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Laboratory developed tests part 2

By Christina Wichmann

Christina Wichmann
Editor in Chief

On October 3, 2023, the Food and Drug Administration (FDA) published its anticipated proposed rule to regulate laboratory developed tests (LDTs) as medical devices.[1] The proposed rule changes the definition of *in vitro* diagnostic products (IVDs) at 21 CFR 809.3(a) with the underlined text below.

In vitro diagnostic products are those reagents, instruments, and systems intended for use in the diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae. Such products are intended for use in the collection, preparation, and examination of specimens taken from the human body. These products are devices as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act (the act), and may also be biological products subject to section 351 of the Public Health Service Act, <u>including when the manufacturer of these products is a laboratory.</u>

The FDA is proposing "to gradually phase out its current general enforcement discretion approach so that most IVDs offered as LDTs would generally fall under the same enforcement approach as other IVDs." The new enforcement policy, as proposed, would be implemented in five phases summarized as follows:

1. End the FDA's general enforcement discretion related to medical device reporting (MDR) requirements and correction and removal reporting requirements. FDA would make this change one year after it publishes a final phaseout policy, which it intends to issue in the preamble of the final rule.
2. Begin enforcing registration and listing requirements, labeling requirements, and investigational use (IDE) requirements two years after the final phaseout policy is published.
3. End the general enforcement discretion approach with respect to quality system (QS) requirements (with a complementary approach with CLIA's QS requirements for LDTs manufactured within a single CLIA-certified laboratory and not distributed outside that laboratory) three years after the FDA publishes a final phaseout policy.
4. Submission of premarket approval (PMA) applications for high-risk IVDs (i.e., class III devices) 3.5 years after final phaseout policy is published, but no earlier than October 1, 2027.
5. End the general enforcement discretion approach with respect to premarket review requirements for moderate-risk and low-risk IVDs (that require premarket submissions) four years after final phaseout policy is published, but not before April 1, 2028.

Comments on this proposed rule must be submitted by December 4. For anyone interested in reading comments submitted electronically, they can be viewed at https://www.regulations.gov/document/FDA-2023-N-2177-0001/comment.

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

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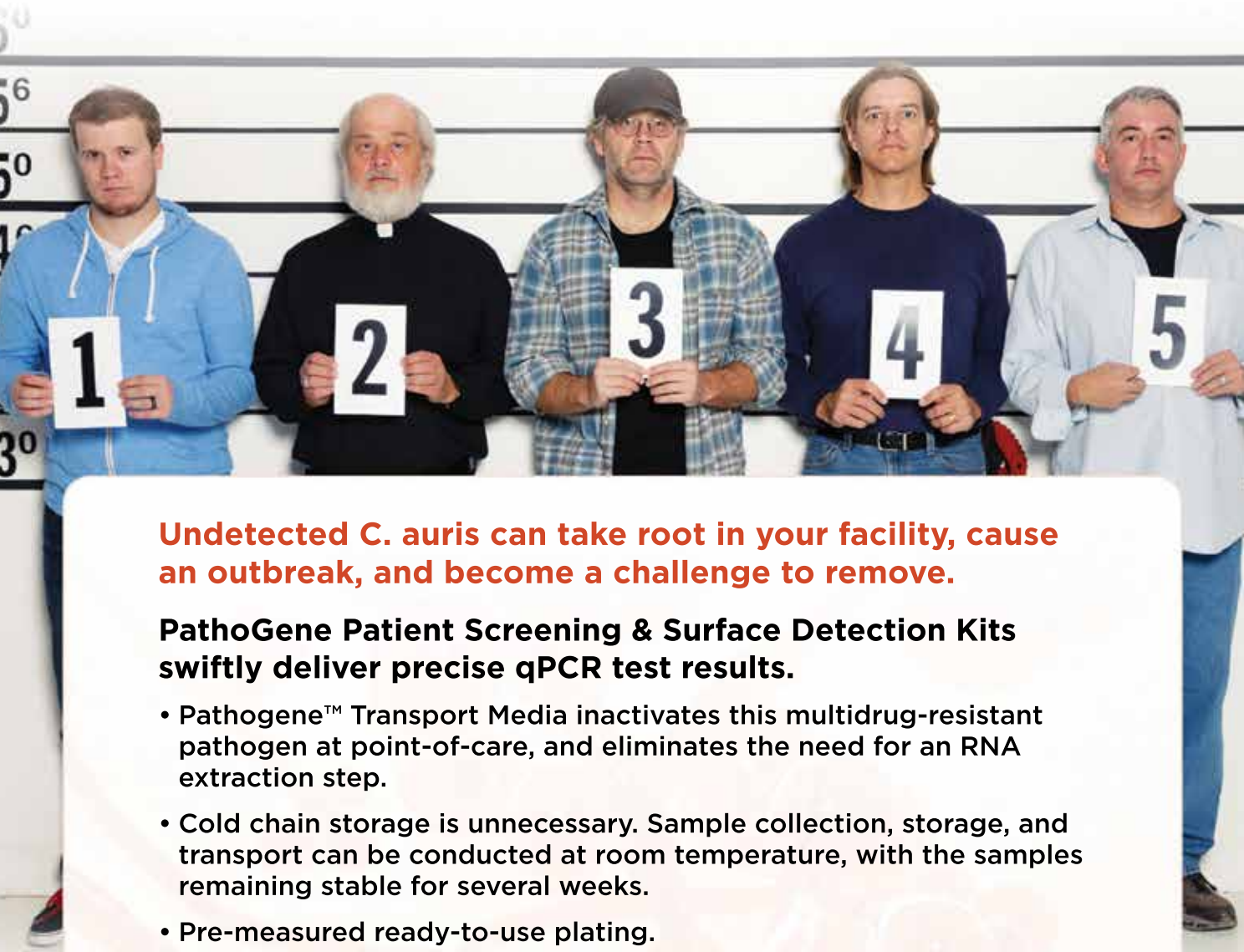

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Fast Facts

U.S. drug overdose deaths more than quadrupled from 1999 to 2020

Researchers from Florida Atlantic University's Schmidt College of Medicine and collaborators explored trends in drug overdose deaths in the U.S. from 1999 to 2020, based on age, gender, race, urbanization and geography. Results of their original research, published in *The American Journal of Medicine*, show that drug overdose deaths in the U.S. more than quadrupled from 1999 to 2020, regardless of race, age, geography or urbanization.

Their findings:

1,013,852

deaths caused by drug overdoses from 1999 to 2020.

4.4

times increase of drug overdose deaths from 1999-2020.

6.9

deaths per 100,000 population in 1999.

13.4

deaths per 100,000 population in 2010.

30

deaths per 100,000 population in 2020.

Source: https://www.fau.edu/newsdesk/articles/drug-overdose-deaths

FDA proposes rule aimed at helping to ensure safety and effectiveness of laboratory developed tests

The U.S. Food and Drug Administration announced a proposed rule regarding laboratory developed tests, or LDTs, which play an important role in healthcare. The rule is aimed at helping to ensure the safety and effectiveness of these tests, which are used in a growing number of healthcare decisions and for which concerns have been raised for many years.

The proposed rule seeks to amend the FDA's regulations to make explicit that vitro diagnostic products (IVDs) are devices under the Federal Food, Drug, and Cosmetic Act, including when the manufacturer of the IVD is a laboratory. Along with this amendment, the FDA is proposing a policy under which the agency intends to provide greater oversight of LDTs, through a phaseout of its general enforcement discretion approach to LDTs.

Under the approach described in the notice of proposed rulemaking, the FDA would phase out its general enforcement discretion approach for most LDTs. The proposed phaseout is intended to better protect the public health by helping to assure the safety and effectiveness of IVDs offered as LDTs, while avoiding undue disruption to the testing market. After this phaseout, the FDA generally would expect IVD makers to meet the same applicable requirements, except where meeting certain requirements under the Clinical Laboratory Improvement Amendments can be leveraged.

The FDA believes this proposal would also advance responsible innovation by both laboratory and non-laboratory IVD manufacturers alike by better assuring the safety and effectiveness of IVDs offered as LDTs and removing a disincentive for non-laboratory manufacturers to develop novel tests. The current approach disincentivizes innovation by non-laboratory manufacturers who meet FDA requirements and who compete with laboratory manufacturers who do not meet FDA requirements. Rectifying the current imbalance in oversight may foster innovation by manufacturers who are positioned to make safe and effective novel tests available to many labs.

In this proposed rule, the FDA also discusses alternative enforcement approaches for some IVDs offered as LDTs. To the extent commenters support or oppose these alternative approaches, the FDA is requesting a public health rationale, supporting evidence and other information to help inform FDA's decision-making. Such different approaches include, among others: a different approach for academic medical center laboratories, the continuation of the current general enforcement discretion approach with respect to premarket review and quality system requirements for some or all currently marketed LDTs (i.e., what some previously referred to as "grandfathering"), a phaseout period tailored for small laboratories, and leveraging programs such as the New York State Department of Health Clinical Laboratory Evaluation Program or those within the Veterans Health Administration, as appropriate. Additionally, the FDA would facilitate increased use of the agency's Third Party Review program.

NIH clinical trial of universal flu vaccine candidate begins

Enrollment in a Phase 1 trial of a new investigational universal influenza vaccine candidate has begun at the National Institutes of Health's Clinical Center in Bethesda, Maryland. The trial is sponsored by the National Institute of Allergy and Infectious Diseases (NIAID), part of the NIH, and will evaluate the investigational vaccine for safety and its ability to elicit an immune response.

While the FluMos-v1 vaccine candidate displays HA from four strains of influenza virus, FluMos-v2 displays HA from six: four influenza A viruses and two influenza B viruses. The researchers anticipate that this will further broaden vaccine recipients' immunity, providing protection against a wider variety of influenza viruses.

The new clinical trial is expected to enroll 24 healthy volunteers, aged 18-50 years, who will receive two intramuscular injections of the FluMos-v2 vaccine candidate. These injections will be given 16 weeks apart. At first, participants will be enrolled in the lower dose group (60 mcg per vaccination). If no safety concerns are identified after at least three participants have received this dose, enrollment will begin in the higher dose (180 mcg per vaccination) group. The study team plans to enroll 12 participants into each dosage group.

For 40 weeks after their first vaccination, participants will receive regular follow-up phone calls and examinations to track their responses to the experimental vaccine. Blood samples will be taken during study visits to measure any immune responses to the vaccine candidate.

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CALL FOR ENTRIES

MLO's Lab of the Year Award celebrates medical laboratories that demonstrate their extraordinary commitment to quality patient care. Submissions will be judged on achievements in five areas. A panel of judges selected from MLO's Editorial Advisory Board will select the winner and two runners-up. All will be featured in the April 2024 issue of MLO, in print and online, and awarded a display wall plaque, with the winner featured on the issue cover.

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The absence of a safety culture; What contributes to laboratory incidents?

By Jason P. Nagy, PhD, MLS (ASCP)CM,QLS

There are different types of errors that occur in the clinical laboratory. Some are based around quality assurance, while others are related to safety. The goal when reducing each of these types of errors is to not only eliminate the potential harm to patients, but to the laboratory staff as well. Laboratory errors, mistakes, and accidents are interconnected (see Table 1), and one can be the cause of another. Laboratory accidents, for instance, are the result of staff errors or mistakes. To reach a goal of reducing laboratory accidents, you must first set out to reduce the occurrence of the errors and mistakes that lead to them.

Noun	Definition
Accident	An unforeseen and unplanned event or circumstance or **an unfortunate event resulting especially from carelessness or ignorance.**
Error	An act or condition of ignorant or imprudent deviation from a code of behavior or **an act that through ignorance, deficiency, or accident departs from or fails to achieve what should be done.**
Mistake	A wrong action or statement proceeding from faulty judgment, inadequate knowledge, or inattention.

Table 1: Definitions from Merriam-Webster online dictionary.

In order to accomplish this, applying a proactive approach to laboratory safety is important. Staff education, physical environment surveys, initial and annual training, and especially management oversight all contribute to a reduction of laboratory errors, mistakes, and accidents while helping to grow a culture of laboratory safety. All four of these aspects of laboratory safety

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LEARNING OBJECTIVES

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

1. Describe the correlation of laboratory accidents, errors, and mistakes.
2. Discuss the importance of standard operating procedures that emphasize laboratory safety.
3. Identify physical environment (PE) categories that should be considered in PE rounds.
4. Describe how to incorporate laboratory safety into training and list effective management oversight tools to review safety indicators and assess staff safety competency.

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require a commitment to safety from laboratory leaders as well as cooperation between those leaders and laboratory staff. To truly excel in the creation of and maintenance of a laboratory safety culture, equal and active participation of lab management and lab staff is required.[1]

> Some of the greatest barriers to maintaining a safe lab environment include a lack of training and availability of training material as references when needed.

Standard operating procedures

Standard operating procedures (SOPs) are written to ensure that proper steps are taken to perform a task correctly and safely. In addition to ensuring accuracy, SOPs also increase the precision around task and test performance. This not only reduces variability, but also lowers the inherent risk involved with the procedure.

Policies and procedures offer a good opportunity to emphasize lab safety precautions and the tools available to further lower the inherent risks involved with laboratory analysis. Therefore, when given the opportunity, it is essential to incorporate safety when drafting or revising your SOPs. When safety steps or tools are written into a procedure, the author should be as specific as possible. For example, the step "don essential personal protective equipment" is quite vague and could be interpreted in several ways. Rather, specific wording such as "don a face shield and cryogenic gloves" would be much less subjective when working with an extreme cold hazard such as liquid nitrogen. Reducing subjectivity within laboratory actions will reduce the potential for mistakes while concurrently strengthening your safety culture.

Where safety-related information is placed within a document could also have an effect in its interpretation. Listing required safety items in sections at the beginning or at the end of an SOP may seem intuitive, but it may have a greater impact if incorporated into the procedure as discreet actions. If a safety action is required to perform a task, the SOP should include a prior step instructing the user to retrieve or utilize the safety device before moving forward. This gives the user a chance to pause and perform the safety action prior to being exposed to a hazard or an unsafe act.

The frequency and process of reviewing your SOPs can also impact your safety culture. The College of American Pathologists (CAP) requires the laboratory director or designee to review all technical policies and procedures at least every two years. This is the minimum requisite, and additional revisions should be made when new equipment is introduced to the lab or when processes change that affect how lab staff perform their duties. The Occupational Safety and Health Administration (OSHA) has more stringent requirements when it comes to safety and recommends laboratories review SOPs related to certain safety regulations. For example, procedures related to hazardous chemicals must be reviewed annually to certify that they are accurate and current (29 CFR 1910.119(f)(3)).[2] Again, these are minimum requirements that should be reviewed further anytime the processes in the lab are altered.

Additionally, increasing the number of individuals who review the SOP can also offer a different perspective on the documents and creates the potential to catch errors and missing information. Laboratory managers, subject matter experts, and technical staff who utilize these procedures on a regular basis should all be included in the review process, and their input should be requested.

Physical environment rounding

Monitoring the laboratory's physical environment can preemptively resolve safety issues that might lead to accidents and errors, and the practice can help others develop good housekeeping awareness to reduce accidents. Hospital physical environment (PE) rounds, sometimes referred to as environment of care (EOC) rounds, should be conducted often to maintain a safe and functioning facility environment. However, the areas of the hospital or lab that require PE rounding, and the frequency of evaluations, are not always clearly defined. The determination may be dependent on the laboratory or hospital accrediting agency. For example, Centers for Medicare & Medicaid Services (CMS) regulations (42 CFR 482.41) state that "the overall hospital environment must be developed and maintained in such a manner that the safety and well-being of patients are assured," leaving the individual facility to determine the frequency of PE Rounds.[3] Other hospital accrediting agencies, like Det Norske Veritas (DNV) refer to the National Integrated Accreditation for Healthcare Organizations (NIAHO) standard PE.3 SR.5, which states that "the Safety Management System shall require periodic surveillance of the hospital grounds to observe and correct safety issues that may be identified."[4] Some accrediting agencies have different requirements for patient areas and non-patient areas. The Joint Commission (TJC) requires environmental rounding in patient areas that must occur every six months and annually in non-patient areas (TJC standards EC.04.01.01, EP 12 and EC.04.01.01, EP 13 respectfully).[5]

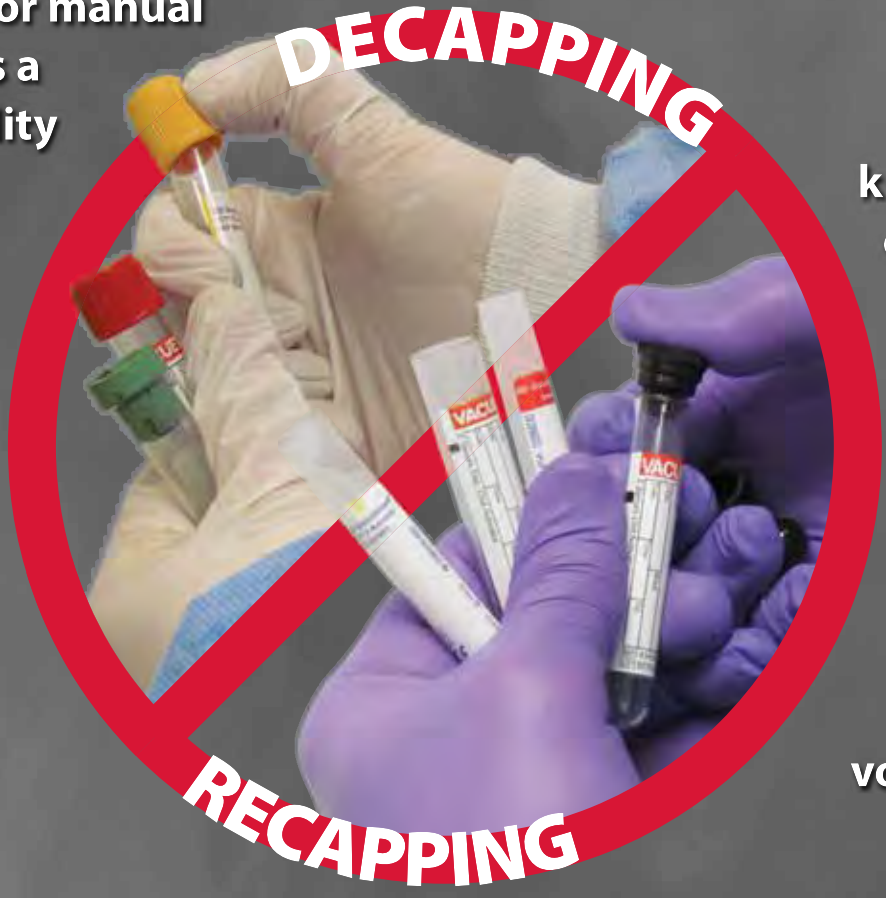
Physical environment monitoring checklists can be broken up into different categories and can include sections such as fire and electrical safety, life safety, hazardous waste, and infection prevention **(see Table 2)**. Additional sections can include staff knowledge and emergency management. Upon completion of rounding, the survey should be reviewed to evaluate potential

PE Rounding Section	Examples of Inspection Items
Fire and Electrical Safety	• Electrical cords are free of breaks or frays • Fire extinguishers are not obstructed and inspected monthly • Extension cords are prohibited
Life Safety	• Exit signs are clearly visible • Hallways and stairwells are free from obstructions • 18" of clearance between stored items and sprinkler heads
Hazardous Materials	• All flammable chemicals are properly stored • Spill kits are readily available • Personal protection equipment is available • Emergency eyewash and shower maintenance completed and documented
Infection Prevention	• Chairs are free from rips/tears • Alcohol-based hand sanitizers are not expired • Soap and hand sanitizer dispensers are filled and operational • Clean and soiled linens/supplies are separated

Table 2: PE rounding sections and checklist items.

SAFE SOLUTIONS

Even with minimal tube volumes, the potential for injury from manual decapping or manual recapping is a real possibility



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Discipline	Training frequency
OSHA Blood borne pathogen (1910.1030)	• At initial hire and annually thereafter.[10]
Portable fire extinguisher training 1910.157(g)(2)	• At initial hire and annually thereafter.[11]
Personal Protective Equipment	• Included in BBP training.
Formaldehyde[8]	• At time of initial assignment. • Whenever a new exposure to formaldehyde is introduced into the work area. • The training shall be repeated at least annually. 1910.1048(n)(3)(ii)(A)
Chemical hygiene Plan 1910.1450(f)(2)[12]	• At the time of an employee's initial assignment to a work area where hazardous chemicals are present and • Prior to assignments involving new exposure situations. • The frequency of refresher information and training shall be determined by the employer.

Table 3: Training requirements.

safety issues, and if found, resolved swiftly to eliminate any risk to employee safety.

Training

Inadequate training can result in undesired outcomes across all three phases of laboratory testing: pre-analytical, analytical, and post-analytical. New hire and initial training sessions are your first chances to introduce your learners to new material, so first impressions are very important. In addition, emphasizing safety from the beginning of employment can help build and strengthen your laboratory's safety culture. Ongoing training and monitoring are also critical and will be essential components of your education program as a means to reduce laboratory errors and accidents.[6] Some of the greatest barriers to maintaining a safe lab environment include a lack of training and availability of training material as references when needed.[7]

General new hire training can include topics such as bloodborne pathogens and chemical hygiene training, but safety learning does not stop there. When reviewing SOPs initially, it is important to concentrate on the safety equipment and processes associated with safety found in SOPs. For example, the OSHA Formaldehyde standard states that formaldehyde training should include topics such as dangers associated with working with the hazardous chemical, exposure limits and monitoring requirements, signs and symptoms of exposure, correct spill responses, how to use the required PPE, and what to do in emergency situations (OSHA Standard 1910.1048).[8] Users should be able to speak to similar points before being able to work independently with similar hazardous materials.

PPE training should not just include enforcement of use, it should cover the reasons why certain PPE is necessary in order to help educate the employee to best understand the need. According to the OSHA standard regarding PPE training, in addition to knowing which protective equipment to use, employees are required to know the reason PPE is required for a particular task, how to properly don and doff the PPE, and even to understand the maintenance and limitations of the equipment.[9]

As with SOPs, the frequency of staff training can be regulated by your accrediting agency **(see Table 3)**. Many different training modules and/or classes are required at initial hire and annually thereafter. These may include bloodborne pathogen training, fire and electrical training, and hazardous waste management.

In a research paper published by the National Bureau of Economic Research, it is established that maintaining a strong safety culture does not have a negative impact on the productivity of academic research labs. The impetus for the study was the "crackdown" on research lab safety after the accidental death of a California student in 2008, but the information in the study can be applied to clinical labs as well.[13] It is unfortunate that injuries and even death had to force better safety oversight and practices in these labs, but it is good to prove that prioritizing lab safety and providing adequate training is now known not to hamper the work done in the laboratory setting.

Indicator Type	Examples
Leading Indicators	• Performing safety audits • Performing PE rounds • Safety meeting attendance • Reported near-misses/ good-catches • Safety survey results
Lagging Indicators	• Safety audit scores • Percent completion of safety training — initial and continuing • Percent completion of PE rounds • Injury exposure rates • OSHA recordable rate

Table 4: Laboratory safety indicators.

Management oversight

The continuous monitoring of safety issues and the timely response to incidents is key to reducing accidents and errors. Lab management has the responsibility of ensuring a safe environment for staff and addressing safety concerns brought to their attention.

One method of monitoring lab safety is through evaluating safety indicators **(see Table 4)**. By utilizing safety indicators, laboratory leadership can assess the effectiveness of their safety culture and reduce any potential hazards. Managers can identify safety issues before an accident occurs through leading indicators while simultaneously evaluating the effectiveness of their safety program through lagging indicators. This information is not useful, of course, if it is not analyzed and acted upon. As with other performance indicators, managers should include a review of the data collected as part of their performance monitoring system and make adjustments to improve indicator scores such as injury rates and safety audit scores.

As with other performance indicators, managers should include a review of the data collected as part of their performance monitoring system and make adjustments to improve indicator scores such as injury rates and safety audit scores.

In addition to indicators, laboratory managers must also monitor staff performance and compliance with safety policies and procedures. Laboratory leaders should hold staff

Adding a safety component to initial and annual competency assessments allows for staff accountability once training is complete and on an ongoing basis.

accountable for unsafe practices and behavior in the lab. Lack of oversight can lead to poor quality of work and potentially increased errors and accidents.

A challenge to holding staff accountable for safety in the lab is the perceived power distance that may exist amongst the different positions of employees. In some environments, those responsible for safety may be apprehensive about coaching someone in a perceived higher position (i.e., manager, medical director) about a safety issue. Those in "higher" roles might choose to ignore certain safety requirements, which can lead to the occurrence of errors and accidents.[14] Power distances should be lowered or eliminated in a laboratory setting since it is important that safety applies to all in the department.

One method of holding staff accountable regarding safety is to include safety in the lab annual competency assessments. The College of American Pathologist lists six requirements to assess the competency of laboratory employees in the various sections of the lab. A helpful addition to these requirements would be an element of laboratory safety. It may be assumed that staff are conducting their daily operations in a safe manner, yet this is not assessed or documented, so it is unknown if deviation from laboratory safety policy occurs. Adding a safety component to initial and annual competency assessments allows for staff accountability once training is complete and on an ongoing basis. In addition to ongoing monitoring, an annual assessment of staff safety practices provides staff with awareness that safety is a focus for lab leadership, and it is important to the organization.

Summary

There are several factors that can contribute to laboratory errors and accidents as a result of staff mistakes. Understanding the safety hazards in the lab and how to mitigate the associated risks, in addition to timely and effective training, the monitoring of the physical environment, and manager engagement are tools that can aid in the reduction of safety incidents. These four components of laboratory operations help contribute to the overall safety culture of the workplace by making staff and laboratory leadership aware of the dangers they may encounter and by preventing these undesired events.

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Jason P. Nagy, PhD, MLS (ASCP)CM,QLS is the Laboratory Safety Support Coordinator at **Sentara Health**, a multi-hospital system in Virgina and North Carolina. Jason brings almost 20 years of laboratory experience to the lab as a medical laboratory scientist (MLS) and more recently in laboratory safety and education roles.

The absence of a safety culture; What contributes to laboratory incidents?

NOVEMBER 2023 *[This form may be photocopied. It is no longer valid for CEUs after May 31, 2025.]*

Passing scores of 70 percent or higher are eligible for 1 contact hour of P.A.C.E. credit.

TEST QUESTIONS

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

1. **Laboratory errors are based around**
   - A. Quality assurance
   - B. Safety
   - C. Both A. and B.
   - D. None of the above

2. **Laboratory safety is interconnected and involves**
   - A. Errors and accidents only
   - B. Accidents and mistakes only
   - C. Errors, accidents, and mistakes
   - D. None of the above

3. **Which of the following factors does not contribute to a reduction in laboratory errors?**
   - A. Memorizing a procedure
   - B. Physical environment surveys
   - C. Initial and annual training
   - D. Staff education

4. **To excel in the creation and maintenance of a laboratory safety culture, equal and active participation of lab management and lab staff is required.**
   - A. True
   - B. False

5. **SOPs are written to ensure _____ and to _____ precision and _____ variability.**
   - A. Function, decrease, reduction
   - B. Accuracy; increase; reduction
   - C. Accuracy; decrease; increase
   - D. Function; increase; reduction

6. **Safety items included in SOPs may have a greater impact if they were incorporated**
   - A. At the beginning of a procedure
   - B. At the end of a procedure
   - C. Within the procedure as discreet actions
   - D. All of the above

7. **CAP requires all technical policies and procedures to be reviewed at least every**
   - A. 6 months
   - B. 12 months
   - C. 18 months
   - D. 2 years

8. **Which organization has more stringent guidelines on the review of laboratory SOPs?**
   - A. CLIA
   - B. FDA
   - C. ASCLS
   - D. OSHA

9. **All but the following individuals should be included in the review process of SOPs.**
   - A. Laboratory managers
   - B. Hospital physicians
   - C. Subject matter experts
   - D. Technical staff who utilize the procedures

10. **Monitoring and resolving safety issues in the laboratory's physical environment is referred to as**
    - A. PE rounds
    - B. SOP rounds
    - C. Safety rounds
    - D. None of the above

11. **Physical environment rounding checklists shouldn't be broken up into categories because it will not help to resolve any safety issues that are found.**
    - A. True
    - B. False

12. **The greatest barrier to maintaining a safe lab environment includes**
    - A. Laziness in laboratory staff
    - B. Lack and availability of training material
    - C. An overly fast-paced environment
    - D. All of the above

13. **OSHA's blood borne pathogen, portable fire extinguisher, personal protective equipment, formaldehyde, and chemical hygiene requirements are topics that should be required in**
    - A. Safety indicators
    - B. Physical environment rounding
    - C. Training requirements
    - D. Both B. and C.

14. **The following are examples of leading indicators except**
    - A. Injury exposure rates
    - B. Performing safety audits
    - C. Performing PE rounds
    - D. Safety survey results

15. **The following are examples of lagging indicators except**
    - A. Safety audit scores
    - B. Percent completion of PE rounds
    - C. OSHA recordable rate
    - D. Safety survey results

16. **In addition to leading and lagging indicators, managers should also monitor staff performance and compliance with safety policies and procedures.**
    - A. True
    - B. False

17. **Those in _____ roles might choose to ignore certain safety requirements.**
    - A. Lower
    - B. Higher
    - C. Parallel
    - D. None of the above

18. **CAP lists _____ requirements to assess the competency of laboratory employees in the various sections of the lab.**
    - A. 2
    - B. 6
    - C. 10
    - D. 13

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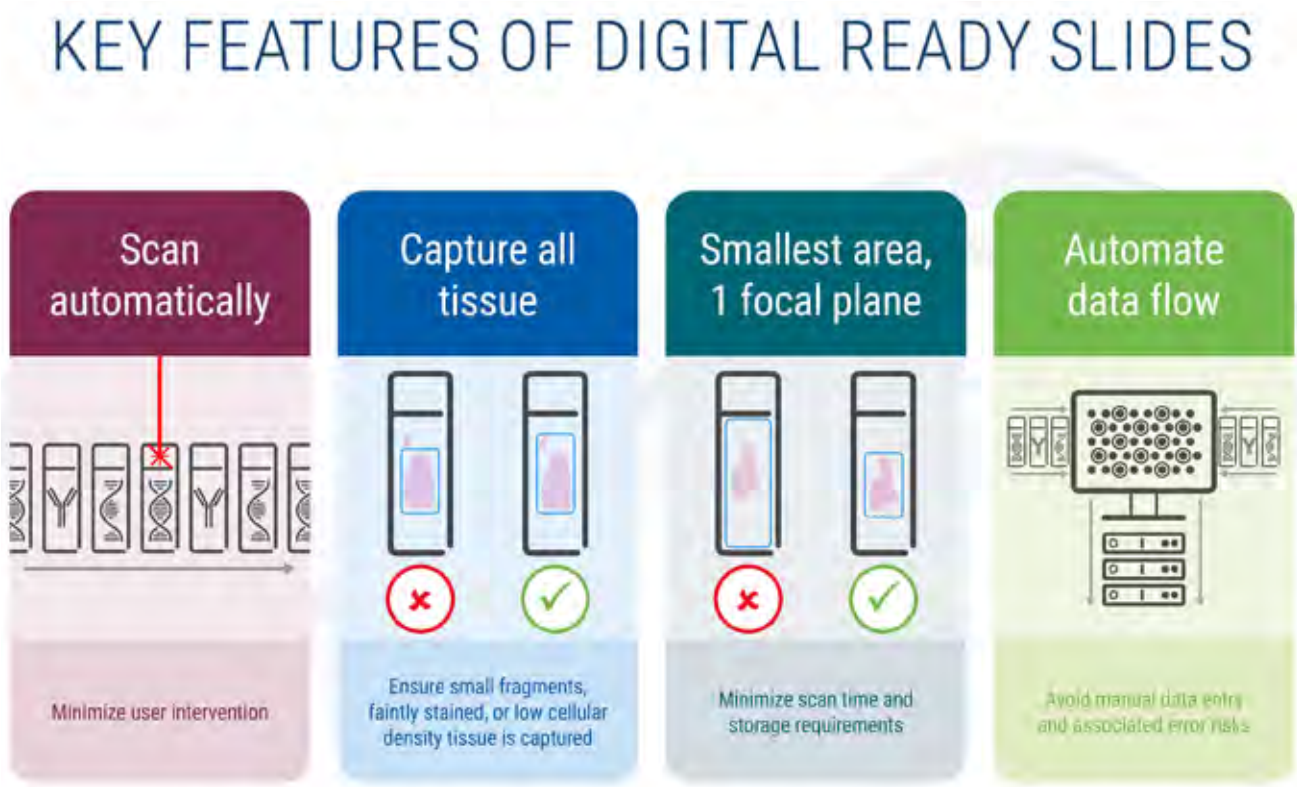


Credit: Leica Biosystems

Creation of Digital Ready Slides affects multiple process steps within the histopathology laboratory, which should be taken into consideration when implementing digital pathology either for routine use or AI development.

Quality in, quality out: Practical considerations for 'digital ready' slides

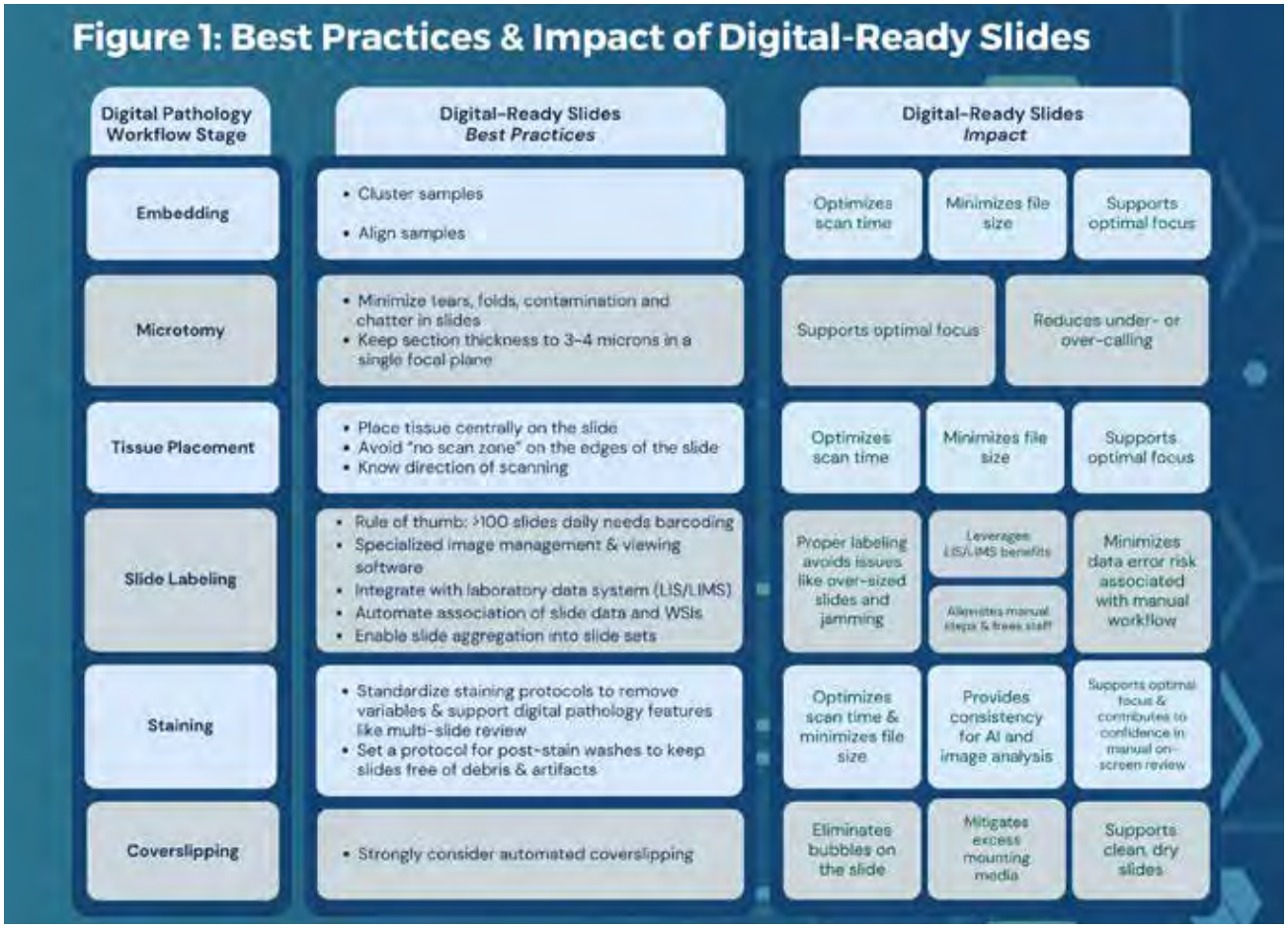
By Rob Monroe, MD, PhD

Optimizing lab workflows to produce high-quality 'digital ready' slides for whole slide images (WSIs) is essential for organizations using digital pathology. A growing body of peer-reviewed evidence documents the benefits of digital pathology for clinical use, including enhanced accuracy and precision, the ability for digital images to be uploaded and reviewed remotely by multiple pathologists, and the acquisition and processing of large and complex datasets — ultimately resulting in a more efficient workflow, a better experience for pathologists and lab personnel, and improved patient care.

The last two decades have seen significant advances in digital pathology to the point where the acquisition speed, image quality, and infrastructure to support WSIs is at a level of maturity to facilitate routine, on-screen diagnostics.[1-3] Moreover, there is growing acceptance for the use of digital pathology in the clinical setting in both normal times and public health emergencies such as the COVID-19 pandemic.[4-6] Further, development of AI for pathology applications is growing rapidly and typically requires large datasets of WSIs for training and validation.[7,8]

High-quality WSIs are the foundation for clinical utilization of digital pathology and the building blocks for enablement of histopathology AI tools. Collation of WSI datasets is facilitated by the creation of so-called 'digital ready' slides, which are optimized for whole slide imaging. Capturing 'digital ready' slides involves more than installing a scanner in a lab. Standardization of histological slide preparation requires focus on both optimization of individual workflow steps as well as a holistic understanding of the complete process from sample acquisition to diagnosis. Knowing this in advance and taking appropriate steps to effectively support change management can promote engagement of stakeholders and pave a path to success.

We've learned from our work with organizations around the world that each step in the pre-scan process can be optimized for WSI — from embedding, microtomy and tissue placement to slide labeling, staining, and coverslipping. Doing so involves professionals across the lab establishing and adhering to agreed-upon standards. Technical University Munich began its journey to digital in 2013 and has identified several lab workflow steps imperative to efficient digitization of high quality WSIs. "For the workflow to remain efficient, we provide recommendations to the lab in terms of slide preparation," says Viola Iwuajoku, Digital Pathology Team Lead at Technical University Munich. "For example, they need to be sure the coverslips are intact,



Credit: Leica Biosystems

that the barcodes are clearly readable, and that the slides are properly dried and no longer sticky from the embedding and staining processes."

I concur these factors are essential, adding the importance of creating slides that embed all tissue in the smallest area possible on a slide — ideally in one focal plane — including tissue fragments, faintly stained tissue, or paucicellular tissue. Doing so can help labs refine and reduce scan time per image, limit scanner downtime due to jammed or broken slides, minimize image file size, and address file storage limitations, among other benefits **(See Figure 1).**

Image quality is of utmost importance for pathologists to make an accurate and confident diagnosis. Simple changes to how we prep slides can aid the adoption of digital pathology and highlight its many benefits including efficient review of cases, ease of collaboration with specialists, and remote work flexibility.

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Key points of intersection in diagnosis and treatment of cancer

Linking microbiology and technology with cancer diagnosis and treatment

By Lisa-Jean Clifford

With the advancement and expanded uses of technology in the laboratory we have a host of opportunities in the hands of physicians and scientists to explore and study diseases in-depth and in a way that we historically have not been able to. We are seeing an unprecedented application of these technologies combined with the expertise of these human resources to open those avenues and take deeper dives into the study and understanding of tumors and cells and their behaviors, having a significant impact on the diagnosis and treatment plans for patient populations.

What are microbes and how do they play a key role in the diagnosis and treatment assumptions for cancer now? Without being condescending, or as a refresher, microbes can be both helpful and harmful in the human body — they can cause diseases like cancer, or they can help with inhibiting disease and promoting health. Their role and relationship with cells, tumors, and the immune system can vary greatly. They help with the diagnosis of cancer by producing biomarkers, which are found in bodily fluids and are therefore easy to test for and to identify. Some also produce toxins which damage cells and can cause them to mutate where this can both cause cancer and be an early predictor for cancer in diagnosis. Other early detectors or indicators for diagnosis are microbes that naturally create contrast elements; these help reveal tumors by producing light or magnetic elements that are highly visible in diagnostic images.

There are bacteria that have the ability to impact the body's own immune system, either negatively by suppressing it or positively by boosting it, in both cases, impacting how the body both responds to cancer cells and their development or progression and in how the patient will respond to specific therapeutics. By increasing the body's response to immunotherapy drugs, they are increasing the effectiveness of the drug and the body's defense against the tumors. Conversely, bacteria can also suppress the body's immune system and reduce its ability to fight the development of the cancer, or they can reduce the toxicity of chemotherapy drugs, also having a negative impact on the ability to reduce the cancer's development in a given patient.

When we combine that with disciplines like next-generation sequencing, we have a roadmap for studying tumors, host genomes, and the microorganisms that subsist within them. We are now learning that these microbes may communicate or have an interactive relationship with certain cancers. This leads to the possibility that they may also have the ability to direct or control the response to specific treatments.

Microbiome data can be used to identify certain tumor signatures and biomarkers, which can be used to determine cancer risk as well as provide insights for how those tumors will respond to specific therapeutics or even to determine the most likely outcome for a patient. This information is extremely valuable in the diagnosis and treatment plans for patients but also for researchers and drug and pharma companies in the development and testing of new therapies. Incorporating the ability to target microbiomes in research and clinical trials will enable us to see how the microbiomes interact with, or direct, the tumors response to different cancer treatments. The treatments currently being investigated include both transplantation and precision-guided molecular

applications. Some of these findings can include predictors for developing toxicity in treatments and how those interplay with increased, or decreased, microbiome response.

Another approach for study and research includes the relationship between microbes and their responsibility for cancer developing or in the progression of it within the body. It is known that certain bacteria have been directly associated with certain types of cancers such as colorectal and oral. The ability to manipulate or interfere with these bacteria using technological advances and information can help identify the impact of certain treatment plans, based upon understanding the microbiomes response. We are gaining a great deal of information, through technology, on how they respond to specific tumor and treatment combinations. Bacteria and fungi that live around tumors help those tumors thrive and grow while others can work together with specific treatments to help the body's immune response to tumors, which can render treatment more effective.

The opportunity for the development of new, personalized treatments through the use of technology focused on this subject is extensive now. These could have a significant impact on the outcomes, longevity, and eradication of cancer for patients. Immunotherapy is an area that has become widely focused on for research and development due to the number and results of studies with microbiomes. As the information regarding their uses and responses to cancers and immune responses becomes readily available and shared, it becomes more a part of the drug development pipeline.

The focus of scientists and researchers is really on the two use cases for immunotherapy in cancer:

- Enhancing, or strengthening, the innate defenses of the immune system so it is better able to find and fight cancer cells
- Creating manufactured elements that mimic, but are better targeted, immune system structures for use in improving how the immune system works to locate and fight cancer cells

Using immunotherapy to treat cancer is not new, this has been a focus and an option for therapy for several years, but the advancement of technologies such as imaging, digital pathology, and artificial intelligence has provided new ways of approaching treatment development and new ways of working with the immune system. These technologies have also had a significant impact on the speed of discovery, development, and testing of these techniques.

As we have covered, immunotherapy works better on certain types of cancer than it does on others — but the focus is also on the current understanding of how it works better when used in combination with some treatments versus others.

As a summary, we can look at the different types of immunotherapies being used in the treatment of cancer today. Keeping in mind that certain types of cancer use different types of targeted immunotherapies and there are several being developed and in research today.

Types of cancer immunotherapy

- **Checkpoint inhibitors:** These drugs basically take the 'brakes' off the immune system, which helps it recognize and attack cancer cells.
- **Chimeric antigen receptor (CAR) T-cell therapy:** This therapy takes some T-cells from a patient's blood, mixes them with a special virus that makes the T-cells learn how to attach to tumor cells, and then gives the cells back to the patient so they can find, attach to, and kill the cancer.
- **Cytokines:** This treatment uses cytokines (small proteins that carry messages between cells) to stimulate the immune cells to attack cancer.
- **Immunomodulators:** This group of drugs generally boosts parts of the immune system to treat certain types of cancer.
- **Cancer vaccines:** Vaccines are substances put into the body to start an immune response against certain diseases. We usually think of them as being given to healthy people to help prevent infections. But some vaccines can help prevent or treat cancer.
- **Monoclonal antibodies (mAbs or MoAbs):** These are man-made versions of immune system proteins. mAbs can be very useful in treating cancer because they can be designed to attack a very specific part of a cancer cell.
- **Oncolytic viruses:** This treatment uses viruses that have been modified in a lab to infect and kill certain tumor cells.

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Why quality matters

'Quality is not an act but a habit.' -Aristotle

By Ian Wilkinson PhD, DClinChem, CSCC(Cert), MBA

Quality is the mantra of medical laboratory professionals, but what is quality? What does it really mean? Why does it matter? Isn't quality *control* (QC) good enough? Isn't it the same thing as quality *assurance* (QA)? If we run quality control samples, why do we bother with external proficiency testing (EPT)? Isn't plotting QC results on graphs good enough? What is the point of spending all this time and money on quality? Is it really worth it?

Quality is almost like a religion that everyone working in a medical laboratory is expected to believe in and practice. We run QC samples, controls, and the occasional EPT testing sample and may think that is good enough. Running these samples and controls is an excellent start but in itself is insufficient. Anomalous fridge/freezer temperature, QC, and EPT data need to be acted upon. There is no point in dutifully plotting out-of-range QC data or fridge and freezer temperatures without taking action. During accreditation inspections, I have seen beautifully plotted QC and temperature data that are outside their target ranges and yet no action had been taken to rectify the situation. Quality assurance is not just measuring and plotting numbers, it is about taking action to address any deviations from the target ranges, and whenever necessary, changing policies, procedures, and processes to reduce or eliminate errors and to try to reduce the probability of future errors occurring. This is the essence of continuous quality improvement (CQI) and of total quality management (TQM).

Quality control versus quality assurance

Quality control is a subset of quality assurance. They are not synonyms. Quality control is only the beginning of quality assurance. Quality assurance includes quality control; external proficiency testing; continuous and timely actions to address any deviations from target ranges; regular cleaning and maintenance of equipment; appropriately trained and qualified staff; a clean, safe, and sanitary physical workspace; correctly stored and processed reagents and samples; and the use of in-date reagents and equipment, including less obvious items such as personal protective equipment. The Clinical Laboratory Improvement Amendments (CLIA) of 1988 require a medical laboratory to have QC procedures to monitor the accuracy and precision of its testing processes. Laboratories may create an individualized quality control plan (IQCP) for their particular testing environment and patients.

How good is 'good enough'?

If 99.99% of a laboratory's reportable results are ok then that is good enough, right? If you think that 99.99% is good enough, then consider the following facts:

- 144 incorrect medical procedures would occur each day.
- 18 babies would be given to the wrong parents each day.
- 20,000 incorrect drug prescriptions would be written in the next 12 months.
- 567 pacemaker operations would be performed incorrectly this year.
- 810 commercial airline flights would crash every month.
- Every day, two plane landings at Chicago O'Hare International Airport would be unsafe.

If 99.99% is not good enough, then what is? The answer is at least 99.9999998%. This is known as the Six Sigma approach to quality. 'Sigma' refers to the standard deviation of a set of data. **(See Figure 1 and the Glossary of terms)**. The goal of Six Sigma is to ensure that processes such as medical laboratory testing must not produce more than 3.4 defects per million 'opportunities.' A defect is any nonconformance to a standard requirement.

You may be wondering why the Six Sigma goal is no more than 3.4 defects per million opportunities instead of no more than 0.002 (it is actually 0.00197 to be more precise) as seen in **Figure 2**. The answer is that in order to reflect real world experience, a Six Sigma process is allowed to move 1.5 σ on either side of the mean over

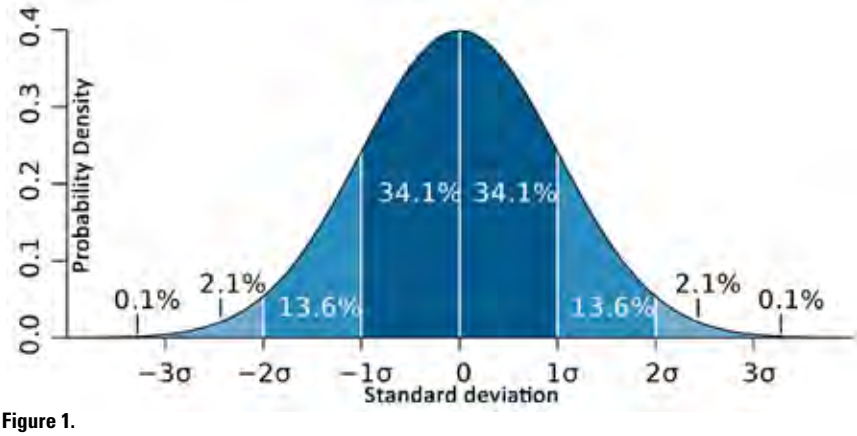

Figure 1.

time, where σ is the standard deviation (See Glossary of terms.) For example, if there is a shift of 1.5 σ to the right of the mean then 4.5 σ (6.0 - 1.5) is the acceptance area on the right and –7.5 σ (-6.0 - 1.5) on the left. With this shift, the rate will be 3.4 defects per million opportunities: if P = the probability density then, P(z<= -7.5) + P(z >+4.5) = 3.4×10^{-6} = 3.4 defects per million opportunities, where 'z' is the number of standard deviations from the mean (the z-score).

The true costs of quality

The total cost of quality is not always obvious. Some costs are highly visible but others are hidden or 'invisible' without looking deeper **(See Figure 3: The Quality Iceberg)**. The total cost of quality can be measured. Quality-related costs can be divided into four categories:

1. Costs associated with preventing errors (prevention costs).
2. Costs associated with monitoring quality (monitoring costs).
3. Costs associated with internal laboratory failures.
4. Costs associated with pre- and post-analytical errors.

1. Prevention costs

- The cost of a dedicated quality assurance (QA) person.
- A portion of the time dedicated to QA by the laboratory director, managers, and other staff.
- Preventive maintenance contracts etc.
- A portion of laboratory information system (LIS) costs, office supplies, printing, copying, etc. dedicated to QA.
- Competency assessments of staff, continuing education, and other training.

2. Monitoring costs

- Quality control (QC).
- Calibration and control reagents and analyses.
- Temperature monitoring and alarm systems.
- Annual accreditation, including inspection costs and annual accreditation fees.
- Self-inspections required by an external accreditation agency.
- External proficiency testing.

Sigma (σ)	Percent falling within the sigma range	Defects per million opportunities
+ / – 1	68.27	317,300
+ / – 2	95.45	45,500
+ / – 3	99.73	2,700
+ / – 4	99.9937	63
+ / – 5	99.999943	0.57
+ / – 6	99.9999998	0.002

Figure 2.

3. Internal laboratory failure costs

- Expired reagents and disposables.
- Repeated QC and calibration testing.
- Correction of transcription errors, specimen processing, and accessioning errors.
- Repeated sample testing. Failure to follow SOPs (standard operating procedures) and cost of retraining staff. For example, correction of testing procedure errors, performing the wrong test on the wrong sample, etc.

4. Pre-and post-analytical costs

- Correction of pre-analytical errors that occurred before analyzing the samples, for example, requisition data entry errors, specimen collection, transport and processing errors.
- Correction of post-analytical errors, such as transcribing the wrong results, sending patient results to the wrong client, or delays in reporting test results to clients.
- Poor quality is expensive. Remember, if there was not enough time and money to do it right the first time, why do you think there is enough time and money to do it over?

Figure 3.

Goodwill

Medical laboratory results must be timely and trustworthy. Physicians and other healthcare professionals need to know that any test results that they receive from your medical laboratory are trustworthy. Trustworthy results are your medical laboratory's *raison d'etre,* i.e., they are why your lab exists and why you have a job. Physicians and other healthcare professionals rely on these tests for the diagnosis and treatment of patients and also to monitor therapeutic drug levels, among other things. Quality is your responsibility whether it is in your job title or not. Successful medical laboratories know that their reputation is paramount. It takes time, money, and total quality management to build a great reputation. On the other hand, a good reputation can be lost in seconds if the quality of your products and services is poor or inconsistent.

Consistent high-quality builds goodwill. Goodwill is an intangible but valuable asset. It is the value of a company's

Whose responsibility is quality?

There was an important quality assurance job to be done and Everybody was asked to do it. Anybody could have done it, but Nobody did it. Somebody got angry about that because it was Everybody's job. Everybody thought Anybody could do it, but Nobody realized that Everybody was not doing it. Consequently, it ended up that Nobody told Anybody, so Everybody blamed Somebody, and the job was never done.

reputation. For example, Microsoft, Amazon, and Apple all have very large intangible assets (goodwill) built on their reputations. A company's intangible (goodwill) value may far exceed the value of its tangible assets such as buildings, inventory, land, etc. In business, including medical laboratories, reputation is everything. Reputations must be built and maintained. It is already too late if you only begin to think about quality just before the next external accreditation inspection is due. Think, live, and breathe it every day. Quality means doing it right even when there is no one looking. Quality is everyone's responsibility. Quality is not just a theory or a mantra: it is a lifelong habit!

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Glossary of terms

Name	Notes
Accurate	How close a result is to the true value. Not to be confused with precision (See Precision).
Calibration	For example, using a set of standard solutions of varying but known concentration to confirm the linearity of a test methodology
Continuing quality improvement	The constant process of improving quality through changes to processes, policies, training, additional quality monitoring, and more effective and efficient application of quality data.
Cost of quality	A set of methods for calculating the costs of 'good' and 'poor' quality.
External proficiency testing	Assessing the performance of a medical laboratory by analyzing samples obtained from an external agency such as the College of American Pathologists (CAP). Results are compared with target values and also compared with results produced by other laboratories using the same methodology.
False negative	A test result which incorrectly indicates that a particular disease is absent.
False positive	A test result which incorrectly indicates that a particular disease is present.
Laboratory information system	A software / hardware system that processes, stores, and manages patient and other data related to laboratory processes and testing.
Levey-Jennings control chart	A graph for plotting QC results. The vertical ('y') axis shows the target mean and lines representing 1, 2, 3 etc. standard deviations above and below it (See Standard deviation). Levey-Jennings charts use the calculated standard deviation (or a known standard deviation) to set the control limits. The horizontal ('x') axis shows the date / time.
Negative control	For example, a component that is part of a test but is not expected to show any change when treated as though it were a test sample.
Normal distribution	Also known as a Gaussian distribution or Bell curve. Many (but not all) sets of data follow a normal distribution with the following properties: The majority of data values fall close to the mean value and are distributed symmetrically about the mean. A few data points fall much further from either side of the mean. As can be seen in Figure 1: The Normal (Gaussian) Distribution, this curve has several characteristic properties. For example, 68.2 % of the data will fall within plus or minus one standard deviation from the mean (See Standard deviation).
Positive control	For example, a component that is part of a test procedure and is expected to show a readily identifiable change if the test procedure is working properly.
Precision	How close together two or more repeated results are. Not to be confused with accuracy (See Accurate). A series of repeated test results could be precise but not necessarily accurate.
Probability density	As shown in Figure 1: The Normal (Gaussian) Distribution, the probability density ('y' axis) is a measure of the likelihood or probability of finding a given data point at a particular location. It is more likely that a data point will lie at or close to the mean. The total probability (the area under the curve) adds up to 1.0 or 100%.
Quality assurance	A system of policies, procedures, processes, staff competencies, equipment maintenance, calibration, QC, etc.
Quality control	For example, including special 'samples' or 'controls' of known concentration or value, together with patient samples during analysis. This is to check whether or not the analytical system is working correctly.
Sensitivity	Sensitivity is a test's ability to detect those patients with a disease as positive, i.e., true positives (TP). A highly sensitive test therefore has few false negative (FN) results. Sensitivity = TP/(TP + FN). Medical laboratory tests are usually not perfectly sensitive and/or perfectly specific (See Specificity).
Six Sigma2	Sigma is the Greek letter for 's'. In statistics it represents the standard deviation of a set of data such as test results from the average (mean) value (See Standard deviation).
Specificity	The specificity of a test measures its ability to detect those patients who do not have a disease i.e. a true negative test (TN) result. Specificity = TN /(TN + FP) where FP = false positive result (See Sensitivity).
Standard deviation*	A measure of the amount of variation or dispersion of a set of data around the mean. A low standard deviation indicates that the majority of values lie close to the mean of the data set. A high standard deviation indicates that the values are spread out over a wide range around the mean. (See Figure 1: The Normal (Gaussian) Distribution).
Standard operating procedure	An approved, written procedure for performing a task, for example, a medical laboratory test.
Total quality management	The philosophy, culture, and management practices which ensure continuous quality improvement (See Continuous quality improvement]
Westgard rules	A set of criteria developed by Dr. James O. Westgard that may be used to assess whether or not a series of data are within a target range.
Z-score	The number of standard deviations a data point (x) is away from the mean (See Standard deviation).

* In statistics, the symbol 'σ' refers to the standard deviation of a population, whereas the symbol 's' refers to the standard deviation of a sample drawn from a population. The formulas for calculating the standard deviation are different for a population versus a sample.

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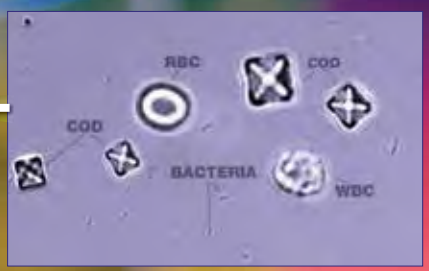

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Why your lab should leverage testing with allergen components for sesame allergy analysis

By Gary Falcetano, PA-C, AE-C; Jessica Murphy, MLS(ASCP)CM

Sesame allergies currently affect roughly one in 200 U.S. citizens and are increasingly becoming a serious public health concern as the number affected continues to rise.[1] Given the potential severity and fatality of allergic reactions, and the fact that less than 30% outgrow a sesame allergy, it's a pressing issue that demands attention.[1]

In response to the rising prevalence of sesame allergies, the Food and Drug Administration (FDA) recently mandated explicit sesame allergen labeling on product packaging.[2] The new regulation helps consumers make safer food choices, allowing individuals with sesame allergies to avoid products potentially harmful to them.

While the changes are a big step toward public health safety, it has also introduced challenges for both consumers and diagnostic testing labs. There is a "transition period" as manufacturers adjust to the new labeling requirements, posing a temporary risk for consumers relying on precise allergen information to protect their health. And in the longer term, it puts increasing pressure on labs, as the new rule is likely to trigger an increase in sesame allergen testing as more people seek to understand their potential allergies.

To prepare for the imminent surge in testing requirements, it is vital that labs employ precise and efficient allergy diagnostic tools to streamline their workflows. Additionally, labs must offer the most comprehensive test menu, otherwise clinicians may send their bloodwork elsewhere.

Testing with allergen components — an *in vitro* blood test that can help determine more precisely which protein a consumer is allergic to — offers deeper insight into a patient's condition.[3] This diagnostic tool is automated and can accurately provide vital details on sesame allergies, enabling labs to meet the demands of an increasingly allergen-aware landscape effectively. This article explores the impact of the new FDA regulations, their potential effects on the lab industry, and how testing with allergen components can help labs rise to these challenges.

Unpacking the FDA's new act and its effects

Eight major food allergens, including milk, eggs, and peanuts, have historically caused the majority of serious allergic reactions to food in the US.[4] In response to the increase in sesame allergies, the government passed the Food Allergy Safety, Treatment, Education and Research (FASTER) Act in 2021, declaring sesame as the ninth major food allergen.[5] Effective from January 1, 2023, the FDA requires sesame, alongside the other eight major allergens, to be clearly labelled on packaged foods.

However, food products that were already on shelves, or on their way to shelves prior to 2023, did not need to list sesame on their labels. This causes a precarious transition period, as long-life products on the shelves in 2023 that do not indicate sesame as an allergen might still contain it. Consumers therefore face potential hazards if they rely solely on labelling to make their food choices during this period.

Additionally, as the effects of the new labeling requirements unfold, some manufacturers have begun intentionally adding sesame to their products. By knowingly making sesame-containing products, manufacturers mitigate the requirements and associated costs of proving food products are safe from cross-contamination, which can be expensive and challenging to do. Consequently, certain previously "sesame-safe" restaurants and foods might not be so anymore, and consumers with suspected allergies face unnecessarily restricted diets unless they confirm their sesame allergic status.

Owing to these factors, the labeling shift has escalated the demand for testing with sesame allergen, as increasing numbers of consumers are seeking diagnoses to determine if they can safely eat sesame-containing foods. This surge in testing demand underscores the pivotal role that labs play in providing precise sesame-allergy diagnostic tests.

A closer look at testing with sesame allergen

Currently, two main types of tests are employed for measuring sensitization to

	SPT	Specific IgE blood testing
Discontinue allergy medications (3-10 days) before test?[11]	Yes	No
Can be used regardless of skin condition?[11]	No	Yes
Can elicit systemic reaction?[11]	Rarely	No
Same day results?[11]	Yes	No
Sensitivity	High (>85%)[6]	High (84-95%)[12]
Specificity	Moderate (40-80%)[6]	High (85-94%)[12]

Table 1: The advantages and disadvantages of tests to determine sesame sensitization.

sesame: skin prick tests (SPT), and blood tests for specific immunoglobulin E (IgE) to whole sesame. SPT measures reactivity of specific IgE bound to mast cells in skin, and blood tests measure specific IgE antibodies in serum.

Each test offers valuable insights, but comes with its respective strengths and limitations, summarized in **Table 1.**

The above tests, while providing useful insight, must be used in conjunction with a thorough clinical history and evaluation of symptoms to make a diagnosis. Furthermore, clinicians should ideally use the tests together to build up a comprehensive picture of an individual's allergy profile.

The most informative way to determine an allergy is through oral food challenges (OFCs). In a sesame OFC, the individual ingests tahini paste in a controlled environment, such as a hospital, and specialists monitor them for any allergic reactions. This is useful to diagnose an adverse reaction to food, but results can be misinterpreted if testing is not done in a masked (or blinded) manner. What's more, while OFCs are performed in controlled environments to increase safety, there is still a risk of life-threatening anaphylaxis.[6] Therefore, OFCs should only be performed when it is acceptable and poses a low risk to the individual.

Clinical history and blood testing with whole allergens are typically used to predict suitability for an OFC, but they are not fully reliable indicators. The need for more precise and comprehensive diagnostic tools, therefore, is critical. Testing with allergen components is one such tool, but what exactly is it?

Testing with allergen components: A breakthrough in sesame allergy detection

The standard allergen blood test is the sIgE test, which considers sesame as a whole. But different proteins present in the allergenic food — allergen components — are associated with the likelihood and potential severity of a clinical allergic reaction, and so it is vital to determine which proteins an individual is sensitized to.[7] While blood testing with whole sesame allergen provides useful information, it does not reveal which specific protein a patient is sensitized to, thereby limiting treatment personalization.[3]

Testing with allergen components determines which specific protein(s) in a food source a patient is sensitized to. As such, it can offer deeper insights into their condition or help determine if there is irrelevant cross-activity. Ultimately, it is a crucial tool to bridge the gap between testing with whole sesame and OFC, helping to predict whether a patient is likely to have a systemic reaction to sesame **(see Figure 1)**. In fact, the FDA recently cleared a sesame allergen component blood test for *in vitro* diagnostic use, marking a significant advancement in food allergy diagnostics.[8]

The Ses i 1 allergen component test

Ses i 1, a storage protein and major sesame allergen, has emerged as a predictor of sensitization to sesame.[9] It is a particularly problematic protein as it is stable to heat and digestion, which significantly elevates the risk of systemic reactions and anaphylaxis.

Patients can now undergo testing for Ses i 1 IgE antibodies, which offers a more complete understanding of their risk for systemic reactions when consuming sesame.[7] However, while the test can indicate clinical reactivity, its results should always be interpreted within the context of a patient's comprehensive clinical history.

A recent study conducted in Japan highlighted the accuracy of Ses i 1 testing, examining 92 sesame-sensitized children divided into symptomatic and asymptomatic groups.[7] Upon testing for Ses i 1 sensitization, 92% of the symptomatic group and 32% of the sensitized but asymptomatic group tested positive. The optimal cut-off of IgE level to Ses i 1 was determined to be 3.96 kU_A/L, with a remarkable sensitivity of 86.1% and specificity of 85.7%.[7]

Integrating testing with Ses i 1 allergen component into your profile of tests can provide several benefits:

- **Enhance patient care:** The approach may help improve the diagnosis of a sesame allergy and optimize patient management.[7]
- **Improved risk stratification:** It helps clinicians determine the most suitable candidates for OFC, optimizing resource allocation while ensuring patient safety.[3]
- **More accurate results:** Allergen component tests can help distinguish cross-reactivity — for example, between peanuts, tree nuts, and sesame — thereby enhancing the accuracy of diagnoses.[3]
- **Streamline workflows:** The incorporation may help to minimize send-out costs and decrease turnaround time for results.

The promising future of testing with allergen components

As FDA regulations shift and the incidence of sesame allergies rise, more and

Figure 1: Testing with allergen components, when used in the context of a patient's clinical history, can help indicate clinical reactivity and suitability for OFCs.

more patients are seeking sesame allergy diagnoses to determine what foods they can safely consume. The importance of providing accurate and reliable allergy testing, therefore, has never been more critical. Testing with Ses i 1 allergen component represents a significant breakthrough in the field, making it easier to accurately determine which patients are suitable for OFC.[10]

Incorporating such a tool in the laboratory setting not only streamlines the diagnostic process but also substantially improves patient diagnosis and care. By providing more precise results, labs can meet rising testing demands and provide vital support to clinicians and patients alike, ultimately improving healthcare outcomes in the face of increasingly prevalent food allergies.

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Jessica Murphy, MLS(ASCP)CM is a Senior Technical Laboratory Educator at **Thermo Fisher Scientific** and has been an ASCP certified Medical Technologist for 12+ years. Before joining Thermo Fisher Scientific, she spent time in specialized and clinical laboratories. She is skilled in allergy and autoimmune disease testing and instrumentations.

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State of the Industry

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Molecular diagnostics (MDx) testing expands while lab supply shortages shrink

By Kara Nadeau

The molecular diagnostics (MDx) market is estimated to be worth $16.6 billion in 2023, and expected to reach $28.6 billion by 2028, as "Rapid progress in technologies such as next-generation sequencing, gene editing, and personalized medicine will drive increased adoption of molecular diagnostic tests."[1]

To reflect the broadening availability and use of MDx testing, and a shifting focus from COVID-19 testing to other applications, the 2023 *Medical Laboratory Observer* (MLO) State of the Industry (SOI) survey on molecular diagnostics (MDx) featured some new questions and expanded response categories designed to identify emerging trends.

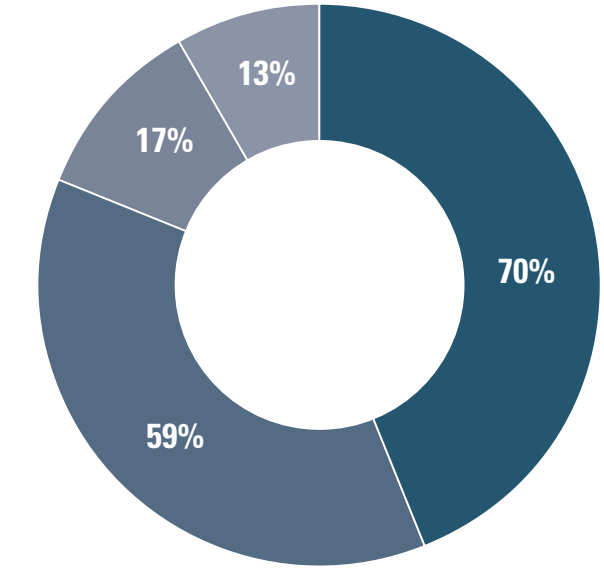
As in past years, the survey queried lab professionals on MDx testing volumes and quality assurance practices. We also retained questions related to supply chain challenges and excess analyzer capacity to gauge whether there were shifts in these areas since our last survey on this topic in fall 2022.

Nearly 100 lab professionals participated in the survey, with the majority (70%) of respondents in Lab Manager, Administrator, Supervisor, or Lab Director positions. This year, we added additional response categories to the place of employment question. While most respondents work in hospital/health system labs (59%), one-third are employed by physician lab offices (17%) or reference labs (13%).

MDX TESTING MODALITY TRENDS

When asked what types of MDx tests they use in their laboratories, topping the list were reverse transcriptase quantitative polymerase chain reaction (rRT-qPCR) with 62% of respondents using these tests, rapid molecular tests (59% of respondents), and rapid antigen tests (43% of respondents).

What is your title/position within the lab facility?



Among other tests, flow cytometry and next generation sequencing were tied at 18%, DNA/genetic testing was reported to be used by 15% of respondents, 12% use reverse transcription loop-mediated isothermal amplification (RT-LAMP), and 9% recombinase polymerase amplification (RPA). Further down on the list in terms of usage was liquid biopsy at 5% and CRISPR-based diagnostics at 2%.

"We have different types of molecular testing modalities available based on the type of patient who needs to get testing," said Jim Dunn, PhD, D(ABMM), Director of Medical Microbiology and Virology, Texas Children's Hospital. "For example, when performing respiratory virus testing on patients who are otherwise generally healthy, we have molecular platforms and assays that target only a few specific viral pathogens, such as flu, RSV and SARS. And generally, for those types of patients, that is sufficient."


Jim Dunn, PhD, D(ABMM)

"And then for other types of patients, such as those who are immunocompromised, transplant, oncology, we have broader syndromic type panels and platforms that go along with those to test for a wide variety of respiratory pathogens, if they have respiratory illness, or gastrointestinal pathogens if they have GI illness," Dr. Dunn continued. "So, we try to reserve the broader, highly multiplex type of molecular panels for those more medically complex types of patients."

Qiagen CEO Thierry Bernard shared his insights on MDx testing trends, stating:


Thierry Bernard

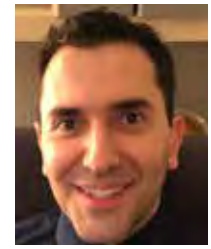
"The COVID-19 pandemic has been a catalyst for remarkable advancements in molecular diagnostics, driving widespread adoption of PCR and nucleic acid testing technologies. This unprecedented expansion has opened doors to broaden infectious disease testing and improve global health outcomes."

Bernard described how multiplex or syndromic testing is gaining momentum due to its efficiency and cost-effectiveness. He noted how it is set to become the new standard because it is essential for detecting a wide array of pathogens. He added how multiplex testing is especially valuable for identifying co-infections and tackling the growing threat of antimicrobial resistance. "In oncology, liquid biopsy is revolutionizing cancer detection and monitoring as a non-invasive alternative," Bernard continued. "Additionally, minimal residual disease testing quantifies remaining cancer cells post-treatment, shedding light on the likelihood of disease recurrence and guiding personalized treatment strategies." "T-cell monitoring extends beyond PCR capabilities, providing researchers with a deeper understanding of the immune system's responses to infections and paving the way for cutting-edge therapies and vaccines," Bernard added.

MDX TESTING VOLUME TRENDS

With regards to the number of molecular-based tests (non-COVID-19) performed by their labs daily, the results were quite different from last year, possibly due to a shift in respondent demographics (e.g., lab types). In 2023, 56% of respondents said they performed 0–100 tests each day, down from 75% in 2022, while 23% said they perform 400+ tests daily, up from 5% in 2022.

The other responses held steady over the past 12 months: a reported 101-200 daily tests at 12% (13% in 2022), 201–300 tests at 6% (5% in 2022), and 301–400 tests at 2% (same as 2022).


Giorgos Manolopoulos

Giorgos Manolopoulos, Lab Manager, Pathology Reference Lab, San Antonio, offered his insights on lab testing trends, noting how testing volumes are being redirected to bigger labs because of mergers and acquisitions, including practices joining larger managing companies that bring with them their own lab services. He commented on how this trend is impacting the lab profession:

"The negatives of this transition are 1) people will lose jobs as everything will become more consolidated and more efficient. 2) turnaround time for results will slow down in many cases as big national labs have slower turnaround times than smaller regional labs. The reason for that is that these labs are busier and also have to ship specimens across bigger distances to get tested, screened, etc. 3) customer service for clinicians will go down because a) smaller labs cater to their clients, repeat testing easily and faster upon request etc., and b) it is easier to reach someone knowledgeable to talk to at a smaller lab if a clinician wants to ask a question, get clarification, etc."

"The positive is that testing may become more efficient," Manolopoulos added. "That means fewer people or instruments needed to do the work as more testing capacity will be consolidated in certain locations nationwide. That should mean increased profits for the big labs, but will it also translate to savings for the insurance companies and the people they cover? Probably not."

"We are seeing a continued need for automation and workflow efficiency in the lab to keep up with testing demands, especially during times of high-volume testing coupled with ongoing staffing shortages."

QUALITY CONTROL TRENDS

The survey questioned lab professionals about their quality control measures, asking how they handle questionable results with MDx tests. Over half of respondents (55%) said they repeat the test, 15% verify all pre-analysis steps are performed correctly, and 8% send results to another lab for verification and second test.

When asked what steps they take to reduce the number of potential false positive test results:

- 33% decontaminate work/test area per laboratory procedures
- 22% verify all pre-analysis steps are performed correctly
- 7% refer to quality assurance program guidance
- 15% repeat the test with another method and compare results
- 14% repeat the test with the same sample and new extractions

RESPIRATORY TESTING TRENDS

With the Department of Health and Human Services (HHS) announcing the end of the COVID-19 Public Health Emergency on May 11, 2023, MLO revised some of its MDx SOI survey questions to reflect the shift in testing focus.

Instead of asking lab professionals specifically about COVID-19 testing volume, we asked how much MDx respiratory testing has increased in their labs in 2023. Half (50%) said their volumes have increased 0–25% since last year, 20% reported a 26–50% increase, 9% a 51–75% increase, 1% a 76–100% increase, 3% a 101+% increase, and 17% said they have seen a decrease in testing.

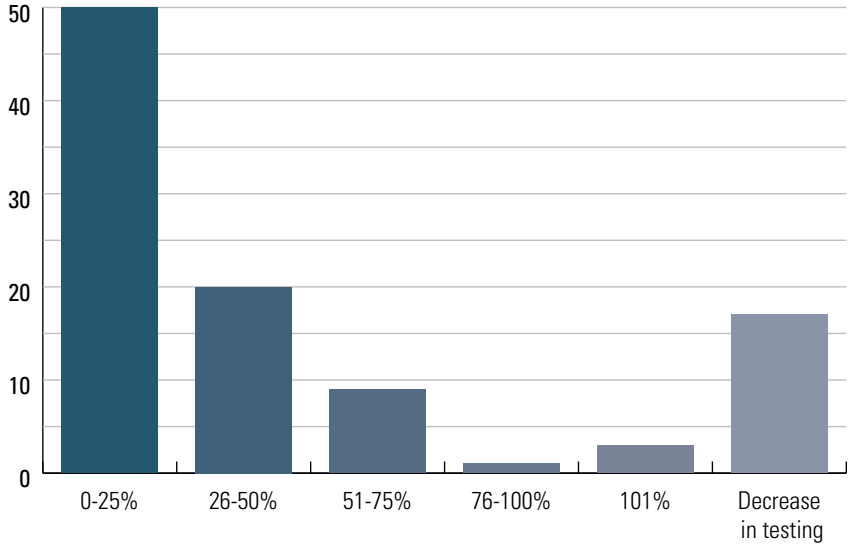
Jennifer Schneiders, PhD

Jennifer Schneiders, PhD, President of Hologic's Diagnostics Solutions Division, commented on what she is seeing and hearing from lab professionals:

"We are seeing a continued need for automation and workflow efficiency in the lab to keep up with testing demands, especially during times of high-volume testing coupled with ongoing staffing shortages. Instruments such as our Panther system have a small footprint and the power to consolidate testing on a single, fully automated platform.

"We are also hearing from labs that they need increased flexibility from their instrumentation as budgets for both space and equipment are tight," Dr. Schneiders continued. "Labs need the ability to perform a high volume of sexually transmitted infection tests or respiratory tests during cold and flu season, for example, while still needing to perform a variety of lower volume tests. We integrated this type of flexibility into our Panther system so labs aren't required to buy new instruments regardless of assay volume."

How much has respiratory testing increased at your lab in 2023?



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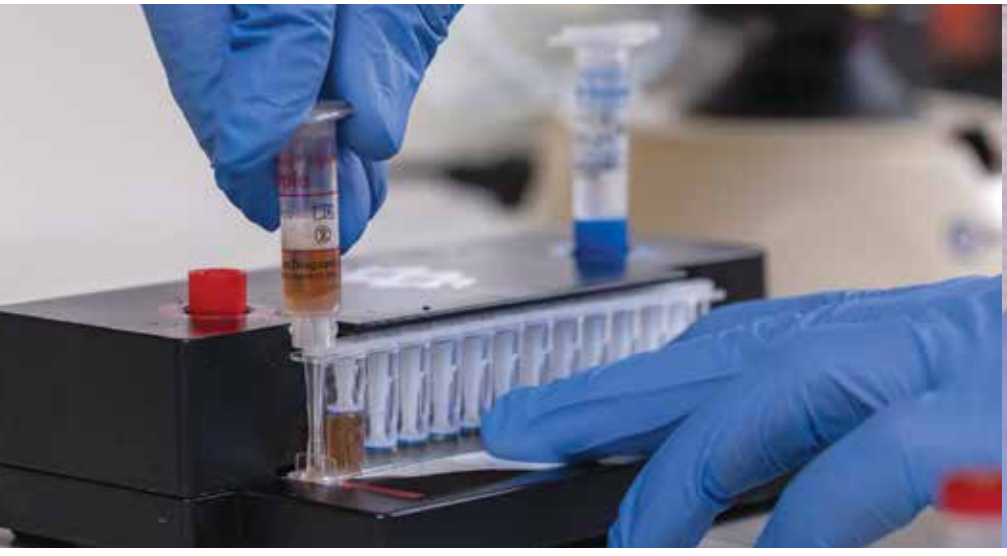

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A higher percentage of lab professionals said they have excess capacity in analyzers originally purchased to handle COVID-19 testing compared with last year (66% in 2023, up from 54% in 2022) and fewer said they don't (34% in 2023, down from 46% in 2022).


Alesia McKeown, PhD

With regards to how they are addressing that excess capacity in analyzers, more respondents said they had added new tests to in-house offerings from among those that are currently sent out to reference labs (53% in 2023, up from 46% in 2022) or had retired some analyzers (22% in 2023, up from 10% in 2022).

Alesia McKeown, PhD, Scientific Partner, Roche Diagnostics, commented on the opportunities presented by having these analyzers in laboratories.

"As we went through the pandemic, we were hit with the realization that labs are severely understaffed and under-resourced. Everybody was trying to get their hands on as many platforms as possible so they could handle even the baseline of COVID needs. Now, at the end of the pandemic, all these laboratorians have all these platforms and are trying to decide what to do with them.

"One of the major obstacles for onboarding any type of molecular diagnostics is having the instrument in house. Now that labs have them on-site, it's opening the door for them to perform PCR testing for so many other critical disease areas."

"We are seeing a huge number of people bringing on STI testing. It's also allowing for smaller labs to bring testing in-house instead of having to send out to larger reference labs.

It's opening up the opportunity for everyone to have this technology for all of the diseases it has been designed to diagnose."

"One of the major obstacles for onboarding any type of molecular diagnostics is having the instrument in house. Now that labs have them on-site, it's opening the door for them to perform PCR testing for so many other critical disease areas."

SUPPLY CHAIN TRENDS

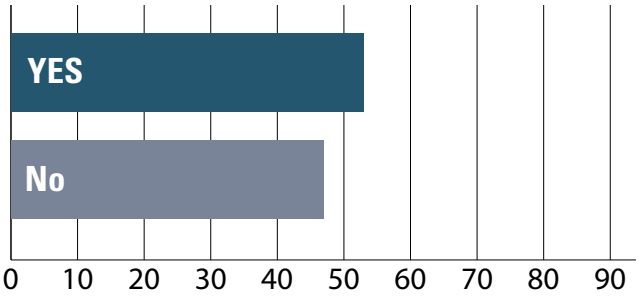
Some of the most significant changes reported in the past 12 months were related to laboratory supply availability. Just over half of those surveyed (53%) said they had experienced issues with maintaining a supply of testing products due to supply chain issues, much lower than the 85% who said they faced this challenge when surveyed in fall 2022. Nearly half (47%) said they have adequate testing supplies to meet testing demands, compared with just 15% last year.

When asked which MDx testing supplies they had trouble sourcing due to supply chain issues, the only category that increased in response percentage was pipettes (25% in 2023, up from 20% in 2022). All others dropped, some significantly, indicating an alleviation of supply challenges in these product categories:

- Blood collection tubes: 27% in 2023, down from 74% in 2022
- Controls/Reagents: 27% in 2023, down from 46% in 2022
- Transport media: 20% in 2023, down from 38% in 2022
- Swabs/Consumables: 19% in 2023, down from 50% in 2022
- Testing kits for SARS-CoV-2: 15% in 2023, down from 43% in 2022
- Winged blood collection sets: 11% in 2023, down from 48% in 2022
- PPE: 9% in 2023, down from 29% in 2022
- Contrast media for radiology: 0% in 2023, down from 13% in 2022
- Cannula syringes: 0% in 2023, down from 5% in 2022

This year's survey also asked about two additional supply categories with regards to supply chain challenges: urine testing supplies with 5% reporting sourcing issues, and lab plastics (outside of other stated categories) with 18% of lab professionals citing issues.

Has your lab experienced issues with maintaining a supply of testing products due to supply chain issues?



LOOKING AHEAD

Among those experts interviewed for the article, some offered their thoughts on the future of MDx testing both in the near and long term:

ALESIA MCKEOWN, PHD, SCIENTIFIC PARTNER, ROCHE DIAGNOSTICS

With the next respiratory season upon us, Dr. McKeown spoke about what she foresees with regard to MDx trends in the coming months.

"Traditionally, respiratory season was referred to as 'flu season.' Then COVID came on board and while it does not yet have a clear seasonality, all

predictions indicate that it will be circulating this fall and winter So, we have those two players (flu and SARS-CoV-2). Then coming into the last couple of years, there has been greater awareness of RSV. As we move into the winter months, I think we'll see exactly what we saw last year — those three different pathogens co-circulating at different levels and having very similar symptoms."

"Many of our customers and key opinion leaders are starting to put a multiplex testing option as their first step in their respiratory algorithm for not just flu, not just SARS, but for all three at once. In my opinion, multiplex is the future, especially for respiratory. Our challenge now is to continue to demonstrate its impact and minimize any reimbursement issues."

JIM DUNN, PHD, D(ABMM), DIRECTOR OF MEDICAL MICROBIOLOGY AND VIROLOGY, TEXAS CHILDREN'S HOSPITAL

"We are on track this year to have similar respiratory testing numbers to what we had in 2022. In the near-term I don't foresee any major changes in how we test for respiratory viruses. We are seeing a slight increase in RSV in our geographic region right now, but how high it's going to go, we don't know. And then when is flu going to pop up? There have been unusual and unseasonal patterns of infection with many of the non-SARS respiratory viruses since the pandemic. So, it's hard to predict."

JENNIFER SCHNEIDERS, PHD, PRESIDENT OF HOLOGIC'S DIAGNOSTICS SOLUTIONS DIVISION

"The 'tripledemic' of COVID, flu and RSV all circulating during the typical cold and flu season will continue to put a significant strain on the healthcare system year after year. Our Panther Fusion SARS-CoV-2/Flu A/B/RSV assay is a critical tool we've developed to help clinicians determine which respiratory virus or coinfection patients have so that healthcare providers can better inform the best course of treatment."

THIERRY BERNARD, CEO, QIAGEN

According to Bernard, AI integration is "revolutionizing molecular diagnostics, enabling rapid, accurate analysis and heralding a new era of earlier disease detection, effective treatment monitoring, and truly personalized therapy." He explained how AI-driven algorithms identify patterns and biomarkers that traditional methods simply cannot discern.

"AI is crucial in managing the immense data generated by molecular diagnostics, especially in bioinformatics," said Bernard. "As genetic and genomic data grows in volume and complexity, AI-based systems become essential for processing, analyzing, and interpreting information, streamlining diagnostics and research while revealing new insights into disease mechanisms and therapeutic targets."

"AI has the potential to bridge the gap between molecular diagnostics and complementary techniques such as imaging – integrating in-vitro and in-vivo approaches for a comprehensive understanding of tumors and enhanced treatment options," he added.

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1. MarketsandMarkets Research Pvt. Ltd. Molecular diagnostics market is expected to reach $28.6 billion. MarketsandMarkets Research Pvt. Ltd. Published July 27, 2023. Accessed September 27, 2023. https://www.globenewswire.com/news-release/2023/07/27/2712169/0/en/Molecular-Diagnostics-Market-is-Expected-to-Reach-28-6-Billion-MarketsandMarkets.html.

Kara Nadeau, has 20+ years of experience as a healthcare/medical/technology writer, having served medical device and pharmaceutical manufacturers, healthcare facilities, software and service providers, non-profit organizations and industry associations.

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H. Total	39,780	32,881
I. Percent Paid and/or Requested Circulation	54.09%	67.53%
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LABORATORY INNOVATOR

Leading El Paso's largest clinical lab

By Christina Wichmann

Anita Miles is the Executive Director of **GYN PATH** Services Inc. Anita has led GYN PATH to become the largest pathology lab in El Paso, Texas for over 40 years. GYN PATH specializes in cervical cancer screening, histology, pathology, and molecular microbiology. Anita is focused on helping her community — from managing the first private laboratory focusing on women's health in the City to starting molecular testing to assist the Department of Public Health, local public schools, and the community during the COVID-19 pandemic. The lab performed more than a quarter of a million COVID-19 tests in the first two years of the pandemic. Anita also collaborates with the all-volunteer El Paso Baptist Clinic by donating our Pathologists time to cervical cancer screenings for patients unable to afford them. Additionally, she sponsors events that advocate women's health, specifically the importance of cervical cancer awareness, including triathlons and college health fairs. On top of her busy schedule, Anita volunteers at the Humane Society of El Paso by fostering over 250 puppies and dogs since 2013.

Could you elaborate on how your lab has advanced healthcare services for women in your area?

GYN PATH was founded by my father, Philip A. Miles, MD, FACOG, FCAP in 1982 and specializes in women's healthcare testing. My father, who is board certified in OB/GYN and Pathology, was one of only two in the country with these credentials. Dr. Miles, through his work and experience, knew that there was a link to HPV being the cause of cervical cancer. In the late 90's we saw the potential for liquid based cytology and were the first lab in El Paso to offer ThinPrep® locally. Shortly thereafter, we brought in HPV testing and were the second lab in Texas to bring in Hologic's ThinPrep Imaging system. This technology revolutionized the way we screened and treated patients with abnormal cytological results.

Your laboratory has been described as a "little lab family." What advice or lessons learned do you have for other laboratory directors regarding improving work culture in clinical laboratories?

Everyone must have the same goal; do what is best for the patient and the treating physician. We value and appreciate our team, regardless of the position they hold. Our couriers are just as important as our MT's and we consistently make them aware we cannot operate when any part of our team isn't working as a cohesive unit. We have employees that have worked with us for over twenty years and strive to make sure they know how valuable they are to us, working effectively and efficiently in the best interest of the patients.

What is the most exciting new technology currently being used in your laboratory?

In 2020, we brought in the Aptima™ BV, CV/TV Assay by Hologic Corporation. The improved sensitivity and specificity of this assay over traditional methods in determining the underlying cause of vaginitis not only means identifying the right infection, but enabling the right treatment, and in turn, reducing the potential for recurrent or persistent infections. This FDA-cleared assay is an in vitro nucleic amplification test that utilizes real time transcription-mediated amplification (TMA), which provides an accurate and objective method for diagnosing vaginitis, a very common and complex health issue affecting millions of women each year.

What is one of the biggest challenges you have faced this year? What does the solution(s) look like?

Some of our biggest challenges have been declining reimbursements and the increase in "managed care" contract exclusions in favor of the larger regional and national labs. Our poor economy and increased inflation have been extremely difficult. Some solutions to this would be to reduce regulation, not allow managed care plans to exclude reputable providers, and not allow payers to reimburse providers less than the Medicare rate. We need to remove the middleman and put patients back in control of their health and the type of care they receive. We will never control costs when someone else is paying the bill.

You and your laboratory are involved in numerous charitable activities in the El Paso area! Could you share the details of some of these activities?

We feel it is important to give back to our community. El Paso is primarily a Hispanic community, and we know that cervical cancer is one of the leading causes of deaths in Hispanic women. We want to change that by educating women on the importance of getting screened. One event we sponsor annually is the "Mighty Mujer Triathlon," which is an event for women only that consists of swimming, biking, and running. It's such an inspiration seeing women of all ages participating in this amazing event while their families cheer them on. Another event we have sponsored is our local Humane Society K-9 Walk. While this event is dear to my heart as a foster mom, our goal is to educate women on the importance of getting screened. Cervical cancer is preventable and so are unwanted puppy and kitten litters by spaying and neutering our pets.

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References:

1.White T, Szelinger S, LoBello J, et al. Analytic validation and clinical utilization of the comprehensive genomic profiling test, GEM ExTra®. *Oncotarget.* 2021;12(8):726-739.

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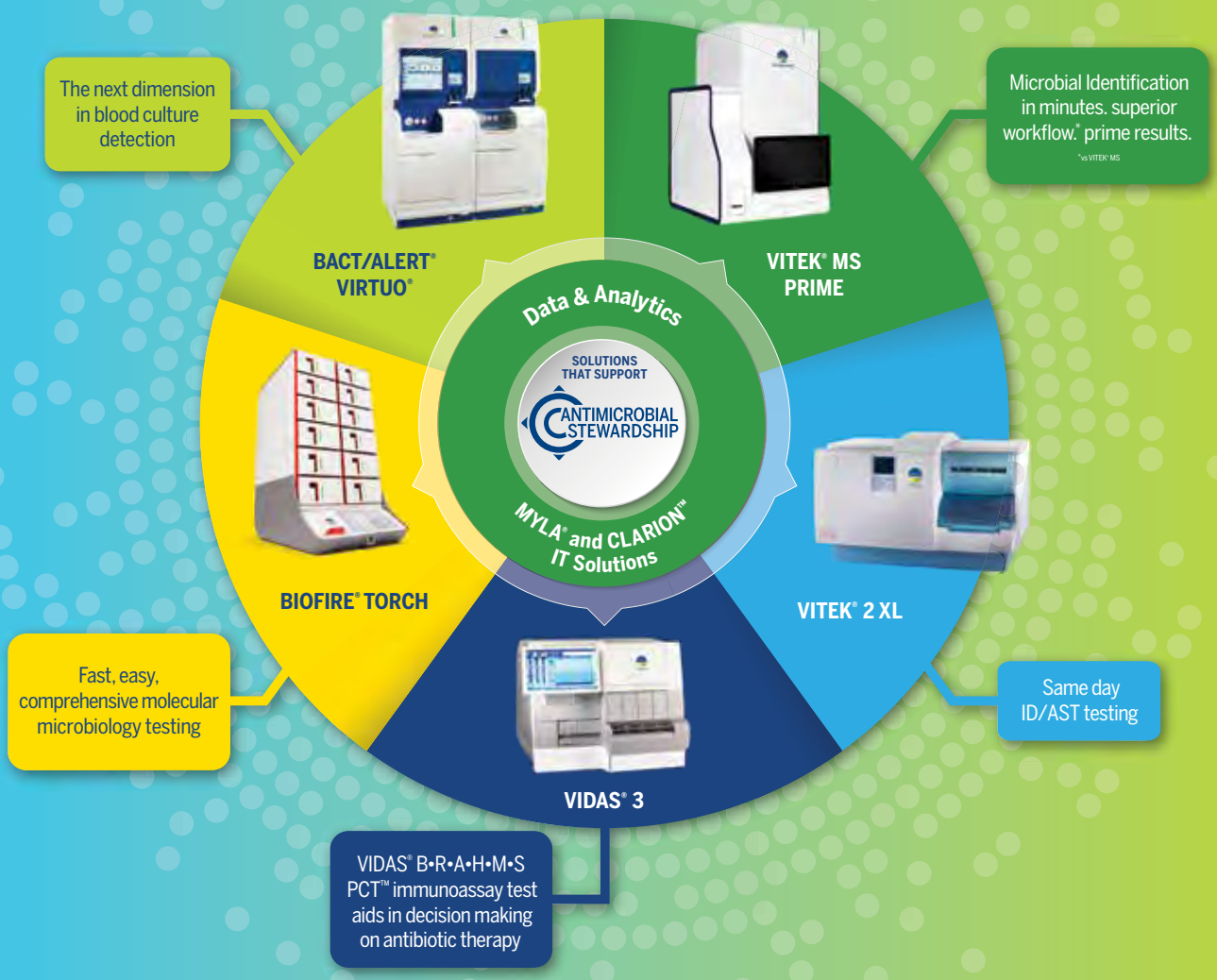

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