May 2021

CLN Clinical Laboratory News

An AACC Publication | Volume 47, Number 4

DRY SWABS FOR SARS-COV-2

Incubating without liquid media worked in new research.

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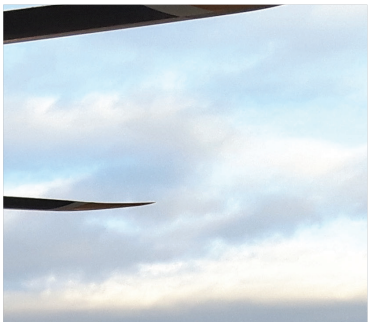
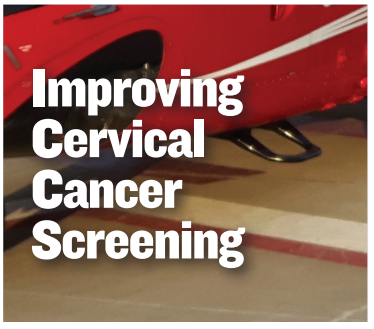
New Heights for POCT

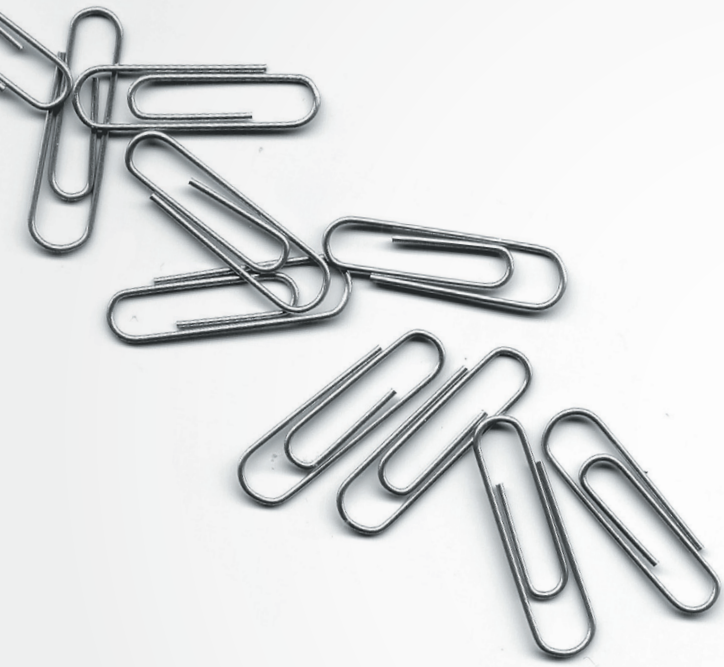


Improving Cervical Cancer Screening



Genetic Insights Heal Families

AACC Better health through laboratory medicine.



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Clinical Laboratory News is published monthly (10 times per year—Jan./Feb., March, April, May, June, July/Aug., Sept., Oct., Nov., and Dec.) by the American Association for Clinical Chemistry. 900 Seventh St., NW, Suite 400, Washington, DC 20001. Phone: +1 202.835.8756 or +1 800.892.1400 Fax: +1 202.877.5093. POSTMASTER: Send address changes to AACC, 900 Seventh St. NW, Suite 400, Washington, DC 20001.

Design and Production Management
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Features

Departments

"It is imperative that laboratory medicine professionals and pathologists treat serum protein electrophoresis and serum immunofixation electrophoresis as a clinical pathology consultation."
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Federal Insider

AACC Coalition Calls for Harmonization Funding

Twenty associations, clinical laboratories, and in vitro diagnostics companies joined an AACC-led coalition calling on Congress to increase funding for the Centers for Disease Control and Prevention (CDC) to continue its efforts to harmonize the reporting of clinical laboratory test results. The coalition is asking Congress to appropriate an additional $7.2 million for harmonization activities directed by CDC's Environment Health Laboratory in the fiscal year 2022 budget.

In a letter to legislators, AACC notes that past funding for harmonization has resulted in expanded harmonization and standardization activities that improve detection and management of hormone disorders, kidney disease, cancer, and heart disease. Using the funds AACC has advocated for in past years, CDC has distributed free reference/harmonization materials for clinical standardization programs for chronic disease biomarkers; developed reference methods for biomarkers used in the diagnosis of multiple diseases, including bone, kidney, cardiovascular, and endocrine disorders, as well as diabetes and cancers; expanded outreach of harmonization/standardization programming to non-traditional markers, point-of-care-testing devices, and patient and payor organizations; and conducted method performance evaluations for laboratories and manufacturers.

"The undersigned organizations believe that every patient should have access to dependable and accurate clinical laboratory test results and that those test results should be harmonized," the coalition wrote in a letter to lawmakers.

FEDERAL ADVISORS EXPLORE PAMA DATA COLLECTION CHANGES

A preliminary report at the April 2 meeting of the Medicare Payment Advisory Commission (MedPac) suggests ways that the Centers for Medicare and Medicaid Services (CMS) could change how it implements the Protecting Access to Medicare Act (PAMA), a law that initiated significant cuts to most routine laboratory tests on Medicare's Clinical Laboratory Fee Schedule (CLFS). In the 2020 Further Consolidated Appropriations Act, Congress mandated that MedPac study CMS's methodology for collecting private payer rates.

PAMA requires that CMS use a weighted median of private rates for CLFS payments. The law's critics have complained that CMS's method of collecting this private payer price data gives too much weight to large, independent laboratories that generally negotiate the lowest rates with insurers.

In the MedPac meeting, policy analysts said that their study showed independent laboratories were indeed "overrepresented" in CMS's first round of data reporting—90% of the private payer data reported to CMS came from independent labs, even though these labs only perform 48% of the tests billed to Medicare.

Further illustrating the discrepancy, MedPac's analysis showed that, compared to independent laboratories, private payer rates were on average 45% higher at hospital outpatient laboratories and 53% higher at physician office laboratories.

The MedPac analysts presented a proposal to collect a more representative sample through a survey instead of the data collection method CMS currently uses.

The MedPac study also found that CMS spending on laboratory testing increased from 2017 through 2019, despite cuts to reimbursement for most tests and even though overall utilization remained about the same. The increase in overall cost was the result of new, high-cost tests, they said. MedPac will issue a final report on the CLFS in June.

BIDEN ADMINISTRATION'S APPROACH BOOSTS INSURANCE ENROLLMENT

The Department of Health and Human Services (HHS) announced that more than half a million consumers have already signed up for health insurance through HealthCare.gov as a result of the administration's special enrollment period (SEP) for the COVID-19 public health emergency and the additional financial assistance from the American Rescue Plan. According to HHS, the new financial assistance has resulted in significantly reduced premiums for consumers using the federal health insurance marketplace.

HHS data also show gains in enrollment among historically uninsured communities, including Blacks and Americans near the poverty level. Of applicants who identified a race, 17% identified as Black, compared to about 11% in both 2020 and 2019. Among consumers requesting financial assistance, 41% reported being at or slightly above the federal poverty level, compared to 38% in 2020 and 33% in 2019.

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Nova Biomedical's Educational Webinar Series Presents:

Plasma Volume Status in Heart Failure: Clinical Implications and Future Directions

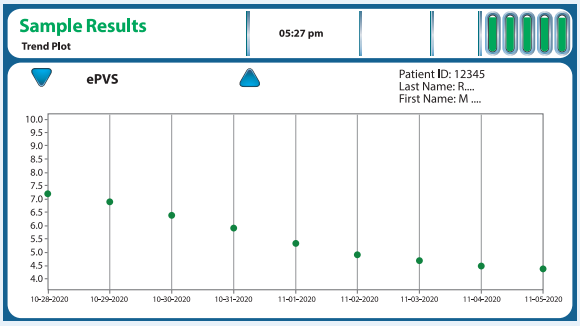
Congestion is one of the main predictors of poor outcome in patients with heart failure (HF). Assessing and monitoring congestion is essential for optimizing HF therapy. Among the various available methods, serial measurements of estimated plasma volume (ePVS) using routine blood count and/or body weight (e.g., the Strauss, Duarte, Hakim formulas) may be useful in HF management. This webinar will summarize the recent evidence supporting the association of ePVS with clinical congestion and outcomes and discuss future directions for monitoring ePVS in congestive heart failure (CHF) patients.

Primary Presenter

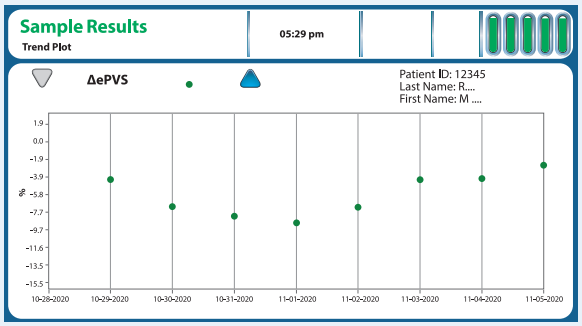
Nicolas Girerd, MD, PhD, Professor of Medicine
Centre Hospitalier Universitaire de Nancy,
Centre d'Investigation Clinique Plurithématique,
Institut Lorrain du Coeur et des Vaisseaux

A Point-of-Care Device for Measuring Plasma Volume in Critically Ill Patients

Plasma volume is one of the top priorities in evaluating and treating many different conditions including shock, sepsis, CHF, acute or chronic kidney disease, and pulmonary disease. ePVS can be calculated only by using measured hematocrit and measured hemoglobin. Studies have shown that both ePVS and percent change values (ΔePVS) are good markers for assessing a patient's volume status and for guiding therapy. Stat Profile Prime Plus® critical care analyzers report both ePVS and ΔePVS real-time at the bedside as part of a comprehensive blood gas/critical care test profile.



Prime Plus screen showing absoute values (ePVS)



Prime Plus screen showing percent change (ΔePVS)

Presenter

Dennis Begos, MD, FACS, FACRS
Associate Medical Director,
Medical and Scientific Affairs,
Nova Biomedical

Webinar Dates:

Thursday, June 10, 11:00 AM ET / 17:00 CEST
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Bench Matters

Navigating Middleware Minefields

Jasmine Messina, MLS(ASCP)CM

Thomas J.S. Durant, MD

The laboratory information system (LIS) is arguably the most prominent piece of software in the clinical laboratory. It is often the first stop for inbound electronic messages (orders) received from the electronic health record and the last stop for outbound messages (results).

However, between the LIS and the instrument now sit an increasing number of software components, most of which have emerged contemporaneously with the increasing prevalence of laboratory automation solutions. Referred to as middleware, these emerging software components often allow laboratory analysts to manage clusters of automated instruments from a central computer workstation.

Per the CLSI AUTO03-A2 standard on automation communications, middleware designed for process control of total laboratory automation (TLA) systems is known as the laboratory automation system (LAS). Indeed, the LAS is a major component of TLA solutions, and it comes with varying degrees of end-user support and maintenance needs.

The growing sophistication of LAS design has profound implications for staff training, organization, and the future of information technology-intensive roles in the clinical laboratory.

Staffing the Laboratory Automation System

In 2018, our institution implemented an automated front-end specimen processing unit that was coupled with clusters of chemistry analyzers. The LAS, which governs the function of these TLA-modules, is a useful and representative example for discussing lessons learned, and the complexity of LAS-middleware support.

One of the fundamental considerations for any newly acquired software system is deciding which team within an organization is going to be responsible for the application. At our institution, we felt it would be beneficial for the LAS support analysts to have hands-on experience with the workflows that the LAS is governing. Accordingly, we chose to train medical laboratory scientists (MLS) in the maintenance and support of the LAS. This created a novel IT-support (ITS) structure within our organization to operate semi-independently from the LIS team, which organizationally resides within a centralized ITS structure serving the entirety of the healthcare delivery organization.

Creating this new LAS team required close coordination with central ITS and training of the MLS employees on institutional IT practices, such as security protocols (e.g., user authentication and authorization), assignment of end-user privileges (e.g., administrative vs. standard users), ensuring a 24/7 on-call schedule for end-user support, and change

Greg Gibson

control for configurations in the LAS (e.g., process control rules).

Change control was a particularly novel concept to the laboratorians involved in this project, although it harbors many parallels with good laboratory medicine practice. In the IT service industry, change control is generally described as a documentation process that captures information about changes made to a software system: What is the change, and why was it made?

At our laboratory, we implemented a form-based change control process that we analysts use for any LAS-modification (see example online at www.aacc.org/cln). These forms undergo two-person review and are ultimately signed by the lab supervisor and medical director. In addition, analysts store all configurations of the predicate state in a readily available location that allows them to revert changes if they observe unintended errors. While the particular change control processes we have implemented may not be widely generalizable across laboratories, they exemplify the significant oversight and process control required for the maintenance of these complex automation systems.

With respect to server maintenance, the LAS support analysts must routinely schedule several software updates in coordination with laboratory operations to allow for LAS downtime during server restart periods. These updates may include the server operating system (e.g., Windows Server), other server application software, and the LAS itself. To minimize downtime, updates need to be done in close coordination with LAS analysts, laboratory staff, and in some cases, the institutional server management teams.

Data storage hardware and disk space also require the careful attention of the LAS support analysts for regulatory compliance (CAP GEN.20377 Record/Specimen Retention). At our institution we have 46 instrument connections to our LAS and verify approximately 8,000 tests per day. In the last 4 months, we have generated approximately 600 GB of data. Due to limitations in our initial storage capacity requirements, we encountered emergency issues that required offloading of data and expansion of storage in real-time.

Rethinking Roles and Relationships

As technology in the laboratory continues to progress, the lines between ITS and laboratory medicine may need to be redrawn with the creation of novel organizational structures. While there are similarities among best practices between both fields, there are sufficient differences. Dedicated training and socialization to informatics culture is a prescient need when considering implementation of automated systems.

As with any complex system, modifications can result in unintended adverse consequences, which in some cases can go unnoticed for prolonged periods of time. To this end, we have tried to implement robust safeguards to protect against these types of errors, in hopes that with the adoption of novel automation systems, we can continue to ensure the fidelity of laboratory results and provide the quality of service our clinical colleagues have come to expect.

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The Sample

Dry Swabs May Make SARS-CoV-2 Testing Safer and Easier

Using "dry swabs" may simplify SARS-CoV-2 specimen collection, make liquid transport media unnecessary, and mitigate safety risks while preserving testing's accuracy, according to researchers (J Appl Lab Med 2021 Feb 25;doi:10.1093/jalm/jfab010)

Processes related to use of universal transport media (UTM) or viral transport media (VTM) used in SARS-CoV-2 testing create a biosafety concern because they may generate aerosols and infectious waste. Dry swabs could provide an alternative because they allow transport of specimen collection swabs in a tube without liquid transport media. Upon receipt, the laboratory hydrates them for analysis in transport media. This process relegates aerosols to a biological safety cabinet, eliminates the need to distribute aliquots of collection media to the collection site, and may eliminate the need for refrigeration.

To test use of dry swabs, researchers used a pool of SARS-CoV-2 positive specimens to inoculate flocked swabs. They immediately placed flocked swabs into UTM after inoculation and ran tests. Meanwhile, the researchers put 15 swabs into sterile 15 mL conical tubes and incubated them at room temperature—some for 1 day, some for 2, and some for 7 days. The researchers repeated the protocol for vital transport media (VTM) and saline.

For comparison, they also prepared a series of swabs and tested them in parallel. However, the researchers stored these swabs in the corresponding liquid transport media UTM, VTM, or saline and incubated them at room temperature. They then tested the swabs at 1, 2 and 7 days after inoculation, and in duplicate. They performed all testing using the Roche cobas SARS-CoV-2 assay.

Results from dry swabs tested at days one, two and seven were within two cycle thresholds (Cts) of the average Ct values for swabs hydrated in the same media and tested on day zero. The researchers found no statistical difference in Ct values for swabs incubated in liquid media versus those incubated in dry swabs at room temperature prior to hydration in liquid media.

The researchers noted that the stability of SARS-CoV-2 nucleic acid on dry swab specimens warrants further study of the new specimen collection and transport technique.

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PANEL COULD AID EARLIER DIAGNOSIS OF PANCREATIC CANCER

Researchers have identified two circulating groups of pancreatic ductal adenocarcinoma cancer (PDAC) biomarkers that may lead to earlier diagnosis of some potentially treatable tumors (Clin Cancer Res 2021; Mar 18: doi: 10.1158/1078-0432.CCR-20-4215).

PDAC is one of the most solid lethal tumors, with most patients diagnosed at an advanced stage when surgery is no longer an option. The only currently useful biomarker for monitoring PDAC patients after surgery and during other treatment—carbohydrate antigen 19-9 (CA19-9)—is nonspecific.

The researchers studied 92 proteins involved in inflammation, development, and progression

PDAC from 701 patients with stage I–IV PDAC, 102 patients with nonmalignant pancreatic disease, and 180 healthy blood donors. The researchers measured plasma CA19-9 in all samples.

Two bioinformaticians worked independently with regression models and identified two high-performing protein panels. One, called index I, contained 9 candidate protein signatures, plus CA19-9. The other, index II, had 23 proteins and CA1-19. Proteins included in both indices are involved in apoptosis (CASP-8, FASLG, and TRAIL), immunosuppression (CCL20, CD4, IL10, MMP-7, MIC-A/B, and PD-L2), inflammation (CRTAM, IL8, CXCL1, IL33, CD40L, IL1a, CSF-1, IL5, and IL12), hypoxia (LAMP-3), chemotaxis (MCP-3, CCL23, and CCL3), and vascular remodeling (VEGFC).

Previous studies involving PDAC cell lines or patients have note that some of these proteins are associated with or involved in the disease. IL8 and IL10 are elevated in patients with PDAC and correlated both with each other and with IL6, a well-known prognostic biomarker in PDAC. IL8 is a proinflammatory chemokine. Its expression is stimulated by various cytokines, hypoxia, and reactive oxygen species. Activated intracellular pathways leading to IL8 expression include NF-kB, PI3K-AKT, and p38 MAPK. They are also known downstream signaling pathways of activated *KRAS*, the oncogene activated in more than 90% of PDAC tumors. Regulatory T cells in the tumor microenvironment secrete IL10, contributing to a local immunosuppressive environment in PDAC tumors.

The researchers call for a formal prospective test of the panel's clinical utility in the initial phase of diagnosis alongside the normal diagnostic work-up for pancreatic cancer.

NEWER GLYCEMIA MARKERS DON'T BEAT HBA1C

A recent study concludes that glycated hemoglobin (HbA1c) is still an important biomarker for maternal and neonatal outcomes in pregnancies among people with type 1 diabetes (Diabetes Care 2021;44:681-689).

HbA1c measurements typically reflect glycemia over the prior 2-3 months, making HbA1c less suitable for weekly or biweekly monitoring of type 1 diabetics during pregnancy. Meanwhile, an HbA1c alternative, continuous glucose monitoring (CGM), has been shown to improve maternal and neonatal outcomes, including a substantial reduction in newborn intensive care unit (NICU) admissions. Research has also highlighted new approaches to glycemia monitoring, including alternative laboratory markers such as glycated CD59 (gCD59), 1,5-anhydrogluticol (1,5-AG), fructosamime, and glycated albumin.

To shed light on which metrics, used at which time points, would best predict pregnancy outcomes, researchers assessed how well HbA1c, CGM metrics, and alternative biochemical markers for type 1 diabetes detect pregnancies at risk for suboptimal outcomes. The researchers randomized participants who were pregnant or planning pregnancies to real-time CGM with CGM or capillary glucose monitoring alone for diabetes management. Women in the capillary glucose monitoring group also had short periods of masked CGM to allow comparison of CGM metrics between groups.

The researchers monitored women for preeclampsia, proteinuria, neonatal hypoglycemia requiring intravenous dextrose, and NICU admission for at least 24 hours.

Of 225 participants who gave birth to live infants, 157 gave at least one additional sample for laboratory testing of alternative glycemia markers, including fructosamine, 1,5-AG, glycated albumin, and gCD59.

The researchers found that HbA1c, CGM metrics, and alternative laboratory markers of glycemia all identified pregnancies at increased risk of suboptimal neonatal outcomes, even from the first trimester. However, neither laboratory markers nor CGM metrics provided strong prediction of any pregnancy outcome. Markers and metrics mostly had areas under the receiver operating characteristics curve (AUROC) of 0.70.

Alternative laboratory markers did not appreciably increase the AUROC for predicting pregnancy outcomes more than widely available HbA1c or CGM metrics, such as time within and above target glucose range.

Point-of-Care Testing by Ambulance Teams: An Opportunity for a New Standard

Patients depend on reliable testing from air and ground ambulance teams, and the complexity of these environments deserves special consideration.

Both the Canadian Society of Clinical Chemists (CSCC) and AACC have recently issued recommendations for how laboratories can take an active role in ensuring robust quality for point-of-care-testing (POCT) performed by their organizations (*1*,*2*). Recommendations include either direct oversight of all POCT or establishing an interdisciplinary committee.

In the Canadian province of Alberta, laboratory oversight of POCT performed by ambulance teams has been inconsistent (*3*). However, work is underway to better understand current POCT workflows and POCT-related challenges for these teams. This article provides an overview of what we have learned to date and proposes a standard for POCT performed by ambulance teams in Alberta and elsewhere.

AMBULANCE SERVICES IN ALBERTA

As a large province that covers 254,825 square miles (660,000 square kilometers)—including large areas of wilderness—Alberta relies heavily on ambulance teams to provide its population with emergency and critical care outside of hospitals. The full fleet includes more than 500 ground ambulances, 11 airplanes, 8 helicopters, and a mobile stroke unit. The majority of the province's ambulance teams perform some form of POCT in order to allow earlier, more effective patient interventions.

Ground ambulance teams almost exclusively use small, portable glucose meters (such as the Roche Accu-Chek Performa), while most air ambulance teams use hand-held Abbott i-STAT1/i-STAT Alinity blood analyzers. The mobile stroke unit relies on four different POCT systems:

BY ANNA K. FÜZÉRY, PHD, DABCC, FCACB, AND GERALD J. KOST, MD, PHD, FAACC

a Performa meter, an i-STAT1, a Roche CoaguChek XS Pro prothrombin time/international normalized ratio (PT/INR) meter, and a Sysmex pocH-100i hematology analyzer.

POCT WORKFLOWS IN AMBULANCES

POCT workflows for Alberta's ambulance teams are similar across air and ground units (*3*), and they typically encompass three phases (Figure 1). Despite the similarity in workflows, ambulance teams throughout the province have adopted heterogeneous approaches to each testing phase. For example, validation of POCT devices and reagents prior to use may include calibration verification, quality control testing, patient sample comparisons with the laboratory, and/or electronic simulator testing.

The validation may be done by emergency medical services (EMS) personnel, laboratory personnel, or a combination of both. The source of this heterogeneity is multifold and includes operational silos within the healthcare system, varied oversight of POCT in EMS programs by laboratories across the province, and a lack of provincial, national, and international guidelines for POCT performed by ambulance teams.

POCT CHALLENGES IN THE MOBILE ENVIRONMENT

Even in the most ordinary circumstances, POCT presents laboratorians with special concerns, from documenting test results to standardizing methods with the central laboratory. For ambulance teams in Alberta, the nature of the patient care environment creates a host of additional, unique considerations. These challenges include communication difficulties, temperature extremes, other environmental constraints, lack of backup testing, confounders to POCT result interpretation, and more (*3*, *4*). Others have documented similar challenges for ambulance teams elsewhere *(5–7)*.

Communication. Alberta's ambulance teams attend to a variety of patients with communication difficulties. Some patients may be unconscious or incoherent, while others may be unable to communicate effectively in the absence of a language interpreter. These communication difficulties pose several issues to performing POCT.

First, the ambulance team may be unable to ascertain the medical history of the patient and whether any of it is relevant to the testing that will be performed. For example, has the patient ingested any substances that may interfere with a particular POC assay and that may lead to inaccurate results? Second, a lack of positive patient identification prevents POCT results from making it into the patient's permanent medical record. This may lead to compromised patient

F1 Typical Point-of-Care Testing Workflow for Alberta's Ambulance Teams

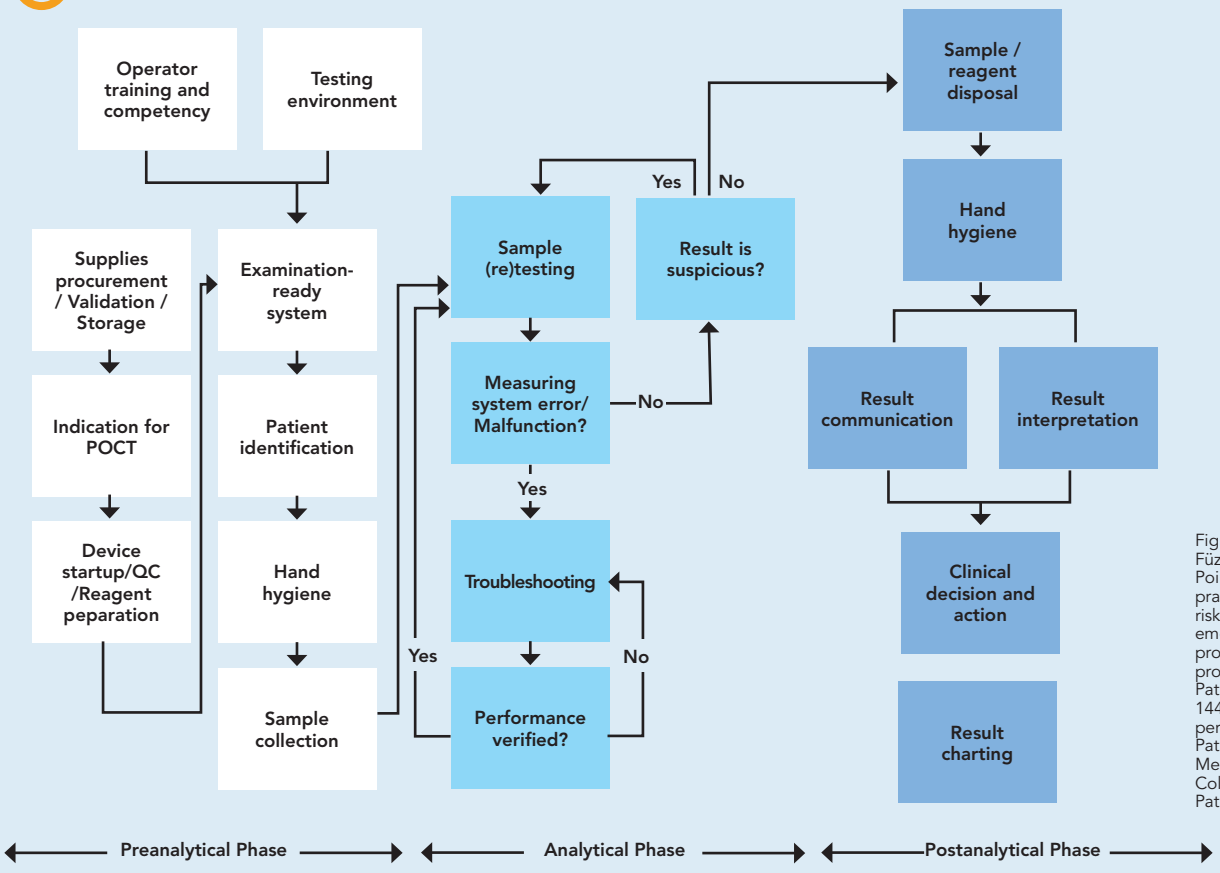

Figure is reprinted from Füzéry AK and Kost GJ. Point-of-care testing practices, failure modes, and risk-mitigation strategies in emergency medical services programs in the Canadian province of Alberta. Arch Pathol Lab Med 2020; 144(11): 1352-1371. With permission from Archives of Pathology & Laboratory Medicine. Copyright 2020. College of American Pathologists.

Previous page: Courtesy of STARS air ambulance, Royal Alexandra Hospital (Edmonton, Alberta, Canada); ollo / iStock

care further downstream, as some members of the healthcare team will receive an incomplete report of the patient's EMS encounter.

Temperature extremes. Average winter daytime temperatures in Alberta range from 25°F to 32°F (-4°C to 0°C), while average nighttime temperatures range from 7°F to 18°F (-14°C to -8°C). Ambulance cabins quickly cool to temperatures near 32°F (0°C) when exposed to these winter conditions which, in turn, leads to the cooling of POCT devices below operational temperatures. Making matters worse, inexpensive and compact transport containers with active temperature control (e.g. thermo-modulating capability) that can keep POCT systems warm are not commercially available in Canada. In-house-developed transport containers provide some degree of insulation and slow down the cooling process, but they do not eliminate it completely. This forces ambulance teams to resort to inconvenient workarounds, including warming a POCT device inside a jacket and leaving a vehicle running while attending to a patient.

Temperature extremes may also impact POCT in other, less well-understood ways. Temperature-dependent analytical performance data for POCT systems is not readily available from manufacturers, but a handful of published studies indicate that clinically significant result changes may arise after a brief exposure to thermal stresses (*8*). The direction and magnitude of the change is dependent on the POCT system, the nature of the thermal stresses, and the length of exposure. Notably, the impact of repeated exposures to such stresses over a longer period of time is even less well characterized. Alberta has yet to undertake local studies that validate the short- and long-term performance of POCT systems under field conditions.

Other environmental constraints. Ambulance teams encounter additional environmental constraints: Lighting conditions are sometimes poor, a flat and stable testing surface is not always available, and the surrounding environment may be loud, stressful, and fast-paced.

These constraints enhance the risk of error in all phases of the POCT workflow. For example, a sample may be applied incorrectly to the POCT device, leading to either an inaccurate result or to a measurement error message. Patient identifiers may be manually entered into the POCT device with typos, leading to an incorrect association of the results with a different or nonexistent patient. Mistakes may also occur while reading the results off of a POCT device, especially with older devices that allow minimal control of screen backlighting.

Lack of backup testing. Alberta's ambulance teams are often required to urgently administer life-saving or stabilizing interventions while on scene or in transit. POCT results may influence the decision around a particular intervention, such as a blood glucose result guiding hypoglycemia treatment. Despite this critical dependence on POCT, ambulance teams have limited options for backup testing in the event of a suspect result or a POCT system malfunction. A backup device is not routinely carried in most ambulances, owing to space constraints.

The urgency of the situation does not allow for a blood sample to be dropped off at a nearby laboratory. This leaves ambulance teams with three options: 1) retest the already collected sample to see if the repeat result is less suspect, 2) collect and test a new sample to see if the new result better matches available clinical information, and 3) troubleshoot and, if possible, fix the malfunctioning device. One or more of these approaches may prove to be

POCT results may influence the decision around a particular intervention, such as a blood glucose result guiding hypoglycemia treatment.

T1 Proposed Standard for POCT Performed by Ambulance Teams

Component	Details
Overall Oversight	• Ultimate accountability and authority to designate responsibilities for training, quality assurance, and other components lies with an accredited laboratory. • The accredited laboratory has a suitable laboratory director, or equivalent, with appropriate qualifications.
Training and Competency	• Theoretical and practical training on sample collection and handling under field conditions • Training on interferences and other factors that may impact result accuracy in the field • Ongoing competency program based on refresher sessions, rather than on completion of a certain number of tests per year
System Selection	• Evidence from clinical, analytical, and human factors studies performed locally and elsewhere • Input from clinical stakeholders • Cost and space considerations • Operator and QC lockout is preferred (if available) • Connectability is preferred (if available) • Relevant operating ranges for field conditions • Screen backlighting (if available) • Long battery life (if applicable) • Testing consolidated onto 1–2 systems at most • Ease of use in highly stressful, noisy, and/or fast-paced environment
System Validation	• Analytical and connectivity validation prior to implementation • Preimplementation analytical validation includes environmental conditions that simulate those encountered in the field • Postimplementation validation of new lots and shipments of reagents • Postimplementation validations always (preferred) or periodically include environmental conditions that simulate those encountered in the field
System Storage	• Adherence to manufacturer's specifications for storage at EMS base and when in the field • Transport containers with insulation and/or active temperature control (preferred) • Transport containers with continuous-read temperature and humidity data loggers (preferred) or irreversible temperature and humidity indicators • Review of postimplementation QC, EQA, split-sample comparison, and new reagent validation data for short-term and long-term reagent stability trends • Storage protocol includes sufficient time for adequate battery recharging
Connectivit	• Adherence to data and security standards • Ability for remote operator management, software updates, automated result transmission • Connectivity infrastructure that allows real-time transmission of results while in the field (preferred) or delayed transmission once back at EMS base
Troubleshooting	• Roles for clinical operators, POCT personnel, manufacturer • Availability of loaner systems • Protocol for confirmatory laboratory testing • Strategies for troubleshooting in the field when backup testing and/or troubleshooting support from laboratory personnel may not be available • Availability of remote troubleshooting support from laboratory personnel • Alternate patient care protocols when a POCT test is unexpectedly unavailable
QA: QC	• Adherence to manufacturer's requirements at minimum • Performance of liquid QC • Performance of any nonautomated internal/external electronic controls • All QC performed on reagents that have been taken out into the field at least once or multiple times (preferred) and that were subsequently returned unused
QA: EQA	• Participation in an EQA program (proficiency testing) • Performed on reagents that have been taken out into the field at least once or multiple times (preferred) and that were subsequently returned unused
QA: Laboratory Comparisons	• Split-sample comparisons between POCT device and laboratory analyzer at least once per year, but preferably more frequently • Performed on reagents that have been taken out into the field at least once or multiple times (preferred) and that were subsequently returned unuse
Documentation	• Standard operating procedures, checklists, forms • Complete documentation of all activities related to POCT • Document control • Access to standard operating procedures and checklists (especially those relevant to troubleshooting) while in the field • Connectivity and real-time (preferred) or delayed transmission of patient results • Strategies for manual posting of POCT results to patient's permanent medical record if automated transmission unavailable • Protocol for linking in a traceable manner an unidentified patient with their results in all relevant clinical documentation systems • Protocol for posting of results to a patient's permanent medical record once the patient's identity has been established
Safety	• Infection prevention and control protocols • Personal protective equipment • Positive patient identification • Protocols for communicating and acting on critical results

Abbreviations: POCT, point-of-care testing; QA, quality assurance; QC, quality control; EQA, external quality assurance; EMS, emergency medical services. The term "system" encompasses the POCT device, reagents, docking station (if applicable), battery charger (if applicable), and any other supplies required to test a sample on the POCT device.

successful in some instances, but at other times ambulance teams have to make their decision in the absence of a POCT result.

Confounders to result interpretation. POCT result interpretation may be confounded by many factors. For example, a difficult sample collection can lead to sample hemolysis, causing false increases or decreases in selected test results. Sample contamination with intravenous fluid can have similar effects. Medication administration may lead to testing interferences unless sufficient time has elapsed for the medication to be cleared from the patient's system.

Laboratories commonly implement sophisticated rules in their laboratory information systems to flag suspect test results, and may also set up automatic reflex testing algorithms to better define the confounding factors. Alberta's ambulance teams do not have access to such tools and instead use their training, experience, and intuition to identify any confounders to POCT result interpretation. This task grows in difficulty with the number of systems onboard an ambulance and the complexity of clinical intervention.

POCT SUPPORT AND GUIDANCE

Alberta has recently embarked on the design and implementation of standardized support programs for POCT throughout the province. The overall approach uses previously published POCT guidance documents (*1*, *2*, *9*) to develop a robust support framework with components that include training and competency, POCT system selection/validation/storage, connectivity, troubleshooting, quality assurance, documentation, and safety. The inclusion of features that address the special challenges of ambulance teams has been limited to date, but this is expected to change as local, national, and international guidelines become available on this topic.

Based on our experiences (*3*, *4*, *8*) and those of others (*5-7*), we propose in Table 1 a standard for POCT performed by ambulance teams in Alberta and elsewhere. This standard incorporates features that are already considered best practices for all POCT, as well as features that aim to mitigate the special challenges encountered by ambulance teams. For example, initial training and ongoing competency is considered an essential component of all POCT (*1*, *2*, *9*). We propose that this initial training and ongoing competency program incorporate a targeted section on best practices for sample collection and handling under the environmental constraints described earlier.

A CALL TO SHARE DATA

Our recommendations provide a starting point for supporting ambulance teams, but they may need to be revised as the evidence base for POCT in this setting continues to grow. Laboratories and ambulance teams should trial the recommendations for their feasibility and effectiveness, and should then share their experiences widely. This process will facilitate revision and further development of the proposed standard, and will ultimately lead to local, national, and/or international guidelines on POCT performed by ambulance teams.

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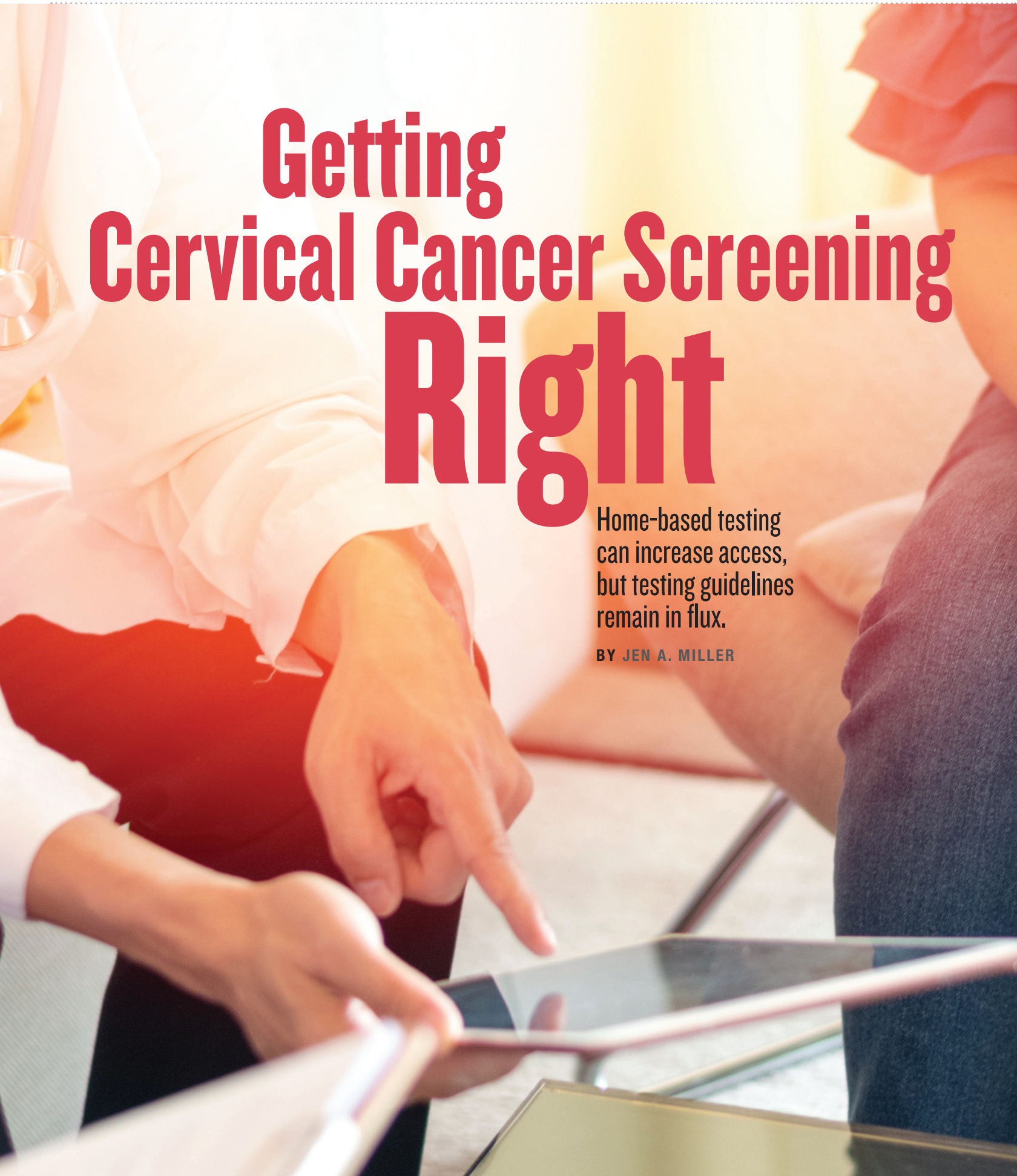

Getting Cervical Cancer Screening Right

Home-based testing can increase access, but testing guidelines remain in flux.

BY JEN A. MILLER

Amid COVID-19 restrictions, data show that health screenings have plummeted. Cervical cancer screenings in particular have dropped, portending worse outcomes for at-risk women. Self-sampling kits—the predominant method of cervical cancer screening in some countries—are undergoing clinical trials in the U.S., which could help bridge this gap in areas that do not quickly bounce back from pandemic restrictions. At the same time, sliding guidelines on cervical cancer screenings, and debates about which kind of test is best are are muddying the waters for patients and clinicians about the best way forward.

In light of all this, experts say that clinical laboratorians must prepare to advise health systems and clinicians not only on test selection and interpretation, but also how various screening efforts should restart—or even escalate—as the pandemic's effect on routine screenings and healthcare visits wanes.

SCREENING WORKS—WHEN IT HAPPENS

Expanding access to cervical cancer screening is critical. About 14,000 new cases of cervical cancer are diagnosed in the U.S. each year, according to the National Institutes of Health, and more than 4,000 Americans die of the cancer every year.

Screening has proven its value and reduced the incidence of cervical cancer deaths by more than 60% since it was introduced in the 1950s. However, even before the COVID-19 pandemic, a Mayo Clinic study found that less than two-thirds of women were up to date on their cervical cancer screenings (J Womens Health 2019;28:244-9). Among those age 21–29, just over half were current.

Lead author of the study Kathy MacLaughlin, MD, wrote that these results should encourage healthcare providers to look for new ways to reach patients for screenings. The study encourages testing clinics to offer evening and Saturday hours, and urgent care clinics to offer cervical cancer screenings. Another option not addressed in this study: at-home testing kits.

DATA REVEAL HOW SHUTDOWNS LEAD TO SKIPPED SCREENINGS

The COVID-19 pandemic greatly exacerbated screening problems. As hospitals shifted their focus to treating COVID-19, patients with less-serious conditions steered away from medical centers. In some cases, physicians were forced to postpone nonemergency care. For these and other reasons, women skipped regular cervical cancer screenings along with other preventive care.

According to the Centers for Disease Control and Prevention, in a group of approximately 1.5 million women in the Kaiser Permanente Southern California network, cervical cancer screening rates dropped about 80% during California's first stay-at-home order from March 19, 2020 to June 11, 2020 (MMWR Morb Mortal Wkly Rep 2021;70:109–113). Screening rates were 78% lower among women ages 21–29 and 82% lower among women ages 30–65. The decrease was similar across all racial and ethnic groups. The silver lining—rates returned to near normal after reopening.

The results weren't shocking, according to Chun Chao, PhD, cancer epidemiologist at Kaiser Permanente Southern California, and she was encouraged when rates returned to baseline so quickly after the lockdown. "That's good but a little surprising," she said.

The results also point to where at-home testing kits could help women stay on target. "At Kaiser, we screen for colorectal cancer this way. They take a sample and mail it back. That has continued during the pandemic and even after the stay-at-home order," said Chao. "At-home self-collection could play a very important role if, God forbid, we're in a similar situation again."

CAN HOME TESTING BRIDGE THE GAP?

There are no Food and Drug Administration-approved at-home screening kits for cervical cancer, but they are in the works, as are clinical trials. Later in 2021, the National Cancer Institute plans to launch a multisite trial of about 5,000 women to see whether self-testing for human papillomavirus (HPV) is comparable to going into a physician's office. This effort goes beyond how to screen during a pandemic and toward tackling how difficult it is for many women to navigate the U.S. healthcare system.

This effort goes beyond how to screen during a pandemic and toward tackling how difficult it is for many women to navigate the U.S. healthcare system.

"A lot of women who most need to be screened don't have those resources, so who knows when they're going to come in," said Anna Giuliano, PhD, founding director of the Center of Immunization and Infection Research in Cancer at the Moffitt Cancer Center. At-home screening has its limits, though. "If they test positive for a cancer-causing HPV-type, they will have to come to a health center for further diagnoses and treatment," she added.

Healthcare systems would also need to set up the infrastructure to mail, collect, and perform those tests, and have a process in place for suspected positives, Chao noted. "The first priority is to look at those women who normally don't come in. Can you get them to send their samples back with this new approach?" she said.

This isn't a radical idea either. Self-collection kits are already the primary method of screening in New Zealand, Australia, and Europe, and they're the recommended method of screening by the World Health Organization.

In a recent review of the literature around cervical cancer and other screening programs, researchers from the International Agency for Research on Cancer in Lyon, France, emphasized that healthcare professionals should consider the many disruptions caused by the pandemic as an opportunity to improve screening programs (JCO Global Oncology 2021;7:416-24).

"In these unprecedented times, reassessing a cancer screening program could be an opportunity of building back better services," the authors wrote. "Performing a situation analysis and planning accordingly, prioritizing, and keeping focus on evidence-based practices, considering implementation of evidence-based innovations (telehealth and new algorithms), and considering deimplementation of nonevidence-based practices."

GUIDELINES ON SCREENING KEEP CHANGING

Beyond the hurdle of improving access to screening for patients, recent changes in testing recommendations have created confusion about the best way to screen in general. In July of 2020, the American Cancer Society (ACS) updated its guidelines for cervical cancer screenings in several ways.

One of the most significant changes in the ACS guidelines is a preference for HPV testing alone instead of cotesting, which pairs a Pap test with an HPV test. ACS also recommended that anyone with a cervix start screening at age 25 instead of 21, and that those ages 25–29 be tested every 5 years with an HPV test instead of every 3 years

T1 Cervical Cancer Screening Guidelines from ACS, ACOG, and USPSTF

	ACS 2020	ACS 2012	ACOG	USPSTF
21–24	No screening	Pap test every 3 years	Pap test alone every 3 years HPV testing is not recommended	Pap test every 3 years
25–29	HPV test every 5 years (preferred) HPV/Pap cotest every 5 years (acceptable) Pap test every 3 years (acceptable)	Pap test every 3 years	Pap test alone every 3 years HPV testing is not recommended	Pap test every 3 years
30–65	HPV test every 5 years (preferred) HPV/Pap cotest every 5 years (acceptable) Pap test every 3 years (acceptable)	HPV/Pap cotest every 3 years (preferred) Pap test every 3 years (acceptable)	HPV/Pap cotest every 5 years (preferred) Pap test alone every 3 years (acceptable)	Pap test every 3 years, HPV test every 5 years, or HPV/Pap cotest every 5 years
65 +	No screening if a series of prior tests was normal	No screening if a series of prior tests was normal	No screening if a series of prior tests was normal and no history of moderate or severe abnormal cervical cells or cervical cancer	No screening if a series of prior tests was normal and not at high risk for cervical cancer

ACS, American Cancer Society; ACOG, American College of Obstetrics and Gynecologists; USPSTF, United States Preventive Services Task Force; HPV, human papillomavirus

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with a Pap test. For those ages 30–65, the recommendation is now an HPV or cotest test every 5 years or Pap test every 3 years, where before the recommendation had been a cotest or Pap test every 3 years. These new recommendations still differ from those of the U.S. Preventive Services Task Force and the American College of Obstetricians and Gynecologists (See Table 1).

Nicolas Wentzensen, MD, PhD, senior investigator at the National Cancer Institute Division of Cancer Epidemiology & Genetics said in a National Institutes of Health blog post that all three tests can find warning signs of cervical cancer, and that HPV tests are more reliable and accurate than Pap tests. Pap tests also detect abnormal cells that have nothing to do with HPV, which can create false positives, he emphasized. Those in turn can result in inappropriate treatments, which typically involve removing tissue from the vagina and cervix, and can "permanently alter the cervix. That may raise the risk of serious complications in future pregnancy including pregnancy loss and pre-term birth," he said.

However, not everyone in laboratory medicine is on board with the new screening recommendations. A recent study from Quest Diagnostics and the University of Pittsburgh Medical Center found that the HPV and Pap tests done alone are less likely to detect cervical cancer and precancer than using together in a cotesting scheme (Am J Clin Pathol October 2020;154:510-516).

The study assessed the sensitivity of an HPV test alone, Pap test alone, and cotesting in nearly 19 million cotest results performed by Quest Diagnostics between 2010 and 2018. Of 1,615 cotests taken at any time prior to cancer diagnosis, 86.90% were positive by cotesting with a false negative rate of about 13%. By comparison, false negative rates in Pap tests and HPV testing alone were nearly twice as high: 26.4% for the Pap test and 28.4% for the HPV test.

Researchers also found that cotesting detected significantly more women who developed biopsy-confirmed adenocarcinomas, a particularly aggressive form of cervical cancer. Cotests identified 82.3% of this cancer compared to 61.2% by HPV and 59.7% by Pap.

"The bottom line is that cotesting is better than either test alone," said Harvey Kaufman, MD, senior medical director at Quest Diagnostics. "It's not really a comparison of Pap or HPV, it's that with either test versus cotesting, cotesting wins."

That doesn't bode well for the efficacy of at-home kits based on HPV detection. Plus, Kaufman said, an annual exam isn't just a test. "The doctor is doing more than collecting a specimen," he said. The clinician takes a patient's history and performs a physical exam, which is also why he doesn't think virtual visits will replace regular care. "They're trained to look for anomalies and you can't do that remotely," he said.

Kaufman said that despite being critical of some of the ACS changes in the guidelines, he realizes that laboratory professionals have no control over how they were developed. "The best a laboratorian can do is carefully review the literature to guide decision-making," he said.

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Perimortem

Laboratory leadership is key to a sustainable solution that offers answers to grieving families.

BY LINDSAY RAGSDALE, MD, FAAP, FAAHPM

Facing the tragedy of a child's death has profound effects both on families and their medical teams. In the midst of their grief, many families ask questions about why their child died. They yearn for the name of a disease or anatomic findings to which that they can direct their feelings of anger and pain. Knowing the "why" helps bereaved families understand what happened to their child and enables them to begin framing both their past and their potential future family planning.

Unfortunately, answers are not easy to offer. While autopsy is immensely helpful in discerning the cause of death, there are times when the family may decline autopsy—or the findings are inconclusive—and further testing is warranted.

Genetic testing during the perimortem period (at or before the time of death) sometimes can offer critical resolution to these etiologic questions. But it poses a number of unique challenges for laboratorians and clinicians, including: discussing potential cause of death and need for further testing with the bereaved family, determining which tests to order, ensuring appropriate specimen collection and integrity, adhering to the goals of laboratory stewardship committees to reduce unnecessary laboratory testing, and determining a payer source when insurers deny coverage. Moreover, families and clinical care teams often have to make rapid decisions under emotionally strained circumstances.

At Kentucky Children's Hospital, we developed an innovative, transdisciplinary approach to the perimortem genetic testing process. We created a philanthropic fund to help offset the cost of testing for families and established family meetings to discuss the results and plan future steps.

A FAMILY'S JOURNEY INSPIRES ACTION

We were inspired to create a process for perimortem testing at our institution—by one poignant clinical case in which the parents were shocked to learn that their pregnancy was imperiled when an ultrasound revealed significant arthrogryposis (joint abnormalities) and severe skeletal anomalies. Their daughter was born with severe respiratory failure that did not improve with maximal medical support, and she died a few days after birth.

Specimens were obtained to perform genetic testing; however, because of her death, their insurance denied coverage of any testing due to the "testing not impacting her current medical care." Clinicians made many attempts to appeal or find other funding sources without success.

In the meantime, the parents became pregnant again, and the fetus again showed signs of arthrogryposis. This news was devastating for the parents, and they had many questions about how this could happen to them again. This case underscored the importance of finding the "why" to a child's death, both to help the family cope and to provide more information for family planning strategies if desired.

Stakeholders across the institution—from pathologists, laboratory scientists, and clinical chemists to geneticists, pediatric palliative care specialists, hospital administrators, business partners, philanthropists, and legal/compliance professionals—assembled to tackle this problem as a process-improvement project. The overall project was broken into steps: Create a policy and process for perimortem genetic testing; ensure specimen integrity and handling; create a philanthropic fund and approval committee; and develop a review committee to oversee the process and approval of testing. We set a goal to offer genetic testing to at least 90% of bereaved families that met criteria when indicated using our new process.

The project took about a year and a half of work from the perimortem genetic testing committee, and refinement to the process is ongoing. The initial policy work emphasized the balance of patient-centered care with fiscal responsibility, similar to any other laboratory stewardship program. The committee wanted to ensure a transparent process with well-defined inclusion criteria for genetic testing in the inpatient setting that was also agile enough to respond

Genetic Testing

rapidly to the clinical demands of life-threatening cases.

Honest communication among this interdisciplinary team proved essential. Our committee was successful in openly discussing the tension between clinical indications for testing and the financial burden to families or the institution if insurance coverage is denied. The committee looked for sustainable solutions to ensure patient- and family-centered care for bereaved families. The formation of a philanthropic fund became a viable avenue to shoulder the burden of cost for underresourced families in need of answers.

DEVELOPING A PHILANTHROPIC FUND

Insurance plans largely do not cover perimortem genetic testing for the purpose of family planning or developing future reproductive strategies. As a result, some families may be put in financial jeopardy because they have to pay many thousands of dollars out of pocket for testing that isn't covered by insurance. Our team worked to create a process to approve and allocate funds to pay for genetic testing to find answers, inform family planning, and avoid putting families through financial hardship.

Our team was inspired to create a philanthropic fund after taking care of the Embry family (who graciously gave me permission to share their story). Jill and Brandon Embry were excited to find out they were having a girl during their second pregnancy and named her Claire. Prenatal genetic testing, however, revealed that Claire had CHARGE syndrome (Coloboma of the eye, Heart defects, Atresia of choanae, Retardation of Growth and development, and Ear abnormalities). While this news was devastating for the Embrys, they used the genetic testing information to help create a birth plan that ensured Claire's comfort and bonding with both her parents and brother before she passed away.

The Embrys wanted to find purpose through the grief of losing Claire by raising money for genetic testing for other families. Our team was able to add the funds the Embrys raised to existing funds given by a pathologist named Dr. Golden, establishing the Golden-Embry fund. Funding is usually the rate-limiting step for philanthropic development, so with this step solidified, our team our team focused next on developing a solid process for ensuring that funds were approved and allocated in a just and equitable manner. Creating this

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funding allocation policy and referral guideline was a multistep process with stakeholders including laboratory scientists, pathologists, geneticists, genetic counselors, the palliative care team, hospital administrators, the legal team, and philanthropy officers.

Figure 1 shows the authorization process for using funds for genetic testing. Initial referrals to the Golden-Embry fund come from two primary teams—genetics and palliative care. The primary social worker assesses and documents financial need. The laboratory formulary clinical utility subcommittee reviews the case for testing indication and testing type and ensures financial need is documented. A recommendation from the lab formulary utility subcommittee then goes to the Golden-Embry fund steering committee for final approval.

The fund steering committee includes the chairs of pediatrics and pathology and the associate chief medical officer for the children's hospital. The steering committee may decide to approve the total amount for testing up to the maximum per patient, allocate funds for DNA extract and hold, or deny the request. In the 2 years since the funding process was established, 22 bereaved families have had the opportunity for genetic testing with this mechanism, and the authorization process has usually taken no more than 2 days. No cases have been denied funding to date. Several cases have revealed a direct etiology that explained the child's cause of death, and for many of the families, genetic testing has been able to rule out inherited diseases and inform family planning strategies.

TRANSDISCIPLINARY REVIEW COMMITTEE

The collaborative and transdisciplinary character of the perimortem genetic testing committee has been a key to its success. At the beginning of this project, we discovered a lack of coordination among different departments in the hospital and no unifying process or protocol. We learned that establishing communication channels was just as important as creating policies and a process for testing. Many of the frontline clinicians discovered the complexity of billing in the postmortem period, and the laboratory scientists and pathologists discovered the difficulty of obtaining specimens at the bedside. Learning from each other helped us comprehend the full scope of the process and work together to create a solution.

The ongoing collaboration among all of these stakeholders who initially gathered to address perimortem genetic testing became the foundation for the hospital's creation of the lab formulary clinical utility review subcommittee in Figure 1. This committee reviews pediatric perimortem genetic testing and meets regularly to refine the process. The subcommittee set up a shared database of cases to speed asynchronous communication and avoid duplication. This subcommittee reports to the hospital-wide lab formulary clinical utility committee that reviews all genetic testing cases above a certain dollar threshold and manages lab stewardship across the health system.

This review subcommittee has been key in the sustained effort required to ensure continued forward movement of each case through the process. And the transdisciplinary meetings have sparked new initiatives and quality-improvement projects, including initiatives to ensure specimen collection and integrity.

For example, to close the gap between bedside clinicians and laboratory professionals, our perimortem genetic testing subcommittee identified barriers to specimen collection including availability of appropriate media, collection tubes, and requisition forms. Pathology developed a streamlined protocol for on-call pathologists to help bedside clinicians obtain and store specimens. These refinements have successfully changed the workflow for specimen collection and storage for perimortem genetic testing, and also improved relationships between the laboratory professionals and pathologists with bedside clinicians.

THE LABORATORY'S ROLE IN BEREAVED FAMILY MEETINGS

A crucial part of testing pathways and funding protocols is the follow-up with families after testing is completed. The participation and insights from laboratory medicine professionals are critical to ensuring these discussions meet the family's needs.

Family meetings have a dual purpose: They provide families space to reprocess the events of their child's death and an opportunity to talk about completed testing or autopsy reports. Sometimes, families ask questions that may have surfaced weeks or months after the death.

The meetings can also help resolve guilt and blame, which can be common among bereaved families. Reassurance from a trusted provider can be beneficial for many families. Feelings of guilt and blame are a common theme among bereaved families, and it can be liberating to hear from

Key Lessons in Developing a Perimortem Genetic Testing Process

- Start with the fundamentals of good communication among all stakeholders. Each stakeholder should come to the table with curiosity about the parts of the process that they may not understand completely. This open-minded approach encourages creative solutions and avoids the pitfalls of institutional convention.
- Specimen integrity and collection in the perimortem period is crucial and can be a major barrier in an established process. We suggest creating a mock patient and walking through the steps of deciding which test is indicated, ordering a test, obtaining a specimen, coordinating with the laboratory for specimen processing, obtaining results, billing, and discussing the results with families. A test case can highlight pressure points in the process that can be remedied before a real patient scenario.
- To develop a philanthropic fund, an institution needs access and permission for donor-funded activities. It is essential to find ways to highlight to potential donors why perimortem genetic testing is important, as some of the nuances of genetic testing may not be as familiar to potential donors. Ensuring compliance with legal regulations is crucial for this process as well.
- Assembling a transdisciplinary team is essential in establishing a process for perimortem genetic testing and troubleshooting the pressure points in the system. An additional benefit: We have been able to use this team to identify other areas for improvement in our health system as well.

a trusted provider about their role in their child's care. Such questions also give the healthcare team an opportunity to review all the ways that the parents advocated and cared for their child. Some families want to know all of the details of the testing and autopsy, so we come prepared to show pictures or review scans.

Other families request a more high-level review of the information, with emphasis on the meaning behind the results and their future implications. We recommend asking families what kind of information they would like and how they prefer to review it. This respects their boundariesand can avoid further traumatization.

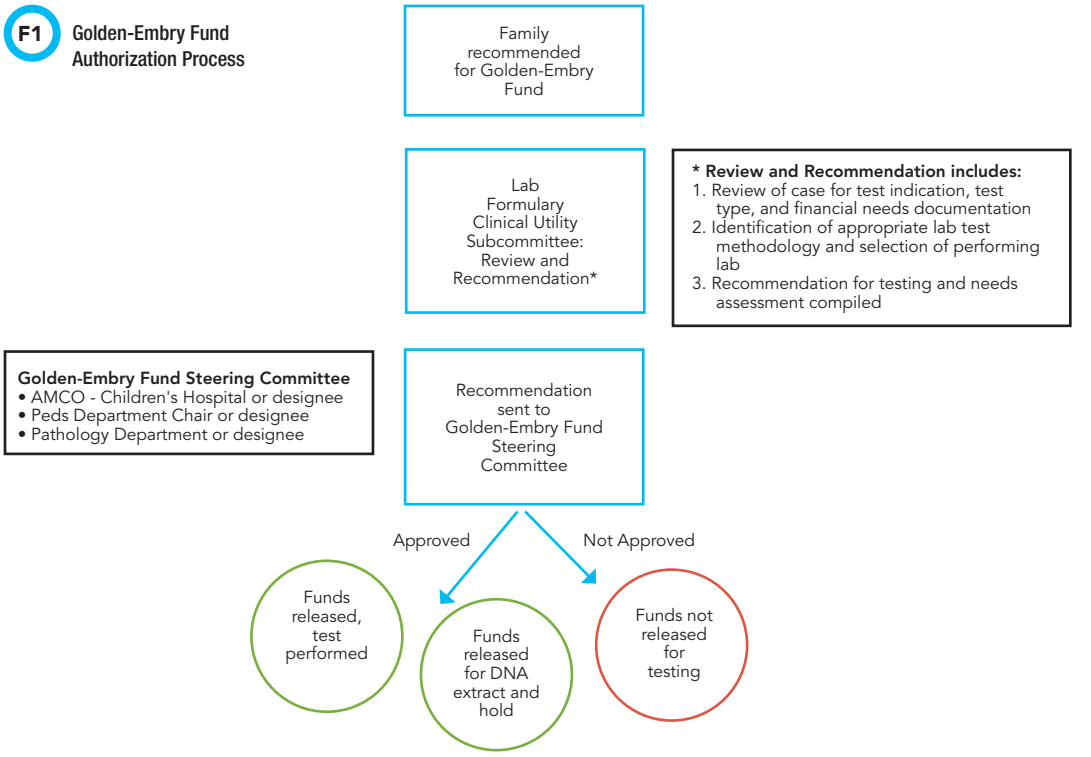
We have used multiple modalities for family meetings including in-person, video conferences, and over the phone, depending on family preference. If an in-person conference is preferred, our team has made parking vouchers, water, and tissues available for family members. In the past two years, we have offered meetings to 18 families, and 14 have accepted. All of the meetings have been well received, and the families have expressed gratitude for the ability to discuss their child with the team.

The professionals present for a family meeting vary based on each case and requests from the family, but could include representatives from the primary medical team, subspecialists, bedside nurses, pathologists, geneticists, genetic counselors, chaplains, social workers, the palliative care team, and child life specialists. We designate one person as the facilitator, and he or she introduces all the people present and manages the meeting.

THE NEED FOR BETTER COVERAGE FROM INSURERS

While we are proud of the progress of our testing process, we hope that insurers will extend coverage of perimortem genetic testing so we will no longer need to rely on philanthropy to cover these tests. Insurance companies could in the future take a broader view of families' health, and offer coverage of genetic testing for family planning strategies, cause of death, and recurrence risk.

The downstream health implications for bereaved families are significant, and establishing a cause of death can be critical in preventing complicated grief and minimizing mental and physical health effects of enduring trauma. In the meantime, we will continue to rely on our transdisciplinary team to help bereaved families find answers in the midst of a tragedy.



We would like to thank Dr. Golden and his family, and Brandon and Jill Embry, for their generous donations and their commitment to the well-being and health of families who have a child with serious illness. We also appreciate the commitment of the members of our transdisciplinary team, who works tirelessly to ensure bereaved families can seek answers.

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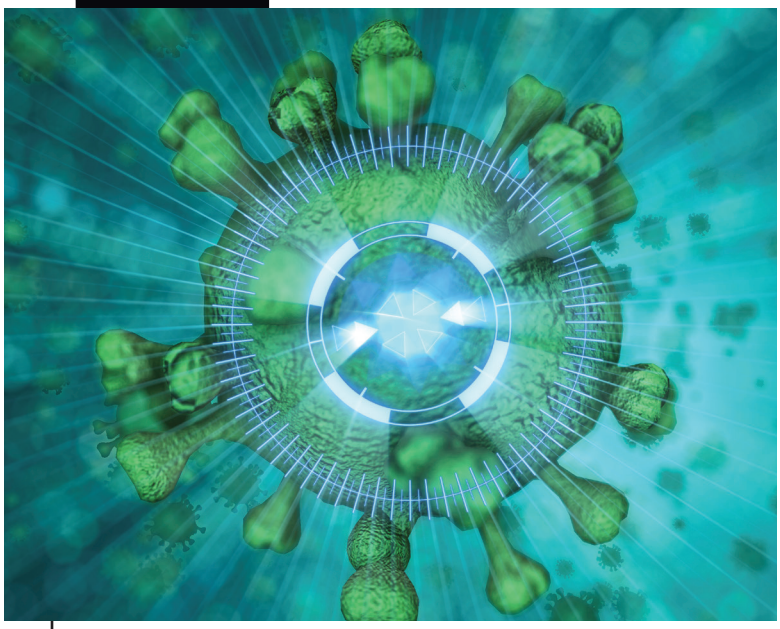
Regulatory Roundup

Adaptive Biotechnologies Gets FDA Authorization for SARS-CoV-2 T Cell Response Test

The Food and Drug Administration (FDA) has issued an emergency use authorization for the T-Detect COVID test developed by Adaptive Biotechnologies. This test uses next-generation sequencing to analyze DNA sequences from T cells to help identify individuals with an adaptive T cell immune response to SARS-CoV-2. A positive test result indicates recent or prior infection with SARS-CoV-2, while a negative test result indicates that a patient is unlikely to have been infected with the virus. However, negative results do not preclude acute or current SARS-CoV-2 infection, and the test should not be used to diagnose current SARS-CoV-2 infection.



A T cell response may be detected in the blood several days after initial infection, and the T-Detect COVID test is indicated for use with samples from individuals who are 15 days or more postsymptom onset. However, in a statement about the test, FDA noted that it is unknown how long the T cell immune response persists following infection and what level of protection it may provide.

Currently, use of the T-Detect COVID test is limited to laboratories designated by Adaptive Biotechnologies that are certified under CLIA and that meet the requirements to perform high complexity tests.

FDA OKS ABBOTT'S RAPID SARS-COV-2 ANTIGEN TEST FOR OVER-THE-COUNTER USE

Abbott has received Food and Drug Administration emergency use authorization for over-the-counter use of its BinaxNOW COVID-19 Ag self test. This new indication allows individuals with or without symptoms to buy the test without a prescription. As of April, Abbott planned to ship the test to major food, drug, and mass merchandising retailers and expected the test to eventually be available through some of these stores' websites.

Individuals ages 15 years or older can use BinaxNOW with self-collected samples, and the test also can be used on children as young as 2 years old when samples are collected by an adult. Samples are collected using a nasal swab, and all materials required to perform the test, such as the swab, test card, and reagent solution, come in the box. The test produces results in 15 minutes, enabling individuals who test positive to immediately isolate themselves. The BinaxNOW self test also comes in a two-count box so that users can perform serial testing.

ROCHE SARS-COV-2, FLU COMBO TEST COULD GIVE FALSE POSITIVE RESULTS, FDA WARNS

The Food and Drug Administration (FDA) has issued a letter alerting clinical laboratory staff, point-of-care facility staff, and healthcare providers that false-positive results can occur with the Roche cobas SARS-CoV-2 & Influenza A/B nucleic acid test, which is designed for use on the cobas Liat system. Roche has observed two different issues with this test that could cause false positives. The first issue is that the assay tubes may leak sporadically, obstructing the optical path in the Liat analyzer and producing abnormal polymerase chain reaction (PCR) growth curves. The second issue is that abnormal PCR cycling in the reaction tubes may also occur and produce abnormal PCR growth curves.

In light of these potential issues, FDA recommends that users of the cobas SARS-CoV-2 & Influenza A/B test should monitor for unexpected

clusters of positive influenza B results, as this may indicate the cobas Liat system has experienced a tube leak. Additionally, users should repeat tests when two or three analytes are positive. Different results on the repeat test may indicate abnormal PCR cycling. If after following these steps users suspect that either of the two aforementioned issues has occurred, they should stop using the cobas Liat system and contact Roche.

FDA CAUTIONS THAT THREE CEPHEID SARS-COV-2 TESTS COULD BE IMPACTED BY VARIANTS

In addition to tests from Mesa Biotech, Thermo Fisher Scientific, and Applied DNA Sciences, the Food and Drug Administration (FDA) also has added three tests from Cepheid to its list of SARS-CoV-2 assays that are impacted by variants of the virus. These tests are Cepheid's Xpert Xpress SARS-CoV-2, Xpert Xpress SARS-CoV-2 DoD, and Xpert Omni SARS-CoV-2. FDA's analysis indicates that two independent single-point mutations in the SARS-CoV-2 genome reduce these tests' sensitivity for detecting the N2 gene. When enough virus is present, though, the tests still detect the E gene. Detection of the E gene without detecting the N2 gene is reported as a presumptive positive result by the Xpert Xpress SARS-CoV-2 and Xpert Xpress SARS-CoV-2 DoD tests, and as a positive result by the Xpert Omni SARS-CoV-2.

Overall, since Cepheid's tests are designed to detect multiple genetic targets and these mutations do not lead to false-negative results, FDA concludes that the impact on test performance does not appear to be significant. However, out of an abundance of caution, the agency still thought it best to alert healthcare professionals about this potential issue.

CE MARK GRANTED TO BIO-TECHNE'S EXOSOME DIAGNOSTICS FOR PROSTATE LIQUID BIOPSY TEST

Exosome Diagnostics, a brand of Bio-Techne Corporation, has received the CE mark for the ExoDx Prostate test (EPI-CE) kit, which is a noninvasive, urine-based genomic test that helps clinicians determine whether or not a patient needs a prostate biopsy. The test is a risk assessment tool and is intended for use when patients have an ambiguous prostate-specific antigen test result. In studies, the EPI-CE test demonstrated comparable results to the Food and Drug Administration-approved version of the test, with a sensitivity of 92% and a negative predictive value of 89% for ruling out clinically significant prostate cancer. By ruling out the need for prostate biopsy, Bio-Techne hopes the test will help reduce complications from this invasive procedure, which can include pain, hematuria, infection, and potentially hospitalization. Now that the test has received the CE mark, Bio-Techne is offering it at the company's Munich ISO 15189 accredited clinical laboratory and is also making it available throughout Europe.

Industry Playbook

Roche Acquires GenMark in $1.8 Billion Deal

Roche and GenMark Diagnostics have entered into a merger agreement in which Roche will fully acquire GenMark for $1.8 billion.

Through the acquisition, Roche aims to expand its portfolio of molecular diagnostics with GenMark's expertise in syndromic testing. The companies believe that GenMark's ePlex systems will enhance Roche's work in managing infectious diseases and antibiotic resistance. The ePlex platform is designed to detect multiple pathogens from a single rapid test and a patient sample, allowing clinicians to determine a cause of infection and prescribe treatment within hours.

"The rapid identification of bloodstream infections and the detection of antimicrobial resistance genes are more essential than ever for hospitals and their patients," said Thomas Schinecker, CEO of Roche Diagnostics. "Acquiring GenMark Diagnostics will broaden our molecular diagnostics portfolio to include solutions that can provide lifesaving information quickly to patients and their healthcare providers in the fight against infectious diseases."

GenMark's offerings also will complement Roche's portfolio of COVID-19 diagnostic solutions, as Roche will gain access to GenMark's Respiratory Pathogen Panels, which identify the most common viral and bacterial organisms associated with upper respiratory infection, including SARS-CoV-2. GenMark in return will broaden commercialization of its products through Roche's worldwide network of consumers.

The acquisition was unanimously approved by the board of directors of Roche and GenMark. Under the terms of the agreement, Roche will receive all outstanding shares of GenMark's common stock. The companies have agreed to $24.05 per share for an all-cash deal.

CAREDX AND BFS MOLECULAR MERGE FOR TRANSPLANT MONITORING

CareDx, a precision medicine company focused on transplant patients, has acquired BFS Molecular, a posttransplant surveillance company.

CareDx offers a number of services to transplant patients that include genetic matching solutions, human leukocyte antigen typing technologies, and digital healthcare solutions designed to personalize care from the beginning to the end stages of transplant procedures. Similarly, BFS Molecular focuses on transplant patients by using next-generation sequencing (NGS) to monitor the health of transplanted organs and stem cells over time. Through the acquisition, CareDx will gain access to BFS Molecular's software and algorithms.

BFS Molecular has developed the StemScan assay for posttransplant chimerism detection in allogeneic hematopoietic stem cell transplant patients, and the OrganScan assay for donor-derived DNA detection in solid organ transplant patients. According to the company, the NGS data from both assays is processed and analyzed by their Graftrack software to produce a clear picture of each transplant patient over time.

By acquiring the Graftrack software, CareDx aims to advance its AlloSeq cfDNA NGS-based transplant monitoring test and its AlloSeq HCT chimerism testing kit.

COMPANIES SIGN $2.9 MILLION DEAL FOR COVID-19 RISK TEST

Genetic Technologies and Infinity Biologix (IBX) have signed a $2.9 million agreement for IBX to commercialize the Australian-based company's COVID-19 risk test in the U.S. The terms of the agreement also state that IBX will be hands-on in the production, distribution, sales, and marketing of the test.

According to the companies, the risk assessment test, which the companies have agreed to brand

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"GeneType," will have the ability to determine whether patients are at risk of developing severe disease if diagnosed with COVID-19. Through a questionnaire and saliva-based genetic analysis, the test will combine patients' clinical risk factors such as hypertension, diabetes, cancer status, and age with their genetic information to determine the probability of their conditions deteriorating.

Before building the risk test, Genetic Technologies conducted a large-scale study of 7,500 patients known to be infected with SARS-CoV-2. The company studied the genetic profiles of infected patients to assess any patterns associated with people who had a more severe response. The company then used the genetic markers to develop risk models for disease severity.

The companies state that IBX currently has the capacity to process more than 100,000 risk tests a day between its two U.S.-based labs. Both parties agreed to a three year deal under which IBX will pay Genetic Technologies $50,000 upfront, followed by minimum payments of $850,000 in the first year and $1 million in the second and third years.

BIOCEPT AND AEGEA BIOTECHNOLOGIES AIM FOR NEW HIGH-SENSITIVITY SARS-COV-2 ASSAY

Biocept and Aegea Biotechnologies are teaming up for the development of a highly sensitive, next-generation polymerase chain reaction (PCR)-based assay for detecting SARS-CoV-2. The companies plan to design the test based on Biocept's expertise with its Switch-Blocker technology, which is currently used in assays for rare oncology-related genetic mutations in large numbers of clinical samples.

With this new assay, the companies are aiming to increase the sensitivity for detecting SARS-CoV-2 and the various strains of the virus. According to the partners, the test will detect low copy numbers of viral RNA, potentially enabling it to detect the virus at much lower levels than current PCR-based tests. The companies also state that the test will be capable of distinguishing SARS-CoV-2 from other coronaviruses.

Though the companies are currently focusing on COVID-19, the agreement includes plans to expand the highly sensitive PCR assay potentially to detect other infectious diseases as well.

IDT GAINS SWIFT BIOSCIENCES FOR ADVANCED RESEARCH IN NGS

Integrated DNA Technologies (IDT) has announced acquisition of Swift Biosciences to combine IDT's next-generation sequencing (NGS) products with Swift's established portfolio of library preparation kits for more efficient research methods.

Since the company's first foray into NGS products in 2013, Swift has worked to develop its library of NGS preparation kits to maximize data output, provide comprehensive coverage, and reduce sequencing costs for academic, translational, and clinical research. With IDT's experience in developing and manufacturing nucleic acid products for academic and commercial research, agriculture, medical diagnostics, pharmaceutical development, and synthetic biology, the companies believe the acquisition will be valuable for both parties.

"Swift's research tools are being used for cancer, inherited disease, and other health applications, as well as research in agrigenomics, metagenomics, and the biotech/pharmaceutical industry," said Trey Martin, president of IDT. "Their broad portfolio of library preparation and enrichment products are highly complementary to IDT's existing NGS product line, giving us an increased ability to provide gold standard offerings to researchers and to be well positioned for future growth."

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Ask The Expert

The Ins and Outs of Reporting SPEP Findings

EXPERT
By Gurmukh Singh, MD, PhD, MBA

What do serum protein electrophoresis (SPEP) and serum immunofixation electrophoresis (SIFE) detect?

A: The most common and perhaps most important rationale for performing SPEP and SIFE is to detect monoclonal immunoglobulins (MIg). Reporting the status of MIg and other immunoglobulins is therefore essential—but it's also entirely inadequate. SPEP reflects other aspects of patient health such as acute and chronic inflammation, nephrotic syndrome, cirrhosis, alpha 1 anti-trypsin deficiency, complement consumption, and haptoglobin and transferrin abnormalities. When it comes to the first three of these conditions in particular, it is not uncommon for SPEP findings to be the first indication of their presence. Thus, it is imperative that laboratory medicine professionals and pathologists treat SPEP/SIFE as a clinical pathology consultation and report the results in the context of the individual patient, following review of all clinical and laboratory findings.

What information should labs include when reporting SPEP findings?

SPEP (followed by SIFE, if needed) should document the presence, location, isotype, and concentration of the MIg, if present. Comments about other proteins, especially background immunoglobulins, should be included. If the MIg overlaps a normal protein, generally in the beta region, the combined concentration of the two proteins should be documented along with a statement about the overlap. Preliminary studies show that techniques to deplete the contribution of normal beta proteins to MIg could enable more accurate determination of MIg concentration, which in turn could improve the diagnosis of light chain predominant multiple myeloma (MM) (Lab Med 2020; doi:10.1093/labmed/lmaa057). Reporting Hevylite measurement, however, has not been shown to add value.

On first SPEP examination, labs should notify the provider via email if an MIg is detected and a review of the clinical record indicates that a MIg disorder is not under consideration. This is to ensure that the finding does not go unnoticed, especially in ambulatory patients. Simultaneous notification of the hematologist/oncologist and hematopathologist should also be considered.

When should SIFE be performed in addition to SPEP?

With or without an order from a clinician, reflex SIFE should be performed on first SPEP examination if an MIg is noted or suspected, abnormality is noted in one of the normal proteins in the beta or alpha region, or if hypogammaglobinemia is noted. Other reasons include if clinical records indicate lytic bone lesions, osteoporosis and pathological fracture, undiagnosed hypercalcemia, undiagnosed neuropathy, history of lymphoid malignancy, autoimmune disorder, hematopoietic or solid organ transplantation, or amyloidosis. If SIFE is not performed on first or subsequent SPEP examination, a statement to that effect should be included in the report. It is also worth noting that it is perfectly acceptable not to perform SIFE if there is no valid indication, even if a clinician does order it.

Monitoring of MIg in patients with monoclonal gammopathy of undetermined significance or smoldering MM does not warrant repeat SIFE after the first examination. In these cases, reporting the concentration of the MIg is sufficient. The same holds true for patients being treated for MM. However, SIFE is warranted in MM patients if testing following treatment does not reveal an MIg on SPEP, as SIFE is more sensitive.

What else should labs consider when reporting SPEP/SIFE findings?

All cases of light chain myeloma are detectable with urine protein electrophoresis (UPEP) and urine immunofixation electrophoresis (UIFE). If UPEP and UIFE are performed at about the same time as SPEP and SIFE, it is useful to include the results of both examinations in the reports for SPEP and UPEP.

Additionally, apparent MIg seen in patients treated with daratumumab and elotuzumab warrants special consideration, as does the emergence of oligoclonal bands following hematopoietic stem cells.

Gurmukh Singh, MD, PhD, MBA, is the Walter Shepeard Professor of Pathology at the Medical College of Georgia at Augusta University.
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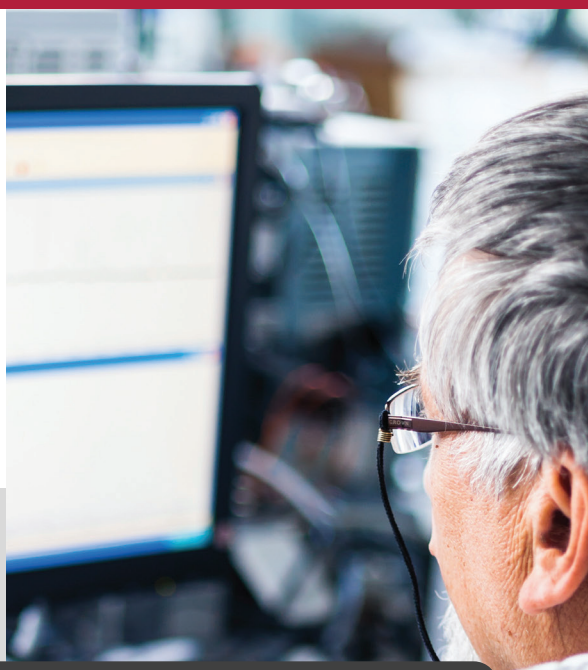

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BFR0001-3010-01