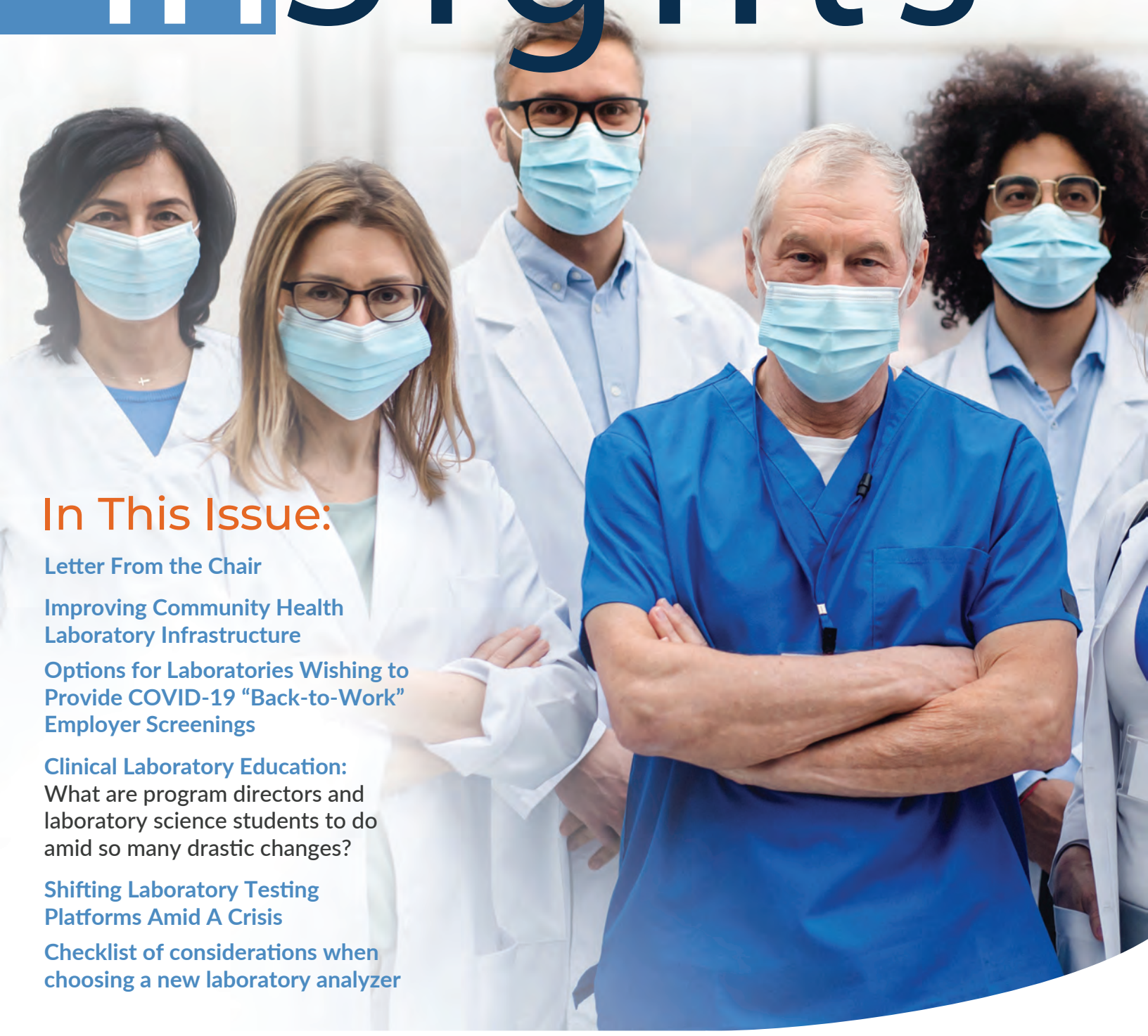
COLA'S Fall Edition 2020

inSights



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COLA

LETTER FROM THE CHAIR

AUGUST/SEPTEMBER 2020

The COVID-19 pandemic has drastically changed the world of clinical laboratories. While those of us involved in the clinical laboratory community have always known that laboratory testing is a vital component of healthcare, historically we have not seen laboratory testing at the top of the national news every single day. Seeing the spotlight on access to quality laboratory testing tells the public what we in the community have always known – that testing is crucial in diagnosing, tracing, treating and mitigating infectious diseases.

While laboratory professionals have typically not been considered to be on the "front lines," they have had a vital role in supporting their communities by providing specimen collection and/or testing for COVID-19. Navigating the supply chain limitations, and selecting the COVID-19 test methodology that best fits the laboratory and community needs, has presented unique challenges, especially for smaller laboratories. And with so much information, and sometimes misinformation, to sift through, laboratories and those in laboratory oversight roles have also played an important role in answering questions about COVID-19 testing. Many have stepped up to these challenges and are working hard to supply more testing, accurate testing, and timely testing that is so important in controlling the spread of the virus.

We are all hoping for this pandemic to be in our rear-view mirror as soon as possible. But the reality is that there is just so much that we have yet to discover about COVID-19. COLA continues to perform onsite surveys in some areas of the country and has implemented a Virtual Survey Process to do a thorough review of compliance for laboratories in some areas where it is not safe to go onsite. This will offer an opportunity for COLA to provide feedback and to help laboratories stay on track during the pandemic and uphold patient safety. I am proud of all that COLA has done to support the Surveyors, as well as the accredited laboratories, during the pandemic.

Accurate and reliable laboratory test results are, and always have been, an important component of quality healthcare. The pandemic, while devastating, has brought the significance of laboratories to the front page and into everyone's living room. So when you thank the hardworking and dedicated healthcare heroes, don't forget the laboratory professionals. **They are heroes too.**

COLA INFORMATION RESOURCE CENTER:

IMPROVING COMMUNITY HEALTH LABORATORY INFRASTRUCTURE

By Patricia Street

Patricia Street is a COLA Surveyor with more than 25 years' experience as a clinical laboratory generalist with concentration in Microbiology, Molecular testing and Laboratory Management.

History is not always accurate or complete in its depiction of infectious disease due to the lack of scientific input into the recording our history. While it is true that empires have been brought to their knees by plagues and contagion, there is also much to be gained from our human history with disease and understanding the spread of disease is paramount. (1)

Reflecting on the Coronavirus pandemic or COVID-19 (Virus name SARS-CoV-2), we are awakened to the fact that viruses are ubiquitous, capricious, and seemingly impossible to eradicate, especially if they transcend from the animal world to humans. While the geopolitics dominates the news and impedes disease collaboration, science must prevail. One nation's weak response could endanger the world, and globally, we must not let this happen. Through intense and skillful efforts of all affected areas, together with international and regional conglomerates, outbreaks can be contained.

Coughs and Sneezes spread Diseases, sounds simplistic but deadly accurate.

SARS shook the world in 2003. This virus had a low transmissibility compared to COVID-19. Where SARS grows and replicates deep in the lung, COVID-19 replicates in the airways. Because of this difference, COVID-19 spreads easier and faster because an infected person does not know they are ill when they are actively contagious. Classic public health measures like isolation and personal hygiene put SARS under control. Travel was somewhat restricted and the genome was identified 5 months later, but these things did not contribute to control as much as the precautions pulled from the "19th century toolbox" of containment. (2)

THE URGENCY FOR NEW TOOLS

With 8,000 cases of SARS worldwide in 2003 compared to more than 25 million cases of COVID-19 as of September 1, we have to do more than the use of that toolbox. Identifying the virus and quarantining all positive case and their contacts, halting travel, and stopping all persons from leaving their homes may seem like a knee jerk reaction to quell this pandemic. It is not. The impact of airline exit screening also contributed to the reduction in risk and transmission of SARS.

The virus SARS-CoV is listed as a Category A organism in the select agent and toxin registry. This means that these organisms can easily be disseminated or transmitted from person to person, and cause high mortality (MERS had a 30% mortality rate). They may afflict large numbers of people and overwhelm the health care and public health systems. These agents may cause public panic, social disruption, and require special precautions such as enhanced surveillance, diagnostic capabilities, and stockpiles of medicine and equipment to protect the public health. (3) Does this sound familiar? Getting test results in hours is critical in the face of an emerging threat such as COVID-19. Public Health Laboratories and/or the Laboratory Response Network have improved their capabilities over the years. These entities are involved in rapid molecular testing for biological and chemical threat agents as well as novel diseases, which pose a public health threat. The imperative of partnership and communication

"The Laboratory Response Network (LRN) was established by the US Department of Health and Human Services (HHS), Centers for Disease Control and Prevention (CDC), in accordance with Presidential Directive 39, which assigned specific missions to federal departments and agencies in the face of a terrorist attack.

The LRN collaborates with the Association of Public Health Laboratories (APHL) to improve the nation's mission to respond to terrorism or high priority public health emergencies. These entities maintain an integrated network of State, and Public Health Laboratories, which are part of the public health infrastructure used to collect, test and disseminate accurate data." (3)
CDC Laboratories sequenced the genome for the coronavirus believed to be responsible for the global epidemic SARS. This sequencing paved the way for a high confidence test for the identification of SARS.

With the COVID-19 pandemic, the CDC needed to develop a test very rapidly. This resulted in the rapid development of a molecular method used to identify this causative agent. The molecular test that the CDC created initially had problems. " It is unclear why quality control did not detect this issue before the kits were sent out to states and then reclaimed. There was sporadic reactivity in the negative control that could have been assay design or contamination. Their delay forced state and local governments to accelerate their response to the outbreak without up-to-date data about how far the disease spread." (5)
Today, there are more than 200 Emergency Use Authorized (EUA) tests for COVID-19, including commercially available molecular, antigen, antibody, and Laboratory Developed Tests (LDT).

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Due to the learnings from the SARS epidemic, the US made plans to be better prepared for an influenza pandemic with the deployment of the A/H5 avian (Asian lineage) virus assay. This was expected to be eminent. State and Public Health Laboratories helped validate test results and the Food and Drug Administration (FDA) facilitated a quick approval of the assay as an in vitro diagnostic test in February 2006. I personally worked on the creation of viral collection kits for surge capacity at the local health department. We were ready. The expected influenza epidemic didn't happen.

So what went wrong between then and now?

FAILING TO PLAN IS PLANNING TO FAIL

The National Response Plan (NRP) is an incident management effort to mitigate terrorism, major disasters, and other emergencies with minimization of damages and to recover from the emergencies that occur. There are international interagency plans that the NRP follow in the event of specific emergencies. There is a plan for response to a highly contagious animal disease/emerging disease incident. The U.S. Department of Health and Human Services (HHS) maintains CONOPS (Concept of Operations) for Public Health and Medical Emergencies, and this plan establishes a framework for the management of public health and medical emergencies. In 2015, there was an Ebola CONOPS in place. (6) This was a successful effort.

This type of national response, with the following elements, could contribute to a successful operation:

1. Have a unified operational plan
2. Ensure that all communication is secure and dependable
3. Coordinate support and oversight with the CDC
4. Have available a cadre of standardized testing platforms
5. Make sure laboratories are safe to work in and laboratorians are safe
6. Have high confidence molecular diagnostic testing
7. Ensure all laboratorians are fully trained and competent
8. Ensure a quality lab result perhaps by the use of an internal proficiency test
9. Make result reporting rapid and secure
10. Participate in drills to ensure readiness during an event (4)

With this approach, laboratories in partnership with various agencies could accomplish testing tens of thousands of clinical specimens daily using a multi-level network of laboratories. Both public and private laboratories could be coordinated with the CDC and other public health agencies for this purpose. Procedures to accept and transfer specimens to appropriate facilities would perform support in the event of a surge or capacity overload.

Finally, we should ensure that there are adequate medical supplies in the strategic national stockpile. We should strengthen public health surveillance systems; deploy rapid diagnostics, therapies, and preventatives by investing in research and development initiatives.

While no plan is perfect these measures could contribute to the rapid response of a community health emergency.

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2) Radcliff, Shawn, reviewed by Chesak, Jennifer: Can we learn anything from the SARS Outbreak to Fight COVID-19? Retrieved from https://www.healthline.com/health-news/has-anything-changed-since-the-2003-sars-outbreak 2020,March 11

3) Department of Health and Human Services: Centers for Disease Control, Partners in Preparedness: Laboratory Response Network 2006 Pamphlet handouts

4) The Laboratory Response, LRN Our Partnership Defined: First Sentinel Workshop, Detroit Public Health Laboratory, Detroit, MI., September 24, 2007

5) Scher, Isaac: Early CDC Tests could not distinguish between Coronavirus and water. Retrieved from https://www.businessinsider.com/early-coronavirus-CDC-tests-distinguish-covic-water 2020, August 20, 2015

6) Ebola Concept of Operations (ConOps) Planning Template, August 20,2015

FOR MORE INFORMATION: www.emergency.cdc.gov/lrn www.aphl.org

OPTIONS FOR LABORATORIES WISHING TO PROVIDE COVID-19 "BACK-TO-WORK" EMPLOYER SCREENINGS

By Jennifer MacCormack

She serves as COLA's Post Survey Team Leader where she provides valuable consultation to laboratory clients regarding regulatory compliance and quality lab practices, and guides member laboratories through the accreditation process.

As states and counties implement their plans to reopen businesses and recreational facilities after the initial wave of COVID-19 infections, many employers are looking for ways to screen their employees for the virus before reopening their doors. There are various ways that a laboratory can participate in back-to-work COVID-19 testing while maintaining compliance with all applicable CLIA regulations.

ON-SITE COLLECTIONS, OFF-SITE TESTING

One of the simplest options is to have specimens collected on-site at the employer's facility and sent out for testing at a CLIA-certified laboratory of appropriate complexity. In this instance,

- All testing would be performed under the existing laboratory's CLIA certificate, by the laboratory's trained and qualified staff
- Qualified specimen collection personnel could either be provided by the laboratory or hired separately by the employer
- Staff on-site at the employer's facility would need access to appropriate packaging and shipping materials, and clear instructions for packing and shipping the specimens to maintain their integrity for testing

This setup works best if the specimens are nasal or nasopharyngeal swabs or blood tubes collected by venipuncture. This setup is not possible if the test is intended to be a finger-stick test performed at the point of care.

Note that if serum is to be tested on site, the location must have appropriate electrical support for a centrifuge. The centrifuge must be able to accommodate the RPM required by the blood tube manufacturer.

If serum separator tubes (SST) are used, follow all manufacturer instructions for centrifugation, including centrifugation within a specified amount of time after collection, and always keep tubes in an upright position.

MOBILE LABORATORY

A laboratory may operate a mobile unit under its existing CLIA certificate. A mobile unit is a trailer, bus, or other vehicle containing laboratory testing equipment that can be brought out to different sites within the community. If a laboratory wishes to operate a mobile unit, they must apply to their state CLIA office for permission to do so.

- A CMS-116 form would need to be submitted, indicating the laboratory's intent to operate a mobile unit under their existing CLIA certificate
- The application must also list what testing will be performed, and the Vehicle Identification Numbers of all mobile units
- The mobile unit is intended to be a self-contained system, with refrigeration and other temperature and humidity controls as required for the scope of testing
- Reference Link: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107c06.pdf
- The laboratory should notify their Accreditation Organization, if applicable

TEMPORARY TESTING SITE

In the context of the COVID-19 public health emergency, a laboratory can apply to their state CLIA office for permission to operate a "temporary testing site" for COVID-19 testing.

A laboratory intending to set up testing equipment and personnel at a secondary location for a short period can complete a CMS-116 form indicating their desire to operate a temporary testing site. It can be helpful to also include a letter with this application, explaining the planned expansion, including the location and timeframe. The laboratory should also notify their Accreditation Organization, if applicable.

- This secondary site would need to be treated as an extension of the main laboratory and all regulatory concerns would apply, from daily temperature checks to instrument QC to staff training
- All documentation (requisitions, QC, results, etc.) from this temporary site must be retained per regulatory guidelines and made available to laboratory surveyors at the time of the inspection of the main laboratory
- Center for Medicare and Medicaid Services (CMS) have provided Frequently Asked Questions: CLIA Guidance During the COVID-19 Emergency. https://www.cms.gov/files/document/clia-laboratory-covid-19-emergency-frequently-asked-questions.pdf

NEW LABORATORY AT EMPLOYER'S ADDRESS

If the "temporary" location will be performing testing for a longer period – greater than a week – then that location will require its own CLIA certificate. This will require a CMS-116 application for a new laboratory.

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- If the testing is not waived, this would be a Certificate of Registration for Accreditation or of Registration for Compliance
- This laboratory will need its own qualified staff and Laboratory Director
- Staff can be rotated from the main laboratory, as long as they meet the requirements for the complexity of testing performed and that the Laboratory Director is not already directing the maximum number of non-waived laboratories according to CLIA and state guidelines

Note that as it is operating under its own CLIA certificate, this laboratory will be completely independent of the primary laboratory and will need to have its manuals and procedures, and perform its verifications of instrument performance specifications and proficiency testing. Staff will also need evidence of training and competency *specific to this location.*

OTHER CONSIDERATIONS FOR BACK-TO-WORK TESTING

No matter the arrangement, certain considerations must be taken into account when deciding to contract with an employer for COVID-19 back-to-work testing.

Retaining an attorney with experience in healthcare and laboratory testing and billing may be wise, to ensure that the contract complies with applicable laws. It may also be advisable to identify or obtain a qualified Technical Consultant with specific experience in opening up new laboratories, as they will be familiar with the required regulatory steps.

ORDERING PHYSICIAN, CLINICAL CONSULTANT, AND RELEASE OF RESULTS

- In a majority of states and counties, even under the COVID-19 public health emergency, a physician order is still required for all laboratory testing. Refer to your state and local health department for any changes to these requirements.
- Whether it is physician-ordered or self-directed testing, a requisition is still required for all tests and must be retained per regulatory guidelines.
- A physician must possess an understanding of these tests, their use, and their interpretation should be available for consultation as needed.
- It is important to make clear to both the employer and to the patient what the specific type of testing entails, and what the results do and do not mean.
- For example, antibody testing is ***not diagnostic*** for COVID-19 infection, and positive results ***do not necessarily indicate immunity.***
- Resource Link: https://www.fda.gov/news-events/fda-voices/insight-fdas-revised-policy-antibody-tests-prioritizing-access-and-accuracy
- Resource Link: https://www.cdc.gov/coronavirus/2019-ncov/lab/serology-testing.html
- Resource Link: https://www.ama-assn.org/delivering-care/public-health/serological-testing-sars-cov-2-antibodies

Also consider whether follow-up testing will be required for certain results, and if so, how the patient is to be counseled and directed to an appropriate place for that testing. To ensure that patients completely understand what the testing involves and who will have access to the results (for example, employers), a thorough consent form should be provided to employees, and translated into any appropriate languages such that informed consent can be given.

REPORTING RESULTS TO HEALTH AGENCIES

Public health organizations, from the county level up to the federal level, are collecting data about COVID-19 testing, including the tests used and the demographics of the patients tested. Employer testing is not exempt from this reporting, although in some cases antibody testing may be exempt. Confirm all reporting requirements with appropriate agencies so that ensure the laboratory is collecting the correct data.

CLINICAL LABORATORY EDUCATION:

What are program directors and laboratory science students to do amid so many drastic changes?

By Dani Stroughton Duncan

Dani has been a generalist for over a decade working in urgent care, private laboratories and hospital settings. She is an educator for Anne Arundel Community College and Morgan State University.

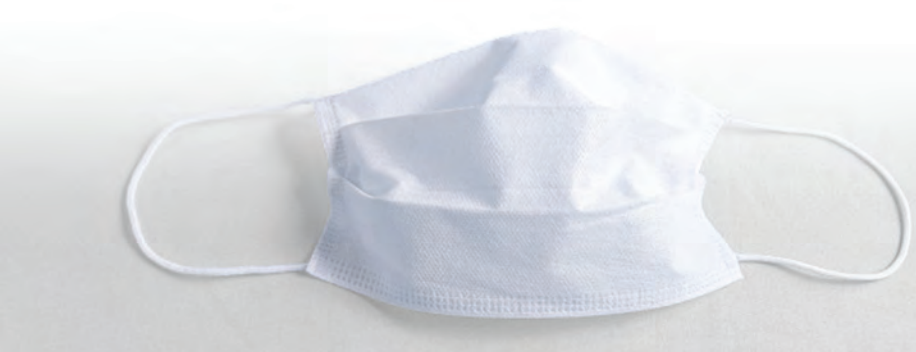
Every news headline has focused on the current COVID19 pandemic. There is no person, industry, or geographical location that has not been affected by COVID-19. Clinical laboratory education programs are no different. Students are facing the harsh realities of degree postponement, career changes, immigration status challenges, and complexities of remote learning environments. Education is a goal for many people because it is a way to improve economic status and propel themselves in their careers. Many people sacrifice time, money, and obligations to achieve their education. John King Jr. stated regarding the pandemic "It's eroding students' academic success, their emotional well-being, and their finances."(Fain,2020) Higher education programs began to face the brutal reality of the disproportionate effects on students and the critical need to focus learning on the demands of the country. A poll from Education Trust and Global Strategy Group revealed that about 77% of undergraduate students were concerned about graduating on time. (Fain,2020) These fears were higher among underrepresented populations. Some students are facing withdrawing from schools due to the economic stress the pandemic has created. The poll also revealed the growing concern with job placement and gaining skills for the workplace.
Laboratory programs were already tuned into the need of the laboratory industry. Unlike some other industries, there is a growing need for qualified laboratory professionals.

Program directors now had a new charge to continue to produce quality clinical/medical laboratory scientists, medical laboratory technicians, phlebotomists, and laboratory assistants through a quarantine state. Dr. Diane Wilson, program director for Morgan State University Medical Technology Program stated "the pandemic has created an opportunity for MLS/MLT faculty to evaluate their present program goals, objectives and curriculum. Partnering with the clinical faculty, the didactic faculty will be able to develop and implement a relevant and contemporary curriculum that will better serve the university and affiliates, and most of all the patients."

Laboratory programs have been an extremely hands-on learning process. Program directors had to switch gears and employ new methods to abide by the National Accrediting Agency for Clinical Laboratory Science (NAACLS) requirement of MLS/MLT/CLA programs. In April, NAACLS approved a pilot virtual site visit program to maintain compliance in the programs. The implementation of a virtual site visit is groundbreaking for NAACLS and unavoidable during this pandemic. NAACLS held to its requirements in the wake of the crisis but offered the ability for programs to be flexible and creative while maintaining the standards. Programs were able to be fluid on modes of education delivery and unique partnerships that met requirements.

Clinical rotations are the hallmark of many laboratory programs. Students can spend time in a variety of laboratories putting their classroom knowledge to the test. For many students, it serves as unofficial job interview. Some students shared hesitations in proceeding with laboratory rotations but in the same vein were excited to jump into the frontlines. Laboratory students are trained to be prepared for real-world laboratory experiences. While no one may have been able to prepare for a pandemic, the students can utilize many of the fundamental tools. Lorraine Doucette, MS, MLS(ASCP)CM the Academic Chair, MLT, MLA, and Phlebotomy Programs at Anne Arundel Community College noted there was a significant impact on phlebotomy students.

Some have not been able to complete the spring semester of the phlebotomy program because the clinical sites are recently starting to allow phlebotomy students again. Phlebotomy students must complete required phlebotomy sticks on actual patients to meet requirements. The uncertainty of the pandemic has a direct effect on enrollment in the programs for the fall semester. NAACLS has required laboratory rotations as an intricate part of completion in laboratory programs. Programs needed to be innovative in constructing rotation experience using virtual reality learning or other simulated realities. Doucette reflected that most of the material at Anne Arundel Community College was able to be transitioned to an online platform. The rotation is a glimpse into daily laboratory work that can be fostered by different online forums. She added, "It is time to modernize the way we teach MLT or MLS students."



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The country has been devasted by the effects of the COVID-19 pandemic. A new normal has arisen from the ashes for many areas. Laboratory programs have established new and efficient ways to conduct clinical rotations. Wilson states the Maryland Medical Laboratory Science Didactic and Clinical Faculty are discussing ways to provide the clinical practicum. A September 2020 meeting is scheduled to discuss ways to provide the most effective clinical practicum experience to accomplish the program's goals and objectives. The new normal may look very different than times of hour-long slide deck lectures.

Doucette recommends more critical thinking case studies and complex learning for senior-level students. We can allow some autonomy to student-driven learning. By uniting the lessons learned during this unique period and traditional methods, we can produce a cultivating learning environment that produces critically thinking professionals. The vagueness of the future has many people question what it holds for our healthcare education programs. Laboratory professionals and phlebotomists are resilient.

The demands produced by COVID-19 testing has strained already thin laboratory staffing. We need to take this moment in the spotlight to advocate for the profession and the need for more professionals entering the field.

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SHIFTING LABORATORY TESTING PLATFORMS AMID A CRISIS

By Derrick Mendel

Derrick Mendel is a COLA Surveyor and Technical Advisor with extensive experience in clinical laboratories, including management in Point of Care, auditing, and customer support.

In the wake of the Coronavirus pandemic (COVID-19), the field of laboratory testing is having a front stage moment. We can be seen in the opening segments of evening news stories donning blue gloves, face masks and lab coats, fighting the unknown with the power of our pipettes. We are there on the magazine covers at the grocery store alongside once filled shelves. It is well known that accurate and timely laboratory results help provide a solid treatment plan, taking the guesswork out of the diagnosis. Even smartphones can't compete with the quality of laboratory work. If they could, auto-correct would be even more dangerous. Think about instrumentation automatically changing preset dilutions without user input.

Just like always, the role of the laboratory is to organize and to act swiftly to aid in the diagnosis of many individuals at one time by producing reliable results. These results can drive the decisions that will slow the accelerated spread of COVID-19 around the world and "flatten the curve." False results may have a dangerous impact that goes beyond an individual patient case.

As more tests have received emergency use authorization (EUA) by the Food and Drug Administration (FDA) (by mid-August there were more than 120 approved by the FDA), it is the testing laboratory's job to validate them and be able to swiftly provide data to the medical community. Many of the EUA tests are high complexity, but some of these new tests are qualitative moderate complexity (or even waived) tests that can be done on platforms that already exist that would only involve quickly validating accuracy and precision once installed in the laboratory.

As always, the test systems must undergo approval by the FDA before they can be made available to laboratories. These essential tests are being fast-tracked through the FDA by establishing only the most essential performance specifications and getting clearance through the expedited process of Emergency Use Authorization (EUA). The process involves an application that includes a description of the technology and even the estimated time for which it would take test materials to be produced, along with the abbreviated validation data summarized below.

MOLECULAR – detecting nucleic acids

- Limit of Detection
- Clinical Evaluation
- Inclusivity
- Cross Reactivity

ANTIGEN DETECTION

- Limit of Detection/Analytical Sensitivity
- Cross-reactivity/Analytical Specificity
- Microbial Interference
- Clinical Agreement Study

SEROLOGICAL DIAGNOSTICS

- Cross-reactivity/Analytical Specificity
- Class Specificity
- Clinical Agreement Study

While it is heartening to see clinical laboratories and clinical laboratory professionals being recognized and in the spotlight, we will all be happy to see a return to "normal" laboratory operations when this historic pandemic is behind us!

WEBSITE RESOURCES ARE LISTED BELOW:

https://www.fda.gov/media/135659/download

https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ivd

https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#coronavirus2019

https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/eua-authorized-serology-test-performance

CHECKLIST OF CONSIDERATIONS WHEN CHOOSING A NEW LABORATORY ANALYZER

By Kim Irwin

Kim Irwin is a COLA Surveyor with 30 years of clinical laboratory experience. She has worked as a Trauma Center generalist, Independent Lab Generalist and Hematology Supervisor. Kim has also been a Technical Consultant and Laboratory Director of a Physician Office laboratory (POL).

Acquiring a new analyzer for your clinical laboratory may seem like a daunting project. The following questions can help remove the uncertainty from selecting laboratory instrumentation. Think of purchasing new instrumentation in a similar manner to buying a new car or a new home. You want to make the wisest investment to get a product that is most suitable for your situation.

First, start by considering the complexity of your laboratory related to its CLIA certification. If your laboratory has a Certificate of Waiver then you should consider an analyzer for waived testing. If your laboratory is certified to perform moderate complexity, testing then you can perform moderate complexity and waived testing. If your laboratory is high complexity then you can perform all levels of testing assuming you meet all the requirements for high complexity testing under CLIA. Since some instruments can vary in complexity, depending on the chosen test or specimen type it is important to be sure of your current level of CLIA certification from the start. The manufacturer can assist you in evaluating the tests an analyzer will run based upon your CLIA certification or plans to upgrade or downgrade your CLIA certificate. Keep in mind that if you plan to modify a test procedure then the modified or "off-label use" defaults the test to the high complexity category under CLIA regulations.

Q1. What type of analyzer do I need?

Q2. What are the needs of your laboratory regarding testing platforms?

1. What tests am I looking to add and are they available on the instrument?

2. Are there additional tests currently available or on the horizon that I may wish to add at a later date?

3. What is the sample size required? For example, a pediatrics office may require an analyzer that uses a smaller sample volume.

4. How many tests can be performed from a single sample?

5. What is the hourly output of test results?

6. Can STAT samples be programmed to bypass routine samples?

7. Can specimens be continuously loaded?

8. What is the turn-around time (TAT) and is it more cost effective to batch specific tests? An urgent care setting may require faster results than a reference laboratory, whereas, a reference laboratory may be more dependent on a continuous load system with high throughput.

9. Does the instrument have a barcode reader or provide walk away capability to allow staff to perform other testing or duties if this is important for your situation?

10. Can the analyzer handle closed tube testing?

11. Is primary tube sampling available or does the instrument require sample cups or wells?

12. Does the system perform automatic dilutions when necessary?

13. Will the analyzer prevent operation when maintenance is overdue, or when function checks, calibration, or QC are not within acceptable limits?

Laboratory instruments have environmental conditions that need to be met. Find out what the temperature and humidity requirements are for the analyzer.

Q3. Is my facility capable of meeting the requirements of the analyzer?

1. How much space does the analyzer require?

2. Are there other suggestions such as positioning the instrument away from direct sunlight or an air vent?

3. How much heat will the instrument emit?

4. Does the manufacturer require specific electrical requirements?

5. Are there any known effects caused by static electricity?

6. Is a water source necessary for the analyzer?

7. How much down time is there for the analyzer?

8. What are the requirements for startup, maintenance and function checks, scheduled service, calibration time, and shutdown?

Laboratory equipment can be purchased, leased, or arranged as a reagent rental. Check with the vendor to see which one is most suitable for your laboratory. Find out what the warranty and service contracts include for each option and how much they cost.

Q4. How do I calculate the cost of the analyzer?

1. How quickly can a service representative provide remote or in person support?

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2. What is the cost of instrument reagents, calibrators, quality control materials, or maintenance and consumable supplies?

3. What is the open stability for reagents, calibrators, and controls?

4. How many calibrators are there and will you need to provide calibration verification materials?

5. What is the frequency of calibration?

6. What are the manufacturer quality control requirements for the assay?

7. Are any other items required to perform the testing such as heat blocks, incubators, freezers, refrigerators, centrifuges, pipette, and mixers?

Proficiency testing is required for all regulated analytes. Check with your current as well as other proficiency testing providers to find an appropriate peer group for each test. The peer group should use the same instrument reagent combination that is used by your laboratory.

Ask yourself if the instrument will be interfaced to your Laboratory Information System (LIS)? If so, check with the vendor as to whether or not the interface is unidirectional or bidirectional.

Q5. Are there any other things to consider?

1. What is the cost of the interface set up and maintenance?

2. Do they have experience interfacing to your current LIS?

3. Does the manufacturer offer training to laboratory staff?

4. Is training offered on-site or is it at a training center?

5. Are there any costs involved with initial or follow up training?

Finally, consider asking other laboratory professionals who already have the instrument and read any available online reviews. Sometimes, the vendor will connect you to other users in your area.

1. Ask how the instrument is performing for them.

2. How are they comparing to their peers on proficiency testing?

3. Have they had any unexpected downtime?

4. Have they had any issues with patient samples or control materials?

5. Ask them how satisfied they are with their purchase.

Finding answers to these questions will help you to make an informed decision. You will be able to assess if the addition of testing is cost effective by comparing your test volume to the cost per test. You will also be able to determine the analyzer best fitted to your needs. By taking all of these factors into consideration, you will be more comfortable deciding on an analyzer that will be suitable for your facility and staff for years to come.