maintain "quality patient services" even in remote settings that include pharmacies and department stores, as well as large non-medical employers such as Amazon, require a re-engineering of how reliable testing and reporting are maintained.

In Rothenberg's "Adapting to change: How resilient is your laboratory?" he notes, "These times call for more than good management, they call for good leadership, but leadership that is more adaptive and agile than ever before. These times call for leadership that understands change and can adapt by creating an organizational culture of quality through resilience, enabling their laboratory operation to not only survive but prosper and grow, maintaining quality service."[3]

The quality management system

An organized quality management system (QMS), which oversees the entire laboratory operation, is very important for achieving optimal laboratory performance. The quality management system is not only concerned with monitoring QC/QA programs but should also include administrative considerations that may indirectly influence the quality and efficiency of the laboratory operation.[4] A QMS is officially defined as "coordinated activities to direct and control an organization with regard to quality." This definition is used by the International Organization for Standardization (ISO) and by the Clinical and Laboratory Standards Institute (CLSI).

The quality management system model illustrated here organizes all of the laboratory activities into twelve Quality System Essentials (QSE), which are a set of coordinated activities that serve as building blocks for quality management. Each must be addressed if overall laboratory quality improvement is to be achieved. The twelve QSEs are as follows: organization and supervision, personnel, equipment, purchasing and inventory, documents and records, process control, information management, occurrence management, assessment, customer service, process improvement, facilities and safety.[5]

1. Organization and supervision

The structure and management of the laboratory must be organized so that quality management policies can be established and implemented. The laboratory should prepare an organizational chart that includes all management and staff positions with functions and responsibilities delineated for each position. The current duties and responsibilities of the staff must be

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specified in written job descriptions including training required, competency assessments, and relevant experience. A quality manager should be designated to ensure the implementation and monitoring of the quality policies. Processes for monitoring will be needed to ensure that the system is working, and that benchmarks and standards are being met. This element is essential to the primary goal of a quality system, which is continuous improvement. The commitment and leadership by the laboratory director are crucial.

2. Personnel

Competent, trained, and motivated staff are the most important resource for a quality laboratory operation. To ensure this requirement is met, the laboratory must do the following:

- Hire an appropriate number of staff to cover the workload.
- Develop complete and thorough job descriptions for each employee.
- Train each employee in their specific duties and responsibilities.
- Provide orientation for new employees; this is separate from training. This is to ensure that new employees understand the culture of the laboratory; it is an investment in team building as well.
- Perform and record competency assessments on all personnel. It is management's responsibility to verify that trained employees are sufficiently competent to do their work and maintain their competency over time. This can be done through direct observation of the personnel, records monitoring, and/or by analyzing the quality control or external quality assessment results.
- Provide opportunities for continuing education; new techniques or updates for existing methodologies will always occur.
- Conduct annual employee performance appraisals.

3. Equipment

Equipment management is one of the essential elements of a quality management system. Proper management of the equipment in the laboratory is necessary to ensure accurate, reliable, and timely testing. Choosing the right equipment, assuring that the staff is properly trained to use the equipment, and assuring that the new equipment works properly and receives proper maintenance are crucial. Equipment manuals should be available in the laboratory area for easy reference. An inventory of equipment including records of maintenance and repair should be maintained.

The benefits of a good equipment management program are many:

- Helps to maintain quality laboratory performance
- Improves the technologist's confidence in the accuracy of testing results
- Lowers repair costs, as fewer repairs will be needed for a well-maintained instrument
- Lengthens instrument life
- Reduces the interruption of services due to breakdowns and failures
- Increases staff safety
- Produces greater customer satisfaction when service is not interrupted

4. Purchasing and inventory

Efficient and cost-effective laboratory operations require the uninterrupted availability of expected supplies and services. Proper management of purchasing and inventory can produce cost savings in addition to assuring accurate and timely reporting of laboratory results. The inability to test, even for a short time, is very disruptive to clinical care, impairing the quality of services offered.

Purchasing and inventory management procedures should be written and implemented to assure that all reagents and supplies are correctly selected, purchased, used, and stored in a manner that preserves integrity and reliability. The inventory should be kept up to date including information on receipt, storage, and issuance. Package inserts and safety data sheets (SDS) should be archived as part of recordkeeping.

5. Documents and records

Documents provide written information about policies, processes, and testing procedures and comprise the laboratory's Policy and Procedure and Quality Improvement manuals. These manuals include all standard operating procedures (SOPs) that must be adapted to the laboratory's role and testing menu. The SOPs, QC/QA procedures, specimen testing request forms, report forms, and other laboratory forms are all important components of these manuals, which document the quality management system. There should also be manuals related to laboratory safety. Examples of laboratory safety records include request forms, report forms, logbooks, quality control results, patient reports, critical communications, and notices from hospitals or public health authorities.

6. Process control

Quality control (QC) is an essential element of the quality management system. It monitors the processes related to the analytical phase of testing and detects errors in testing. These errors may be due to test system failure, adverse environmental conditions, or flawed operator performance. The goal of QC is to detect these errors and enable corrections before patient results are reported. The steps for implementing a QC program are as follows:

- Establish QC policies and procedures.
- Assign responsibility for monitoring and reviewing QC.
- Select appropriate QC material.
- Establish control ranges.
- Develop graphs to plot control values (Levey–Jennings charts).
- Establish a system for monitoring control values.
- Take immediate corrective action if needed.
- Maintain records of QC results and any corrective actions taken.

7. Information management

Information management is a system that incorporates all the processes needed to effectively manage data — both incoming and outgoing patient information. The information management system may be entirely paper-based, computer-based, or a combination of both. Whatever technology is employed, information management is another of the essentials of a quality system. This information, especially test results, are the final product of the laboratory. Laboratory directors need to ensure that the laboratory has an effective information management system in place to achieve accessibility, accuracy, timeliness, security, confidentiality, and privacy of patient information.

When planning and developing an information management system, here are some important elements to consider:

- Unique identifiers for patients and samples
- Standardized test request forms (requisitions)
- Logs and worksheets
- Processes to assure accuracy of data recording and transmission

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8. Occurrence management

An occurrence (or "incident") is any event that has a negative impact on the laboratory, including its patients, personnel, equipment, or the environment in which it operates. All such events must be addressed in an occurrence management program. Occurrence management (also known as "Incidence management") is a central part of continuous quality improvement (CQI) — it is the process by which errors are identified and handled.

The goal of an occurrence management program is to correct errors that have occurred in testing or communication, and to change the process so that the error is unlikely to occur again. Well-managed laboratories will also review their systems and detect process problems that could possibly cause errors at some time in the future, allowing for prevention of these errors. Occurrence management requires a process for detecting and documenting these occurrences, for handling them properly, and for taking corrective action to reduce the chance of recurrence.

Common errors include the following:

- Patient identification error
- Specimen misplacement
- Specimen transport delayed and proper temperature not maintained
- Specimen not kept in the right environment to maintain its integrity
- Contaminated specimens
- Performing an inappropriate test
- Performing a test inconsistent with the written procedure
- Lack of QC/QA
- Transcription and clerical errors

Occurrences are detected through various means, such as supervisory review, physicians' or patients' complaints, QC/QA results, or findings from external audits. Immediate remedial corrective action should be undertaken before the result is reported. Ultimately, corrective actions should be implemented to prevent similar errors from recurring.

9. Assessment

Assessment is a tool for examining laboratory performance and comparing it to known standards or to performance of other laboratories. Assessment may be internal, performed by the laboratory's own staff, or it may be external, conducted by an external group or agency outside the laboratory.

Internal quality assessments can be conducted by the staff of the laboratory to identify weaknesses and undertake corrective actions. Quality indicators can be defined by the laboratory management and staff to complement the use of internal QC. While internal QC primarily assesses the examination steps, quality indicators can be designed to monitor the pre- and post-examination steps. Quality indicators are addressed in ISO 9001 and ISO 15189 documents and are used to determine how well an organization meets operational and performance expectations.

ISO 9001 requires that quality objectives be measurable and requires collecting and analyzing specific information or data upon which one can determine effectiveness of processes and continual improvement. Thus, the objectives or indicators must be quantifiable or otherwise capable of analysis, allowing for an assessment of the success of the quality system.

ISO 15189 requires the laboratory to implement quality indicators to systematically monitor and evaluate the laboratory's contribution to patient care, including outcomes. Also, laboratory management must ensure that the medical laboratory participates in quality improvement activities. Quality indicators measure data through the following:

- Provide information about the performance of a process.
- Determine quality of services.
- Highlight potential quality concerns.
- Identify areas that need further study and investigation.
- Track changes over time.

External quality assessment (EQA) is a system for objectively checking the laboratory's performance using an external agency or facility. There are three commonly used EQA methods or processes:

- Proficiency testing (PT) is performed through a set of unknown specimens sent regularly to the laboratory by a PT provider. The laboratory reports the results back to the PT provider who compares the test results with peer determined results and grades a pass (all results concordant) or fail (any discrepant results) for the PT.
- Confirmation by sending split samples to a reference laboratory for testing and comparing the results.
- On-site visits conducted by governmental, certification, or accreditation bodies.

The value of a well-designed assessment is that it will reveal weaknesses in the pre-analytical, analytical, and post-analytical phases. Information is gathered about:

- Processes and operating procedures
- Staff competence and training
- Equipment
- Environment
- Handling of samples
- Quality control and verification of results
- Recording and reporting practices

The findings are compared with the laboratory's internal policies and to a standard or external benchmark. Any breakdown in the system or departure from procedures will be identified.

10. Customer service

Customer satisfaction is a major component of a quality management system. Medical laboratories have a range of customers including patients, physicians, public health agencies, and the community. It is the responsibility of the laboratory director to ensure that customers' needs are met.

The quality manager is responsible for measuring the degree of customer satisfaction, using surveys, indicators, and audits to take preventive and corrective action. All laboratory staff must understand the importance of customer satisfaction. Laboratory personnel must always interact with customers in a way that is appropriate, provides needed information, and is courteous.

The initial request for service originates with the physician or healthcare provider. It is important to note that in a hospital setting, the healthcare provider will be assisted by many other people, including nurses, medical assistants, phlebotomists, and secretaries or clerks. These vital hospital personnel should also be considered clients of the laboratory, and their needs must be addressed.

Another important client for the laboratory is the patient, usually including their family. Family members may play a very important role in patient management, and may help with sample collection and transport.

In many situations, laboratory tests can be ordered by the patient directly without referral from a physician or nurse. Some patients do not have the knowledge or expertise to order the right test or to interpret results. Laboratory personnel may have to provide assistance in test selection and interpretation.

11. Process improvement

The primary goal of a quality system is continuous improvement of the laboratory processes in a systematic manner. A number of tools have been described above to identify errors, such as customer service surveys, internal QC, EQA, auditing, and quality indicators. Rigorous analysis of all these tools should lead to improvements in procedures and practices. These changes should be recorded and reflected in the SOPs and implemented in the laboratory. Open communication among staff members is also important to encourage suggestions that may improve the quality and efficiency of the laboratory.

12. Facilities and safety

The laboratory should develop SOPs for biosafety, basic safe operating procedures, and waste management that are adapted to their specific role in the laboratory and in conjunction with institutional policies. The development of safety protocols and organizing appropriate safety training is the responsibility of the laboratory director but may be delegated to the quality manager. The steps for designing a safety management program include the following:

- Developing policies and procedures for safety and biosafety in the laboratory
- Organizing safety training that teach staff to be aware of potential hazards and how to apply safety practices and techniques. The training should include information about universal precautions, infection control, chemical and radiation safety, how to use personal protective equipment (PPE), how to dispose of hazardous waste, and what to do in case of emergencies
- Setting up a process to conduct risk assessments — this process should include initial risk assessments, as well as ongoing laboratory safety audits to look for potential safety problems

Creating a Culture of Quality

Creating and maintaining a quality laboratory operation means that the dynamics of teamwork, trust, transparency, awareness, and experience work in sync to create an environment where unbiased assessments of laboratory operations can take place, resulting in the efficient implementation of necessary changes. The key to developing and maintaining this environment is the empowerment of the staff to make decisions at the level nearest to where the work is performed. It is through the buy-in of all involved, that the goals of better patient care, efficient laboratory operation, and improved staff morale are achieved.[6]

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Laboratory quality – a comprehensive look

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TEST QUESTIONS

Circles must be filled in, or test will not be graded. Shade circles like this: ● Not like this: ○ X

1. What was the focus of the original definition of quality in laboratory medicine?
- A. Pre-analytical phase of testing
- B. Analytical phase of testing
- C. Post-analytical phase of testing
- D. All of the above

2. In recent years, a quality assurance program has evolved to encompass
- A. ATP
- B. CTP
- C. TTP
- D. QMTP

3. QC is only one component of a QA program.
- A. True
- B. False

4. Quality assurance includes all except
- A. Running controls at the beginning of each shift
- B. Setting quality goals
- C. Implementing corrective action
- D. Auditing the effectiveness of policies and procedures

5. When is quality control performed?
- A. After calibration or when patient results seem inappropriate
- B. At the beginning of each shift and/or change of lot
- C. After instrument service
- D. All of the above

6. The landscape for quality management is changing, including many factors pertaining to the operating environment around the traditional components of quality care.
- A. True
- B. False

7. How many building blocks are there in the newly developed quality system essentials (QSE).
- A. 25
- B. 12
- C. 7
- D. 3

8. Which building block includes written job descriptions and a designated quality manager and implements processes for monitoring?
- A. Equipment
- B. Documents and records
- C. Organization and supervision
- D. Personnel

9. The assurance that there are competent, trained, and motivated staff is descriptive of
- A. Organization and supervision
- B. Occurrence management
- C. Process control
- D. Personnel

10. What part of QSE involves proper management of equipment, choosing the right equipment, and ensuring that equipment works properly.
- A. Facilities and safety
- B. Equipment
- C. Process improvement
- D. Documents and records

11. The uninterrupted availability of expected supplies and services and documentation of the supplies fall under this building block.
- A. Equipment
- B. Assessment
- C. Personnel
- D. Purchasing and inventory

12. The building block that consists of the laboratory's policy and procedure and quality improvement manuals is
- A. Documents and records
- B. Process control
- C. Information management
- D. Organization and supervision

13. Which part of the QSE includes the implementation of a QC program?
- A. Information management
- B. Assessment
- C. Process control
- D. Occurrence management

14. _____ is a system that incorporates all the processes needed to effectively manage data.
- A. Organization and supervision
- B. Documents and records
- C. Process control
- D. Information management

15. Which building block houses the process by which errors are identified and handled?
- A. Occurrence management
- B. Information management
- C. Assessment
- D. Personnel

16. What part of the QSE examines laboratory performance and compares it to known standards or to the performance of other laboratories?
- A. Organization and supervision
- B. Documents and records
- C. Assessment
- D. Occurrence management

17. _____ is the building block where the quality manager measures the degree of customer satisfaction.
- A. Personnel
- B. Assessment
- C. Occurrence management
- D. Customer service

18. Rigorous analysis of customer surveys, internal QC, EQA, auditing, and quality indicators occurs in
- A. Process improvement
- B. Customer service
- C. Facilities and safety
- D. Occurrence management

19. Which building block describes the development of safety protocols and organizing safety training by the laboratory director?
- A. Personnel
- B. Process improvement
- C. Facilities and safety
- D. Documents and records

20. Staff must be empowered to maintain and develop a quality laboratory operation.
- A. True
- B. False

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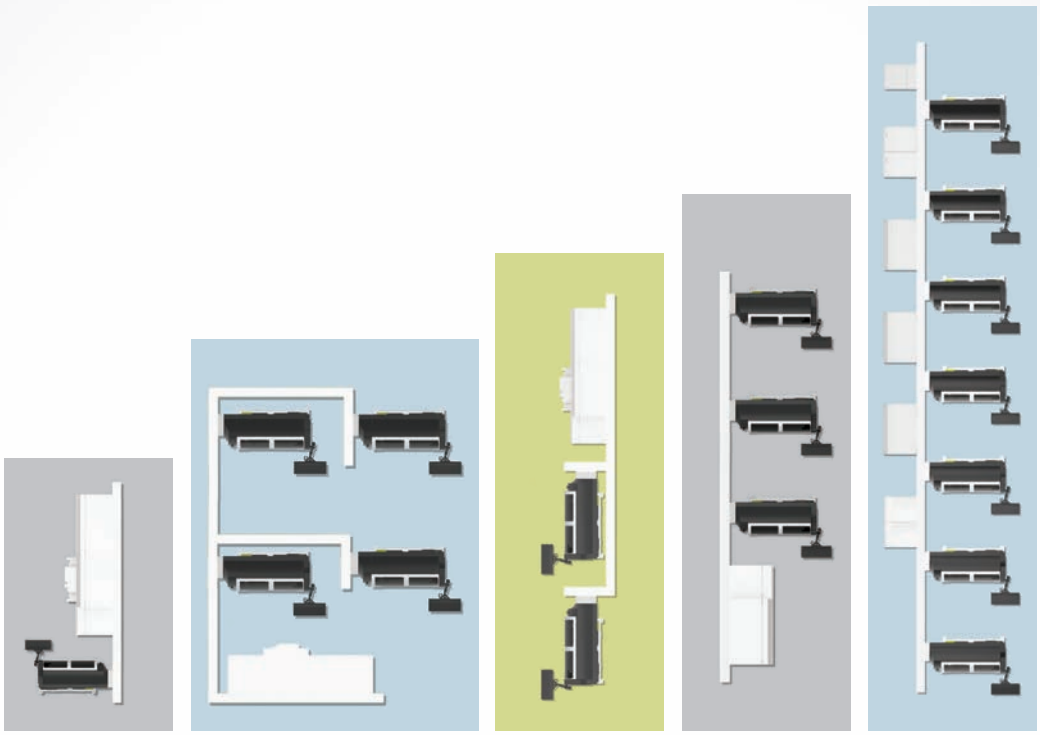

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Cross-reactive carbohydrate determinants — history and relevance in allergy diagnostics

By Johannes Grosch, Dr. rer. nat. and Friedrich Altmann, Dr. nat. techn.

The story of cross-reactive carbohydrate determinants (CCDs) is a fascinating journey that spans over 30 years of research and takes us on a global adventure. Historically, CCDs are a confounding factor that can lead to false-positive blood test results in up to 30% of patients allergic to plants or insect venoms.[1] However, recent research has shed new light on the relevance of CCDs in the field of carbohydrate epitopes in allergy: remnant CCDs on solid-phase *in vitro* diagnostic technologies and their impact on accurate allergy diagnosis.

CCDs – a brief history

Let's start at the beginning, about 30 years ago, when a group of scientists in the Netherlands made a remarkable discovery in the study of allergies. They observed that some patient sera reacted to an array of allergen extracts, including pollen, food, and insect venoms. To investigate this phenomenon, the scientists incubated the extracts with periodate, a reagent used to break down terminal sugar residues in carbohydrates. Their findings revealed a significant reduction in reactivity, thus establishing, for the first time, a link between carbohydrate epitopes and allergy diagnostics.[2]

Since then, much has been discovered about CCDs, including the fact that a partial motif of certain glycosylations of some plant and insect allergens, a core α-1,3-fucose, is responsible for the observed cross-reactivity[3,4]. However, the clinical relevance of sensitization to CCDs has been a longstanding issue that still persists to some extent. Several studies, mostly based on functional assays such as basophil activation tests (BAT), have been performed to obtain an unambiguous answer.[5-9] After many years of careful observation, it is now generally accepted that immunoglobulin E (IgE) directed against CCDs cannot cause allergic symptoms. Yet, anti-CCD IgE plays a relevant role in allergy diagnostics.

CCDs in modern allergy *in vitro* diagnostics

Blood tests in allergy diagnostics measure the presence of IgE directed against allergens. If a clinically non-relevant, cross-reactive IgE epitope is present on the surface of an allergen, a false-positive result can complicate the diagnosis in patients with matching IgE. In the worst case, incorrect diagnoses are made, and the wrong therapy is initiated.

To address this problem, physicians have several options, including in vivo allergy testing (with the risk of inducing a severe systemic reaction in patients), the use of cellular assays (such as the labor-intensive BAT), component-resolved diagnostics (CRD), or the inhibition of anti-CCD IgE with artificial CCD inhibitors. However, each of these options comes with its specific set of caveats, such as the increased risk of systemic re-

actions, sampling issues, or cost-efficiency.

Over the past two decades, the use of molecular allergen components (i.e., CRD) has become more established as a means of choice in allergy diagnostics. Recombinant, CCD-free components that are not affected by the anti-CCD IgE in patient sera can be produced using artificial expression systems. CRD not only solved the CCD issue but also enabled physicians to assess the risk and severity of a potential allergic response.

All's well that ends well? Well, according to a 2009 study conducted by French physicians and scientists, the answer is no. The study compared solid-phase and liquid-phase allergy diagnostic systems in patients with peanut and pollen allergies and found that the solid-phase system produced twice as many false-positive results as the liquid-phase technology. This was also reflected in the significantly higher specificity of the liquid-phase system. The authors were also able to link the false-positive results on the solid-phase platform to CCD sensitization in individual patients.[10]

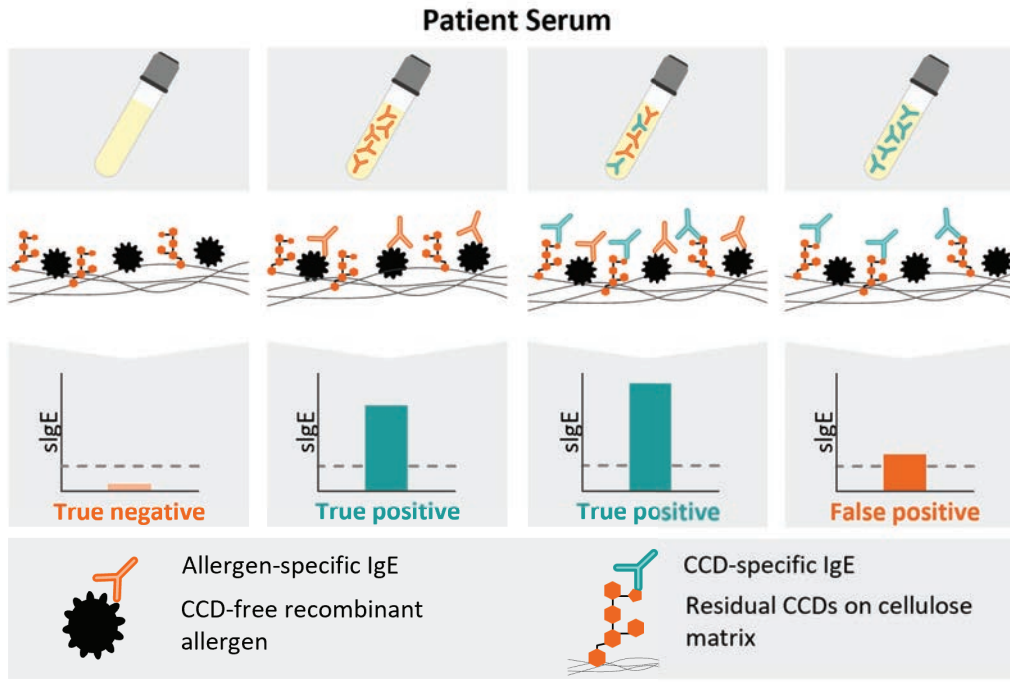

Figure 1. Impact of CCD residues on solid-phase in vitro technologies for allergy diagnosis.

However, it was not until 2018 that Austrian scientists identified the cause of diverging results in solid- and liquid-phase technologies. The solid-phase system, most frequently used in allergy diagnostics, is based on a cellulose matrix that can have remnant proteins with CCDs on its surface, introducing this confounding factor into the underlying assay design. The authors tested different allergy patient groups on a solid-phase system that was utilizing a cellulose matrix before and after incubating patient sera with CCD inhibitors. This study confirmed that CCD sensitized patients are more prone to be diagnosed with artificially elevated IgE titers or even false-positive results on solid-phase systems even if tested with an "empty" (i.e., allergen free) test or recombinant, CCD-free components **(Figure 1)**.[11]

With more than 100 million people affected by allergies in the United States alone,[12,13] a reliable diagnostic tool is crucial. Statistically speaking, 25 million allergic patients in the United States are sensitized to CCDs and therefore at risk of being impacted by the diagnostic pitfalls of cellulose-based, solid-phase technologies.

The million-dollar question is, do liquid-phase systems provide a viable alternative? Researchers from the United States tackled this challenge head-on in 2020 with the assistance of Johns Hopkins University. The study compared the impact of CCD inhibition on IgE results generated on solid-phase and two liquid-phase platforms. The results showed that liquid-phase technologies are less susceptible to CCD interference, with minimal reductions in IgE titers post-CCD inhibition. In contrast, the solid-phase system experienced a significant impact, providing additional evidence of remnant CCDs on the cellulose matrix.[14] The liquid-phase systems utilized in this study are based on CCD-free microparticles and beads, making them less susceptible to anti-CCD IgE.

With more than 100 million people affected by allergies in the United States alone, a reliable diagnostic tool is crucial.

Conclusion

In conclusion, the story of CCDs is a tale of scientific discovery and technological advancement that spans over three decades. While CCDs were initially identified as a confounding factor in allergy diagnostics, recent research has revealed the importance of re-addressing this issue to ensure accurate diagnoses and appropriate treatments for patients. The development of CRD has revolutionized allergy diagnostics, allowing for the production of CCD-free allergen components that do not interfere with anti-CCD IgE in patient sera. However, the solid-phase IVD technologies often used in allergy diagnostics have introduced new challenges, with remnant CCDs on cellulose matrices leading to elevated or even false-positive results in patients sensitized to CCDs. The evidence suggests that liquid-phase technologies offer a viable alternative, with CCD-free microparticles and beads proving to be less susceptible to anti-CCD IgE interference.

With millions of people affected by allergies worldwide, the accurate diagnosis of allergic sensitization is essential to ensure the appropriate management of symptoms and to prevent potentially life-threatening reactions. The ongoing research into CCDs and their impact on allergy diagnostics highlights the importance of continuing scientific inquiry and technological innovation to improve patient outcomes in allergy management.

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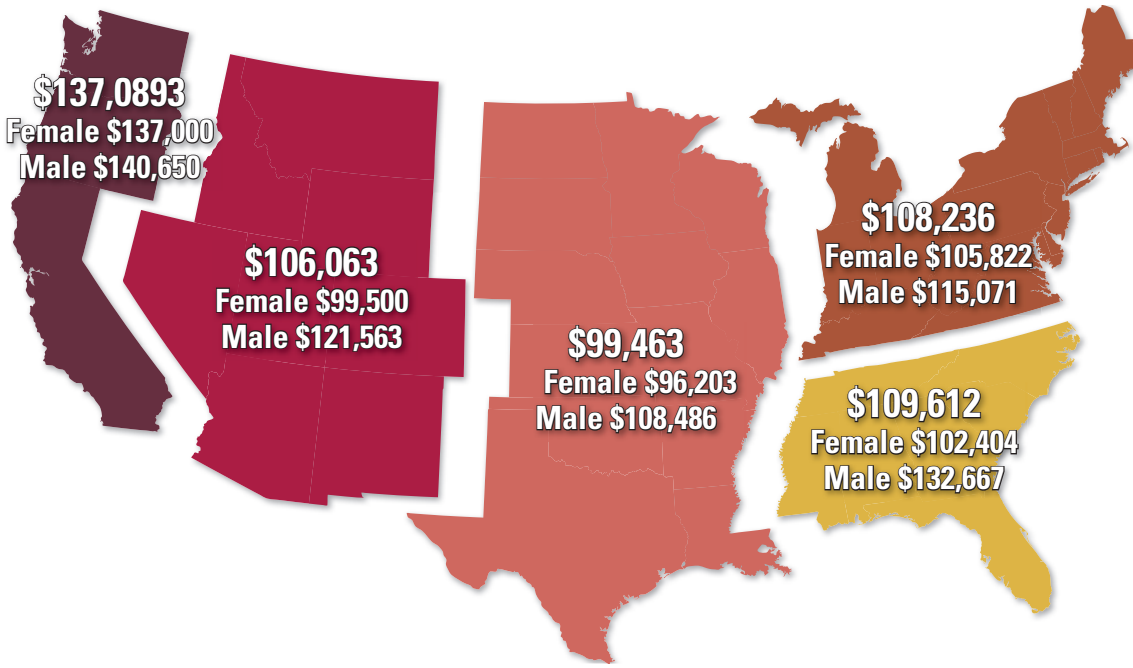
Dr. Friedrich Altmann is a biochemist with an extensive track record in the field of glycobiology and glycoimmunology. With more than 400 peer-reviewed publications, he is one of the leading experts on clinically relevant glycosylations. He holds a full professorship at the University of Natural Resources and Life Sciences, Vienna.



MLO's 2023 salary survey of laboratory professionals

By Christina Wichmann

The results of *Medical Laboratory Observer's* 2023 annual salary survey of laboratory professionals indicated that the average salary has increased, most are satisfied with their jobs, and job security remains high; however, 83 percent of respondents noted that staffing shortages have had a "moderate to large impact" on operational efficiency.

Of the 436 survey respondents, the majority were female (72.9 percent), 24.5 percent were male, and 2.5 percent preferred not to answer. Most respondents were 46–65 years old. The vast majority of respondents (97 percent) work in hospital laboratories in management positions. And most, 53 percent, work an 8 hour day, while 19 percent work 10 hours, and 14 percent work 9 hours. We will make comparisons between the 2023 and 2022 surveys, but the sample sizes are very different as almost twice as many responded to this year's survey over last year's.

Average salary increases

The average compensation of a laboratory professional rose by $14,792 from the 2022 to 2023 surveys: $92,146 in 2022 to $106,938 in 2023. This year, the average salary of female respondents is $102,970, and the average salary of male respondents is $118,028. Certain laboratory positions experienced a significant increase in average salary, while others experienced a moderate increase or stayed fairly the same. The positions that showed the highest average increases were as follows:

- Chief/assistant chief medical technologist increased to $105,200 in 2023 from $75,833 in 2022.
- Compliance/QA coordinator/manager increased to $103,087 in 2023 from $94,667 in 2022.
- Hospital administrator increased to $160,000 in 2023 from $125,500 in 2022.

AVERAGE ANNUAL BASE SALARY: $106,943

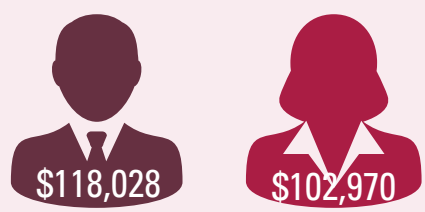
DID YOUR SALARY CHANGE IN 2022?

76.4% Yes, it increased
21.6% It remained the same
2.1% No, it decreased

PERCENTAGE INCREASE EXPECTED OVER LAST YEAR

2.87%

AVERAGE PAY BY GENDER



MALE FEMALE

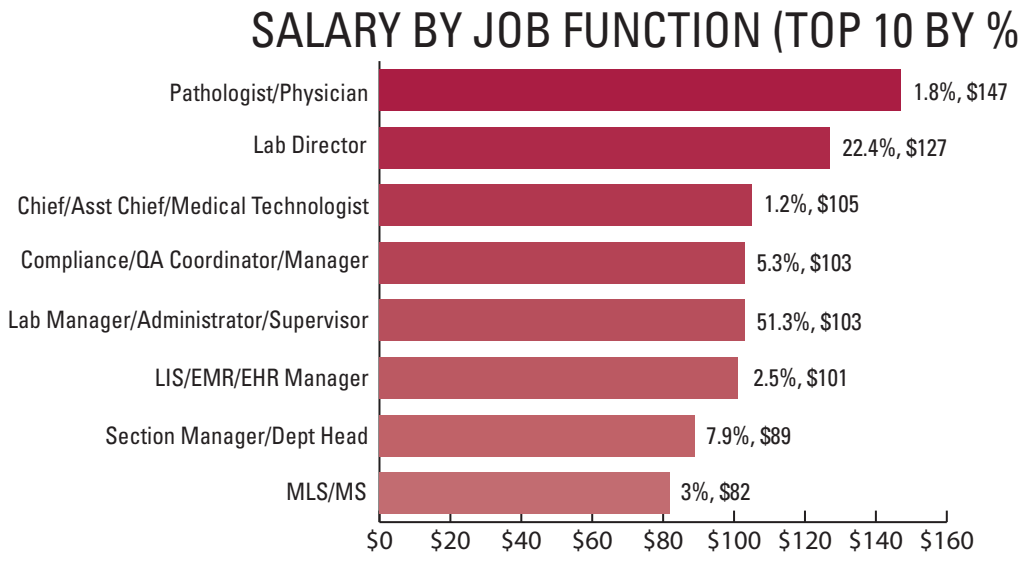
DID YOU RECIEVE A BONUS IN 2022?

38.5% Yes
61.5% No

GENDER OF RESPONDANTS

72% Female
24.5% Male

2.5% of survey respondents chose not to disclose their gender



- Laboratory manager/administrator/supervisor increased to $102,953 in 2023 from $96,246 in 2022.
- LIS/EMR/EHR manager increased to $100,545 in 2023 from $88,083 in 2022.
- MLS/MS increased to $82,269 in 2023 from $63,559 in 2022.
- Medical laboratory technician increased to $69,167 in 2023 from $63,389 in 2022.

Annual volume of tests	2023 average salary	2022 average salary
More than 2,000,000 tests	$121,753	$109,709
1,000,001 to 2,000,000 tests	$108,005	$87,798
500,0001 to 1,000,000 tests	$107,506	$92,404
100,001 to 500,000 tests	$99,651	$94,173
50,001 to 100,000 tests	$89,650	$80,115
25,001 to 50,000 tests	$86,944	$80,292
Less than 25,000 tests	$105,778	$96,500

- POCC/POCT coordinator increased to $116,500 in 2023 from $79,000 in 2022.

Positions that experienced a moderate increase from 2022 to 2023 include lab director — $123,500 in 2022 to $126,531 in 2023 and section manager/department head — $83,735 in 2022 to $88,647 in 2023; and clinical laboratory scientist — $69,500 in 2022 to $71,250 in 2023. Position salaries that stayed fairly the same were pathologist/physician ($147,313) and microbiologist ($70,357).

The three regions with the highest average salaries were the Pacific ($137,893), Southeast ($109,612), and Northeast ($108,236).

Lab size and testing volume

Respondents were spread pretty evenly across lab sizes, and their salaries reflect the size of lab they work in, i.e., lab professionals working in larger labs continue to earn higher salaries. Among those who work in laboratories with more than 100 employees, the average salary is $122,103. The average salary for those working in labs with 51–100 employees is $114,328; 21–50 employees is $102,439; 11–20 employees is $96,174; and 1–10 employees is $85,113.

Annual volume of tests does not exactly follow the same trend as lab size and salary, though significant increases are seen from last year to this year.

Employer benefits

The 2023 benefits for laboratory professionals are similar to the 2022 salary survey benefits. Nearly all respondents receive health insurance, dental insurance, vision insurance, and a 401(k) or pension plan. A significant proportion of respondents receive life insurance (88 percent), paid time off (86 percent), and disability insurance (76 percent).

Benefits that decreased from 2022 to 2023 are overtime pay (33 percent in 2023; 45 percent in 2022), bonuses (28 percent in 2023; 33 percent in 2022), and paid COVID leave (20 percent in 2023; 31 percent in 2022). The least common benefits in 2023 are flextime (13 percent) and child care (6 percent).

Challenges and opportunities

Since the pandemic, staffing shortages have been one of the primary topics in the healthcare field. In 2023, most respondents indicated that the current shortages have had a moderate to large impact on their operational efficiency. This year, 46.1 percent indicated moderate impact and 37.2 percent indicated large impact. The degree of impact has gone down from last year when the numbers indicated 43.2 percent large impact and 40.3 percent moderate impact.

The percentages have remained relatively stable on laboratories outsourcing tests due to staffing shortages: 73.9 percent indicated "no" in 2023 and 26.1 percent "yes." In 2022, it was 71.6 percent "no" and 28.4 percent "yes."

The biggest changes in today's clinical laboratory are automation, artificial intelligence, and digital pathology. These technological changes are making lab operations more efficient and effective. However, the number of laboratories automating new procedures this past year has decreased but laboratorians' awareness of these changes in their lab has increased.

Did your lab automate or further automate new procedures in?		
	2022	2021
Yes	41.5%	50.2%
No	56%	41.2%
Do not know	2.5%	8.6%

Degrees, certifications, and continuing education

The majority of lab professionals hold bachelor's or post-graduate degrees, at 57 percent and 38 percent respectively. Those with associate degrees are at 5 percent. As expected, one's salary is connected to their education. The average salary of a lab professional with a post-graduate degree is $121,277, bachelor's degree is $100,374, and associate degree is $72,167.

Most respondents hold a medical laboratory scientist (MLS) or medical laboratory technician (MLT) certification from the American Society for Clinical Pathology (ASCP) Board of Certification (BOC), followed by certification through a state or the American Medical Technologists.

As for continuing education, 33.5 percent of respondents earned between 11–20 hours of continuing education credits in 2023, and 18.6 percent earned over 20 hours of continuing education credits. Those earning 10 or less hours spread from varying percentages of 1 percent to 9 percent.

When asked how satisfied they are with their lab's education and training programs, 52.5 percent indicated somewhat satisfied, 22.9 percent indicated somewhat dissatisfied, 17 percent indicated very satisfied, and 7.6 percent indicated very dissatisfied.

Job security, satisfaction, and tenure

Lab professionals feel a little less secure with their job positions this year with 56.9 percent indicating very secure (60.5 percent in 2022) and 37.6 percent indicating somewhat secure (35 percent in 2022). Job satisfaction rates are similar this year to last year. In 2023, 53.2 percent are somewhat satisfied (50.2 percent in 2022), 30.3 percent are very satisfied (32.1 percent in 2022), 13.5 percent are somewhat dissatisfied (13.2 percent in 2022), and 3 percent are very dissatisfied (4.5 percent in 2022).

There is significant longevity in the lab professions: 53.2 percent of respondents have been in the lab industry over 30 years, 14.9 percent 25–30 years, and 10.6 percent 20–24 years. Respondents were pretty evenly spread for their years at their current employers; however, 20.2 percent of respondents have been with their current employer over 30 years!

Years at current employer	Percentage of respondents
Less than 3	8.9%
3–5	12.6%
6–9	10.8%
10–14	12.2%
15–19	15.8%
20–24	11.5%
25–30	8%
Over 30	20.2%

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Sample to Insight

Preventing cross contamination in an infectious disease testing laboratory

By Rajasri Chandra, MS, MBA

In the context of an infectious disease testing laboratory, cross contamination can be defined as an accidental introduction of an extraneous material into the specimen or laboratory instruments. A few examples of such extraneous material are infectious agents such as bacteria, viruses, or a specimen of another patient.

Though limited data exists on the incidence of cross contamination in clinical laboratories, cross contamination does occur and consequently the affected laboratory witnesses an increase in false positive results. There have been a few reports of increased false positive results due to cross contamination. A report was presented at the European Congress of Clinical Microbiology & Infectious Diseases (ECCMID) in Lisbon, Portugal during August 2022 about an incidence of cross-contamination of COVID-19 samples in a PCR lab in Belgium resulting in a high rate of false positive results. The cross-contamination occurred due to the lab personnel's failure to change gloves.[1]

In a meta-analysis of data from 31 studies that evaluated 29,839 tuberculosis (TB) cultures, the researchers found that 2% (95% confidence intervals [CI] 1–2%) of all positive TB cultures are false positives caused due to laboratory cross-contamination. Moreover, 9.2% (91/990) of all patients with a preliminary diagnosis of TB had false-positive results and received unnecessary and potentially harmful treatments.[2]

In 2006, the Centers for Disease Control and Prevention (CDC) reported an incidence of cross-contamination of clinical specimens with Bacillus anthracis in two Idaho hospital laboratories that were conducting proficiency tests. It triggered brief concern about a potential anthrax attack.[3] Thus, cross contamination can have several damaging consequences. It may not only damage the reputation of the laboratory but also badly affect the laboratory operation. Laboratory testing is suspended until the laboratory is totally decontaminated leading to delay in sending out results. Samples that were being processed are to be re-tested after the laboratory is back up and running. Hence, following good laboratory practices and taking measures to prevent cross contamination is the best path to take. Some of the measures to prevent cross-contamination episodes are as below.

Proper laboratory design

To minimize chances of errors, mix-ups, and contamination, laboratories should be designed such that the flow of the sample processing is unidirectional. The area where samples are received and accessioned should be separate from the area of reagent preparation and sample processing and analysis. Reagent preparation should be carried out in the clean room.

Clinical laboratories performing molecular testing especially the highly sensitive PCR-based assays, should take extreme care in facility design and operation to avoid sample-to-sample contamination from carry-over of nucleic acid from previous amplification of the same or similar target.

Figure 1 illustrates how the flow of materials, staff, and waste should be organized to separate processes and minimize incidence of errors and cross contamination.[4] It is recommended that each area have its own dedicated storage facilities so as to avoid mixing up test items and/or reagents. And each designated area should have separate labware, lab coats, gloves, equipment (e.g., pipettes, laminar flow hood, refrigerators etc.). The clean reagent preparation room should have positive air pressure to keep contaminants out whereas the room where PCR is carried out should be under negative air pressure to keep amplicon contaminants in.

Following good laboratory practice of aseptic technique by laboratory professionals

It is the responsibility of all laboratory professionals to follow good laboratory practices such as ensuring that the correct workflow is followed and they are trained to take necessary precautions to follow aseptic technique and minimize contamination and cross-contamination. When performing microbiological or molecular analysis, it is necessary to follow standard aseptic technique. This requires that all materials are sterilized and care is taken not to introduce new microorganisms from the environment into cultures.

Aseptic procedures are as follows:

- Not eating, drinking, or smoking in the laboratory.
- Wearing a disposable lab coat (that should not be taken out of the lab). If it gets contaminated with biologicals, it must be disposed of properly as a regulated medical waste.
- Washing hands before and after handling microorganisms.
- Wearing disposable gloves and safety goggles when handling cultures.
- Using disinfectants to clean the bench top before and after use.
- Washing hands with soap and water upon removing gloves and disposing of them properly.

Procedures for proper handling of bacteria stocks, cultures, and media are as follows:

- Preparing the work area by cleaning the bench top with disinfectants.
- Sterilizing the loop or needle before and after transferring bacteria.
- Only partially lifting the plate cover to prevent the introduction of foreign bacteria from the air.
- Flaming the tops of tubes before and after the transfer of microorganisms.
- In case of culture spillage, the area should be flooded with disinfectant immediately.
- Cultures should not be taken out of the laboratory.

A major source of PCR contamination in a molecular testing laboratory is aerosolized PCR products, which being small, travel and easily spread all over benches and equipment. The aerosolized PCR product then finds its way into a PCR reaction and becomes amplified. Laboratory professionals should use aerosol-free/aerosol filter pipette tips when working with PCR assays to prevent aerosol formation.

If laboratories performing PCR/real-time PCR testing discard all amplified products without opening the reaction tubes or using sealed plates can minimize the chance of contamination.[5] Also, aseptic cleaning before and after PCR work of all work surfaces — bench tops, pipettors, and all touch points are necessary to prevent cross contamination.

Following good laboratory practice handling patient samples

The utmost care must be taken when handling patient samples. The person

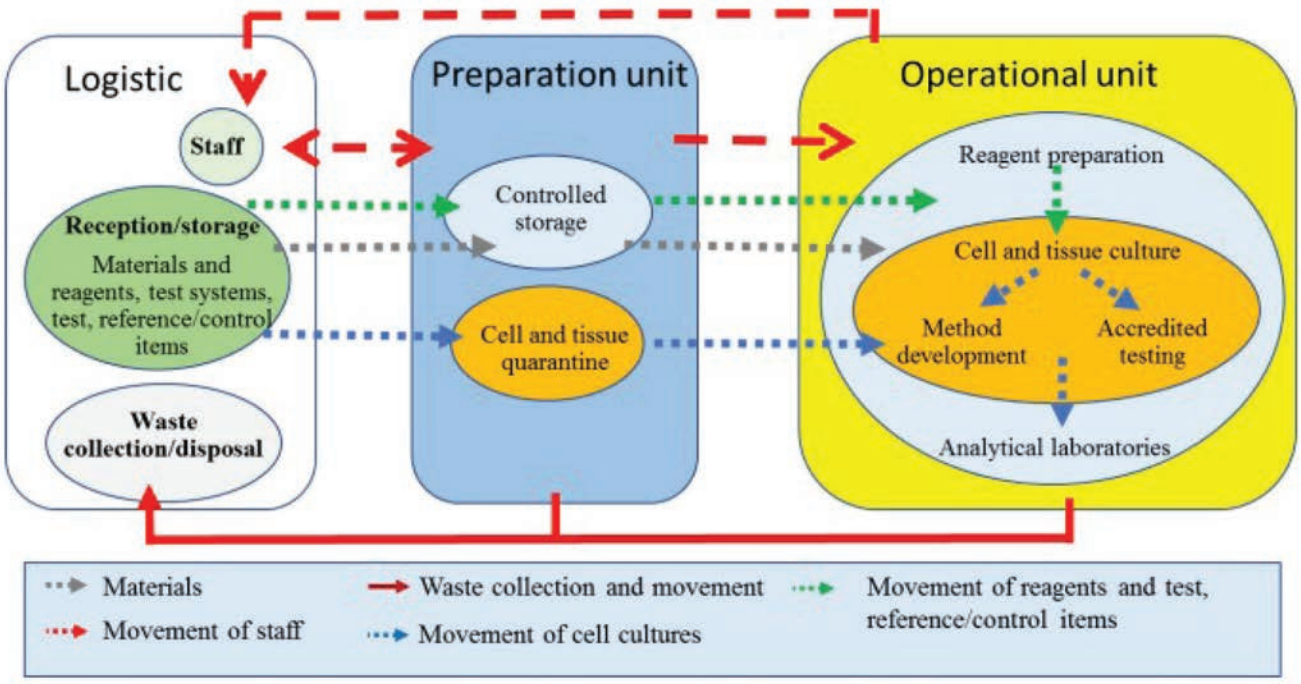

Figure 1.

drawing the sample should wear clean gloves, a mask, and head cover. Samples should be collected using sterilized or clean sampling tools in sterile or clean tightly sealed, leak-proof containers. The sample should be labeled appropriately using two identifiers. The sample should be maintained in the recommended environment until it is analyzed.

For sample analysis, samples should be kept and accessioned in the designated dirty room. Care should be taken to prevent aerosol formation. If sample extraction needs to be carried out prior to analysis, as is the case with samples for molecular testing, it should be performed in a separate area. The addition of the sample in the reagent mix should be done aseptically in the laminar flow hood.

Care should be taken to avoid splashing of samples during liquid dispending with pipettes. Open and close all sample tubes and reaction plates carefully to avoid splashing of samples. Briefly spin the tubes/plates before opening to prevent aerosols when opening them.

It is necessary to change gloves from time to time and especially if the gloves get dirty with the specimen or reagent splash. One should not leave the room wearing gloves.

Routine cleaning and disinfecting laboratory

In addition to cleaning and disinfecting the work area before and after every operation with disinfectants such as 10–15% bleach followed by 70% ethanol or turning on the UV lamp of the laminar flow unit for 30 minutes followed by 70% ethanol, a standard procedure must be in place to sterilize the laboratory routinely. There are various disinfection and sterilization options the laboratory can select that will be best suited for its operation.

Following stringent quality control

Laboratory staff should be well trained and follow standard operating procedures, and the laboratory should follow strict quality control procedures. Rate of positive and negative results should be monitored and if a high positive result is observed for a particular analyte, it must be investigated if any cross-contamination has occurred. There needs to be a routine for swipe tests to ensure no environmental contamination has occurred. In the swipe test, a sterile swab dipped in sterile saline is wiped on potentially contaminated surfaces of a laboratory (e.g., benches, pipettes, handles of fridge/freezer, centrifuges, etc.) and then analyzed like a specimen. If the swipe test shows a positive result, it indicates environmental contamination.

Conclusion

As the clinical laboratory working with clinical specimens is prone to contamination, every laboratory professional working in the laboratory should take utmost care in following measures to prevent incidences of cross-contamination. If an episode of cross-contamination occurs, it leads to wasted time, increased costs, and damage to reputation. Hence, it is better to be safe than sorry.

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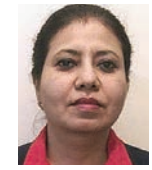

Rajasri Chandra, MS, MBA, is a global marketing leader with expertise in managing upstream, downstream, strategic, tactical, traditional, and digital marketing in biotech, in vitro diagnostics, life sciences, and pharmaceutical industries. Raj is an orchestrator of go-to-market strategies driving complete product life cycle from ideation to commercialization.

New care settings and innovation will usher diagnostic testing into the future

By Brooke Story

The 1918 influenza pandemic went down in history as a plight of epic proportions, taking the lives of an estimated 675,000 people in the United States alone, according to the Centers of Disease Control and Prevention (CDC).[1] And so, it is sobering to realize that deaths from COVID-19 in the United States surpassed 1.1 million in January 2023.[2] With new variants and subvariants constantly emerging, the hopes for near-term eradication of the disease have diminished. Yet even as some organizations and governments are ready to classify COVID-19 as endemic, it will be with us for the foreseeable future.

In 2019, just like in 1918, people were unprepared for the devasting impact that would lay ahead. There were no definitive diagnostics, treatments, or vaccines. Today, thankfully, we have vaccines, testing, tracking, tracing, and treatments available for both the flu and COVID-19, but the processes of tracking and treating — and therefore, of potentially saving lives — begins with testing.

Diagnosing respiratory viruses

Prior to the COVID-19 pandemic, if a person developed a cough, our initial thought was, "Is it a cold or is it the flu?" In children, we may also ask "Is it RSV?" since nearly all children before the age of two are diagnosed with the disease.[3] When COVID-19 hit and lockdowns were put in place, our risk for becoming infected with any of these viruses was limited. However, as we lifted restrictions and returned to a state of normalcy, flu, RSV, and COVID-19 received an open invitation to spread. While fears of a "tripledemic" this respiratory season have largely diminished, testing remains a critical tool that healthcare providers rely on to ensure accurate diagnosis and treatment for their patients.

In fact, about 70% of all medical decisions are based on diagnostic test results.[4] To aid medical professionals in diagnostic testing, there are now combination tests available that work by testing a single sample from a patient for multiple respiratory diseases, such as COVID-19 and seasonal flu, which can show similar symptoms. A recently developed combination test can detect COVID-19, the flu, and/or RSV from one nasal sample. The test was recently authorized for emergency use by the U.S. Food and Drug Administration (FDA) for testing by authorized laboratories.[5]

At-home diagnosis

With the delivery model of healthcare having been reinvented over the past few years and accelerated because of the COVID-19 pandemic, there have been major opportunities for the industry to improve access to healthcare, improve patient outcomes, and reduce costs all around. Today, tests for flu or COVID-19 can be conducted at local pharmacies and individual's homes. Soon, a wide range of diagnostics will be available for use in these new care settings, as will easier and less invasive ways of doing so. These advanced technologies increase accessibility and allow patients to take more control of their health by helping them prevent, monitor, and manage disease — not just react to health emergencies.

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In addition to at-home care, new technologies are enabling digitally integrated diagnostics. Making care even more accessible to patients, the electronic transmission of results to patients and providers will enable earlier intervention in the progression of disease. Data analytics from at-home tests will be another area of transformation. Researchers will have better tools and data sets to pioneer breakthroughs, including diagnostics, devices, and other technologies.

At-home tests are a profound transformation that will increase access to testing and allow patients to take more control of their health. To this end, we envision a future where more testing solutions will be made available in new care settings, as well as at-home tests to monitor and help manage chronic disease conditions. At-home testing and self-sampling is not just convenient, it also provides greater access to diagnosis of potentially deadly diseases, like cervical cancer. Some countries in Europe and many other parts of the world offer self-sampling for cervical cancer screening with a Pap or HPV test, giving women the ability to collect their own sample for lab-testing in privacy, at the time and place of their choosing.

Conclusion

We are entering a world where every lab test, doctor's visit, injection, procedure, and implant will be supported by advances in artificial intelligence, machine learning, and connectivity. Digital tools will equip providers to make better-informed decisions, faster — enhancing care for patients. This means earlier diagnosis, easier medication management, and more proactive care interventions.

Smart, connected care in new care settings to diagnose and manage disease is not only the future of healthcare, it is already here.

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Brooke Story is worldwide president, Integrated Diagnostic Solutions for **BD**. BD recently received FDA Emergency Use Authorization for the BD Respiratory Viral Panel assay for BD MAX System. Development of this combination test has been funded in whole or in part with federal funds from the Department of Health and Human Services; Office of the Administration for Strategic Preparedness and Response; Biomedical Advanced Research and Development Authority.

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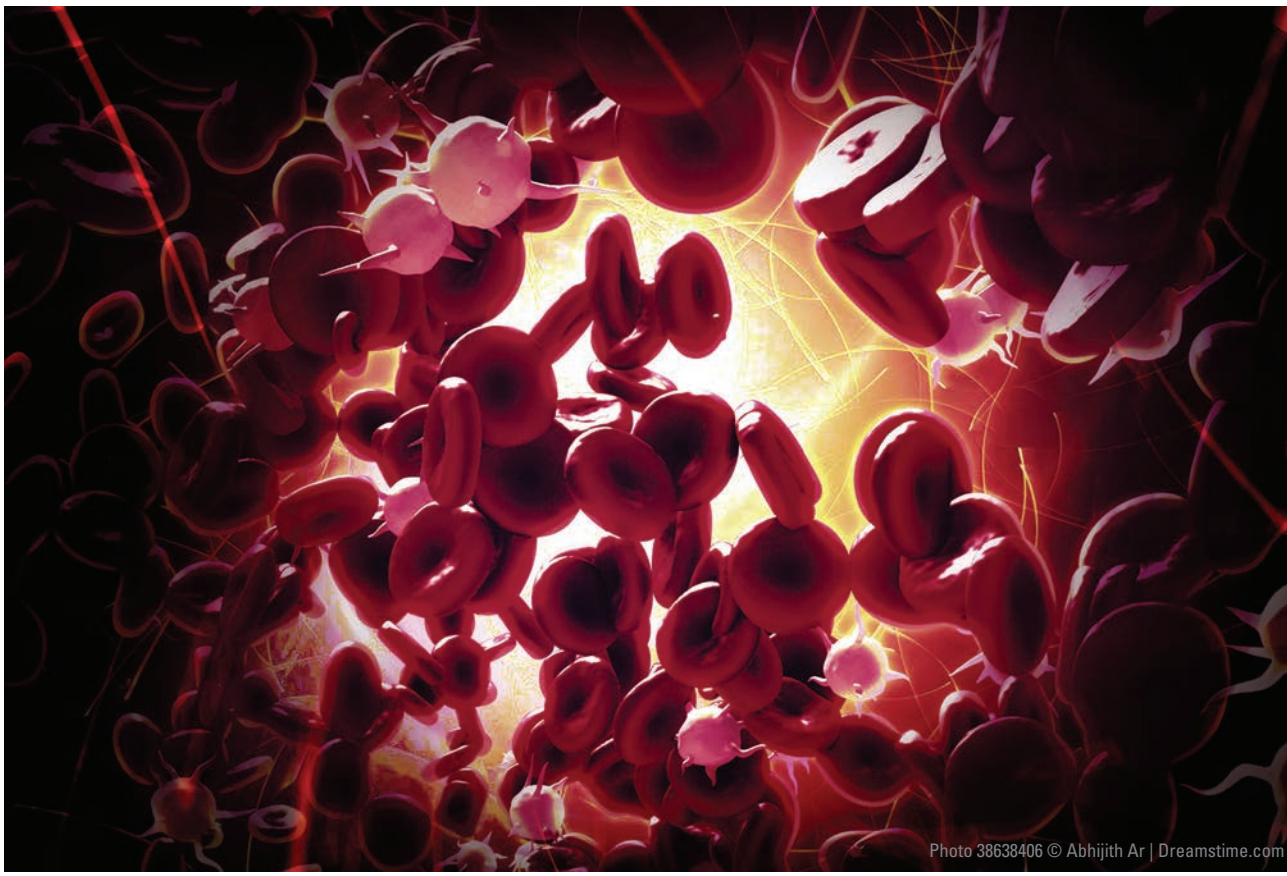

Novel and classical insights into Lp(a) concentration and the effects on various cardiovascular conditions

By Jason Armstrong

Despite advances in understanding and technology, cardiovascular diseases (CVDs) remain a major source of mortality across the world. The World Health Organization (WHO) estimates that 17.9 million people died due to CVDs in 2019, accounting for around 32% of deaths that year.[1] First described in 1963, lipoprotein(a) [Lp(a)] is a macromolecular lipoprotein complex[2] that is thought to display proatherogenic, proinflammatory,[3] and prothrombotic[4] potential and is considered an independent causal risk factor for various types of CVD.[5] These properties provide several mechanisms in which elevated Lp(a) levels may contribute to CVD, however, the true nature of the Lp(a) relationship to CVD remains largely enigmatic.

Lp(a) concentrations in plasma are principally regulated by variation in *LPA* gene and levels remain relatively stable throughout one's lifetime with lifestyle factors having little effect on their concentration.[6] Due to the highly heritable nature of Lp(a) concentration, those with a family history of familial hypercholesterolaemia (FH), elevated Lp(a) levels, or atherosclerotic cardiovascular disease (ASCVD) should be screened, their plasma Lp(a) concentration determined, and their risk of CVD established.

Lp(a) concentrations in plasma are principally regulated by variation in *LPA* gene and levels remain relatively stable throughout one's lifetime with lifestyle factors having little effect on their concentration.

In the last ten years, there have been many advances in the understanding of this ambiguous lipoprotein, which support the causal association with CVD, clarify the established evidence, and introduce novel mechanisms of action in relation to Lp(a), shedding light on its obscure pathophysiology. However, there are still diagnostic complications associated with Lp(a) measurement as there is little standardization in methods of determination.[5]

Physiology and genetics

Synthesised mainly in the liver, Lp(a), like LDL, is composed of a lipid centre made of cholesteryl esters and triacylglycerols,

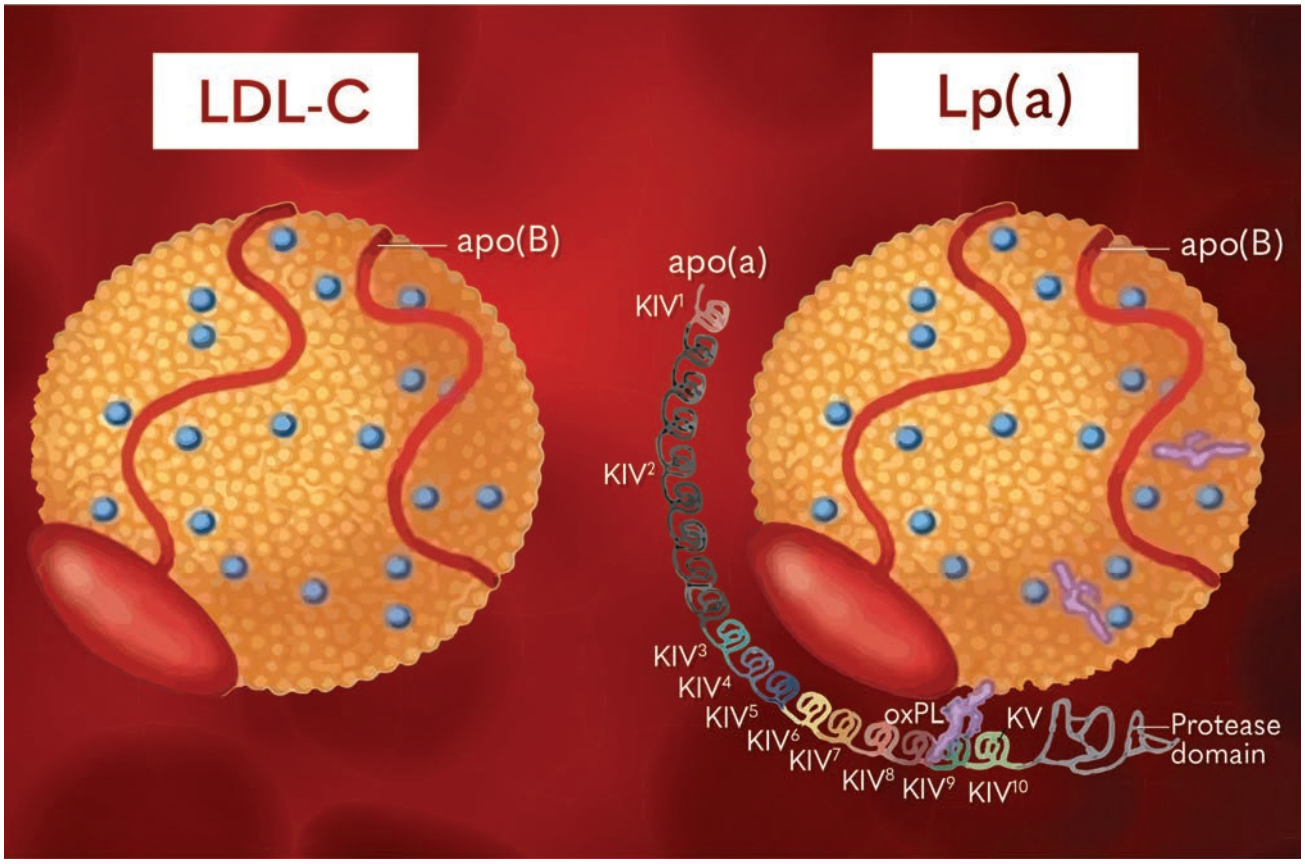

Figure 1.

surrounded by a shell of phospholipids, free cholesterol, and an apoB-100 molecule. The major difference between other LDL molecules and Lp(a) is the presence of a polymorphic glycoprotein, apo(a), bound to apoB-100 by a single disulphide bond.[5] It is this apo(a) molecule that contributes to Lp(a)s pathophysiology.

Apo(a) is thought to have evolved from the plasminogen gene (PLG) around 40 million years ago and shares 78–100% sequence homology within the untranslated and coding regions of the fibrinolytic enzyme.[2] Like plasminogen, apo(a) contains unique domains named kringles.[5] While plasminogen contains five different kringle structures (KI to KV), apo(a) has lost KI to KIII and instead contains several forms of KIV, namely, one copy of KIV-1, one copy of KIV3-10, 1–40 copies of KIV-2, one copy of KV, and an inactive protein domain at the carboxyl terminus of the molecule.[7] These hydrophilic subunits are highly polymorphic due to the variation in KIV-2 repeats. Individuals may possess two different isoforms of apo(a) — one of which will have been passed down from each parent, which are expressed codominantly.[2] These isoforms are dependent on the number of KIV-2 repeats they contain.[2] Isoforms with less KIV-2 repeats produce smaller apo(a) isoforms, which are found at a higher concentration compared with larger isoforms[8] due to the increased rate at which the smaller molecules can be synthesised.[5] The polymorphisms in KIV-2 repeats account for up to 70% of the variation seen in concentration between individuals, with the remainder being attributed to differences in protein folding, transport, and single nucleotide polymorphisms (SNPs).[5] SNPs are central in the heterogeneity of apo(a), effecting RNA splicing, nonsense mutations, and 5′ untranslated region of the *LPA* gene resulting in shorter gene translation.[5,8]

Pathophysiology

Lp(a) is thought to contribute to the risk of CVD through multiple mechanisms. Firstly, Lp(a) molecules display all the same atherosclerotic risk as LDL-C molecules due to their similar fundamental composition; for example, their propensity for oxidization upon entering the vessel wall and promotion of atherosclerosis through inflammatory and immunogenic mechanisms.[9] **(See Figure 1.)** However, Lp(a) displays more proatherogenic potential due to the presence of the apo(a) molecule. The structure of apo(a) results in decreased fibrinolysis. Due to its structural similarities, apo(a) competes with plasminogen for binding sites, competitively inhibiting plasminogen, ultimately resulting in reduced fibrinolysis.[9]

Lp(a) is thought to be a preferential carrier of oxidized phospholipids2 (OxPLs), which covalently bind to apo(a), increase expression of inflammatory proteins, and stimulate the secretion of IL-8 and monocyte chemoattractant protein-1, enhancing its ability to cross the vessel wall.[9] Some claims require further investigation, however, studies have been carried out that show inhibition of plasminogen activation in the presence of Lp(a).[10] It is this indirect mechanism that Lp(a) is thought to conduct its prothrombotic activity.[8,9]

Clinical evidence

Many studies have been carried out to determine the association of Lp(a) concentration and CVD risk. Studies such as the Copenhagen General Population Study, the Copenhagen City Heart Study, Dallas Heart Study, and Ischemic Heart Disease Studies provide strong evidence for Lp(a) as a causal risk factor for CVD. Data analysis of the Copenhagen General Population Study reveal that 20% of subjects displayed Lp(a)

There are various assays available for the determination of Lp(a) concentration, which vary in accuracy and precision.

concentrations of more than 42mg/dl, or around 105nmol/L,11 which is considered to result in increased risk of atherosclerotic disease.[5] It is important to note, there is no accepted conversion factor for converting Lp(a) concentration from mg/dl to nmol/L due to the variability of apo(a) kringles. The unitage will depend on the assay method used.[5] Another study in a healthcare organization in Israel showed that myocardial infarction (MI) and coronary artery disease were 2.5 times more common in those with high levels of Lp(a) than in the age and sex matched control group.[3] This study,[3] along with others,[5,6,12] describe a linear relationship between Lp(a) concentration and CVD risk, showing at least a three-fold increase in ASCVD and MI events in adults with Lp(a) concentrations in the top 1% when compared with those with concentrations in the bottom 20%.[3]

The major variation in Lp(a) concentration seen throughout the population is further evident between ethnicities and sexes. On average, Caucasian subjects display the lowest Lp(a) concentrations, with Black subjects displaying the highest concentrations.[5] However, the large number of functional variants are consistent across ethnicities suggesting that it is the KIV-2 repeats and SNPs that are the major factors contributing to Lp(a) concentration regardless of ethnicity. Lp(a) concentrations are higher in women than men[8] with levels increasing post-menopause thought to be caused by a decrease in oestrogen.[3]

Testing and screening

The European Atherosclerosis Society (EAS) recommend that all adults are tested at least once in their lifetime to identify individuals who have high levels of Lp(a) and therefore high CVD risk. Screening is also recommended in children who have a family history of ischaemic stroke, premature ASCVD, or high Lp(a) levels in the absence of other identifiable risk factors.[8] Testing has been associated with reduced mortality rates. This is thought to be because of increased and intensified therapy for those who are identified as high risk due to high plasma Lp(a) concentration.[6]

There are various assays available for the determination of Lp(a) concentration, which vary in accuracy and precision. Many of these assays utilize polyclonal antibodies which recognize different antigenic determinants.[8] Due to the variability in apo(a) structure and KIV repeats, these assays often overestimate the concentration of large isoforms and underestimate concentration of small isoforms when determining the true Lp(a) levels.[9] This variation can be partially nullified by using a calibrator series and by selecting a method that is traceable to WHO and International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) reference materials. This allows laboratories to confidently identify individuals considered high risk but may still prove problematic when patients' results report closer to the assay thresholds.

One study[13] compared five commercially available Lp(a) assays on an automated clinical chemistry analyzer. The assays tested were manufactured by Diazyme, Kamiya, MedTest, Roche, and Randox. The authors show that all the assays tested met the manufacturers' claims for sensitivity, linearity, and precision. However, significant bias was observed in 4 out of 5 assays. The only assay that did not display significant bias was the Randox Lp(a) Assay, which is traceable to WHO/IFCC reference material. This report highlights the importance of measuring and reporting Lp(a) in molar concentration rather than in mass units to facilitate standardization and harmonization in Lp(a) testing.[13]

Current and emerging therapies

Statins are one of the most potent treatments for the primary prevention of ASCVD through the reduction of LDL-C concentration. However, recent studies reveal that statins have no effect on Lp(a) concentration[3] and others suggest that statin administration can increase Lp(a) concentration by up to 11%.[5,9] Nonetheless, the EAS does not recommend statin therapy be halted as their strong ameliorative effects on CVD risk are well established and surmount the risk related to increased Lp(a) concentration.[8]

Niacin (nicotinic acid) is another established treatment for the reduction of CVD events and acts by increasing HDL levels. Niacin can reduce Lp(a) concentration though the reduction of gene expression in a dose-dependent manner.[5] However, niacin therapy has not been proven to have beneficial effects on CVD risk.[8]

A recent metanalysis showed a 26% reduction in serum Lp(a) concentration through treatment with PCSK9 inhibitors. This is thought to be due to a shortage of apoB-100 molecules either because of reduced synthesis or competitive binding with other LDL receptors, resulting in reduced Lp(a) concentration.[5] Several studies show the efficacy of PCSK9 inhibitors in reducing CVD risk, but this is not yet an approved therapy.[5,8]

New therapeutic strategies aim to target hepatocytes, the site of apo(a) synthesis, to reduce Lp(a) concentration. Antisense oligonucleotides (ASOs) inhibit apo(a) mRNA in the nucleus and cytoplasm, ultimately inhibiting Lp(a) secretion5 through the cleavage of the sense strand by ribonuclease H1.[9] While still in clinical trials, ASO therapies show promise in the battle to reduce CVD risk with some studies displaying an overall reduction in Lp(a) concentration of more than 80%.[9]

Conclusion

There have been major advances in the understanding of Lp(a) pathophysiology in the last ten years establishing this macromolecular complex as an independent causal risk factor for various forms of CVD, however, more investigation is required to fully understand the mechanisms responsible for this association. With many national healthcare organizations and the EAS recommending universal testing for Lp(a) in adults, more emphasis should be placed on raising awareness of the importance of Lp(a) screening. Finally, more research is needed into therapies that succeed at lowering Lp(a) concentration. While some therapies are in clinical trials, there are currently no approved therapies that achieve this goal.

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Recent MDx advances make congenital CMV testing more feasible

By Michelle Tabb, PhD

Human cytomegalovirus (CMV) could practically be a tale of two pathogens. Among healthy adults, CMV infections are quite common and largely asymptomatic. Indeed, by age 40, at least half of all people in the United States will have had a CMV infection; most will never even know it happened.[1] But in developing babies or newborns, CMV is no harmless visitor. Congenital CMV has been associated with pregnancy loss, and babies born with congenital CMV are at significantly increased risk of hearing loss and neurodevelopmental issues.

With early antiviral treatment, these babies have much better outcomes. Unfortunately, current CMV testing models do not typically enable such quick intervention. To distinguish between congenital CMV — cases passed from mother to fetus through the placenta — and the less dangerous CMV infections that occur after birth, testing must be performed in the first few weeks of life. But CMV is rarely included in newborn screening tests, and symptoms of congenital CMV can be so difficult to spot that diagnostic testing is seldom ordered in this short window.

Recent advances in rapid molecular testing have made it easier to perform CMV testing in newborns, generating results quickly enough to allow for intervention as soon as possible. In addition, efforts to raise awareness about the importance of congenital CMV testing have begun to pay off with the consideration of new universal screening policies.

The health risk

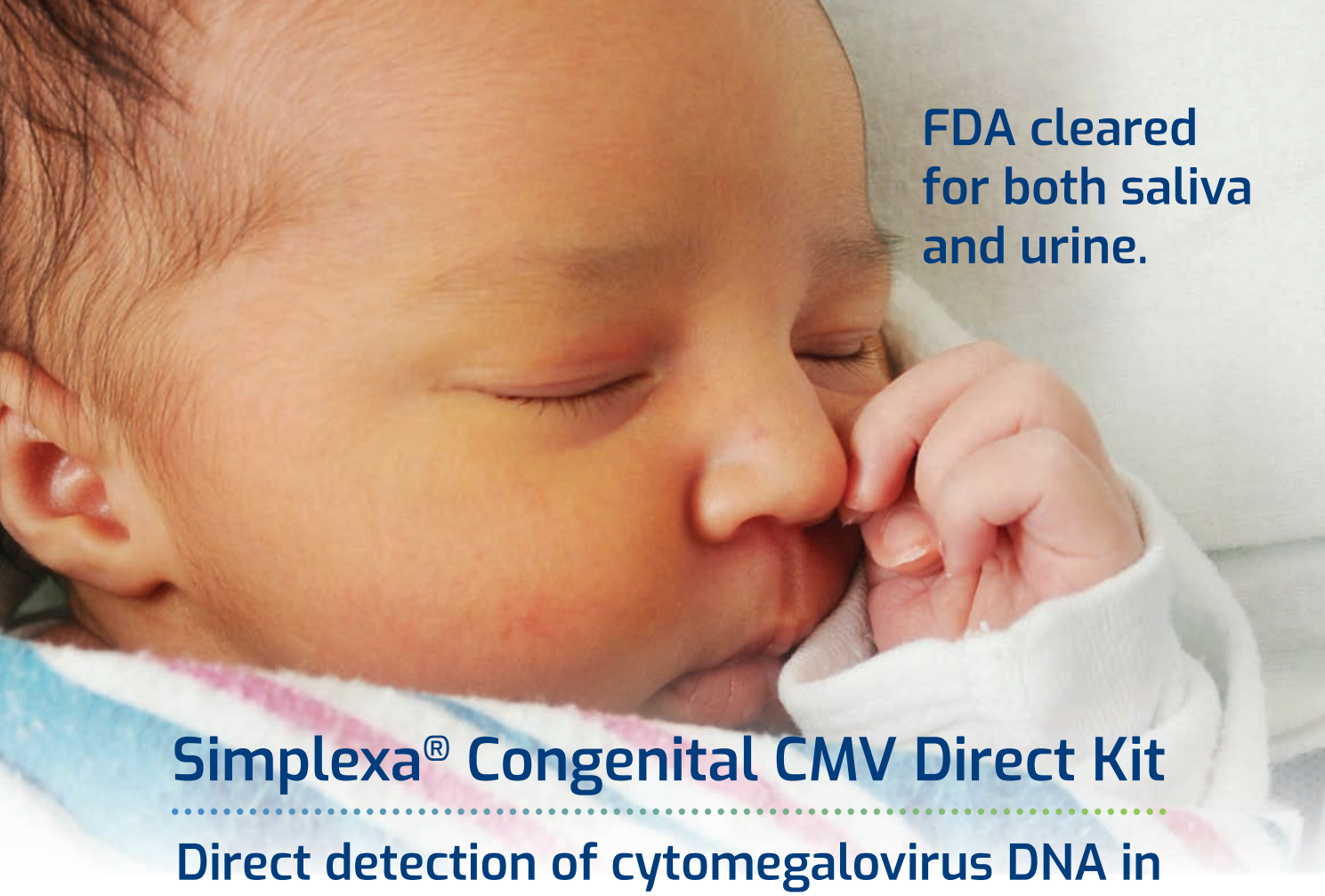
Like Zika and other viruses that can wreak havoc in a developing fetus, congenital CMV can lead to severe symptoms that manifest in the months and years after birth. The vast majority of babies born with CMV — about 90% — have no signs of infection and appear completely healthy. But this is deceiving: babies born with CMV are at risk of developing symptoms later and can even die from complications of the infection.

Common (and typically lifelong) symptoms for babies who survive the infection include hearing loss, developmental delays, and neurodevelopmental abnormalities such as seizures or microcephaly. Indeed, congenital CMV is the most common nongenetic cause of hearing loss in infants. In the United States, about 1 in every 200 babies born each year — a total of 30,000 babies — is believed to have congenital CMV. Just 1% of those babies are diagnosed with CMV based on clinical signs and symptoms.

There is hope for these babies, but only with early intervention. Antiviral treatments such as ganciclovir or valganciclovir may mitigate some symptoms and give healthier outcomes to these infants.[2,3] But these treatments are most effective when administered in the first months of life. That, of course, is only possible when congenital CMV cases are caught early enough to allow it.

Universal screening

CMV infections must be detected in the first three weeks of life to diagnose possible congenital CMV infection. In some states, CMV testing is recommended for infants who fail their newborn hearing screening. While this makes sense on paper, it does not hold up in real-world practice. Newborn hearing screening can be unreliable, with a sizable number of false positives and false negatives. Even when accurate, the screen does not detect cases of CMV-infected babies whose hearing loss may not be present at birth and instead occurs later in life due to the infection. The recommendation for CMV testing based on hearing screening results often occurs after mothers and babies have been released from the hospital, letting too many of these families slip through the cracks due to a lack of follow-up. A special consideration



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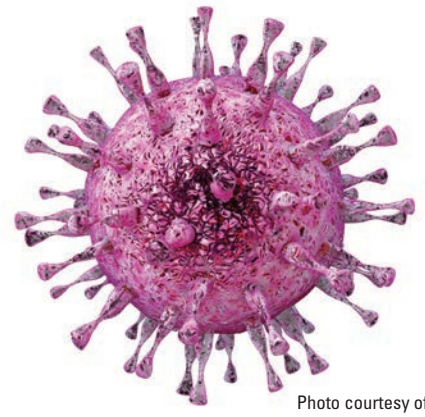
is premature babies who may be hospitalized for many weeks after birth but may not receive a newborn hearing screen until they are well past the 21-day window in which CMV testing could differentiate a congenitally acquired infection.

A far more effective approach would be to include CMV testing as part of each state's universal newborn screening programs. By testing all babies shortly after birth, the clinical laboratory community would have a chance to identify and confirm every case of congenital CMV and guide physicians to the appropriate treatment in a clinically relevant time frame. In addition, universal screening would finally permit a more comprehensive view of the incidence of congenital CMV — numbers that have until now been based on estimates and inference.



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Human cytomegalovirus (CMV)

Recently, there has been some progress on this front. Minnesota just became the first state to implement universal CMV screening for all newborns, adding it to the more than 60 other conditions for which the state recommends testing at birth. In 2019, the National CMV Foundation nominated CMV for inclusion in the Recommended Uniform Screening Panel, the list of conditions and disorders recommended by the Department of Health and Human Services for newborn screening in all states.

Universal CMV screening is beginning to gain traction outside the United States too. A recent study from researchers in Italy evaluated the benefit of universal screening for congenital CMV infections by testing all newborns at three clinical sites. The study, which covered more than 3,000 babies, identified 21 CMV infections.[4] Recognizable clinical symptoms of congenital CMV were only noted in three cases. The authors pointed out that without universal screening, the rest of the infected babies would likely not have been diagnosed until long past the ideal time frame for early intervention.

Molecular testing

Because of the pressure to diagnose congenital CMV cases as quickly as possible, traditional tests such as viral cultures have never been a good fit for this clinical need. Any assay that takes weeks to return results or lacks sensitivity is incompatible with the stringent requirements for newborn CMV testing.

Molecular diagnostic tests offer a more promising approach, but not every specimen type has delivered the sensitivity required for a screening test. Although dried blood spots (DBS) would be an ideal sample type since blood is already collected on Guthrie cards from every newborn in the United States, study results have shown that DBS-based tests can lack sensitivity.[5] Importantly, positive DBS PCR confirms congenital CMV but a negative result does not rule it out.[6] However, robust and sensitive PCR-based assays can be run on either saliva swabs or urine samples, making them flexible enough for newborns and compatible with the sample types recommended by the Centers for Disease Control and Prevention and many expert-developed guidelines for congenital CMV diagnosis. In addition, molecular tests typically produce reliable results more quickly than their conventional counterparts, delivering answers in a matter of hours and enabling recommended confirmatory urine testing following a positive saliva swab test.

Not all molecular tests are equally easy to deploy, though. For clinical laboratory teams looking to implement congenital CMV testing for the first time, the most straightforward approach might come from a commercial sample-to-answer system. Such systems are highly automated, running all steps — from sample preparation and processing to data generation — without user intervention. Technicians load the sample and reagents into a cartridge or consumable device, place it in the instrument, and press a button to start the run.

There are several sample-to-answer systems on the market, and they typically share a number of critical features. They minimize the need for extensive staff training because they are designed to be very user-friendly. They usually take up little bench space and are built in compact footprints for notoriously space-limited laboratories. They produce results quickly, potentially in just an hour or two, and support a broad menu of tests because most platforms can be used with a variety of test-specific cartridges or consumables. Sample-to-answer systems are usually sold by commercial diagnostic developers, and their test consumables are often cleared by the U.S. Food & Drug Administration for use as *in vitro* diagnostics.[7] With all of these traits, easy-to-install automated systems can be an effective option for congenital CMV testing at hospitals where babies are born.

Universal screening will be more technically feasible as more testing options become available for easy, rapid, and cost-effective congenital CMV diagnosis. With new studies demonstrating its benefit across populations, policymakers may follow suit. Clinical lab teams may find it useful to start planning now for increased demand for congenital CMV testing.

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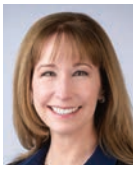

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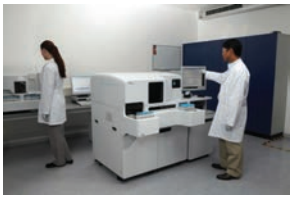

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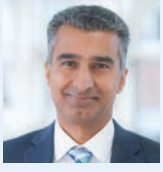

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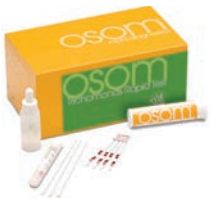

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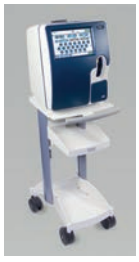

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Observations on leadership

By Christina Wichmann

Tony F. Freeman, BS, HT(ASCP) is a Laboratory Specialist with the Accreditation Commission for Health Care (ACHC). Tony is an ASCP-certified Histologic Technician and has decades of laboratory compliance, safety, and managerial experience operating high-complexity U.S. Air Force and private-sector pathology laboratory organizations. He holds educational degrees in Healthcare Management, Histotechnology, and Logistical Management. Tony received his formal Histopathology education and training in 1997 at the former Armed Forces Institute of Pathology's (AFIP) Tri-Service School of Histotechnology located in Washington, D.C., where he earned Distinguished Graduate Honors.

Retired Master Sergeant Freeman ended his military career as the Non-Commissioned Officer in Charge of the Anatomic Pathology Department at Wright-Patterson AFB Medical Center, Ohio, and ended active-duty service in October 2008 after 26 years in the U.S. Air Force. He retired from service with numerous military decorations and awards including the Meritorious Service Medal and the Air Force Commendation Medal (two Oak Leaf Clusters).

Are there particular 'lessons learned' you can share from your experience conducting accreditation surveys in different types of laboratories?

In my experience, all laboratories share one common goal: To provide the best patient specimen testing within their scope of services. This scope of service may range from a major multi-specialty hospital laboratory to a single-specialty Mohs surgery office laboratory. Because ACHC laboratory accreditation covers all levels of testing complexity and all clinical settings from point-of-care waived tests performed in a physician's office to high-complexity testing in independent or hospital-based laboratories, I've been afforded the opportunity to see a wide range of settings as an ACHC Surveyor. My greatest lesson learned from the experience of conducting accreditation surveys is that the best laboratories have a strong leadership presence that fosters excellence in teamwork. Knowledgeable and dedicated laboratory leaders bring the vision and guidance that are key to achieving the laboratory's goals. Their leadership strengths filter down to the laboratory team members to support and enhance team collaboration. It is always a privilege for ACHC to be invited to partner with these laboratories on their compliance journey.

What do you enjoy most about being a Laboratory Specialist with ACHC?

I enjoy being a part of an organization that is dedicated to delivering the best laboratory accreditation experience through a partnership philosophy. ACHC's education-first approach helps maximize a laboratory's ability to deliver healthcare excellence. Our accreditation standards align directly with CLIA requirements, which ensures regulatory compliance. We add more by being a team of dedicated subject matter experts with decades of laboratory experience. It is an incredible gift to be instrumental in supporting a laboratory's commitment to continuous quality improvement for the patients it serves.

In our recent salary survey, the majority of MLO readers shared that the current shortfall of medical personnel has had a moderate-to-large impact on their lab's operations. How has ACHC seen laboratories addressing shortages of staff?

The current shortfall of laboratorians is definitely a topic of concern and conversation in the laboratories I have surveyed. Laboratory leadership is feeling this shortfall in large and small systems across the country with small-town rural hospital laboratories being especially vulnerable. In these settings, the absence of even two laboratory team members can have a major impact on the lab's operation. That said, I have seen these resilient smaller laboratories address staffing in some very innovative ways, for example, the recruitment of highly qualified and skilled medical laboratory technicians from other countries and the consolidation or outsourcing of some laboratory services and processes. Overall, the consensus in the field is that there is no quick solution to this medical personnel shortage and each laboratory will need forward-thinking leadership to address its specific needs.

What do you see the future laboratory looking like?

The current laboratory staffing issues coupled with emerging testing innovations will drive the future laboratory environment. I envision laboratories of the future increasing the use of automation, molecular diagnostic platforms, and digital pathology. The future is challenging to forecast, but I am confident that laboratories will continue to advance and evolve, and our industry will look very different in the next ten years.

Do you have a particular past lab survey that stands out in your mind?

More than one stands out! What those that come to mind first have in common is active involvement of the entire leadership team from the CEO to the assistant laboratory manager. I've witnessed evidence of this engagement through interaction by each team member beginning with the survey's opening conference and continuing to our exit conference. To the surveyor, this demonstrates a solid commitment to the laboratory as a whole as well as to the accreditation process. These surveys tend to go very well and conclude with an unequivocal accreditation decision because of the leadership's direct involvement with the laboratory professionals. Through this involvement, they understand the needs and are able to consistently provide the resources for the laboratory to achieve its goals as a whole and for each individual team member to grow their own skills and knowledge.

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[1] Brown, H. *Improving the Diagnosis of Vulvovaginitis.* Population Health Management. Vol. 23, suppl 1, 2020

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