# WhitePaper

## 2021 Forecast

# Clinical Laboratories Use Automation to Expand Their Data Capabilities

## And Strengthen Their Resilience to Respond Faster During a Pandemic and Beyond

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# Introduction

The healthcare system, including the clinical laboratories that support hospitals, long-term care facilities, clinics, and physicians, has been significantly stressed by the ongoing coronavirus pandemic. When COVID-19 treatments appropriated the slots previously reserved for elective surgeries, procedures, and routine tests, clinical laboratories lost revenue. The sheer volume of COVID-19 tests to process lengthened turnaround times.

The technology—both for running the actual COVID-19 tests and administering necessary documentation—was not as efficient as it could have been. All of the pressures were further compounded by demand from federal and state authorities for immediate compliance with new COVID-19-related data reporting requirements, another process for which automation has been woefully underused.

Charles Robbins, MT(ASCP), who has worked in clinical laboratories and now serves as principal solutions consultant at OpenText, says "most technology that is in place was not built for this type of workflow. Most lab systems are based on a patient encounter—either in a clinic or in a hospital—and COVID-19 testing often falls outside of those parameters. This is particularly true for large institutional testing, like universities or within prison systems where there is no provider interaction, and there is testing on a broad scale."[1]

Since this latest healthcare crisis began, lessons have been learned. The medical frontlines, including clinical laboratories, have pivoted and adapted. Nevertheless, the number one question confronting clinical laboratories is how long into the future labs will need to offer COVID-19 tests on a large scale.

Some clinical laboratory CEOs expect that demand for COVID-19 testing will stretch far into 2021 and even 2022, depending on the need for ongoing antibody testing and the potential for new virus strains. Therefore, with urgent needs related to the pandemic, clinical laboratories have an opportunity to strengthen their resilience and redefine their role and offerings. Now more than ever, the value of the

clinical laboratory extends beyond simply providing test results.

David G. Grenache, PhD, President of the American Association for Clinical Chemistry (AACC) and Chief Scientific Officer at TriCore Reference Laboratories, agrees. "Lab medicine professionals not only provide test results," he explains, "we play a central role in improving patient safety and quality of care by ensuring that the right tests are ordered for patients and used effectively, and that the results are interpreted correctly."[2]

Clinical laboratories are in a position to offer more than diagnostics, said Chair, President, and CEO of Quest Diagnostics Steve Rusckowski during a 2019 interview with *Advisory Board*. Diagnostics, he explained, "is at the beginning of every costly decision. Diagnostics is only 2% to 3% of health care costs, and yet 70% of decision making in health care is based upon those lab values. Yes, we are one of the world's largest labs, but that's not our business. We're in the business of empowering better health with diagnostic insights, which we define as diagnostic information services." As you move away from the biology and chemistry of labs, he adds, "you realize that the information and services are becoming more important."[3]

Now and in the year ahead, clinical laboratories are pushed to use their actionable data to report on infection patterns, along demographic lines, and to track and predict infectious diseases. There is also the need to trend chronic health condition clinical biomarkers toward predictive modeling and risk stratification.[4] Such data structuring enables these labs and the physicians they serve to sound alarms and make observations that can support infection and disease control, treatment protocols, and eradication—and this has the potential to lead to downstream healthcare savings.

*This white paper explains the key steps and results of strengthening the data service infrastructure of independent clinical laboratories and labs that serve hospitals and health systems.*

Progress in these areas, however, depends on clean, reliable data.

Clinical laboratory data must be originated efficiently and without errors to truly add value downstream and prove value upstream, where it can improve healthcare and reduce costs. Labs can simultaneously strengthen their resilience, expand their capabilities, and demonstrate value by using automation to collect, process, and report their data.

## Part 1:

# Strengthening the Clinical Laboratory Data Service Infrastructure

With new clinical laboratory data reporting demands, the Centers for Medicare and Medicaid Services (CMS) acknowledges the problems that many organizations have with capturing and reporting data sufficiently, accurately, and in a timely manner. The coronavirus pandemic continues to underscore ongoing data collection and utilization challenges to which most clinical laboratories have become accustomed.

"Clinical laboratories typically manage many sources of disparate data, and now at much higher volumes than they ever imagined," says Anne Tate, MT(ASCP), SC, MBA, MHI, Co-Owner of Talking Laboratories, a clinical laboratory consultancy. "Laboratory directors and managers know they have valuable data, but transforming it into usable data is the main problem most labs encounter."[5]

The current system is marked with a lot of manual work, from hard-to-read, handwritten orders to faxing to follow-up phone calls. This manual processing of data often results in data incongruity, such as incomplete information, errors, or omissions, notes Tate. "Clean data collection is a pain point for laboratories," she says.

When parts of the process are handled manually, the risk of "dirty" lab data increases. The manual collection and reporting process can result in slower turnaround times due to entries with errors or omissions that require lab staff to correct. Such delays on the front end result in delays on the back end, which in turn affects relationships with practitioners, patient care, and even getting reimbursed in a timely manner. "When your turnaround time is slow, you look like a bad lab," observes Tate. "Plus, when your data is inaccurate, it cannot be used in any other broader, more valuable capacity."

It was not all that long ago (2012) that the White House declared a new "National Strategy for Biosurveillance." That effort reinforced the dangers of both unstructured data and barriers to health data sharing—all within the context of national security.

"A key to improving all-hazards incident management is to focus efforts on collecting, analyzing, and disseminating information to facilitate timely decisionmaking, whether a health incident is a naturally occurring phenomenon, accidental, or deliberate in nature," states the National Strategy for Biosurveillance archive.[6]

While the National Strategy for Biosurveillance document is not a direct address to clinical laboratories, the document delivers four imperatives that are relevant for labs today. They are "enablers for strengthening," and they consist of:

1. integrating capabilities,
2. building capacity,
3. fostering innovation, and
4. strengthening partnerships.

The good news to come of the pandemic so far is that it quickly triggered nearly all four of the enablers for strengthening. First and foremost, the pandemic accelerated new partnerships between clinical laboratories and multiple vendors (*in vitro* diagnostics and others) to expand capacity by adding automated platforms in order to satisfy community lab testing needs. The pandemic also accelerated innovation in the rapid development of COVID-19 testing methodologies and flexible testing environments.

Now, at the forefront with the pandemic disruption is the opportunity—and imperative—to strengthen the healthcare data service infrastructure. With clinical laboratory testing an essential service of the entire healthcare system (health emergency or no health emergency), 2021 may begin a sea change in healthcare data collection, integration, and interoperability. This white paper explains the key steps and results of strengthening the data service infrastructure of independent clinical laboratories and labs that serve hospitals and health systems.

## Part 2:

# Key Steps for Realizing Accuracy, Expanded Capacity, and Reporting of Clinical Laboratory Data

***Fact:*** Timely and detailed clinical laboratory data is king now more than ever before. This is because of both federal clinical laboratory and hospital data reporting requirements and also an urgent need for national biosurveillance and risk stratification.

However, a crucial and necessary *first step* for clinical laboratories is to improve their data collection process by reducing manual inputs.

"When laboratories receive paper-based orders, the standardization of the data they receive is hard to control when someone from the doctor's office is filling out the information," Tate explains. "The patient information is incomplete or wrong and then when the practice receives this information, staff has to manually enter the data into their system, now compounding the errors in data loss and incongruence. Labs then have to use labor to call the doctor's office to get the information they need to clarify the order, the patient, and key information that goes with the patient."[7]

When the data is inaccurate or incomplete, the clinical laboratory cannot run the test. For example, Tate shares, if a date of birth is missing, then reference ranges cannot be applied to some tests. Or, if a patient's full name or unique ID is missing, then labs cannot identify if they have seen the patient before and may open duplicate records, thereby interrupting the continuity of patient information and potentially causing gaps in the medical record.

To avoid the issues of incomplete and incorrect data, there are three primary tasks for improving the flow of clinical laboratory data collection, capture, and reporting:

**STEP 1**

Improve the data collection process of clinical laboratories by reducing manual inputs: three primary tasks.

- *Encourage practices to adopt an electronic interface to replace paper and error-prone processes that are tedious and repetitive.* This means investing in automation for front-end procedures and back-end reporting. In their 2015 paper "Management of Laboratory Data and Information Exchange in the Electronic Health Record," Dr. Myra L. Wilkerson and colleagues wrote that "reworking orders that are incorrectly coded, have missing information, or are missing medical necessity checks is expensive. It has been estimated that each order requiring rework by laboratory personnel costs approximately $25."[8]

- *Ensure interoperability to promote data integrity standards (health information exchange, or HIE, protocols).* The February 2019 AACC article "Strengthening the Chain of Interoperability" stated that "interoperability signals an ability to share data automatically and seamlessly among multiple devices and organizations." Clinical laboratories must take "steps to integrate laboratory information systems (LIS) and electronic health record (EHR) software programs while leveraging automation and robotics technologies to more efficiently process test results."[9] Again, the end goal is to improve data efficiency and accuracy.

- *Improve bidirectional communication between provider and hospital.* What the provider sends to the clinical laboratory must then be able to be interpreted by the hospital, and vice versa.

"The less human handling you have with patient results, the better," says Joe Trevino, Senior Account Executive at OpenText.[10] For more than 27 years, Trevino has worked in the clinical laboratory field, as a manager, owner, and consultant. His experience has given him firsthand insights into the challenges of a laboratory manager's daily routine. He understands where the breakdowns occur, and he knows that data quality improves with less manual intervention.

***Fact:*** Clean order entry ensures faster lab test to result and a smoother, quicker reimbursement process. Neither of these critical aspects of clinical laboratory testing is achievable without the *second step* of improving the quality of data captured so that orders get to the lab faster.

In accomplishing the second step of clinical laboratory data service improvement, three best practices ensure clean order entry for the laboratory.

**STEP 2**

Ensure clinical laboratory clean order entry: best practices.

- *Assurance that data fields are completed with each clinical laboratory test order.* Another statistic noted in "Management of Laboratory Data and Information Exchange in the Electronic Health Record": Patient misidentification errors occur 324 times per 1 million billable tests. Most of the errors are caught, but catching them requires manual follow-up.[11]
- *Standardized data entry adherence.* This creates a common language among all parties in the patient's care.
- *Appropriate prescribed lab test ordering based on established best-practice guidelines.* The best way to ensure this happens is through automation, believes Tate. "EMR (electronic medical record) order logic will check when someone is entering orders at the provider for missing fields, incorrect test against the diagnosis, or patient details," she says. That said, "There are hundreds of EMRs out there," says Leslie Tucker, Director of Cloud Services at OpenText, "and each one can use a different approach to order entry. There are a lot of nuances to getting the necessary data in there, including regulatory requirements. Some EMRs do a good job of establishing protocols and making sure fields are input correctly. Others do not. The best-case scenario is for the automation system to have the checks in place to ensure all necessary fields are completed so the order arrives cleanly and can be processed quickly, thus ensuring better patient care."[12]

***Fact:*** Data automation strengthens core clinical laboratory testing services and builds laboratory resilience. Resilience can mean rebounding, as has been necessary for labs during the COVID-19 pandemic, or, as the authors of "Ten Simple Rules for Increased Lab Resilience" define more deeply, it can mean "the ability to retain the core lab mission and functioning when faced with a significant crisis."[13] Either definition applies going forward. Automation in the clinical laboratory varies from facility to facility, but it matters profoundly at the points of intaking the order and dispatching the final results.

Clinical laboratories that have implemented automated systems to streamline routine testing, expand capacity to test for COVID-19, and respond to new testing demands and opportunities also gain from a new level of clinical informatics that such new systems afford.

Applying data automation in the clinical laboratory at the enterprise level fully realizes advantages of the *third step*—embracing data automation. How does clinical laboratory data automation strengthen lab resilience and data veracity?

**STEP 3**

Implement automation to strengthen clinical laboratory data quality, data veracity, and resilience: what to expect on an enterprise level.

- *Clean orders faster to improve overall turnaround time.* Because automation typically standardizes order information and thus eliminates the need to double-check intake directions or patient details, overall turnaround time is reduced. Tate explains: "The electronic automation of input standardizes the data so that it can be reused for other data-driven programs within the lab and as the data moves vertically up into the organization."[14] It is true that the time from order to result was longer than expected with COVID-19 tests, but, according to Dr. Grenache, those delays had more to do with getting reagents and test kits rather than a breakdown in expediency of orders.[15]

- *Ability to quickly adapt and pivot to surges and changes in lab testing volume.* A good example of this is demonstrated by adding auto-verification rules to LIS or other software systems that receive result data. Auto-verification can review and process large quantities of results with more accuracy and precision than tedious

 

manual review processes. The use of rule logic to streamline results review so that 85% or greater of the results are auto-verified increases the laboratory's ability to adapt to surges, changes, and unexpected volume—without adding more resources.[16]

- *Quicker results to confirm or clear suspected diseases or predict progression.* When staff are released from manual duties, they are free to focus on client care, which translates to a focus on processing samples and getting the lab test results back to physicians as quickly as possible.

***Fact:*** Organizing and filtering data for expanded use assures internal and vertical integration of electronic health records. This translates into better patient care and added value for the clinical laboratory. With this *fourth step*, three truths become evident after implementing automation that allows for organizing and filtering clinical laboratory data:

**STEP 4**

Organize and filter clinical laboratory data for internal, vertical, and external integration: three truths that become evident.

- *Clean data is more valuable as it moves both up the chain and downstream.* As Robbins notes, "If you can get all the input data clarified up front, then you have a clean testing process all the way through to the actual release of the results." Sara Heath, who wrote "4 EHR Best Practices for Improving Clinical Workflows," observed that clean data transferred electronically resulted in better downstream billing and collection rates.[17] As for moving data up the chain, the cleaner it is, the more this data positions clinical laboratories to report accurate information to local and federal agencies, and hospital and health system leaders.
- *Standardized data can be used to build clinical laboratory tools.* These include dashboards and reports that can be used internally and externally for data-driven programs. The ability to create reports makes it easier and more efficient to comply with mandated reporting requirements as well as generate insights toward population health initiatives.

*Verified data can be stratified better to identify trends and insights of the pandemic's trajectory and impact on community behavior and vaccine outcomes (immunity responses).* In more common scenarios, verified data can be stratified to identify trends in costly chronic health conditions. It is here where the laboratory's opportunity for added value appears.

In 2018, a federally qualified health center asked Sonic Healthcare USA to use its clinical laboratory data to improve patient outcomes and reduce the cost of care for patients with diabetes and chronic kidney disease. It developed a scorecard for patients with chronic diseases who were overdue for routine lab monitoring. Sonic would not have been able to do this without verified data that could be manipulated to identify trends among patients. During a presentation that same year, Philip C. Chen, Chief Healthcare Informatics Officer at Sonic Healthcare USA, said, "Our service includes an integrated stratification system that uses diagnostic codes to help us predict the likelihood of a high-risk event." Ultimately, the lab was paid "for the value of its actionable intelligence."[18]

In his article "Sonic Uses Lab Data, Patient-Contact Tools to Improve Outcomes," writer Joseph Burns summarizes: "Sonic helped physicians use a data-driven approach to population health management that incorporated integrated financial and clinical analytics …. From its work with this health center, Sonic was asked to be more than a lab provider."[19]

# Conclusion

There will continue to be pressure for healthcare data management to keep pace with innovation as well as new standards for infectious disease and public health reporting.[20] Clinical laboratories' data organization, interoperability, and reporting capabilities must be significantly improved. Doing so will positively impact downstream healthcare cost savings and opportunities to benefit from value-based care arrangements.

Certainly, the value is there. Dr. Grenache spells it out: "Lab medicine professionals are using the vast troves of patient data generated by laboratory testing to guide population health initiatives that significantly improve patient outcomes while saving money for healthcare systems overall.

*Clinical laboratories and their hospital partners—that on an enterprise level use accurate, actionable data generated by the laboratory and its physician networks to define health patterns—will truly have an advantage with healthcare service funding programs, reimbursement, and enhanced patient care.*

"Generally speaking, labs' data represents a gold mine for managing population and public health. The concept of volume to value (through data) is resonating in our profession, and I think many labs have already done so or are beginning to explore how their data can contribute to institutional goals around these issues," says Grenache, whose organization, TriCore Reference Laboratories has used this strategy to work with a health plan in improving diabetes and prenatal care. These efforts resulted in improved outcomes and decreased the total cost of care. "We also demonstrated that clinical laboratory results are just as accurate as the CDC's population disease surveillance method to estimate the incidence and prevalence of diabetes," Grenache explained.[21]

Although the healthcare system and clinical laboratories remain significantly stressed by the COVID-19 pandemic, flexibilities continue to develop. Indeed, healthcare providers are in a unique position, with clinical laboratories the developers, custodians, and distributors of volumes of data that offer opportunities for improving healthcare outcomes. Therefore, it is incumbent upon lab leaders and their hospital and health system stakeholders to now think strategically given the current circumstances.

In fact, as noted by Giuseppe Lippi and Mario Plebani in their opinion piece, "The Critical Role of Laboratory Medicine During Coronavirus Disease 2019 (COVID-19) and Other Viral Outbreaks," there are at least three major areas where *in vitro* diagnostics can also provide essential contributions to diagnostic reasoning and managed care of patients. These include etiological diagnosis, patient monitoring, as well as epidemiologic surveillance.[22] However, such contributions require clean data and order operations.

Trevino notes that when hospitals, clinics, and physician offices adopt a middleware solution with embedded order validation, such as OpenText's EMR-Link, the entire data process is much more efficient.[23] Hospital IT departments don't deal with other EMRs on a daily basis, so "it's like re-inventing the wheel every time for some of these IT departments at the hospitals," he says. "What they may take 100 hours to do, we might be able to do in 15 hours. While they may be making one connection into an EMR, we might be making 300. With EMR-Link, we've been able to scale the process and make it efficient."

"We're essentially a consolidator and translator," adds Tucker. "We can pretty much guarantee that an order isn't going to error out." The OpenText system is designed to enable leveraging of clinical laboratory data—starting at data entry, with the provider at the point of care—according to Tucker.[24]

Finally, diabetes, kidney and cardiovascular issues, and other challenging or chronic health conditions all call for proactive monitoring and advancements in predictive modeling. Therefore, those clinical laboratories and their hospital partners that develop a unified vision and data use plan—that on an enterprise level uses accurate, actionable data generated by the laboratory and its physician networks to define health patterns—will truly have an advantage with healthcare service funding programs, reimbursement, and enhanced patient care.

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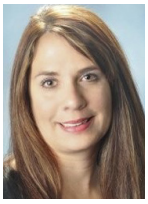

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