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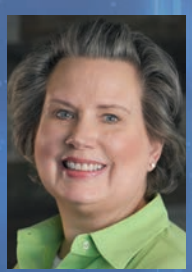

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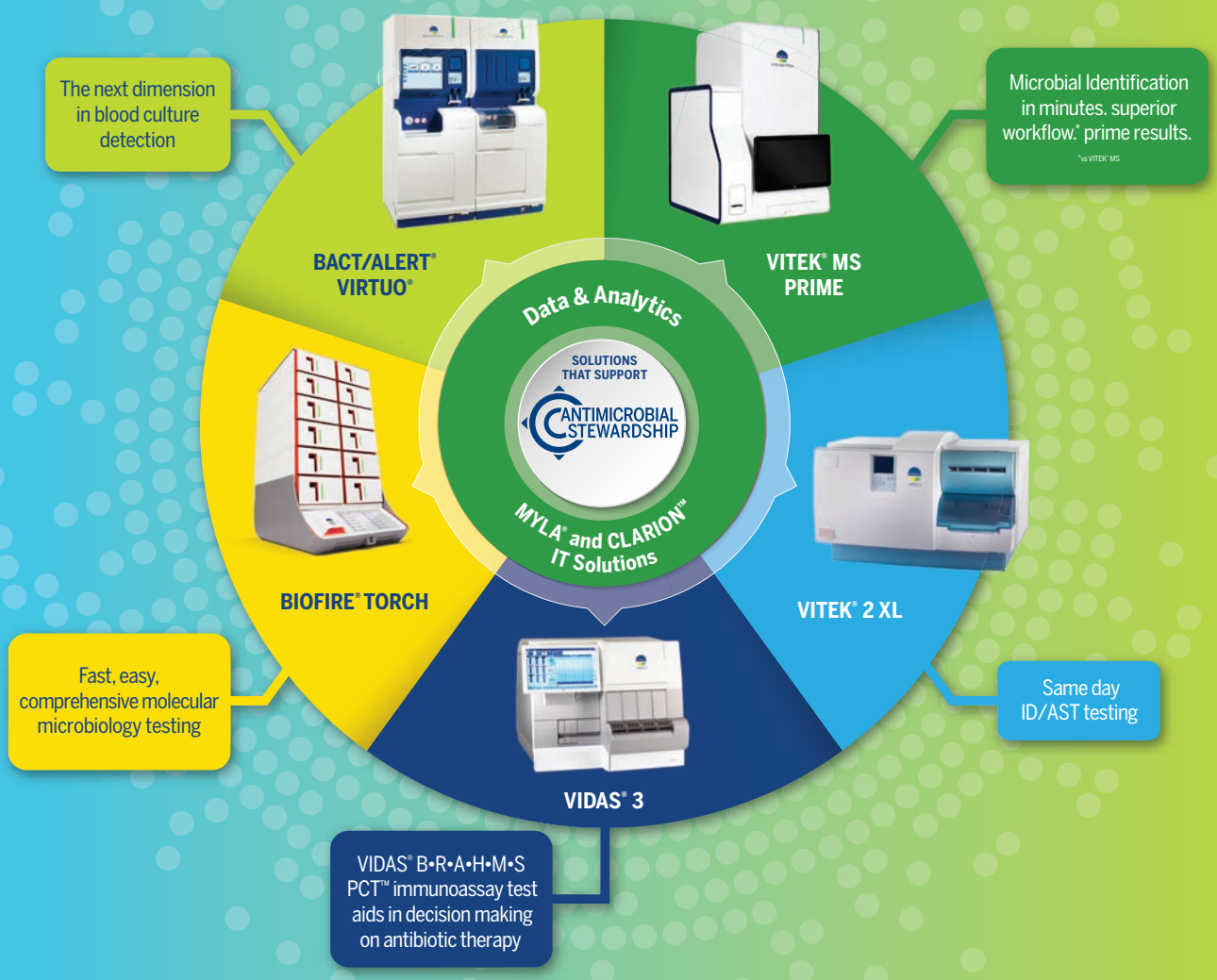

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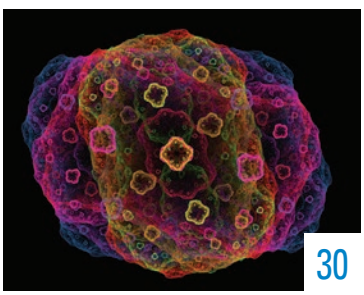
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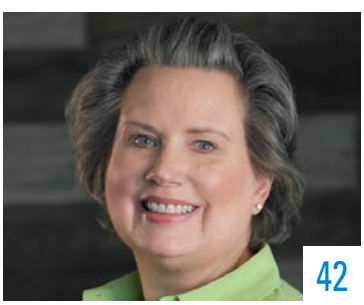
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Are we there yet?

By Christina Wichmann

By Christina Wichmann
Editor in Chief

I am comfortable around technology, but I wouldn't consider myself a techie. I rarely use Siri on my phone. I can never remember which buttons are supposed to be pushed on the iPhone 13 to get her to come on. But I used her a ton during the infamous spring break drive to Florida in 2017! I drove my three kids: 6-year-old twins and a 4-year-old from the Chicago area to Orlando by myself. "Are we there yet?" started about two hours into the trip. By the time we hit Georgia, I was the one who kept asking Siri, "Are we there yet??!?!" to get an ETA on the conclusion of that drive.

The authors of "AI in the clinical laboratory: Fact or science fiction?" (pg. 22) use ChatGPT as an illustration in the beginning of their article to explain the differences between artificial intelligence and machine learning for us. Their article then goes much deeper into artificial intelligence and machine learning in the clinical laboratory.

However, their example stuck out to me. Even though more than 100 million people are using ChatGPT,[1] I was not one of them. So, I set out to learn a little more about this "new thing." I found an interesting article on *Forbes* written by a "world-renowned futurist, influencer, and thought leader in the fields of business and technology" titled, "Revolutionizing healthcare: The top 14 uses of ChatGPT in medicine and wellness."[2] A summary of some of these uses is as follows:

- Virtual assistants for telemedicine: A virtual assistant to help patients schedule appointments and manage their health information.
- Clinical decision support: Provide real-time, evidence-based recommendations to healthcare providers to improve patient outcomes.
- Medical recordkeeping: Generate automated summaries of patient interactions and medical histories.
- Medical translation: Provide real-time translation services to facilitate communication between patients and healthcare providers.
- Medication management: Help patients manage their medications, including reminders, dosage instructions, potential side effects, and drug interactions.
- Patient triage: Triage patients by asking them questions about their symptoms and medical history to determine the urgency and severity of their condition.
- Remote patient monitoring: Monitor patients remotely by analyzing data from wearables, sensors, and other monitoring devices, providing real-time insights into a patient's health status.

I just downloaded ChatGPT on my phone. Right off it has the disclaimer that "ChatGPT may provide inaccurate information about people, places, or facts." I asked it a burning question of mine: "What is the best face cream for middle-aged women?" (LOL) I wasn't too impressed with the answer. Look for hydration (*duh*), anti-aging benefits (*duh*), sun protection (*duh*), and then it ended with advising me to go to a dermatologist for a personalized (i.e., good) recommendation.

Are we there yet? Probably not, but a lot of exciting changes are in the future.

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

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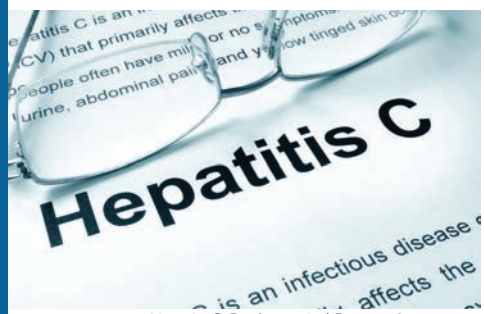

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Fast Facts

Breakthrough cures for hepatitis C still fail to reach the vast majority of Americans who need them

A new Centers for Disease Control and Prevention report suggests the majority of people with hepatitis C still have not been cured nearly a decade after breakthrough treatments that clear the viral infection were first approved in the United States. The findings highlight the urgent need for a proposed national program that would end much of the suffering and death from hepatitis C by eliminating the disease in the United States.

CDC findings:

>2 million

people in the United States have hepatitis C.

>14,800

people died from hepatitis C in 2020 despite the existence of a cure.

1 in 3

adults diagnosed with hepatitis C in the U.S. in 2013-2022 were cured overall.

1 in 4

adults diagnosed with hepatitis C in the U.S. in 2013-2022 were cured without health insurance.

1 in 4

of the cured were under the age of 40.

1 in 6

of the cured were under 40 and cured without health insurance.

Source: https://www.cdc.gov/media/releases/2023/p0629-hepatitis-c.html

Low-dose aspirin may increase risk of anemia in older adults

A recent follow-up analysis of data from an international, National Institutes of Health-funded clinical trial suggests daily low-dose aspirin increases the risk of anemia in people age 65 years and older by approximately 20%. Given these findings, older adults on low-dose aspirin and their care providers may want to consider periodic monitoring of red blood cells or hemoglobin. Anemia in older adults is associated with functional decline, increased fatigue, disabilities, depressive symptoms, and cognition problems.

Published in the *Annals of Internal Medicine*, scientists from the Aspirin in Reducing Events in the Elderly (ASPREE) study examined the effect of long-term low-dose aspirin use on incident anemia and the effect of aspirin on changes in hemoglobin concentration, as well as ferritin levels, as an indicator of iron deficiency. The researchers found that low-dose aspirin led to increased incident anemia in otherwise healthy older adults at enrollment, independent of major bleeding.

Previous ASPREE data analyses suggested daily low-dose aspirin does not decrease risk for dementia and cognitive decline; and that daily low-dose aspirin had no effect on healthy lifespan in older people.

ASPREE, a joint U.S. and Australian research project aimed at determining the effect of low-dose aspirin on survival without dementia or disability, began in 2010 and completed recruitment in 2014. It was a randomized, double-blind, placebo-controlled, primary prevention trial of daily 100 mg of aspirin in a population of healthy older people in the U.S. and Australia with a period of treatment averaging 4.5 years. The trial involving 19,114 people age 65 and older was distinctive for its size, methodological rigor, and high participant retention rate in both countries.

FDA approves cellular therapy to treat patients with type 1 diabetes

The U.S. Food and Drug Administration approved Lantidra, an allogeneic (donor) pancreatic islet cellular therapy made from deceased donor pancreatic cells for the treatment of type 1 diabetes. Lantidra is approved for the treatment of adults with type 1 diabetes who are unable to approach target glycated hemoglobin (average blood glucose levels) because of current repeated episodes of severe hypoglycemia (low blood sugar) despite intensive diabetes management and education.

The primary mechanism of action of Lantidra is believed to be the secretion of insulin by the infused allogeneic islet beta cells. In some patients with type 1 diabetes, these infused cells can produce enough insulin, so the patient no longer needs to take insulin (by injections or pump) to control their blood sugar levels. Lantidra is administered as a single infusion into the hepatic (liver) portal vein. An additional infusion of Lantidra may be performed depending on the patient's response to the initial dose.

The safety and effectiveness of Lantidra was evaluated in two non-randomized, single-arm studies in which a total of 30 participants with type 1 diabetes and hypoglycemic unawareness received at least one infusion and a maximum of three infusions. Overall, 21 participants did not need to take insulin for a year or more, with 11 participants not needing insulin for one to five years and 10 participants not needing insulin for more than five years. Five participants did not achieve any days of insulin independence.

Adverse reactions associated with Lantidra varied with each participant depending on the number of infusions they received and the length of time they were followed and may not reflect the rates observed in practice The most common adverse reactions included nausea, fatigue, anemia, diarrhea and abdominal pain. A majority of participants experienced at least one serious adverse reaction related to the procedure for infusing Lantidra into the hepatic portal vein and the use of immunosuppressive medications needed to maintain the islet cell viability. Some serious adverse reactions required discontinuation of immunosuppressive medications, which resulted in the loss of islet cell function and insulin independence. These adverse events should be considered when assessing the benefits and risks of Lantidra for each patient. Lantidra is approved with patient-directed labeling to inform patients with type 1 diabetes about benefits and risks of Lantidra.

IDSA releases guidance on treatment of antimicrobial-resistant infections

New guidance from the Infectious Diseases Society of America offers timely practice advice for the clinical treatment of three of the most common drug-resistant pathogens. The guidance was updated in June 2023.

Developed by a panel of six infectious diseases specialists with clinical and research expertise in the treatment of AMR bacterial infections, this first-

in-a-series guidance addresses three groups of AMR Gram-negative bacteria that pose particular therapeutic challenges and have been designated as urgent or serious threats by CDC:

- Extended-spectrum β-lactamase producing Enterobacterales (ESBL-E)
- Carbapenem-resistant Enterobacterales (CRE)
- Difficult-to-treat resistance (DTR)-*Pseudomonas aeruginosa*

The AMR field is rapidly evolving, and the treatment of these infections is complex. Updates to this AMR treatment guidance document will occur regularly through an iterative review process that will incorporate new evidence Furthermore, the panel will expand recommendations to include other problematic Gram-negative pathogens in future iterations.

Experts acknowledge that the ability to address rapidly evolving topics such as AMR is limited by prolonged timelines needed to generate new or updated clinical practice guidelines. As an alternative and a complement to comprehensive clinical management guidelines, which can take several years to produce and publish, IDSA endorsed developing more narrowly focused guidance documents for the treatment of some infectious diseases. These documents will address specific clinical questions for difficult-to-manage infections that are not covered by present guidelines.

Experts say the risk posed by AMR pathogens is compounded by the COVID-19 pandemic because patients who are hospitalized after contracting the novel coronavirus can become further sickened by infections that are difficult to treat without antibiotics.

Because COVID-19 patients are often given a broad spectrum of antibiotics when they enter a hospital, it changes their microbiomes – a major concern of physicians. Infectious diseases experts say they are constantly learning more about the complications of this new disease, as well as how and when to use antibiotics to treat infections in patients with COVID-19.

Announcing the physical activity guidelines midcourse report on older adults

The U.S. Department of Health and Human Services released the *Physical Activity Guidelines for Americans Midcourse Report: Implementation Strategies for Older Adults* (Midcourse Report). The Midcourse Report is a guide to help policy makers; exercise and health professionals; healthcare providers; gerontologists; built environment professionals; local, state, territorial, and tribal leaders; and others working with older adults implement strategies to support physical activity among adults ages 65 years and older.

The Physical Activity Guidelines for Americans (Guidelines) serve as the primary, authoritative voice of the federal government for evidence-based guidance on physical activity, fitness, and health for Americans. Less than 15 percent of older adults meet the recommendations outlined in the Guidelines. The Midcourse Report aims to change this by highlighting effective strategies and interventions to increase physical activity levels among older Americans while reinforcing the message that physical activity can begin or restart at any age.

Materials are available for older adults and healthcare providers, including videos, social media messages, fact sheets, posters, and the newly updated Activity Planner in English and Spanish.

Researchers show how a tumor cell's location and environment affect its identity

Using 3-D models of ovarian cancer tumors, scientists found differences in gene activity based on where a cell is in a tumor, demonstrating how a cell's location and environment in a cancerous tumor can strongly influence which genes are active and the cell's role in the cancer's biology. More specifically, the team co-led by researchers at the National Center for Advancing Translational Sciences (NCATS), part of the National Institutes of Health, showed that gene activity in cells at or near a tumor's surface differed from that of cells closer to the tumor center.

The approach pairs the use of a technology to reveal the genetic activity of single cells within a tumor with fluorescent dyes that spread into tumors. The work could allow researchers to study how the same diseases can vary in people and progress differently. This research could help clinicians identify treatment strategies focused on specific areas in tumors, which could lead to better therapies for cancers and other diseases. The team reported its results June 21 in *Cell Systems.*

CDC recommends RSV vaccine for older adults

CDC Director Rochelle P. Walensky, M.D., M.P.H., endorsed the CDC Advisory Committee on Immunization Practices' (ACIP) recommendations for use of new Respiratory Syncytial Virus (RSV) vaccines from GSK and Pfizer for people ages 60 years and older, using shared clinical decision-making.

Adults at the highest risk for severe RSV illness include older adults, adults with chronic heart or lung disease, adults with weakened immune systems, and adults living in nursing homes or long-term care facilities. CDC estimates that every year, RSV causes approximately 60,000–160,000 hospitalizations and 6,000–10,000 deaths among older adults.

These new vaccines are expected to be available this fall.

WHO outlines 40 research priorities on antimicrobial resistance

The World Health Organization (WHO) has published its first global research agenda for the world's scientists to address the most urgent human health priorities to combat antimicrobial resistance (AMR). It outlines 40 research topics on drug-resistant bacteria, fungi and *Mycobacterium tuberculosis* that must be answered by 2030, in line with the Sustainable Development Goals.

The WHO Global Research Agenda for AMR in human health will catalyze innovation and implementation research, spanning the epidemiology, burden and drivers of AMR, context-specific and cost-effective strategies to prevent infections and emergence of resistance.

It will also involve the discovery of new diagnostic tests and improved treatment regimens, the identification of cost-effective methods to collect data and translate it into policy, as well as how to implement current interventions more efficiently in resource-limited settings. Ultimately, the generated evidence will inform policies and interventions to strengthen the response to antimicrobial resistance, particularly in low- and middle-income countries.

The research agenda was developed based on a review of over 3000 relevant documents published over the past decade. The review identified 2000 unanswered questions or knowledge gaps, which were further consolidated and prioritized by a large group of AMR experts to conclude with the 40 most pivotal research topics. A summary report containing the research priorities is available.

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Applying laboratory quality principles to real world point-of-care testing systems

By Kathleen David, MT(ASCP), Jeanne Mumford, MT(ASCP)

In the Continuing Education article in the April 2023 issue of *MLO*, laboratory quality management systems were discussed and details provided on each component.[1] When it comes to maintaining quality in point-of-care testing (POCT), we are often presented with very different sets of challenges than our laboratory counterparts. While POCT is subject to the same CLIA regulations, minimal guidance is offered on how to meet those needs in POCT systems. One challenge is that testing personnel who perform POCT are non-laboratorians, meaning that some of the guidance available may not be written in language that non-laboratorian staff can easily understand. Another is that POCT is performed in a variety of settings that can include hospital units, ambulatory sites such as doctors' offices, and a variety of other settings. A final challenge is understanding local, state, and/or federal laboratory regulations. Laboratory staff will have a basic understanding of regulations through schooling and on-the-job training, however, clinical staff whose background and training is strictly focused on patient care, may not have the same knowledge of these requirements.

When setting quality standards in POCT, no national standards exist for quality improvement management. The most common metrics measured for improvement across POCT systems include patient identification (ID) errors, ID limit errors, specimen collection errors, and manual test result entry errors. As stated in the July 2020 "AACC Guidance Document on Management of Point-of-Care Testing" published in *JALM*, "A quality assurance program is vital to managing errors and the reliability of POCT results."[2] The purpose of this article is to directly compare the contents of the April 2023 *MLO* article on laboratory QMS in order to help the reader relate the Quality System Essentials that can be utilized in a POCT system. We will specifically discuss how the key components of a laboratory QMS can be developed to addresses the many challenges in POCT.[3]

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LEARNING OBJECTIVES

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

1. Discuss the need for a quality management system (QMS) in point-of-care testing (POCT).
2. List the quality system essentials that are recommended for a laboratory QMS.
3. Describe how each quality system essential can be applied to a POCT program.
4. Differentiate between quality assurance (QA) and quality control (QC).

Quality system essentials

In the following paragraphs, we will breakdown the components, or essentials, of a laboratory QMS. Then, we'll add practical

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Can you auto-recertify?

Managing Devices
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Manual Test Entry Results
From a device or your system?

Measuring POCT Performance
Is my program what it should be?

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examples of how these can be applied to support and improve a POCT program. These essentials may be applied to any size POCT program to include a large health system or a small doctor's office practice.

Organization and supervision

Because POCT is usually performed by staff who do not report to the laboratory, it is essential that lines of communication are clear and defined. The person designated to manage and oversee the point-of-care program should have the necessary credentials, and the CLIA medical director responsible for POCT has clear authority over all testing under the laboratory's CLIA license. Medical laboratory scientists with more than three years of laboratory experience are ideal staff to oversee point-of-care testing. We refer to this person as a point-of-care coordinator, POCC for short. This person is best served with experience in laboratory quality assurance projects.[4] In addition to the CLIA laboratory medical director, the point-of-care coordinator, and representation from other disciplines within your healthcare system should be invited to form a committee to oversee the quality of your POCT program.[2,5]

Personnel

In most cases, testing is performed by non-laboratorians, who are not under the laboratory's supervision. They are nurses, nurse techs, perfusionists, medical aids (MA), certified nursing assistants (CNA), emergency medical technicians (EMT), and other hospital staff. They do not have a background in laboratory medicine yet must understand basic laboratory principles to be successful in testing patients. They need adequate training not only for the testing they perform, but also for laboratory practices like quality control performance. Competency assessment as required by regulations is important to ensure that testing is performed correctly, and results are accurate.

Evidence-based medicine shows that an effective POCT program begins and ends with robust training and competency assessment of operators and testing personnel.[5] Taking the time to invest in training of your POCT operators can be optimized by focusing on unit trainers or superusers. Trainers or superusers are a core group of testing personnel who obtain and utilize additional skills and knowledge of the POCT systems and who will train new personnel and troubleshoot as needed.

Equipment

Unlike equipment purchased in the laboratory, most point-of-care devices are purchased by the units and clinics that use them. The devices must still be validated for use, especially nonwaived devices. Regulatory requirements state what must be validated/verified before patient testing can begin for both waived and nonwaived devices. Laboratory staff overseeing point-of-care testing must ensure that device maintenance is performed and documented. Laboratory staff should understand how to troubleshoot issues with the devices and kits and know when to contact the point-of-care staff.

Purchasing and inventory

Point-of-care devices and supplies are not usually ordered and managed by the laboratory. However, depending on the organization, supplies may be held in the laboratory. If supplies are kept outside of the laboratory, then the point-of-care coordinator must ensure that they are being kept at the appropriate temperature and humidity.

Documents and records

Procedures covering testing that is performed outside of the laboratory must be available to those performing the testing. If the laboratory document control system only allows access to laboratory personnel, there must be a process to make the documents available for testing personnel. Logs must be developed and managed for quality control and temperature/humidity monitoring and be made available to operators.

Process control

To monitor quality in the analytical phase of testing, quality control (QC) is essential. This involves materials that have known concentrations of the analyte in question, which must be performed at intervals specified by regulations. This is true in POCT as well. POCT is performed by personnel who have not had laboratory training, and who therefore do not have a good understanding of what quality control is, and how important it is to accurate results. There is a feeling that any result obtained is acceptable. Many nonwaived POCT devices have internal controls and are eligible for Individual Quality Control Plans (IQCP). Studies are done to determine if QC can be done less often than the CLIA-required two levels of QC per day. A risk assessment is performed, and non-laboratory personnel must be part of the risk assessment. Using an IQCP saves money and time from doing daily QC, while ensuring that the accuracy of results is maintained.[4]

While quality control materials are used to initially verify the lab values obtained on the POCT are accurate and that the tests are performing according to the manufacturer's specifications, quality assessment is a process that should be consistent and utilized to monitor the QC performed on your tests.[4] Quality assessments should be written in a policy and reviewed annually by the CLIA laboratory medical director.

Information management

For any laboratory, managing information is essential. This includes both incoming information such as patient demographics, test requests, and specimen type; and outgoing information such as results, units of measure, test comments, and performing laboratory. Many POCT programs utilize a middleware product that serves as device manager as well as a mechanism to get results from the POCT devices to the laboratory information system and then to the hospital information system. The current middleware products on the market can enhance the useability of instruments and allow for QA measures such as operator management, QC lockout, and QC review. These products also allow for the ability to pull data on patient results that can help with improving or eliminating challenges with patient identification errors.

Occurrence management

Because testing is performed by non-laboratorians, it can be more difficult to manage occurrences. Occurrences are defined as variants to the testing procedure. Two of the strategies developed to mitigate this are operator lockout and QC lockout. The first ensures that only those trained and checked off to use a device have access to use it for patient testing. The second ensures that patient testing is not performed until after QC has been performed as scheduled and is acceptable. Some devices designed for point of care use have both features and some can be managed through the middleware products available. However, there are still point-of-care tests that are either manual or performed on legacy devices that don't have the ability to do lockouts. These tests may require ingenuity to monitor for occurrences.

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Assessment

Point-of-care testing is, by definition, performed outside of the laboratory. Most programs are spread over an entire hospital, and possibly other sites such as clinics, urgent care, and physician offices. This means that assessments will need to be done at all of the relevant sites. Most POCT programs perform routine audits of the testing sites by assessing quality control performance, reagent labeling, temperature/humidity monitoring, maintenance records for devices, and test performance by on-site operators. Having devices interfaced and using middleware to monitor processes are extremely helpful. The POCT team can monitor operator competency compliance and QC performance. In addition, many programs perform internal quality assessments, having the organization's quality team perform audits.

External assessment objectively assesses the performance of testing. Proficiency testing involves unknown specimens sent from an external agency and will assess several aspects of test performance: proper testing protocol, specimen identification, documentation, environmental issues, etc. Investigating proficiency testing failures can bring to light issues that should be addressed in training for operators. If the POCT program is under the same regulatory agency, then non-waived tests must be compared to the laboratory instruments doing the same tests, which is another method for ensuring the quality of POCT results. In addition, POCT programs are subject to inspection by regulatory and accreditation agencies, which will identify any issues with test performance and quality processes.

Customer service

Customers for POCT are generally considered to be clinicians who order/use the tests and nursing personnel who perform the testing. A test request process should be in place to assess the requests. Many POCT programs have a committee comprised of POCT personnel, POCT laboratory medical directors, unit managers/directors, educators, hospital administration, and other departments such as purchasing, quality, infection control and others that have a stake in implementing testing. Standardizing the devices and kits used for POCT is advised. Point-of-care tests are often seen as less accurate than lab tests, and disseminating information on the comparison testing between lab and point-of-care devices can help clinicians feel confidence in POCT results.

Process improvement

Quality indicators, including assessing manual testing quality control errors, compliance with cleaning devices used at the patient bedside, and proficiency testing performance, can be used to improve processes. Internal audits of processes can bring to light issues that must be addressed and resolved to improve the program. In addition, customer service surveys can be done for testing personnel, as well as unit managers/directors and educators, to ensure that the training and competency programs are meeting the needs of quality patient testing.

Facilities and safety

By definition, point-of-care testing is performed outside of the laboratory, and some requirements will be different. Noncompliance with laboratory safety requirements must be explained to the POCT users, as they will not all be familiar with these. It is essential to work with hospital safety, infection prevention, and facilities to ensure that issues relevant to performing laboratory testing are followed. For instance, performing molecular infection disease testing might require a safety shield and testing for contamination. Temperature and humidity monitoring could also be required and needs to be reviewed by POCT staff.

Culture of quality

It is important that point-of-care testing be conducted in the same way and with the same care as testing performed in a laboratory. Test results used for treatment, monitoring, or diagnosis of patients must be consistent no matter where it is performed.[6,7] Quality management of a POCT program needs to be as rigorous and comprehensive as that of a laboratory program. There are differences between the two modalities, but in the final analysis, the patient deserves results that are accurate no matter where they are performed. A POCT quality management program will assure that the test results are high quality and accurate for those clinicians and nursing personnel that rely on them for patient care.

Quality assurance is a key component to a successful POCT program and should be considered in all stages of testing. Quality improvement by way of monitoring data to improve patient safety is also key to ensuring success in POCT.

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Jeanne Mumford, MT(ASCP) is the Pathology Manager for Point-of-Care Testing (POCT) for **Johns Hopkins Medicine**. Jeanne offers 23 years of experience in point-of-care testing regulatory oversight, quality assurance projects, and laboratory inspection preparedness and planning as a medical laboratory scientist. She participates in many professional organizations including the Critical and POCT Division of AACC and the CLSI Expert Panel for POCT.

Applying laboratory quality principles to real world point-of-care testing systems

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TEST QUESTIONS

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1. **POCT must be performed under _____ regulations.**
   - A. CAP
   - B. CLIA
   - C. FDA
   - D. CDC

2. **What is/are the identified challenges in a quality POCT program?**
   - A. Testing is performed by non-laboratorian personnel
   - B. Testing is performed in a variety of settings
   - C. Understanding regulations in local, state, and federal laboratories
   - D. All of the above

3. **There are no national standards set in POCT quality standards.**
   - A. True
   - B. False

4. **The most common metrics that are measured for quality improvement in POCT are**
   - A. User ID errors and patient ID errors
   - B. Patient ID errors, ID limits errors, result entry errors
   - C. Result entry errors, user ID errors, patient ID errors, and specimen collection errors
   - D. Patient ID errors, ID limit errors, specimen collection errors, and result entry errors

5. **There are _____ quality system essentials that can be applied to develop a successful quality management system in POCT.**
   - A. Five
   - B. Nine
   - C. Thirteen
   - D. Twenty

6. **To develop clear and defined lines of communication, it is recommended that an MLS with more than ____ years of experience should oversee POCT as the point-of-care coordinator (POCT).**
   - A. Two
   - B. Three
   - C. Five
   - D. Eight

7. **The _____ quality system essential should focus on taking the time to offer robust training and competency of POCT operators and to designate a unit trainer/superuser for optimization.**
   - A. Organization and supervision
   - B. Personnel
   - C. Process control
   - D. Assessment

8. **The QSE for equipment explains that devices must be validated and verified before patient testing only for waived devices.**
   - A. True
   - B. False

9. **The management of device and supply inventory involves the POCT to ensure supplies are kept**
   - A. The proper distance from patients
   - B. In a locked room
   - C. In abundance
   - D. At the appropriate temperature and humidity

10. **Accessible procedure manuals and QC logs are recommended under the _____ quality system essential.**
    - A. Personnel
    - B. Purchasing and inventory
    - C. Documents and records
    - D. Process control

11. **The process control quality system essential monitors**
    - A. QA ad QC
    - B. Storage conditions of supplies
    - C. Training of personnel
    - D. Documentation of variants in the testing procedure

12. **Information management includes which types of information?**
    - A. Patient demographics, test requests, and specimen type
    - B. Results, units of measure, test comments, and performing laboratory
    - C. Both A. and B.
    - D. None of the above

13. **Operator lockout and QC lockout are strategies to control**
    - A. Assessment
    - B. Occurrence management
    - C. Customer service
    - D. Process improvement

14. **The assessment quality system essential involves routine audits, ordering operator competency compliance, and device QC performance.**
    - A. True
    - B. False

15. **What can help the clinician feel confident in the reliability of POCT results?**
    - A. The cost of the device
    - B. The brand of the device
    - C. Running the sample multiple times on one patient
    - D. Providing information on the comparison testing between laboratory analyzers and the POCT device

16. **The _____ essential uses customer surveys for testing personnel.**
    - A. Process control
    - B. Process improvement
    - C. Customer service
    - D. Facilities and safety

17. **The facilities and safety quality system essential involves detailed explanation of**
    - A. Safety requirements
    - B. Testing for contamination
    - C. Temperature and humidity monitoring
    - D. All of the above

18. **Rigorous and comprehensive quality management of a POCT program conducted in the same way and with the same care as testing performed in the laboratory describes the _____ quality system essential.**
    - A. Culture of quality
    - B. Facilities and safety
    - C. Process improvement
    - D. Customer service

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Dear API Abby

By Danielle Casey, MBA, MLS(ASCP)CM; Anita Hoeksema, MS, MLS(ASCP)CM; Sue Styles, MSI

The American Proficiency Institute (API), a global leader in proficiency testing programs, is dedicated to improving the accuracy and efficiency of clinical laboratory testing. Known for its constant innovation in the field, API offers technical expertise and checklists to help its laboratory customers become more proficient. Below, API's Technical Support Manager, Anita Hoeksema; Quality and Compliance Manager, Sue Styles; and Technical Support Specialist, Danielle Casey offer a series of commonly asked questions with responses aimed to improve laboratory quality.

Dear API Abby:

Our main hematology analyzer, we nicknamed it Oscar, is ready to retire. Our laboratory is seeking an instrument replacement. Will we need to switch our proficiency testing program?

Thank you,
Lost Without Oscar

Dear Lost Without Oscar:

It can be challenging when those stalwarts we have worked with for so long meet their expiration dates. As you investigate those new instrument opportunities, you will need to ensure you have the correct proficiency testing program to match. Most hematology analyzers that test complete blood count with differential will require a proficiency program specific to that analyzer. When you are ready to make the switch, contact your proficiency testing provider to make certain you are enrolled in the correct program.

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Dear API Abby:

I received my proficiency testing evaluation today and, to my dismay, a failure was received! After taking deep breaths and going for a walk, I found my resolve to dive into the cause of this failure. Please help, what do I do now?

Anita Pass

Dear Anita Pass:

You took a positive first step already — when embarking on any stressful situation, it is important to be calm and ready to think rationally. Next, be sure to involve your testing personnel and laboratory director in the investigation, remedial action, and documentation process. Failures can occur for a variety of reasons. API provides a "Corrective Action Checklist," which will help walk you through investigating sample handling, clerical errors, quality control matters, calibration issues, instrument problems, and reagent concerns. Remember, it is important to review past patient results that were reported during the period when your proficiency testing was unsatisfactory! You need to ensure that patient results were not affected or potentially affected during this time. Work closely with your medical director to make certain you have addressed the issue, once identified, and have taken the appropriate mitigation measures going forward.

Dear API Abby:

My co-worker and I are having a disagreement that we hope you will resolve. On our last proficiency test evaluation, we received a score of 100% in the performance summary for our urine adulteration testing. Yet, looking at the comparative evaluation, it shows our result is "not graded." My co-worker believes we should do something with this analyte since it was not graded. I think, since we received a performance score of 100%, we do not need to do anything additional. Who's right?

Resting on My Laurels

Dear Resting:

Your co-worker is 100% correct. You do need to review the comparative evaluation and assess your result. You should compare your results to the expected result(s). If your result falls within the expected range, document that your laboratory obtained the correct response. If your result(s) does not fall within the expected range, you should troubleshoot to determine the cause of the failure. If the expected results are not available, you may need to complete an alternative assessment.

Dear API Abby:

Sorry, but I really dislike doing proficiency testing. I feel this is a waste of our time and resources. Why do we have to do so many?

Ima Bizze

Dear Ima:

Proficiency testing is used to verify the accuracy and reliability of the analytes for which you are testing. It can identify subtle shifts and trends that may not be as evident with quality control. Proficiency testing may be used to validate pre-analytical, analytical, and post-analytical processes, which helps to assess too the competency of testing personnel. Importantly, if problems linger, patient results may be affected.

There are certainly times in life when we must complete tasks we do not like, but knowing that accurate laboratory results are so critical to patients is something that motivates me to action. If that's not enough, remember that proficiency testing is required by the federal government and laboratory accreditation agencies.

Dear API Abby:

Our medical director just approved the use of ten point-of-care (POC) devices that will be used for reporting patient INR (international normalized ratio) results. Ten! How am I going to perform proficiency testing on all of these point-of-care devices?!? We already perform proficiency testing on the main laboratory coagulation instrument, and now I have these additional ones. What should I do?

Counting POC in My Sleep

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Dear Counting:

It's good of you to be concerned when considering proficiency testing for multiple instruments. The Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations state that if a laboratory uses multiple methods to test an analyte, then one instrument/method should be designated as the primary method. Proficiency testing should be performed on that specific analyzer. This scenario may match what you have with your coagulation instrument in your main laboratory, and your POC devices throughout the hospital.

Laboratories should not test proficiency samples during the proficiency testing event with more than one instrument — unless that is how they test all patient specimens. After the primary test due date, your ten POC devices may have proficiency testing performed. API offers verification programs just for this purpose. Laboratories are directed to test verification samples after the proficiency testing due date and submit results online. Verification evaluations are available online when the evaluations for proficiency programs are also released.

The convenience of using proficiency samples and statistics to verify secondary instruments and methods, all while remaining compliant with CLIA regulations, is beneficial to busy laboratorians like you. Plus, you may assign the proficiency test to personnel performing the testing on the hospital floors to help document their competency when performing testing.

Dear API Abby:

I hear so much about wildfire season in the west and hurricane season along the coasts. What happens during these natural disasters if laboratories are unable to do proficiency testing? How can I be prepared if something like this threatens my lab?

Nervous Nellie

Dear Nellie:

We applaud you for thinking of risks ahead of time. Risk management is very important! Regardless of the situation, if you are still testing patients, you still must perform proficiency testing. Proficiency testing providers do not have the authority to excuse you. You will usually have at least two weeks to complete your proficiency testing. Be aware of when your proficiency testing is coming, and don't leave it until the last minute.

If the natural disaster has a significant impact on your area and patient testing is down for the whole period, communicate and document the situation. CLIA requires that you notify your state or accreditation agency and your proficiency testing provider for consideration to be given. Since you already sound like a planner, you could add their contact information and your proficiency testing schedule to the packet of emergency contact information.

If you are able, access your proficiency testing provider's website, complete your result reporting, and indicate that your testing was down for a period of time. This will prevent the 0% scores that proficiency testing providers are required to issue if they do not hear from you. Also document the communication made to your state or accreditation agency. Keep records of when testing was down and when it resumed, the impact of the disaster (e.g., power outage, flooding), and your laboratory's subsequent capabilities. This documentation will be reviewed at your next inspection. Hopefully these tips will help you have your proficiency testing covered.

Dear API Abby:

My laboratory switched proficiency testing providers this year. My friend works at a laboratory that did the same and they had some trouble at first. She can be a bit negative, so it's tough to tell if it was sour grapes or if she truly had problems. Do you have any tips for things to watch out for during this transition?

Hopeful for Smooth Transitions

Dear Hopeful:

A positive and "can-do" attitude is always helpful in approaching any change. From our experience, most laboratories are aware that they should first read sample storage instructions and testing instructions carefully. Reviewing method lists from your new provider to make the correct choice for each of your tests is also kind of obvious, but plan time to ask questions because method choice can affect how your results are evaluated. Also, while you are likely to read website instructions the first time you submit results, be sure you get a confirmation screen acknowledging results have been received! The confirmation should have a date and time listed, or some sort of record that looks like a "receipt" for your transaction. If you aren't sure, submit your results early and call your new provider to confirm receipt. This will avoid getting a failure to participate for your first event due to something small and easily preventable.

What might trip you up may relate to any samples you still receive from your old provider and reviewing your evaluation reports from your new provider. If you are still receiving samples from your old provider, make sure you tell them about any analytes you will not be reporting to them anymore. If you don't, they may continue to expect results from you and could issue you a 0% score. This is considered a clerical error that they cannot remove, so make sure to keep in touch with them ahead of time.

Regarding evaluations from your new provider, make sure you understand how any "not graded" samples are indicated so you may follow up on them. Ask for a tutorial or webinar that may go over the features of the report or how to find any statistical information you need. This may help you complete any internal documentation so you may put that successful proficiency testing behind you and move on to the next item on your to-do list!

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Prioritizing safety in phlebotomy: An overview of best practices

By Clinical and Laboratory Standards Institute

Safety is an important concern for both patients and phlebotomists (and other healthcare providers who perform blood draws). Many avoidable errors that pose significant risks to the patient and the phlebotomist can occur during the collection and handling of blood specimens. When standards aren't implemented, it becomes more likely that patients will be injured, biologically representative specimens won't be obtained from patients, and test results won't be comparable from one facility to another.[1] Throughout this article, "must" is used to indicate a requirement to be followed in order to conform to the standard and from which no deviation is permitted, while the term "should" allows for user discretion.

Each year, specimen collection personnel who deviate from the standard for the phlebotomy procedure injure patients. Some of the most frequent mistakes that can lead to a breach in patient safety are as follows:[2]

- Misidentifying the patient/mislabeling the specimen
- Probing instead of surrendering to a missed vein
- Attempting to draw blood from the first vein found
- Disregarding patient-reported shooting pain during blood draw
- Bandaging in a hurry/not applying pressure to the blood draw site following the procedure
- Drawing from an artery
- Turning ones back on a patient
- Improper positioning of the patient
- Drawing from unorthodox sites

Implementation of a quality management system (QMS) (now referred to as a management system [MS] by ISO) is required for a laboratory to fulfill quality objectives.[3] The MS can be divided into 12 quality system essentials (QSEs), which are the foundational building blocks that support the laboratory's path of workflow.[4]

Facilities and safety for phlebotomy

QSE "Facilities and Safety Management" relates to the laboratory's physical environment and the maintenance and safety programs needed to support it. The facility must ensure that the physical environment for venipuncture procedures and the safety program reflect MS requirements. Facilities must have a policy that includes the disinfection of phlebotomy trays and carts, equipment, and outpatient collection stations on a scheduled basis and, at minimum, whenever contaminated with visible blood or other potentially infectious material.

Specific requirements and recommendations for QSE "Facilities and Safety" for phlebotomy follow.

Hand hygiene

When performing phlebotomy, always change gloves between patients, when glove integrity has been compromised, or when gloves become visibly contaminated. The room should have facilities to allow the phlebotomist to wash their hands between patients.[1] Wash hands with soap and water after glove removal and before donning new gloves. Hands should also be washed at the following times:[5]

- After touching potentially infectious materials.
- After removing gloves.
- After the completion of work (e.g., when completing procedures in one laboratory area and moving to another area to perform different work).
- Before leaving the laboratory.
- Before eating, drinking, smoking, applying makeup, applying lip balm, changing contact lenses.
- Before and after using lavatory facilities.

Venipuncture chairs

Venipuncture chairs should be designed for the maximum comfort, accessibility, and safety of the patient and phlebotomist. Both armrests of the chairs should be adjustable so the best venipuncture position for each patient can be achieved. Chairs without arms do not provide adequate support for the arm or protect fainting patients from falls and must not be used. If the chair has wheels, the chair must be secured to prevent movement during the procedure.[1]

Phlebotomy area

The collection area must be set up to facilitate patient monitoring throughout the procedure. In addition, the following elements should be considered when designing the phlebotomy area:[1]

- A central desk should be considered to serve as a dedicated area for processing daily and future test requests. It should contain a telephone system for handling emergency test request calls, including a paging system for contacting any phlebotomist who is collecting specimens outside the central area. The central desk may also be used to greet patients and to enter their information into the paper or electronic database.
- Phlebotomists should perform venipuncture in a clean, well-lit, quiet, and private environment. Reasonably soundproof rooms for pediatric patients should be considered.
- Work benches and tables should be set up in an ergonomic manner for the phlebotomist to function with minimum physical stress. Supplies should be placed within reach.
- The storage area should be large enough to accommodate necessary supplies.
- Counter space should be adequate and clean for efficient specimen sorting, labeling, and handling.
- The reception and collection areas should be designed for maximum protection of patient privacy and confidentiality.

Accessibility

Facilities should be designed and furnished to accommodate any patient. Considerations need to reflect regional guidelines and standards. The following considerations are highly recommended:[6]

- Allow or make modifications to policies, practices, and procedures to make healthcare services fully available to individuals with disabilities.
- Remove physical barriers to services when possible. If not possible, offer adequate services without barriers to ensure safe delivery of specimen collection services in an alternate setting or location.
- When redesigning and building new facilities, it is recommended that applicable regional guidelines and standards regarding accessibility be consulted.

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The facility should have the following:

- An entrance of sufficient width to allow access to the outpatient phlebotomy area.
- A clear path to the collection station.
- Adequate space on either side of the phlebotomy chair, wheelchair, stretcher, table, etc., to allow for safe and effective transfers and collection of blood specimens. Do not place a phlebotomy chair, wheelchair, or table against a wall in such a way that it prohibits access to one side of the patient.
- Suitable devices, such as a mobile phlebotomy chair arm for wheelchair-bound patients, to ensure an adequate and safe surface to complete the procedure.
- A minimum space of 30 inches (76 cm) wide and 48 inches (122 cm) deep on one side of the phlebotomy chair (e.g., accessible to a patient on crutches).
- Sufficient turning space in the phlebotomy area or room for a patient in a wheelchair to make a 180° turn.
- At least one bariatric-size chair for patients who need additional space.
- Reclined or reclining furniture in the vicinity to lay a patient in a recumbent or semirecumbent position due to syncope risk. In large outpatient collection centers, two recliners or a suitable alternative are recommended in case one is occupied.
- Hydraulic chairs to raise and lower patients to adequate height, which may help prevent back problems for the phlebotomist.
- Wedges, blankets, pillows (with disposable case), and other devices that may be helpful in positioning a patient.
- Phlebotomy chairs with movable arms and reticulating surfaces to help move patients to and from the chair.

Conclusion

Many avoidable errors can occur during the collection and handling of blood specimens. Following established standards can reduce these errors and improve safety for patients and phlebotomists.

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AI in the clinical laboratory: Fact or science fiction?

By Geoff Parker, David Sanders BSc, MSc

In the realm of computer science, artificial intelligence (AI) focuses on developing machines that mimic human intelligence to perform intricate and complex tasks. The ultimate goal of AI is to develop system interfaces that are so instinctive and natural that observers feel as though they are interacting with another human being.

Machine learning (ML) is one of the methods used to create and analyze the datasets used by AI. Machine learning does not rely on a programmer to specify the equations used to analyze data. ML looks for patterns and can 'learn' how to process data by examining data sets and expected outcomes.

ChatGPT has become a ubiquitous example in discussions surrounding AI and ML, from news reports to casual conversation by the coffee machine. ChatGPT is a highly effective computerized question and answer service that allows users to ask questions in plain everyday conversational language. The system provides incredibly detailed and well considered responses as if from a person who is an expert in the relevant field.

How do our definitions above fit with the ChatGPT example?

AI – ChatGPT uses technology called natural language processing to interpret the text of the question submitted.

ML – ChatGPT's underlying technology uses machine learning to match the core components of the question identified by its AI component to search its vast collection of data sources to locate suitable answers.

AI – In the final step of the process, ChatGPT again uses AI to compose a coherent well-structured response to the question.

Where is AI and ML used in clinical laboratories today?

When looking at the current state of AI/ML in the laboratory, one of the most prevalent uses involves the recognition of patterns in images:

- Whole slide pathology imaging
- Cell-based imaging
- Breast cancer screening

In the examples above, large sets of example images are used to train the AI system to recognize key features. Once sufficiently trained, the system can then accept diagnostic images and automatically mark-up features of interest within the images. As these systems do not suffer from typical human frailties such as the need for sleep, rest periods, or distractions they promise to increase throughput and quality of detection above and beyond their human counterparts.

If we look more closely at breast cancer screening, however, there seems to be conflicting opinions about the effectiveness of today's AI / ML models for detecting potential cancers. On one hand television reports and media articles are highly enthusiastic and optimistic about its ability to outperform radiologist review. On the other hand, a search of the *British Medical Journal* provides a more pessimistic outlook on the currently available AI and ML systems in healthcare stating, "Thirty four (94%) of 36 AI systems evaluated in these studies were less accurate than a single radiologist, and all were less accurate than consensus of two or more radiologists,"[1] thereby contradicting those reports in the media. A more recent report in the *Lancet* states "Despite this effort, there remains substantial uncertainty about the accuracy of AI in real-world screening."[2] These examples highlight the inconsistencies between what is perceived as achievable right now with AI and ML in the clinical laboratory versus the reality. In its current form, AI and ML cannot outperform a human. That being said, AI technology is continually advancing towards greater predictive power and enhanced capabilities, which will result in it overtaking human performance in the very near future.

Looking forward, where will AI/ML become crucial in the clinical space?

Personalized medicine has long been considered the next revolutionary step in healthcare. If we needed more evidence of this, our experiences with COVID-19 offer a clue. We have seen the response to the infection in vast populations, and we know they vary dramatically from the asymptomatic to the tragically fatal and

all points in-between. This very public illustration of the individual's unique response to the disease suggests just how powerful personalized medicine promises to be. Could we create therapies for individuals based on their very particular responses to a disease or an illness?

To deliver personalized medicine however the scope of clinical diagnostic testing and the subsequent data produced will need to exponentially grow. Existing data such as healthcare professionals' observations and assessments and patient medical histories and imaging will require evaluation alongside the individual's genomics, proteomics, and biological mechanism data.

To evaluate, make connections between data points, and derive insights for a single person is already a significant challenge. To do this at scale and to learn from population data thereby improving individual diagnosis is a vast undertaking. AI and ML will form a large part of delivering this next step. Companies such as Navignostics are deploying AI/ML in exactly this space, aiming to characterize tumors using spatial single-cell proteomics and identify cancer treatment that will optimally fight each patient's disease.[3]

What do clinical laboratories need in order to facilitate the move towards AI/ML?

The reason image analysis is one of the first examples of AI/ML seen in laboratories is due to the limited scope and uniformity of the data sources analyzed. If we consider a wider scope and complexity of data sources, this raises significant challenges from the technical issue of aggregating vast datasets obtained from diverse sources to the crucial human aspect of securing consent for personal data usage and safeguarding privacy. As discussed, we have medical records and diagnostic test results held within numerous health services from the doctor's office to the emergency room, together with the biochemistry, genomics, proteomics data obtained from clinical laboratories that will need to be collated into a central repository.

A typical workflow for one source of data might be blood work tested on a hematology analyzer within the clinical laboratory. The data ideally will be automatically transferred from the analyzer to an information management system. It might then be combined with personal demographic data in a central repository together with perhaps genetic and proteomic data that has been collected elsewhere. The point here is that we have data flowing from instruments to systems and systems to systems located in, quite likely, different geographical locations. To use the full potential of AI and ML, this data must be combined within a central repository, and that is just the start. For AI to make sense of these data, they must be good quality, clean, well structured, and consistently named.

The routing of data requires seamless integration between systems. The range of instrumentation, analytics systems and information repositories is large and connecting them together is a challenge in itself. Moreover, the need for robust infrastructures capable of handling the transfer of large data volumes across distributed networks, along with adaptable architectures to support the ever-evolving AI and ML tools, further compounds the complexity of the situation. Nonetheless, it is important to note that these challenges can be overcome with the right approach and solutions.

For data to be clean and well-structured, there needs to be strict data governance employed at every data collection point within the process. For the data to be consistently named, tools such as ontology-based systems will need to be employed. Even when data is clean, consistent, and consolidated in a single repository, there are additional considerations with respect to the quality of the data. A paper published on the MDPI website titled "Healthcare Applications of Artificial Intelligence and Analytics: A Review and Proposed Framework" states, "Another important point is that training an algorithm on data containing misdiagnoses, erroneous treatments, or wrong scenarios that have not been reported will also have a negative impact on the performance of the algorithm in their predictions."[4] The risk here lies in feeding flawed data into your AI model, leading to unreliable predictions that cannot be trusted.

While the technical challenges are indeed significant, another paramount aspect in healthcare revolves around patient privacy and informed consent. These elements establish the ethical and legal framework necessary for conducting any research involving human participants. Informed consent necessitates that participants are fully informed about the nature and purpose of the research and how their data will be used in perpetuity. This raises questions about the interpretability of how ML algorithms determine a particular decision and what level of detail the participant needs in order to understand how the algorithm is using their data. AI also introduces a lack of transparency. The algorithms used by ML may incorporate huge datasets of complex information that can be difficult to communicate in a way that is understandable and accessible to a layperson. Organizations will need to both consider implications on consent and develop clear communication strategies.

The future of AI in the clinical laboratory and beyond

AI possesses indisputable potential to revolutionize various domains of healthcare, including the clinical laboratory. However, contrary to media portrayals, we have not yet fully realized this potential. Nevertheless, despite the significant technical challenges and patient privacy concerns, the advantages offered by AI outweigh the drawbacks. The pivotal question remains: how adeptly can we harness AI's capabilities to expedite new techniques such as the introduction of personalized medicines, formulate tailored preventive and treatment strategies to reduce disease occurrence, and optimize treatment efficacy? Through meticulous regulation, ethical considerations, and ongoing technical advancements, AI holds the potential to reshape healthcare, fostering a healthier and more prosperous future.

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Geoff Parker is Co-Founder and Principal Consultant of **Scimcon**. Geoff is a senior project leader with experience working on critical assignments for the biggest names in our profession, worldwide. As Scimcon's customer champion, he has overall responsibility/global oversight of all our projects, ensuring that our performance is of the quality and has the impact clients rightly expect.

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State of the Industry: Disease Management

By Kara Nadeau

The 2023 Medical Laboratory Observer (MLO) State of the Industry (SOI) survey on Disease Management focused on testing for respiratory infections and sexually transmitted infections (STI). Alongside the quantitative survey results, we present insights from U.S. lab professionals and lab equipment suppliers on the trends they are seeing in these two disease management areas.

RESPIRATORY TESTING TRENDS

When asked how many platforms/analyzers their lab uses for polymerase chain reaction (PCR) testing, 64% of respondents said two-to-three PCR platforms/analyzers, 18% said more than three and 14% said they use only one.

Tamara Ranalli

Tamara Ranalli, Senior Vice President of Molecular Business Unit, QuidelOrtho, commented on PCR trends:

"Laboratory quality molecular testing solutions, especially those using reverse transcriptase-polymerase chain reaction (RT-PCR), continue to move closer to the patient while becoming easier to use and with time to results rivaling those of rapid antigen tests. More syndromic tests are likely to emerge, reflecting the need to test numerous pathogens quickly while reducing technician hands-on time and supporting antibiotic stewardship. In addition, ease of use, even within a laboratory environment, is a desired feature given the reduction in available molecular biologists in labs."

Regarding reimbursement for PCR tests to detect SARS-CoV-2 and related COVID-19 conditions, 18% of those surveyed said reimbursement is covering their costs, 9% said it was not, and 64% said they were unsure.

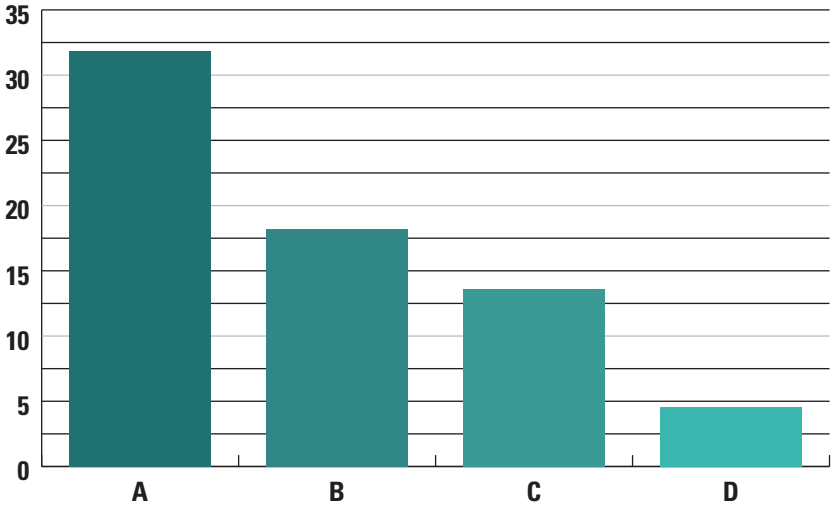
"As SARS-CoV-2 volumes decreased, labs have been looking for ways to take their new PCR capacity and use it as an opportunity to offer other tests, such as onboarding tests for sexually transmitted infections or monitoring of viral infections in transplant patients," said Alesia McKeown, PhD, Scientific Partner, Roche Diagnostics. "That shift can help labs avoid sending tests out, saving expenses and decreasing the time to get results in the hands of clinicians and patients."

Alesia McKeown, PhD

THE 2022–2023 RESPIRATORY SEASON

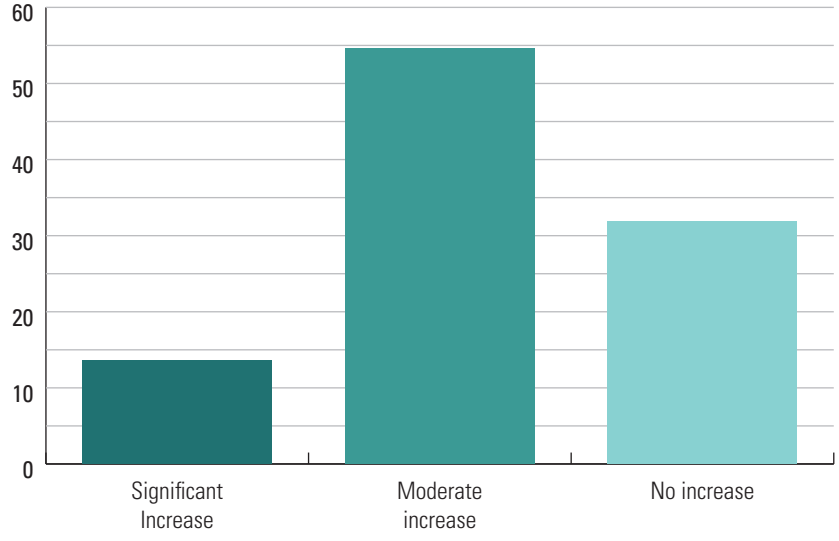
Lab professionals were asked if they had seen an increase in respiratory testing (COVID-19, flu, RSV) as predicted this year. Most reported an increase, with 14% seeing a significant rise in tests and 55% a moderate uptick. About one-third

How many platforms/analyzers are you using for PCR (polymerase chain reaction)?



A. 2 or 3
B. More than three
C. 1
D. 0

Did your laboratory see an increase in respiratory testing (COVID-19, Flu, RSV) as predicted this year?



of respondents (32%) said they experienced no increase in respiratory testing.

Lee Panton, former Lab Director from California who now serves as a consultant, said she has seen an increase in requests for complete panels for respiratory virus screening, but the lab for which she consults does not have molecular testing capability. She described how they handle these test requests:

"In each case, we need to contact the ordering MD and ask for a list of the individual tests that are needed. Then we do the influenza, RSV and COVID tests in house with antigen kits. Other tests are sent to an outside reference lab. This does not allow for prompt diagnosis of all potential respiratory infections. The volume of panel testing is still low. Our corporate office must approve any new testing systems that each of our hospitals are interested in acquiring. Currently, we do not have approval to bring in the new molecular panels."


Lee Panton

PANDEMIC-DRIVEN CHANGES REMAIN IN PLACE

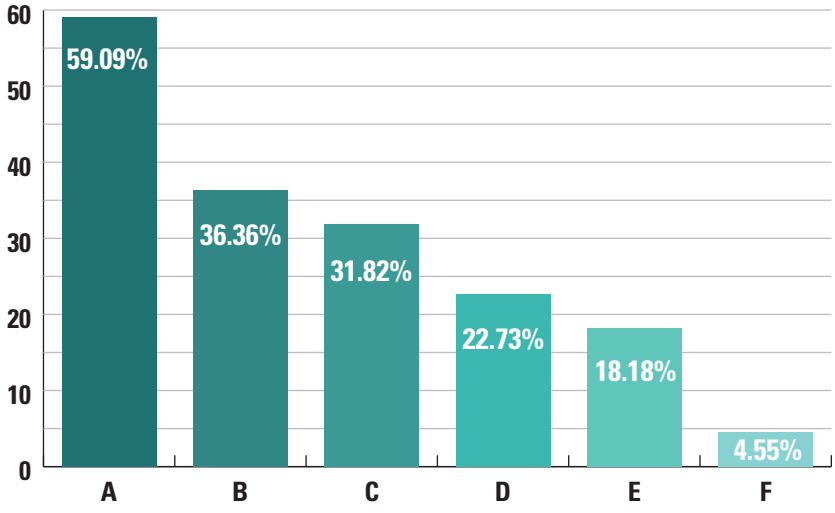
The survey found many changes in diagnostic processes for respiratory testing that were implemented in response to the pandemic are now permanent. Topping the list was multiple vendors for consumable testing supplies (59%), followed by more electronic data and less paper (36%), and reallocated or increased physical space for molecular testing (32%).


Nikos Pavlidis

"As labs continue to struggle with increased post-pandemic testing volumes and decreased staffing, automation is more important than ever to help improve access to testing, accuracy of testing, and speed of testing," Nikos Pavlidis, VP/GM Diagnostics, BD Life Sciences, commented. "High-throughput, fully integrated preanalytical and analytical systems can enhance both laboratory operations and patient management around STI testing by processing tests at a faster rate and at a higher volume than a lab might previously have experienced."

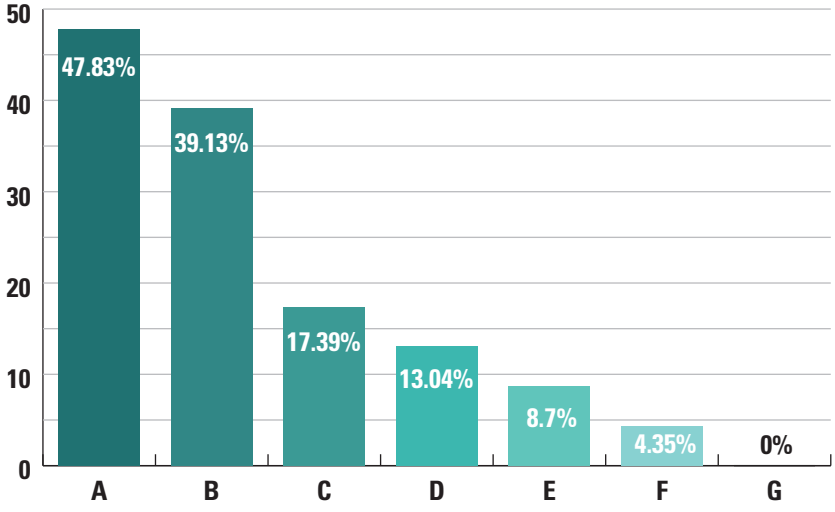
Nearly a quarter of survey respondents (23%) said they continue to have less reliance on just-in-time delivery of products and instead have

Which changes in diagnostic processes implemented in response to the pandemic are now permanent?



A. Multiple vendors for consumable testing supplies
B. More electronic data and less paper
C. Reallocated or increased physical space for molecular testing
D. Less reliance on just-in-time and more standing orders
None of the above
E. Increased use of high-throughput platforms
Increased use of digital pathology
F. Multiple reference labs

Which STIs has your lab seen the most positive results for?



A. Don't know
B. Chlamydia
C. Bacterial vaginosis/Gonorrhea
D. Hepatitis/HPV infection/Syphilis
E. Herpes/Trichomoniasis
F. Pelvic inflammatory disease
G. Mycoplamsa genitalium

more standing orders in place with suppliers. Increased use of high-throughput platforms and digital pathology remain in place in 18% of labs surveyed, and 5% say they are still using multiple reference labs.

STI TESTING TRENDS

U.S. medical lab professionals surveyed reported an increase in STI testing, but mostly modest, with 41% reporting a moderate increase in testing in this area, and 5% a significant increase. Over half of survey respondents (55%) reported no increase in STI testing over the past 12 months.

"There has been an increase in the number of reported cases of STIs, which could be due to factors like access to care and the willingness of professionals to talk to patients about the importance of screening when asymptomatic," said Damian Alagia III, MD, MS, MBA, FACS, FACOG, Senior Medical Director for Advanced Diagnostics and Women's Health, Quest Diagnostics. "It seems the more discussion there is about the impact STIs can have on fertility, quality of life, and a person's health and well-being, the more concerned people are. Yet, STIs are an area of healthcare with significant gaps in care relative to guidelines."


Damian Alagia III, MD, MS, MBA, FACS, FACOG

Patient hesitancy to pursue education on STIs and testing was called out as a challenge by various experts interviewed.

"The focus is less about volume and more about making it easier for people to get tested, reducing stigma to get tested, and providing patients with education on testing," said Allison McMullen, Scientific Partner, Molecular, Roche Diagnostics.

Pavlidis commented on a 2023 BD commissioned Harris Poll survey that found women feel less knowledge-

Educational Seminar

Undetected Point-of-Care Hypoglycemia Can Be Life-Threatening to the ICU Patient

Bedside glucose testing is one of the most commonly performed tests in the hospital and many clinicians take the accuracy and reliability of these results for granted. However, certain glucose meters have interferences from medications and other endogenous factors that can cause erroneous glucose meter results. Five papers published in the last year have reported that inaccurate results from these meters have lead to improper treatment, such as giving insulin to a patient who is hypoglycemic, which can cause catastrophic outcomes including death. This is an ongoing, real-life problem, with erroneous glucose meter results and inappropriate insulin administration.[1-5] In addition to adverse events, meter errors can cause increased length of stay and increase the cost of hospitalization.

This seminar will show how outcomes are achieved through improved glucose meter accuracy, discuss factors which can affect accuracy of some glucose meters and how to avoid them, and review implementation of an interference-free bedside glucose testing system which protects patients and providers.

Topics

- Using comparative reference methods to evaluate glucose meter systems
- Evaluating glucose interferants (e,g., hematocrit, other sugars, acetaminophen, ascorbic acid)
- Preventing glucose meter interferences and adverse events
- Implementing a hospital-wide POC glucose testing program that includes critically ill patients
- FDA and CMS regulations for glucose meter use with critically ill patients

Speakers

Nam Tran
Ph.D., M.S., HCLD (ABB), CLS, MLS (ASCP)^{cm}, FAACC

Professor and Senior Director of Clinical Pathology, University of California, Davis Medical Center

Dennis Begos
MD, FACS, FACRS

Senior Medical Director, Medical and Scientific Affairs, Nova Biomedical. Former surgeon, Chair of the Dept. of Surgery and President of the medical staff, Winchester Hospital, MA. Assistant professor, Tufts University School of Medicine, MA

Cody Maddox
MLS, MLS (ASCP)

POC Coordinator, Pathology Department, LifeBridge Health – Sinai, Baltimore, MD

Dates and Locations

Thursday, September 21
Renaissance Meadowlands
Rutherford, NJ

Tuesday, September 26
JW Marriott Atlanta Buckhead
Atlanta, GA

Registration

Seminar begins at 8:30 am. Presentations follow until 12:00 pm. The seminar includes complimentary breakfast, buffet lunch, and parking. Register for this free seminar at: https://www.novabiomedical.com/hypogly or scan the QR-Code.

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Allison McMullen

able about STI testing and treatment options compared to other vaginal diseases and infections:[1]

"These findings show the importance of providing patients with the knowledge they need to address and prevent STIs. With the CDC reporting that STIs make up five of the top 10 reportable diseases in the U.S.—with increasing incidence—knowledge and education are critical for patients, as is the development of targeted point-of-care diagnostic technologies."

STIs BY THE NUMBERS

Looking at testing for specific STIs, chlamydia was highest on the list, with 39% of lab professionals seeing the most positive test results for this infection among their patient populations. Labs reported a 17% increase in positive results for bacterial vaginosis (BV) and gonorrhea, and a 13% increase for hepatitis, syphilis, and HPV infection.

Lower on the list were herpes and trichomoniasis, with a 9% increase in positive results for both STIs reported, and pelvic inflammatory disease, of which 4% of lab professionals said they have seen increased positive results.

Panton said recent false positive rates for rapid plasma reagin (RPR) tests have presented a major challenge to her lab's STI testing, especially with the increase in confirmed syphilis cases in her area. She stated:

"We send out RPR testing to a reference lab and results are taking longer than expected. A big issue that started about 9 months ago is 'false' positive RPR tests. We get the RPR as 1:1 dilution positive. The confirming FTA is negative. This is happening mostly on pregnant women who are in for their pre-delivery tests. It is causing a lot of confusion because we must contact the MD and report it to Public Health before the FTA is completed."

STI SUPPLY TESTING CHALLENGES

With some STIs on the rise, testing supply shortages continue to pose challenges. Among those surveyed, 55% said they have had trouble acquiring swabs for testing, 36% blood specimen tubes, 27% urine collection devices, and 18% assays.

ADVICE FOR LABS IN DISEASE MANAGEMENT TESTING IN 2023 AND BEYOND

RESPIRATORY TESTING

When it comes to respiratory testing trends, a pervasive message to labs is — prepare for the unexpected.

"Seasonal irregularities do not allow for good predictive models and given supply chain pressures for some items that may not have fully abated, labs may be challenged in maintaining adequate inventories for the unexpected. However, a combination of multiplex assays and a variety of platforms offering throughput flexibility can help cover the bases when used appropriately," said Ranalli.

"Labs have to be ready to pivot quickly so they can address the escalation of any type of respiratory virus, as we've seen how quickly local transmission of viruses can move to larger public health issues," said McKeown. "Part of this ability to respond involves having the right tools, such as PCR instruments, which many labs brought on or expanded capacity during the pandemic."

STI TESTING

Experts emphasized the need for closer partnerships between labs and healthcare providers to support increased STI education and testing.

McMullen encouraged labs to partner with healthcare practitioners to help meet their testing needs, and share information on current and new sexual health test formats available, such as point-of-care testing.

Dr. Alagia stressed the importance of understanding that STI testing is not just a test a provider is performing, but rather part of a bigger picture where the provider is engaging in patient care, with results impacting a person's psychological and sexual health and wellbeing.

"It's our position that providing a test doesn't stand alone but needs to be connected to a system of patient care," said Dr. Alagia. "Those who test for STIs are providing a piece of the clinical care pathway that impacts a patient and their family, and need to ensure that testing is high-quality, consistent, accessible, reliable, and closely monitored. Testing providers must recognize they are essential to patient management; a physician can't diagnose, counsel, or treat without first receiving a test result."

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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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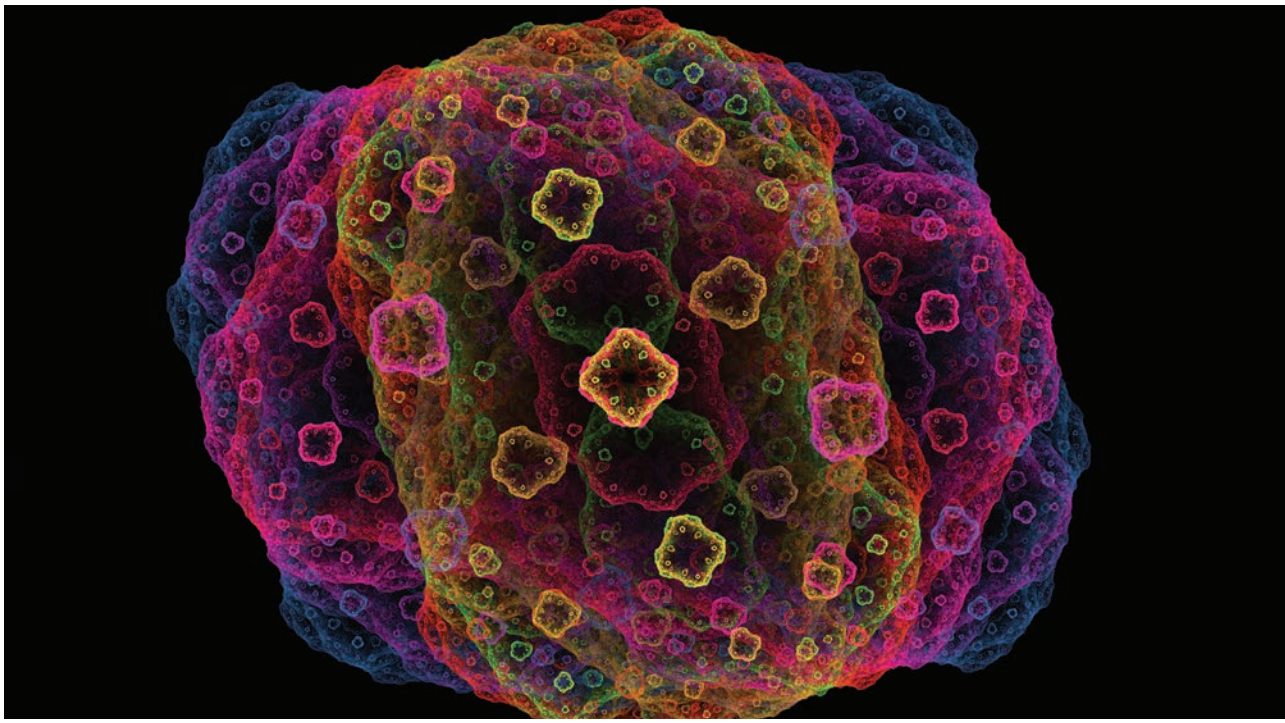


Tim Bird/Moment/Getty Images

Molecular syndromic testing: Will panels improve care?

By Jane M. Caldwell, PhD; Carrie V. Vause, MS; Tamara Ranalli, PhD

The number of infectious disease syndromes commonly seen in primary care, urgent care, and emergency departments in the United States is staggering. Acute respiratory illnesses (ARI), ranging from mild upper respiratory tract infections to serious illnesses such as pneumonia, are the most common reasons to seek ambulatory care[1] with total deaths attributed to COVID-19 on death certificates as 1,132,414.[2] Gastrointestinal tract (GIT) infections such as acute gastroenteritis have been estimated to account for over 175 million cases each year.[3] Sepsis, a serious bloodstream infection, causes up to 381,000 deaths annually.[4] Central nervous system (CNS) infections such as meningitis and encephalitis are associated with high mortality and morbidity[5] with viral forms responsible for nearly 20,000 U.S. hospitalizations per year.[6] The U.S. Centers for Disease Control and Prevention (CDC) reported that 1 in 5 U.S. residents had a sexually transmitted infection (STI) in 2018 which translated to an estimated 26 million new cases that year.[7]

All these infections may be caused by bacteria, fungi, viruses, parasites, or combinations of two or more of the above and present challenges for accurate diagnosis. Furthermore, many pathogens that require widely different treatment plans produce similar symptoms making global screenings for common suspects more useful than individual or sequential tests when time to treatment is critical. Targeted syndromic, multiplex panels that test numerous pathogens rapidly and simultaneously have the potential to reduce uncertainty in diagnoses, improve antibiotic stewardship, and increase both clinician and patient satisfaction in the process.

There is a growing awareness of the multiple positive impacts and cost savings with the judicious use of multiplex molecular panels for syndromic diagnoses. Molecular panels have been shown to improve sensitivity and detection over conventional culture methods in some cases while reducing the need to collect multiple patient specimens, reducing the turnaround time (TAT) for results, and simplifying the testing algorithm.[5] Molecular syndromic panels may be more expensive initially, but they may lower total medical costs by simplifying both clinical and laboratory workflows, improving infection control and prevention, reducing disease progression and morbidity in patients, and reducing unnecessary antibiotic use.

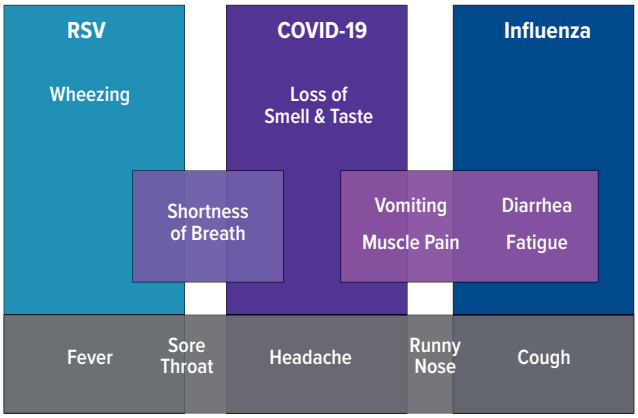
What is syndromic testing?

Syndromic testing refers to multiplex panels that detect common pathogens from patient blood, feces, swabs, and spinal or vaginal fluids using rapid, molecular methods. The molecular panels are either CLIA-waived or considered moderate complexity, which means they can be performed by laboratorians in or near the clinic. The entire panel for a particular kit is assayed and reported to assist in a timely diagnosis, potentially while the patient is still in the clinic. Since many pathogens produce confounding symptoms, molecular panels can eliminate some pathogenic possibilities and help the healthcare provider focus on the true causes of infection.

Respiratory syndromic testing

Respiratory diseases such as influenza, respiratory syncytial virus (RSV), and COVID-19 emerge together seasonally and are difficult to separate based on symptoms alone **(Figure 1)**.[8] Since the development of polymerase chain reaction (PCR) assays over

Figure 1: Common Symptoms of Acute Respiratory Infections[8]



40 years ago, respiratory syndromic testing has been evolving to hasten diagnosis using both qualitative and quantitative measures. During the COVID-19 pandemic, the need for quick differentiation for isolation purposes led to the accelerated development of many more molecular multiplex assays.

Recent studies have been conducted to assess whether these panels improve patient outcomes, antibiotic stewardship, reduce patient length of stay (LOS), and time to actionable results. Patients with point-of-care (POC) testing for ARI in the emergency department (ED) were more frequently assigned a single room for isolation purposes when having a positive PCR test for either influenza, RSV, or metapneumovirus.[9] A 27-study meta-analysis of ED patients found that rapid multiplex PCR for patients with possible ARI reduced LOS and TAT.[9] Additionally, the rapid nature of results for influenza-positive patients improved appropriate antiviral usage and infection-control management **(Table 1)**.[10]

Another study looked at patients with community-acquired pneumonia (CAP). Researchers concluded that molecular panel testing in adults with CAP resulted in a significant reduction in time to actionable results, reduced TAT, and increased microbiological yield compared to standard testing.[11] The most frequent pathogens in the CAP study were *Haemophilus influenzae*, *Streptococcus pneumoniae*, and influenza A virus. Differentiating between bacterial and viral infections had the potential to improve antibiotic stewardship but this parameter was not quantified in the study.

In a 2018 clinical microbiology review article, the author cited several studies that indicated molecular testing reduced the time to diagnosis of influenza, lowered the odds ratios for hospital admissions, reduced the numbers of chest X-rays, and reduced antibiotic use or shorted the duration of use when compared to conventional methods such as viral cultures, rapid antigen testing, and direct fluorescent-antibody testing **(Table 1)**.[12]

The cost-effectiveness of respiratory panels is still being debated in the literature. While the reagents and materials required for these assays are more expensive than those for conventional virus testing, multiplex tests may offer savings in the long run if increasing efficiency and reducing labor, time to therapy, the need for admissions, LOS, antibiotic use, and the need for other diagnostic tests is considered.[5] More important than dollars and cents; patient's special needs, disease risks, and final outcomes should be given top priority. Rapid, molecular respiratory panels are particularly useful for high-risk patients such as children, intensive care unit (ICU) patients, transplant recipients, and cystic fibrosis patients.[5]

Table 1: Clinical and Economic Impacts of Multiplex Respiratory Testing[10,12]

Reference	Benefits of multiplex versus conventional methods
Mahoney et al. 2009	• Cost savings of $291 per patient • Least expensive if the prevalence of viral illness was > 11%
Nelson et al. 2015	Pediatric study More cost-effective than traditional PCR, direct fluorescence, and rapid antigen tests
Rogers et al. 2015	• Shorter duration of antibiotic use • LOS decreased
Rappo et al. 2016	• Decrease in time to diagnosis of influenza virus and noninfluenza virus • Lower odds ratios for admission • Reduced numbers of chest radiographs • LOS decreased • Reduced durations of antibiotic use
Subramony et al. 2016	• Patients were less likely to receive antibiotics for more than 2 days • Less likely to have a chest radiograph performed upon admission • More likely to be in isolation for more than 2 wdays
Brendish et al. 2017	• More patients received single doses or brief courses of antibiotics • LOS decreased • Improved antiviral use for influenza virus-positive patients
Clark et al. 2023 (27 study meta-analysis)	• LOS decreased • TAT decreased • Improved antiviral use for influenza virus-positive patients • Improved infection-control management for influenza virus-positive patients

PCR: polymerase chain reaction; LOS: length of stay; TAT: turnaround time

STI syndromic testing

Many STIs have similar symptoms so empiric treatment based on clinical symptoms alone can cause difficulty in diagnosis and lead to misuse of antibiotics. The increasing rates of STIs require more accurate, rapid POC testing modalities to mitigate the surge.[13] But due to lack of highly sensitive rapid testing options, syndromic STI management is prone to high rates of both overtreatment and undertreatment of patients.

In one recent study comparing a same-day molecular POC test that detected *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, and *Trichomonas vaginalis,* to off-site molecular tests, it was concluded that implementation of the rapid POC molecular panel could reduce overtreatment and undertreatment of STIs and have minimal impact on staff time and visit duration for patients.[13] Patients were willing to wait up to 30 minutes for the results, thus, permitting accurate treatment initiation during a patient visit **(Table 2)**.[13]

Lesion assays utilizing multiple targets have been able to distinguish between single and multi-pathogen infections with similar presentations. A recent study determined that a molecular multiplex panel was able to definitively diagnose lesions in individuals with suspected syphilis.[14] The assay detected a panel of pathogens including the syphilis-causing pathogen *Treponema pallidum*, as well as other lesion-causing

Table 2: Summary of Mentioned Syndromic Infections and Causative Pathogens[9,11,13-15]

Syndromic Infections	Causative Pathogens
Severe acute respiratory infections[9,11]	**Bacteria** • Haemophilus influenzae • Streptococcus pneumoniae • Virus • Influenza A/B • COVID-19 • Respiratory syncytial virus • Metapneumovirus
Suspected sexually transmitted infections with discharge[13]	**Bacteria** • Chlamydia trachomatis • Neisseria gonorrhoeae • Trichomonas vaginalis
Lesions[14-15]	**Bacteria** • Treponema pallidum • Chlamydia trachomatis • Virus • Herpes simplex virus 1 • Herpes simplex virus 2

agents — herpes simplex virus (HSV) 1 and 2, and *Chlamydia trachomatis* serovar L. Their results indicate that over half of syphilis-attributed lesions could be due to other pathogens or causes.[14] Another lesion study evaluating three molecular multiplex panels found all three molecular assays were significantly more sensitive for the diagnosis of HSV 1 and 2 lesions compared to viral culture.[15] In addition to being more sensitive, molecular methods took 1–2 hours compared to over 2 days for viral culture.[15] Utilizing molecular syndromic testing to diagnose clinically similar infections caused by non-descript lesions could improve TAT and reduce misdiagnosis, improper or unnecessary treatment, and the further development of antimicrobial resistance **(Table 2)**.

Other syndromic tests

Clinical trials are emerging that point to the utility of GIT, blood, and CNS panels when compared to conventional testing. One multiplex GIT panel was found to reduce LOS from 3.9 to 3.4 days and was estimated to decrease cost of care by approximately $294 per patient.[16] Another clinical trial assessing a GIT panel for pathogen detection in cases of infectious diarrhea reported that patients assessed with multiplex PCR were less likely to undergo endoscopy (9.6% versus 8.4%) and were less likely to be prescribed antibiotics (40.9% versus 36.2%).[17]

When whole blood molecular panels were utilized in the assessment of critically ill patients and compared to Gram stain and MALDI-TOF, the median time to optimal therapy was shortened (14.68 hours to 4.65 hours) and antibiotics were adjusted in 31.8% of patients.[18] In 98 hospitalized patients with Gram-negative bacteremia, panels reduced median time to pathogen identification from 30.3 h to 19.1 h with ICU LOS shortened by 4 days and 30-day mortality cut in half.19 The estimated net cost savings per ICU patient was $11,661.[19]

When evaluating syndromic panels for CNS infections, it was reported that multiplex panels were able to detect significantly more common pathogens than culture, Gram stain, and MALDI-TOF methods.[20,21] The same CNS panel was evaluated with 4,623 CSF samples and reported to have 96.3% sensitivity and 96.58% specificity.[22]

Rapid detection of GIT pathogens with syndromic panels has been demonstrated to improve epidemiological awareness and hasten efforts to prevent further disease transmission to the general public.[5] In 2013 and 2014, molecular syndromic testing panels provided the initial recognition of an enterovirus outbreak in one case and led to the identification of additional *Shigella* cases not found by conventional laboratory assays in another.[23,24]

Considerations for implementation

Presently, most multiplex panels are limited to the common pathogens capable of causing a specific syndrome.[25] Unfortunately, due to differences in patient populations, prevalence of pathogens, and provider ordering patterns, there is no universal or 'one size fits all' panel.[26] Conversely, some kits may have overstepped their utility by including rare targets that are only found in unique patient populations.[26] The menu of analytes on several syndromic panels now offers access to routine testing previously only offered in reference laboratories or for pathogens that are historically difficult to detect.[27] By consolidating into panels, laboratories can test from the same samples, often minimizing the need for sequential and more cumbersome, testing methodologies. These workflow changes may improve operational efficiency and cost-effectiveness of testing.[27] However, third-party insurers and Medicare contractors have pushed back against certain large panel tests, finding them not medically necessary for most patients; the exceptions being the critically ill and immunosuppressed.[26] To remedy this, panels that allow the clinician flexibility in ordering pathogenic targets — a menu approach — may be advised. Clinicians should practice due diligence by continuing to evaluate the utility of panels based on measurable outcomes. Finally, as with all molecular tests, laboratorians and POC testing operators should be properly trained and certified, instruments calibrated and maintained, reagents certified, and methods validated and backed by continuous monitoring to ensure accurate reporting.

Many clinical guidelines do not include syndromic testing at this juncture; guideline publication is often years behind in technological advancements in clinical laboratory medicine. Syndromic testing has been met with broad enthusiasm from patients, clinicians, and laboratory professionals and a few outcome-based studies are showing direct correlation to improved patient care and cost-effectiveness.[27] This need for data has driven multiple groups and publications, including the *Journal of Clinical Microbiology* and the American Society for Microbiology, to call for additional studies to validate anecdotal benefits.[27] Publication of patient-outcomes data for syndromic testing, combined with technological advancements in sensitivity and specificity, and the availability of CLIA-waived assays, may lead to inclusion of syndromic testing in future guideline publications.

Summary

To provide utility in the post-pandemic world, infectious disease testing will need to demonstrate speed, accuracy, multiple and simultaneous pathogen detection and quantification, and reach all of the desired measurable outcomes for patients and clinicians alike. The multiplex panels could be tailored to report only specific pathogens of concern which fit the patient's symptoms. To be flexible and responsive to outbreaks and seasonal fluctuations, multiplex molecular panels could be updated and reengineered by manufacturers to detect emerging or re-emerging pathogens.

Similarly, in the post-pandemic era of laboratory personnel shortages, the ability to run multiplex tests requires fewer laboratory personnel hours, less hands-on time, fewer reagents, and less operational strain on laboratories.[28] Laboratorians have cited the positive attributes of molecular syndromic platforms

as increased sensitivity, specificity, ease of implementation, and reduced TAT as compared to standard culture or MALDI-TOF assays. Clinicians, in turn, are seeking rapid results that can be obtained during patient visits, targeted treatments based on multiple pathogen screens, improved antibiotic stewardship, and detection of coinfections early in the course of the syndromic disease. At present, many multiplex panels are being evaluated empirically in the clinical setting — especially those that are CLIA-waived or of moderate complexity. It is certain that new and emerging pandemics will spur the development and POC use of these and future syndromic panels.

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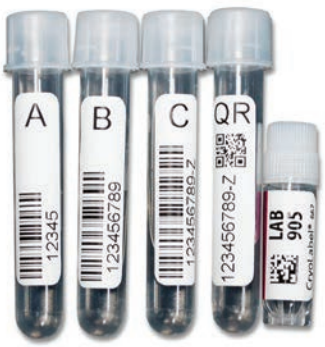

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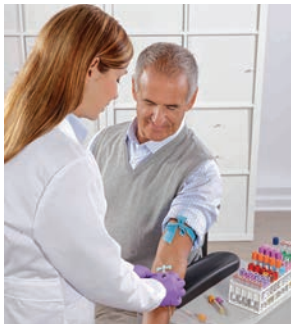

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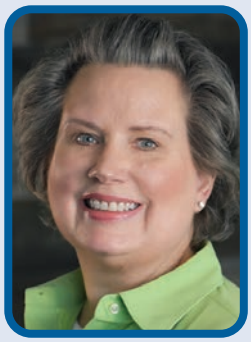
Right patient, right test, and lab efficiency

By Christina Wichmann



Tawni Reller, MA, BS, MLS(ASCP) started her career more than 20 years ago as a medical technologist in large and small hospital laboratories. After working in the clinical laboratory for many years, she made the leap into laboratory information systems and has built her health career from there. She is now product manager at **hc1**. She is responsible for the PrecisionDx Advisor product vision and roadmap in the hc1 Insights division as well as a laboratory stewardship and analytics product. While the core of the hc1 Insights products she manages are laboratory-related, they really encompass the entire healthcare picture using EHR, LIS, billing, and other customer data to provide actionable insight into data in support of problem identification/root cause analysis and performance improvement and management. Tawni is also an advisor for the Clinical and Laboratory Standards Institute (CLSI) panel on Automation & Informatics.

As the healthcare sector faces a critical shortage of medical laboratory professionals, do we need a better way to analyze and visualize laboratory operational metrics (including staffing) in order to close the gaps in care?

Even in today's digital age, many labs may still be utilizing manual processes (running reports from one or more systems, exporting data, consolidating and manipulating data in a spreadsheet, etc.) to document operational metrics, which is extremely inefficient, historical in nature (not real-time), and can lead to discrepancies.

Establishing data best practices creates efficiencies to help health system and hospital laboratory leaders tap into real-time insights and understand how staffing and volume intersect in order to ensure they are properly staffed for the types of testing that needs to be performed. In addition, an operations management solution allows users to track if they are meeting TAT benchmarks, determine if their test volume is level-loaded, and monitor by the hour how many tests are coming in and how many are completed. This can instantly create bandwidth by test and by department to ensure the correct departments are staffed at the correct times and at the correct levels.

Can a better data workflow in the clinical laboratory improve clinical quality?

Monitoring testing trends and gathering lab testing insights in real-time can help create efficiencies and improve care by uncovering where provider test ordering habits are not aligning with testing best practices. Research has shown that approximately 20% of all lab tests are considered unnecessary resulting in wasted resources (time and materials) and may also cause clutter or confusion in the patient's medical record. Solutions that support ordering only the tests a patient truly needs to achieve a timely, accurate diagnosis and treatment plan ensures the right test is administered to the right patient every time.

In addition, it's important to remember that each laboratory may have different needs. For health systems that have multiple laboratories or facilities using different LISs or EMRs, it's important to make sure you are working with vendors that can quickly adapt and customize their solutions to your system, facility, or laboratory-specific needs. Having access to easy-to-read, near real-time dashboards and reports can enable you to see which providers are ordering tests outside of established guidelines. You can then use that information to tailor programs directed at the changes that will have the most impact for your health system and the patients within it.

Healthcare reimbursement models frequently change and it seems that laboratories are consistently reimbursed less for the testing they perform. How should laboratories be preparing for any changes in reimbursement — large or small?

Having a system in place that can quickly and efficiently break down historical and current lab-related information and report data accurately and consistently is imperative as changes impacting laboratories continue to occur. With technology tools in place to continuously analyze your operations using real-time lab testing insights, it's easier to uncover where provider testing habits do not align with testing best practices. That information can help to reign in laboratory costs at any point in time by eliminating the scramble to obtain good data and reinforcing the use of data to support questions or influence change. With established data best practices utilizing a technology platform, laboratories can be better prepared to analyze and potentially offset reductions in reimbursement at any point in time.

What are some of the latest automation advances helping to improve laboratory efficiency?

Automation advances can mean many things: a specimen track, specimen cold storage, analyzer functionality in general, or accessing the data generated by automation/analyzers. Data-related advances tied to automation can be associated back to the LIS and translate to workflow efficiencies. Don't assume that the analyzer integration that has been in place for years is still the best solution. Explore whether driver updates are available with analyzer manufacturers and analyzer middleware vendors, and work with your LIS specialists (or vendor) to determine if more data or fields are available for use with analytic-type

We recognize your **passion** for providing high quality care to patients displaying symptoms associated with respiratory infections, and we appreciate your efforts and **resiliency** working to reduce the number of people impacted by their spontaneous and rapid spread.

At SEKISUI Diagnostics we are committed to providing **high quality, point-of-care tests for detecting the most common causes of respiratory infections**, so you can get the answers fast and your patients back to doing what they love.

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Because every result matters™

LABORATORY INNOVATOR

reporting on your patient samples. Along with those vendors, the Clinical and Laboratory Standards Institute (CLSI) has documentation that supports interfacing and connectivity that is vetted by industry experts and reviewed on a regular basis to ensure the information provided is accurate in our fast-changing technology landscape.

What unique challenges are laboratorians currently being faced with?

For the decades that I have been involved with clinical laboratory work and services, the story has never changed: do more with less. I don't believe there is a 'unique' challenge other than a variation on that theme. Labs are overwhelmed by supply and staffing shortages and are constantly looking for how to 'do more with less.' Lab stewardship programs can influence, from the front end (provider ordering), the amount of testing as well as appropriate testing for a patient and have proven to be effective when implemented and supported by the healthcare system. While data analysis is another specialized skill, it has proven to be a good way to reveal ways to reduce costs and/or increase efficiency of lab testing. An example is inappropriate test ordering behaviors that, once proven with data analysis, reduces lab (and patient) costs and improves patient care (reduces the 'white noise' of unnecessary lab results in the patient's chart). Collaboration within the healthcare ecosystem is a key component of lab stewardship, and the lab has the ability (and the data!) to influence and drive change to 'do more with less' while positively impacting more than the lab.

INDEX OF ADVERTISERS

Alinity i TBI

IT'S MORE THAN A TEST.

IT'S REAL LIFE.

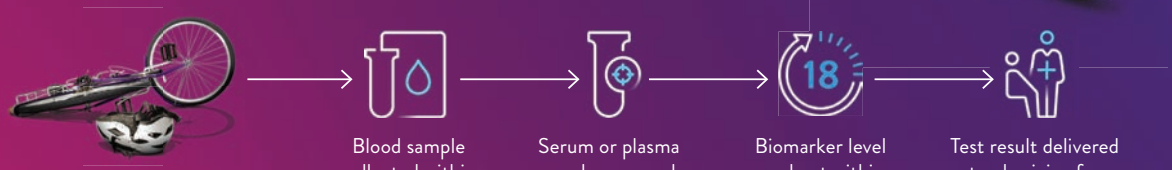
Objective results provide peace of mind for patient and physician, and can aid in faster discharge when a concussion is suspected—impacting measurably better healthcare performance.[1,2]

IT'S THE POTENTIAL TO RULE OUT UNNECESSARY CT SCANS.[1]

Alinity i TBI has high **clinical sensitivity (96.7%)** to detect blood-based biomarkers indicative of the absence of acute traumatic intracranial lesions usually visible on a CT scan.[1]

With a **negative predictive value of 99.4%,** Alinity i TBI offers a high degree of certainty to aid physicians in ruling out the need for a head CT when mild traumatic brain injury (mTBI) is suspected.[1]

ALINITY i TBI TEST PATHWAY



Patient presents to ER with suspected mTBI

Blood sample collected within 12 hours of injury

Serum or plasma sample prepared, test run

Biomarker level read out within 18 minutes

Test result delivered to physician for further evaluation

SCAN THE QR CODE OR STOP BY THE ABBOTT BOOTH (1111) AT AACC TO LEARN MORE.

INTENDED USE

The TBI test is a panel of *in vitro* diagnostic chemiluminescent microparticle immunoassays (CMIA) used for the quantitative measurements of glial fibrillary acidic protein (GFAP) and ubiquitin carboxyl-terminal hydrolase L1 (UCH-L1) in human plasma and serum and provides a semi-quantitative interpretation of test results derived from these measurements using the Alinity i system.
The interpretation of test results is used, in conjunction with other clinical information, to aid in the evaluation of patients, 18 years of age or older, presenting with suspected mild traumatic brain injury (Glasgow Coma Scale score 13-15) within 12 hours of injury, to assist in determining the need for a CT (computed tomography) scan of the head. A negative test result is associated with the absence of acute intracranial lesions visualized on a head CT scan.
The TBI test is intended for use in clinical laboratory settings by healthcare professionals.

IMPORTANT SAFETY INFORMATION

Instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from these instructions.
- For *In Vitro* Diagnostic Use
- Rx Only (For use by or on the order of a physician only)

CAUTION: This product requires the handling of human specimens. It is recommended that all human-sourced materials and all consumables contaminated with potentially infectious materials be considered potentially infectious and handled in accordance with the OSHA Standard on Bloodborne Pathogens. This product contains sodium azide. Contact with acids liberates very toxic gas. Dispose of contents / container in accordance with local regulations.

NOW AVAILABLE! CONTACT A REPRESENTATIVE FROM ABBOTT TODAY.

1. Alinity i TBI [package insert] 802673R01. Instructions for use. Abbott Diagnostics. May 2023.
2. Michelson EA, Huff JS, Loparo M, et al. Emergency department time course for mild traumatic brain injury workup. *West J Emerg Med*. 2018;19(4): 635-640. doi:10.5811/westjem.2018.5.37293

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Carbapenem-resistant Enterobacterales (CRE) are a serious threat to public health. Carbapenems are generally administered as a last resort for treating infections caused by Gram-negative bacteria. Most available drugs are ineffective for treatment of CRE, limiting treatment options drastically. CRE have been associated with mortality rates of up to 50% for hospitalized patients. Hardy Diagnostics is committed to make it easy for you to screen for these dangerous bacteria.

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CRE

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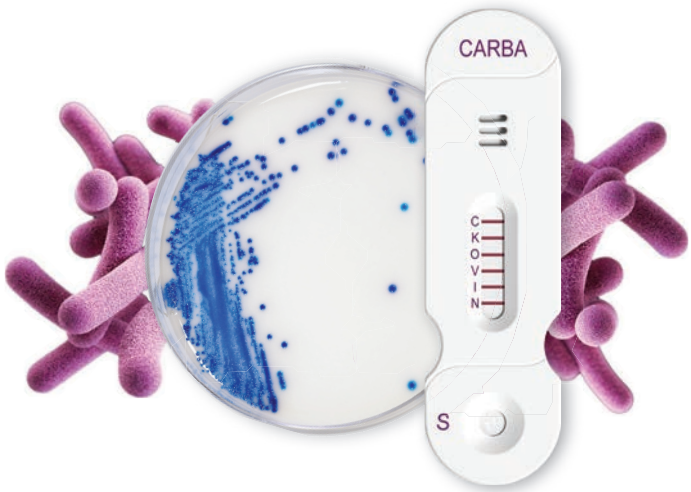
Cat. no. G323



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CARBA 5

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Cat. no. CARBA5

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