

in Sights

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LETTER FROM THE CHAIR

JUNE 2021

The COVID-19 pandemic has brought disaster readiness to the forefront of the minds of laboratorians. Laboratorians have been expected to work in challenging and unusual conditions in order to deliver quality patient care. The pandemic has intersected every area of the laboratory, from personnel, to inventory management, to safety measures. As we begin to see the light at the end of the tunnel in the pandemic, it is helpful to review the lessons learned.

The COVID-19 pandemic was unexpected and unpredictable, forcing laboratories to examine disaster preparedness plans. Many laboratories are assessing the need for new processes and out-side-the box thinking, to prepare for future disasters, pandemic or otherwise. Planning for unexpected disasters is an investment in the overall health of the laboratory. Creating a platform for continuous conversations as we navigate this pandemic will help laboratories formulate new best practices. Addressing various aspects of preparedness can keep the emergency plans current and functional.

Laboratory heroes will come out of this pandemic stronger and more resilient due to the lessons learned in the COVID-19 pandemic, and we hope that the discussions in this issue of COLA Insights will serve to spark those conversations in your own laboratory.



Dr. Donna E. Sweet,
Chair, COLA Board of Directors.

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CASE STUDY:

IMPACT OF THE PANDEMIC ON CLINICAL LABORATORY PLANNING



By Dani Stroughton Duncan

Dani is the Director of COLA's Education Division and 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.

LEARNING OBJECTIVE

To consider the challenges in implementing CDC recommended physical distancing in the clinical laboratory, where some physical distancing measures can result in delayed patient results and interrupt equitable access to resources.

FACILITATOR'S INTRODUCTION OF CASE STUDY

The primary goal of this case study is to generate discussion about adhering to CDC recommendations for physical distancing and lessons learned for future laboratory planning. It raises the question of how the laboratory's layout influences safety during the pandemic, what resources may be needed in disaster preparedness planning, and how leadership can support the laboratory in the process.

The pandemic has placed extraordinary stress on the entire laboratory, including leadership, resources, and personnel. As laboratorians, we are accustomed to rise to challenges that are put in front of us. Thorough disaster preparedness plans will likely require collaboration across multiple departments within the healthcare facility, and this is where laboratorians can share their knowledge and expertise. It is imperative that laboratory leaders are at the table for disaster planning.

CASE STUDY

Amanda is the senior generalist medical technologist employed on nightshift in a 400-bed hospital. She is assigned to different benches each night to include Transfusion Services and Microbiology. The nightshift is staffed with six laboratory technologists and a laboratory assistant. Not all technologists on night shift are cross-trained in each laboratory bench.

The laboratory has been inundated with specimen volume due to COVID-19 testing. On this particular night, the technologist, Ron working in Microbiology is a recent medical technologist graduate. Amanda wants to help Ron because they have a large amount of pending COVID-19 molecular testing. The only hood for COVID-19 testing does not allow for six feet physical distance between Ron and Amanda. The hood is also located in another section of the laboratory, away from Amanda's Chemistry assigned bench. Amanda struggles to adhere to the six feet spacing and still be able to assist a fellow technologist.

Corey is another technologist working the same night as Amanda and has received communication that they are three technologists short for the nightshift. As such, Corey will be responsible for working Transfusion Services, Hematology, and Special Chemistry. Transfusion Services is located on a different floor from the central laboratory. During the night, Corey notices that his face shield is damaged and seeks to retrieve another. Corey enlists the other technologists to help find a replacement face shield. The laboratory assistant notifies the team that the face shields are in a locked cabinet to which staff does not have access. The laboratory manager who has the key has been unavailable due to a COVID-19 diagnosis.

Amanda feels she is not being supported by leadership with the resources needed to maintain testing turnaround and patient care.

QUESTIONS

- 1 What should Amanda do in this scenario?
- 2 What is the purpose of the disaster preparedness plan in this case study?
- 3 What are the key ethical and clinical issues at stake in this situation?
- 4 Describe the challenges that this hospital-based case study raises.
- 5 What part did the laboratory layout play in the ability to provide for physical distance?
- 6 How might patient care be impacted?

REFLECTIONS ON YOUR OWN EXPERIENCES

- 1 Have you experienced short staffing that has challenged the ability to maintain patient testing quality?
- 2 Have you ever been in a similar position as Amanda? What suggestions would you have for Amanda, based on your experience??
- 3 What are some best practices to monitor resource management?

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DEBRIEF

The case study addresses shared pain points among the laboratory community. Discussing best practices geared to common obstacles can assist in producing creative and innovative solutions. Insufficient staffing during the shift created an obstacle for the technologists in the case study to adequately and efficiently service the patients. Cross training personnel can support maintaining adequate turnaround time and patient quality when facing unexpected staff shortages. It can also promote teamwork in the laboratory when personnel can help in other areas outside of their designated workstations. Supply chain issues in the pandemic has strongly impacted the laboratory.

Organizations have tried to allocate limited resources as effectively as possible. In the case study, due to a single point of failure the staff was unable to obtain the necessary safety equipment. A best practice to avoid such an obstacle is to work with other departments to create a command center. The command center can pool resources from various departments to serve overarching needs such as personal protective equipment and; resources, and can foster communication with leadership throughout all shifts. Another avenue on the department level can be to begin a shift safety check-in. The safety check-in can review the volume of supplies and areas to access needed resources.

Communication is key to supporting the successful operations of the laboratory and patient care. Amanda felt lack of support from the leadership because she was not given the tools to support her shift successfully. Constant communication between frontline staff and leadership will promote a culture of teamwork and information sharing. Open and collaborative communication platforms that allow for the review of incidents and discussion of insights gained can bring about dynamic ideas.



LABORATORIES BUILD RESILIENCY AMIDST A PANDEMIC



By Pamela Meadows, Brooke Whitaker and
Carolyn Sabady

Pamela is a member of the American Society for Clinical Laboratory Science (ASCLS) Patient Safety Committee and Past-President of the West Virginia Society for Clinical Laboratory Science. She has twenty-three years of experience as a clinical laboratory practitioner and is currently an Associate Professor in the Clinical Laboratory Sciences Department at Marshall University in Huntington, West Virginia. Prior to teaching, she spent five years in laboratory supervision and point-of-care testing oversight.

Brooke graduated in May 2020 with a Doctorate in Clinical Laboratory Science from Rutgers University and works as Manager, Pathology Laboratory Utilization and Manager, Microbiology Laboratory at Augusta University Medical Center Augusta, Georgia. She is a member of American Society for Clinical Laboratory Science (ASCLS) Patient Safety Committee with twenty years' experience. Prior to moving to Augusta, Georgia she worked in point-of-care and as a generalist in North Carolina.

Carolyn is currently employed at ACL Laboratories as a Phlebotomy Support Services Supervisor for the Wisconsin Central Laboratory. She has 12 years of experience working in specimen processing, inpatient/outpatient phlebotomy, and home health phlebotomy services. The creation of the phlebotomy training curriculum and becoming an EPIC Beaker Credentialed trainer have been the highlights in her career.

As clinical laboratories are pressed to increase testing capacity for SARS-CoV-2, one key question looms. How do we secure the equipment and supplies needed to meet testing demands during this global pandemic? Clinical laboratories have spent the past eight months on what seems like an incessant roller coaster ride in the fight against SARS-CoV-2, the virus that causes COVID-19. An inefficient and fragmented supply chain has made it impossible for many laboratories to successfully navigate the demand for testing, with turn-around times ranging from a few hours to weeks. Delays in testing weakens efforts to stop the spread of SARS-CoV-2 by hindering the ability to effectively and efficiently conduct contact tracing, while the inability to obtain needed supplies has exposed a general lack of guidance and funding from federal, state and local government.

Laboratories have become more strategic in the wake of SARS-CoV-2 as supply chain issues have forced some laboratories to make tough decisions and utilize lean or six-sigma processes.¹ Unable to perform all testing in-house, some laboratories have been forced to prioritize testing to ensure providers and public health agencies receive

prompt results for high-risk patients. Often times this means that outpatient and public SARS-CoV-2 testing is sent to reference laboratories with turnaround times that can exceed seven days due to the avalanche of tests being received.² Laboratories making the decision to perform SARS-CoV-2 testing in-house may mean other non-SARS-CoV-2 testing be sent to reference laboratories, resulting in increased cost for the clinical laboratory and patients.

Increased costs of reference laboratory testing, coupled with skyrocketing costs of equipment and instrumentation due to supply and demand, has placed a financial strain on institutions while forcing management to be more budget conscientious.

The high demand for SARS-CoV-2 related testing supplies has made it impossible for many manufacturers to keep up with production needs. A survey of clinical laboratories in the United States (U.S.) revealed that nearly half of respondents were still struggling to secure vital supplies needed for SARS-CoV-2 testing.³

The survey further revealed that 58% of

laboratories experienced problems obtaining test kits, 46% had difficulty obtaining reagents, while 38% of labs had problems securing nasal swabs.³ For laboratories struggling to secure viral transport medium, the Centers for Disease Control offers guidelines to aid laboratories in preparing their own transport medium.⁴ A manufacturing focus on production of SARS-CoV-2 related supplies has also left many laboratories experiencing shortages of supplies needed to perform non-SARS-CoV-2 testing.² Blood agar, chromogenic agar plates, selective agar, and tryptic soy broth are now on the short supply list. Issues obtaining basic supplies has caused some labs to revive retired procedures to complete testing. This not only decreases efficiency, but also affects patient care and could pose a problem for the management of other infectious disease.

The SARS-CoV-2 pandemic has created unique supply chain issues not only for clinical laboratories in the U.S., but throughout the world.¹ In the spring of 2020, Medical Laboratory Observer (MLO) conducted a survey of clinical laboratories regarding the challenges created by the pandemic.

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Almost half of respondents, 49%, stated sourcing as the single biggest challenge.⁵ One of the biggest challenges to the supply chain comes from major In Vitro Diagnostic (IVD) manufacturers moving production overseas to low-cost nations. The consequences of this move left the U.S. with little to no manufacturing infrastructure and weakened U.S. manufacturer control and influence over increasing production. Additionally, many of these major IVD manufacturers have their own multi-national supply chains, sourcing parts from all over the world.⁶ With major IVD manufacturers having their own supply chain issues, many had to start allocating supplies to current and new customers. Current customers have been able to receive allocations based on the previous

year's volume, whereas new customers have not received allocations on a regular basis.⁶ Additional factors affecting supply chains are the fickleness of SARS-CoV-2, mismanagement of supply chain by federal, state, local governments, and the influx of new companies offering supplies and SARS-CoV-2 test kits. The latter has caused clinical laboratories and healthcare systems to be stuck with unusable testing supplies and/or testing kits.⁶

As we look to the future and examine our quest to provide quality and efficient testing to combat COVID-19, it is also important to note the opportunities brought about by this pandemic. As clinical laboratory professionals, we have learned many lessons from the pandemic. Foremost, we have

learned that we must promote the clinical laboratory profession and demand a seat at the table with government to address issues including supply chain obstacles and the nationwide workforce shortage. The American Society for Clinical Laboratory Science recently partnered with other professional organizations to support the Allied Health Personnel Shortage Act, which would establish scholarships and loan repayment for those pursuing a degree allied health.⁷ By strengthening the clinical laboratory workforce and increasing public and government awareness regarding the complexity of laboratory testing processes and problems observed in the acquisition of equipment, reagents and supplies, we can work together to ensure equitable and quality patient care.



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GET READY FOR INSPECTION DAY



By Dani Stroughton Duncan and Susan Densford

Dani is the Director of COLA's Education Division and 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.

Susan has worked as Surveys Team Leader, Operations Manager and most recently, Director of Accreditation. She has a diverse career in Medical Technology with expertise in Microbiology, having served the specialty for over 28 years.

Preparing for a laboratory survey brings anxiety and stress above and beyond those of a normal work day. But being prepared and doing well on your laboratory survey requires a team effort. In order to prepare for survey day, it is important to understand the various components of the survey process. An on-site survey can include:

-  **Observation of testing**
-  **Review of reports**
-  **Observation of specimen collection**
-  **Employee interviews**
-  **A walk-through of the entire laboratory facility**
-  **Review of laboratory records/documents**
-  **Thorough review of proficiency testing documentation**

In response to the COVID-19 pandemic, accreditation organizations were permitted to perform virtual surveys. COLA was approved by the Centers for Medicare and Medicaid Services (CMS) to conduct virtual surveys in July 2020. The virtual survey is not completely virtual and does include a brief on-site visit, when it is safe to do so. A virtual survey allows for the assessment of laboratory quality and compliance until it is

feasible to perform the on-site survey. On-site surveys continue to be performed where it is deemed safe for patients and employees of the participating organizations.

The preparation for the on-site and virtual survey can be similar in certain aspects. COLA's virtual survey process is outlined in three components. This article will highlight the preparation for an on-site survey as well as the preparation components for a virtual survey.

PLAN AHEAD

- Gather all necessary documentation of all laboratory functions that may be requested by the surveyor
- Decide the method that will be used to submit documents for a virtual survey (fax, upload, software share)
- Designate a Survey "point person"
- Perform a self-assessment of your laboratory
- COLA's self-assessment can help laboratories stay "survey ready"
- Identify an area for surveyors to review documents for an on-site survey
- Schedule accordingly
- Virtual surveys require the use of a computer or tablet with a camera that you can transport to various areas of the lab
- Ensure that the laboratory director and key staff members are available for the video conference portion of the virtual survey

- Be certain to submit your blackout dates on time

DOCUMENTATION REVIEW

In a virtual survey, the laboratory will submit these records to COLA (via upload, fax, file share online via quality management software). Once all of the requested documents have been reviewed, the video conference will be scheduled.

Regardless of the type of survey, the surveyor will be reviewing the following documents:

- A copy of the current CLIA Certificate for the surveyor to review and retain
- Personnel files for all laboratory staff who are filling CLIA mandated positions (including Laboratory Director, Technical Supervisor/Consultant, and Clinical Consultant) as well as for all laboratory employees performing non-waived testing.
 - Files must include proof of education according to CLIA '88 requirements as per either copies or transcripts of their highest degrees (AS, BS, MS, PhD) available
 - Licenses and certifications (e.g. ASCP, RN) will not be accepted as proof of qualification or education in place of academic diplomas
- Competency assessments including all CLIA required methods of evaluation. New employees must be evaluated at six months and also one year after their hire; other employees must be evaluated annually
- Training documents for all new employees

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- Current job descriptions for all employees
- Policy & Procedure Manual(s) including all instrument Operator's Manuals
- Current package inserts for all kit tests and reagents (including all waived methods)
- Package inserts for all controls and calibration materials used during the survey period
- Proficiency testing (PT) records including instrument tapes, test report forms, attestation statements, graded results, and corrective actions taken for all unsatisfactory scores
- Instrument/equipment/pipette calibration, maintenance, and function check records for current and discontinued instruments used during the survey period
- Temperature and humidity records
- All quality control (QC) records, graphical representations, charts
- IQCP documents to include annual reviews
- Test requisitions and report forms used for all laboratory testing. The surveyor may ask to review several patient charts
- Incident Management Plan and any incident documentation

- Incident Management Plan and any incident documentation
- Quality Assessment (QA) Plan and documentation of implementation and follow up QA reviews

VIDEO CONFERENCE: VIRTUAL SURVEYS ONLY

Your surveyor will schedule a date/time with the laboratory for the video conference.

The video conference is held on Microsoft Teams platform (no software download required by the laboratory). The video conference allows the opportunity to:

- Interview multiple personnel
- Use of camera to view processes taking place, look inside refrigerators, check specimen labeling and view documents
- Provide a stage for the exchange of information
- Follow up on any necessary clarification/questions resulting from the documentation review

At the conclusion of the video conference, your laboratory will receive a verbal survey summary. The survey summary includes:

- Commentary on what the laboratory did well
- Any citations issued
- Discussion on how to respond to citations
- The preliminary survey report which indicates the citations that were issued to the laboratory
- The date of the video conference is the actual survey date that is recorded in COLA records

BRIEF ON-SITE VISIT

Prepare your laboratory for a brief on-site visit within four months after the Video Conference. Take this time to tidy up the laboratory and perform some "housekeeping" tasks in preparation for the visit. The surveyor will perform a walk-through of the laboratory to look for safety issues and general order of the laboratory. The surveyor may ask questions of the staff. The surveyor will want to see your CLIA certificate, confirm your test menu, and ask about any Laboratory Director changes.

Laboratory inspections can be a very smooth process to ensure the quality of the laboratory. Citations are opportunities to learn and institute new best practices. Continuous survey preparedness paves the road to a successful survey!



SUGGESTED BEST PRACTICES FOR LABORATORY SUPPLY MANAGEMENT



By Dani Stroughton Duncan

Dani is the Director of COLA's Education Division and 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.

The vital role of laboratory services in patient care is undeniable. The clinical laboratory helps provide critical information on patient diagnosis and monitoring of treatment plans. Laboratory supplies and resources are essential in the performance and completion of tasks. But what happens when you do not have the supplies to perform testing on patient specimens? Where does that leave the patient? During the pandemic, many healthcare organizations were faced with supply chain depletion and had to consistently implement creative ways to serve the patient population. For many organizations, the impact of COVID-19 has created some hard-learned lessons. In this article, we will review best practices regarding supply management.

THE ASSOCIATION FOR MOLECULAR PATHOLOGY

SARS CoV-2 Molecular Testing survey in August reported that greater than 90% of participating laboratories noted supply chain interruptions. The interruptions resulted in diminished testing or extended turnaround times. The supply chain interruptions impacted the testing devices as well as the additional supplies needed for testing, such as swabs and transport materials. The survey identified that all the various types of laboratories experienced similar challenges with managing supply volumes. A best practice that arose in response to this pain point is the need to diversify the supply chain. Laboratories commonly have one leading testing platform and supplier for equipment to support the main testing avenue. The pandemic revealed the need to have multiple platforms for specific testing and suppliers. It is difficult to predict if laboratories will continue to support multiple testing platforms post-pandemic, due to the regulatory compliance upkeep.

It may, however, be beneficial to maintain the diversity in supply chain vendors post-pandemic.

Staying current with policy changes from various regulatory and government agencies is a best practice. The COVID-19 pandemic was uncharted territory globally. The CDC reacted with a temporary solution to alleviate the supply challenges by establishing criteria for the use of SARS-CoV-2 expired testing reagents and supplies. The requirements allow testing with these expired reagents, unless it conflicts with the manufacturer's instructions or testing performance, and when the reagents are not available. It is important to note that CDC does not promote continuous use of expired reagents as a matter of course. These innovative resolutions have eased some of the pressures of acquiring essential testing supplies but should be seen as temporary. As laboratories move past the COVID-19 challenges, the lesson learned about utilizing the communications from government agencies can help successful laboratory operations. Another best practice is fostering communication among laboratory personnel.

The unpredictable nature of the COVID-19 pandemic has thrown aside what we knew to be a standard process. The benefit of this shift has allowed the reexamination and restructuring of dated practices.

Communication among staff, leadership, and physicians to address supply challenges can lead to innovative approaches. Open communication can yield ideas for resource and task sharing. Communication within networks can allow idea sharing to help with common pitfalls. Personnel can join professional social media groups to discuss challenges, and creating a platform for internal communication can benefit the organization as a whole.

The pandemic has changed the playing field in many aspects of the laboratory industry. Supplies procurement once seen as a matter of adequate ordering transitioned into an unpredictable chase for needed resources. The current climate will change and laboratories must carry lessons learned to be prepared for what lies ahead.

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ATTRACTING AND RETAINING LABORATORY PROFESSIONALS

By Dani Stroughton Duncan

Dani is the Director of COLA's Education Division and 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.

The pandemic has added another stressor on laboratory leadership: the need to increase staffing in the laboratory. The rapidly growing volume of COVID-19 testing platforms and demand for qualified testing personnel has made staffing a real-life struggle. One aspect of emergency preparedness is understanding how to properly utilize staff. The first step is attracting and retaining qualified laboratory professionals. Human resources are the key in the hiring and recruiting process and laboratory managers have an intricate role in the process as well. They are responsible for the daily operations and the overall culture of the laboratory. The input of laboratory leadership in the hiring of staff in the pandemic has become increasingly more valuable. We discussed some of the trends and challenges of recruiting laboratory professionals with Shawn Wierzbowski. Shawn Wierzbowski is the founder of Intro Medical Laboratory Recruitment, helping companies find permanent laboratory professionals. Below are some tips for employers and prospective employees:

What are some helpful tips to laboratory leadership in obtaining qualified applicants?

Human resources must understand the needs of your department. They must be clear on the expectations for the type of candidates that will successfully fill the position. It is helpful if the recruiters come and visit the laboratory to further understand the department's requests. Shawn recommends that laboratory leadership be proactive in their search for the right candidate.

One of the most important things that laboratory leaders can do is to make sure that internal recruiters have a thorough understanding of what is needed in the laboratory. Sometimes there may be a disconnect on the specific kind of medical technologist needed or there may not be a full understanding on what skills can be transferred to the vacant position. Often candidates can be accidentally overlooked. Shawn recommends having HR come into the laboratory to get a complete understanding of the needs.

Shawn also recommends that it is very important for laboratory leadership to be pre-active in finding a candidate. They should be networking on social media sites such as LinkedIn with other techs from surrounding laboratories for future openings.

What are things for prospective candidates to consider when selecting a laboratory employer?

New laboratory graduates are entering the field during a pandemic. The pandemic can have an impact on possible candidates' expectations for an employer. Shawn suggests prospective candidates familiarize themselves with other staff in the laboratory and the culture of the laboratory. Also, examine the opportunities for staff advancement and growth potential. It is important to interview at as many places as possible to see all the different possible work environments.

What aspects should be considered when reviewing a salary offer from a future employer?

When reviewing salary, look at the full package. The candidate should assess the benefits, location, and transport, such as parking fees. It is also a good idea to "spread your net" and interview at multiple places to compare options for salaries.

How do you land the interview at that desirable laboratory?

Applying to the position is the first step. It is a good idea to contact the laboratory's management that you have set your sights on.

Start by introducing yourself and let them know that you are interested in the position. Reach out directly to management through LinkedIn or even call in directly to speak with managers about their openings and your background.

There has been continuous discussion of how to retain competent staff. The pandemic has amplified the need to promote retention. How can laboratories improve retention efforts?

Shawn stated, "if people feel taken care of, they will stay." It is crucial to understand the motivators of staff. The motivators could vary from financial to encouragement to growth potential. Frequent check-in with staff can help you learn your staff's motivators and understand the laboratory's culture. Leadership can take a team approach to improve retention efforts. Laboratories struggling with retention should also take self-inventory to examine if any changes are needed within the laboratory. Changes within the laboratory that could assist with retention may be more scheduling options or increased communication with staff.

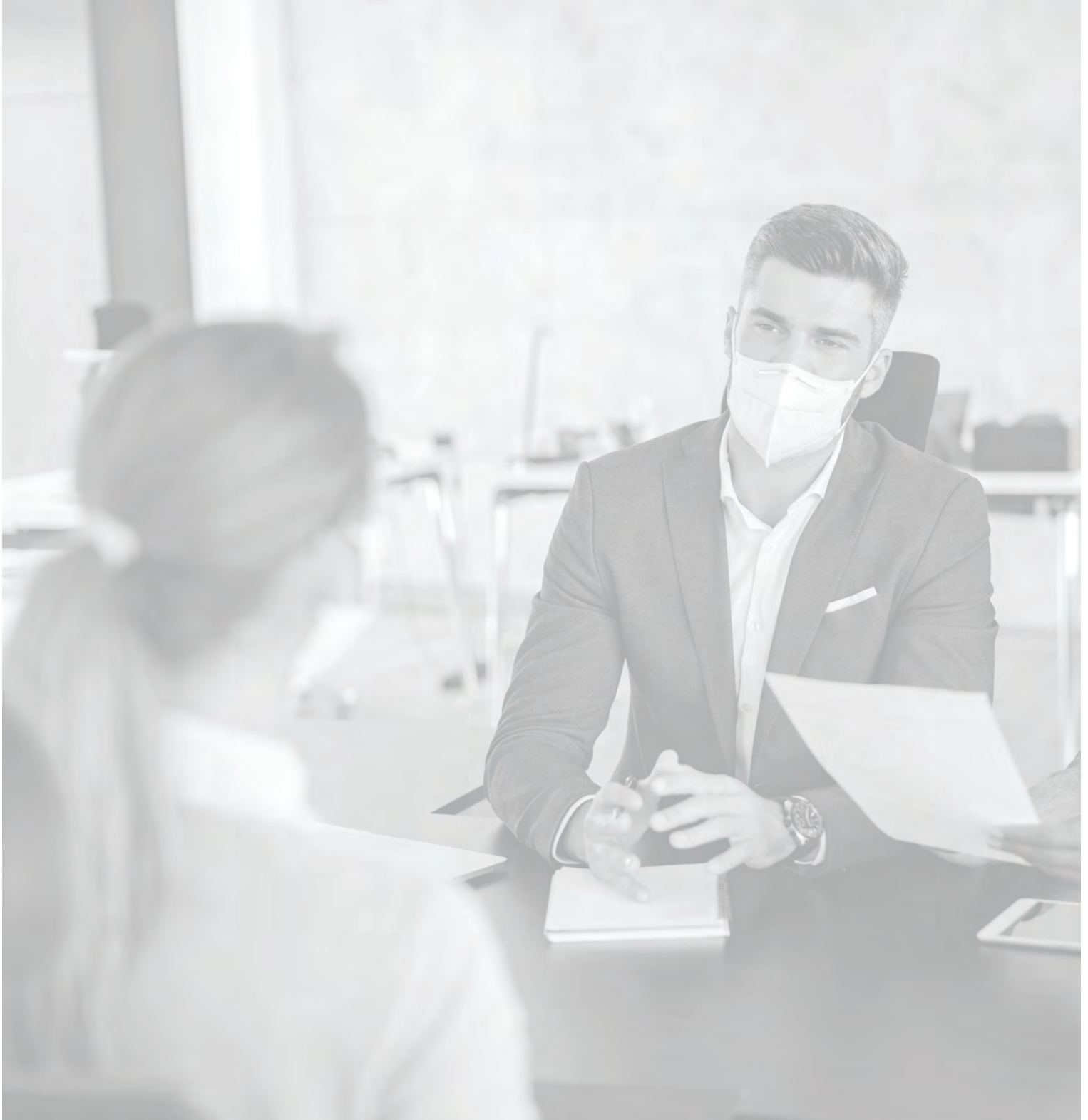
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From your perspective, are there any specific skills or tools that laboratory management is looking for in the COVID-19 pandemic?

There is a need for staff to quickly adjust to the position and show initiative because of increased volume and staffing shortages. Leadership is looking for qualified laboratory professionals who can jump in and perform successfully.

How does Intro Medical Laboratory Recruitment assist in supporting laboratories during the pandemic?

Shawn Wierzbowski founded Intro Medical Laboratory Recruitment in 2020 to assist in finding permanent medical technologists for organizations struggling to attract local candidates. By attracting local technologists' companies can avoid using costly traveler services or "temps".





COLA

OUR COMMITMENT TO YOU

We are a physician-directed organization whose purpose is to promote excellence in laboratory medicine and patient care through a program of voluntary education, consultation, and accreditation.

ABOUT COLA:

For more than 30 years, COLA's accreditation program has provided an extra pair of eyes for laboratories striving to produce quality test results. COLA is also the only provider of a laboratory accreditation program with quality-engineered processes certified to ISO 9001. This means our customers benefit from unique services that are standardized and represent a commitment to customer satisfaction. Just as importantly, COLA provides materials to guide successful completion of inspections and adherence to regulations; and has a dedicated staff of subject matter experts steered by a coaching approach.