WhitePaper

Repurposing Your Lab's Leftover COVID-19 Samples:

Building New Revenue and Better Patient Outcomes Through Collaboration With Life Sciences

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Ovation

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Introduction

SARS-CoV-2 testing in clinical laboratories has rapidly declined with the rollout of COVID-19 vaccines. U.S. clinical labs that were collectively processing 2 million COVID-19 tests per day in January 2021 were doing only about 1 million by March.[1] This precipitous drop caused lab leaders to wonder: What comes next? After all, it was March 2020 that laboratories faced the first major testing crash brought on by the pandemic when routine testing came to a sudden halt. Many labs effectively pivoted then and brought COVID-19 testing to their offerings.

Now labs are having to adapt again, leading forward-looking lab managers and directors to ask questions:

> *What will be the new balance between testing for SARS-CoV-2 and routine diagnostics?*
>
> *Should my clinical laboratory even continue testing for coronavirus? Where is the best opportunity to generate revenue?*
>
> *How do I transition my lab effectively—and efficiently—to best serve patients and the healthcare industry as a whole?*

The answers to these questions affect not only molecular laboratories, but the life sciences industry as a whole, as drug developers and labs find it beneficial to work together in new ways.

UCSF Professor Scott VandenBerg, MD, PhD, draws the connection: "Biospecimens are important because they allow researchers to better understand the causes of diseases and evaluate potential therapies."[2] Labs retain these biospecimens and always have, but COVID-19 has spotlighted their value. Labs actually pay to dispose of their leftover specimens as regulated medical waste. Now, as researchers on the life-science side study coronavirus and other diseases, the value of accumulated biosamples—previously thought to be cost center once used for the original purpose—is being reevaluated.

Drugmakers are expected to prioritize the development of therapeutics for new patient cohorts, such as long-haul COVID-19 patients,

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while verifying the fidelity of biomarkers used to identify and treat comorbidities. Data generated from analysis of leftover COVID-19 samples could dramatically accelerate this process.

Coronavirus is the obvious entry point for such a mutually beneficial relationship between clinical laboratories and drug researchers and developers right now, but the samples associated with other illnesses could accelerate therapies for those studies as well.

This white paper examines how molecular laboratories can generate new revenue while also contributing to the greater good of society. One of the primary ways to achieve both is to harvest more value from samples through new relationships with life science companies and biobanks.

In these new business arrangements, labs would benefit because instead of paying to dispose of their COVID-19 samples, for example, they could biobank them at little to no cost.

COVID-19 and other biospecimens have extended value—particularly for drugmakers hoping to discover life-changing medicines and diagnostics and get them into the hands of patients who need them. This paper posits that laboratories would be at the front end of that process. Moreover, this paper explains what clinical and molecular laboratories need to take advantage of the opportunity to "dollarize" their samples.

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Chapter 1:

COVID-19 Testing: What's Next After the Rapid Ramp Up and Sudden Decline?

In spring of 2020, multiple factors mitigated a swift response for SARS-CoV-2 testing once the pandemic gained its foothold in the U.S. Nearly immediately when officials at the U.S. Centers for Disease Control and Prevention (CDC) and the U.S. Food and Drug Administration (FDA) loosened the regulatory handcuffs on the nation's clinical laboratory organizations, labs started testing for COVID-19 at exponential rates.[3]

Many of these labs had already lost revenue when routine testing crashed with the pandemic shutdown. However, labs rallied, pivoting from traditional diagnostics to COVID-19 testing. Ultimately, the seemingly unending demand for SARS-CoV-2 testing helped labs recoup lost revenue and led to the expansion of molecular testing.

Barry Wark, PhD, is Co-founder and CEO of Ovation, a Cambridge, Massachusetts-based scientific data company that provides a cloud-based, out-of-the-box laboratory information management system (LIMS). According to Wark, more than 343 million COVID-19 tests were performed in 2020 in the United States alone.[4] Laboratory Corporation of America reported 52% year-over-year revenue growth for fourth-quarter 2020, growth driven by COVID-19 testing.[5] Additionally, the lab landscape welcomed startup and pop-up labs dedicated to SARS-CoV-2.

In a recent webinar, Jamie Platt, PhD, MB(ASCP), CEO and Founder of BRIDGenomics, a Tennessee-based company that provides strategic and technical consulting around assay development, noted that at least 48% of clinical labs adopted new testing methodologies or automation in order to meet the demands of COVID volumes.

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This figure, plus the number of labs that have shifted or launched because of COVID-19, points to a significant investment in COVID testing alone.[6]

"We've built over 50 COVID labs or added COVID testing into existing labs," shared Jon Harol, President of Lighthouse Lab Services in Apex, North Carolina. Lighthouse consults with clinical laboratories to build, expand, and/or staff them. About 30 of these laboratories were startups; 20 wanted to add COVID testing. Compared to previous years, Harol estimated that new lab openings were up 20% and very concentrated. "Nobody really wanted to talk about anything besides COVID," he added.[7]

"Laboratories have done an outstanding job in meeting the demand," agreed Platt, "and they've really rallied around the need to increase their capacity. They've had to do it with multipronged approaches. Now that they've implemented these systems—maybe some automated systems, maybe a new molecular device, maybe several new molecular instruments—what are they going to do post-COVID?"[8]

Platt's question is one reverberating throughout the clinical laboratory industry. It is a question driving lab leaders to think about their equipment, their testing capacity, and their menus. No one can predict when COVID-19 testing will stabilize, but everyone knows that it's inevitable.

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Chapter 2:

Looking Beyond COVID-19 Testing to Find Residual Value and Revenue in Collected Specimens

To stay profitable and relevant, every clinical and molecular laboratory's short-term and long-term strategic planning must consider the evolving nature of the pandemic.

"If people have taken on new platforms to do large volumes of molecular testing and those volumes are much bigger than any testing they ever did before, that equipment is probably not going to have a lot of use in that setting [post-COVID-19], and you'll have to make some hard decisions about whether you want to get rid of it or how you might try to repurpose it," said Robert Boorstein, Medical Director at Brooklyn-based Lenco Diagnostic Laboratory.[9]

One way to deal with new equipment purchased to process COVID-19 tests, he continued, is to see if the equipment can be used to transition to new testing menus.[10]

When Lighthouse's Harol consulted with businesses that wanted to either build laboratories or add PCR testing for COVID, he encouraged them to think beyond their immediate needs.

COVID was the catalyst, Harol said, but "we had a lot of conversations around what the long-term plan would be, which would include a lot of infectious disease testing." He listed urinary tract, respiratory, sexually transmitted, gastrointestinal, wound, and nail fungal panels as some of the infectious disease testing that could be performed with most of the open PCR systems established for COVID-19 because the systems "can be easily revalidated into those testing lines." If a closed PCR system was installed, then it has

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limited capability for a post-COVID pivot, such as would be needed to accommodate other infectious disease testing.[11]

However, more molecular testing instruments are in laboratories as a result of COVID-19, and Harol believes molecular testing will become more prevalent and will replace older-style testing, notably in hospitals. The results often are faster and promote better patient care.[12]

While some laboratory leaders are strategizing how to use the molecular platforms they used to respond to the pandemic, others are focusing on the COVID-19 samples themselves and suggesting longer-term value than perhaps originally considered.

Many labs that ramped up their operations for COVID-19 testing do not have a plan for utilizing their leftover COVID samples.

The virus' urgency has ebbed, but it has assumed a place next to other diseases where it still needs research, patients still need care, drugs still need development, and people still need education. The study of SARS-CoV-2 will be ongoing. As a result, labs' leftover samples are now valuable. COVID is the lemon. What it has left behind could be turned into lemonade.

Judging from major investments and record venture funding, COVID-19 accelerated life science companies' opportunities to pursue potential cures and therapies for all sorts of diseases, not just SARS-CoV-2. Indiana's life sciences industries alone captured $257 million in venture capital in 2020, more than triple the amount raised the previous year.[13] The monies raised target cell therapy, biologics manufacturing, new drugs for brain and bowel diseases, diagnostic tools to detect tumors, and other areas.

"There are a variety of different reasons ... maybe they haven't thought about it, or maybe they've thought about it and assumed it's too difficult," says Jamie Platt, PhD, of BRIDGenomics, "but there's a wealth of information in each of those samples."

The healthcare community, including molecular laboratories, academic centers, and life science organizations, has united over a single cause and is now looking at ways to leverage that unification to advance genetic research, therapeutics, and disease understanding.

"We are seeing biologists working with statisticians and public health experts collaborating with logistics experts," points out Katharina Volz, Founder and CEO of OccamzRazor, a digital biotech company that uses artificial intelligence to develop treatments for brain-aging diseases.[14]

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The point is that investors see an opportunity, and research into COVID-19 and other diseases remains top of mind.

Until recently, researchers studying COVID-19 were largely relying on cohort data, particularly among long COVID-19 patients. Because these patients suffer for several weeks or months after showing the initial symptoms of COVID, they present an opportunity to study not only the long-term effects of COVID but also of other viruses.[15] In England, psychiatrist Simon Wessely of King's College London compared population cohorts there to "gold dust," but he also noted that the cohort studies have focused too much on hospitalized patients. Thus, patients who don't go to the hospital are not represented.[16]

Such cohort scenarios accentuate the importance of vast and varied samples because leftover COVID-19 samples and other biospecimens could be used to study both the coronavirus and its relationship to other diseases, particularly those defined as comorbid.

In new working relationships between molecular laboratories and biobanks, COVID-19 samples could be used to explain why some people have little or no reaction, others get extremely sick, and some people die. The specimens also could be used to accelerate the development of drugs or diagnostics used to identify and treat other illnesses, such as cancer, multisystem inflammatory syndrome in children (MIS-C), and pediatric acute-onset neuropsychiatric syndrome (PANS), for example.

"We're asking questions we never asked about, say, the flu," says Carlos D. Bustamante, PhD, a noted genomics researcher. "For instance, we're learning about COVID at a molecular phenotyping detail like we've not done for any other infectious disease."[17]

Bustamante is Professor of Genetics, Biomedical Data Science, and (by courtesy) Biology at Stanford University, as well as Venture Partner at Fidelity's early stage biotech group, F/Prime Capital.

"I see incredible opportunity not only on the research side, but also on the investment side," said Bustamante. "I want to live in a world where data is liquid and can flow to the best researchers working

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on the toughest problems—with patient consents. That can only happen through SaaS [software as a service], and this happens to be the largest area for private equity (PE) investment over the past two decades. There is no doubt this space will continue to grow, and laboratory and diagnostic testing are extraordinarily exciting areas for consolidation and growth over the coming year."

With the community united and funding high, the time is right to give attention to other infectious diseases, whether related to SARS-CoV-2 or not. "You really have to put this same urgency that we have for COVID now and apply it to other diseases that may have a potentially bigger economic and personal impact than COVID," adds Volz, "Alzheimer's and Parkinson's and many others."[18]

As Bustamante says: "I want everything I do to be drafted behind COVID. I'm thinking of the mother of all cycling teams. And you're drafting behind COVID, and then once you've reached the finish line, you can take that energy and hopefully channel it into other disease areas that can be cured."[19]

In another example, Bustamante describes a developing neuroimmune disorders research project aimed at gathering at least 1 million people, consisting of children and their families, that is for the purpose of understanding, diagnosing, and preventing inflammatory brain disorders.

Discovering answers to many of the questions researchers hope to explore can be accelerated with access to a diverse (and a very large) pool of samples. Thus, the abundance of properly consented and curated remnant samples may provide a new source of income for molecular laboratories.

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Chapter 3:

Key Points of Molecular Laboratory Diversification Into Biobanking

Biobanking is good for labs, suggests Joseph Mauro, President of Boca Biolistics, a Florida-based specialty reference laboratory that diversified into biobanking because it provides "a way for labs to supplement their revenue stream." Additionally, participation helps advance research and could lead to "possible business development in other aspects of the lab services space," he says.[20]

Before molecular laboratory leaders can start pouring the lemonade, however, many believe they have to slice through some more lemons. The idea of sending samples to a biobank comes with a list of concerns that makes labs pucker:

- *Proper sample storage and handling;*
- *Types of samples;*
- *Sample procurement;*
- *Sample expiration;*
- *Required sample stewardship;*
- *Patient consent and privacy;*
- *Institutional review boards and others.*

It's true that clinical labs must cross some hurdles, many of them regulatory, says Mauro, which is why it's helpful to "seek out a qualified consultant to help navigate the process."

Traditionally, some challenges have kept labs from entering the space, says Harol from Lighthouse, but if someone can provide easy solutions, then labs should get involved. "Biobanking enables more testing to be available [because] samples don't get thrown away. It is also better for test accuracy because the more sample availability there is at different value ranges, the more granular we can get on validating tests."[21]

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Ovation's Wark acknowledges that biobanking isn't a new concept, yet it traditionally hasn't worked as well as it could because labs are not set up to deal with the many logistical tasks, including getting consent, collecting and managing the samples over time, and building relationships with industry and research partners. The other reason he thinks it hasn't been as effective is the available scale.[22]

"Very few labs have enough scale to service the needs of one research project, let alone many," Wark explains. "It's hard for an individual lab to justify the work and investment required to be able to service even a small number of projects."[23]

Labs may not be set up to deal with the many logistical tasks, including getting consent, collecting and managing the samples over time, and building relationships with industry and research partners.

The recent launch of the Ovation Research Network (ORN), however, offers massive scale and makes it easy for labs to biobank samples. When labs become part of the Ovation Research Network, they no longer have to think about the legalities associated with consent or getting a sample catalogued at a biobank, according to the company. Ovation has already handled the legal review and analysis, and developed language that is sufficient and informs patients about future use of their samples. It also has standardized the collection and cataloguing process.[24]

Wark draws a parallel between common recycling and collecting samples: Instead of labs destroying leftover samples and discarding them with other biohazard waste, they would separate them and place them in ORN containers for collection, much like people do with recyclable plastics, paper, and aluminum cans. Once the containers arrive at biobanks, the samples would be de-identified and frozen.[25]

When clinical and molecular laboratories biobank samples, they make money from selling the samples to biobanks, but, in the case of the Ovation Research Network, labs have the opportunity to get paid for research testing. In short, the labs get paid for their samples coming and going—going to the biobank and then coming back as part of research testing.

But which samples have the most value?

Is a COVID-positive test more valuable than a COVID-negative test,

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for example? Or, is a COVID sample more valuable than an infectious respiratory disease specimen? Generally speaking, all samples are valuable, says Wark. The Ovation Research Network already works with projects in immunology, diabetes, oncology, somatic cancer and cardiology[26]—all of which would benefit from the availability of additional COVID and non-COVID biospecimens.

Moreover, as research into SARS-CoV-2 continues, scientists need samples from patients who either tested positive or negative for COVID-19 since doctors and researchers already observed changes in oncology and neurological risks—to name two examples—in patients who tested positive for the virus.

"Biomarkers are no longer as clear as they were," Wark says. "We're going to need data from patients who have had COVID and those who haven't, and we're going to need to start teasing out the differences in biomarker signatures between those patient populations."[27]

Samples equal data. Through biobanking and joining organizations like the Ovation Research Network, COVID-19 testing labs can make their data useful and profitable.

As Wark explains, "the benefits [of biobanking] for the life science industry are immediate: Noninterventional trials can be completed in months instead of years. In a traditional study, researchers have to find, recruit, and collect samples from a cohort of patients. This process typically takes years and millions of dollars. The impact of this cost is a longer time to market and ultimately higher cost for precision medicine therapies."[28]

Clinical laboratories will see a positive financial impact as a new line of revenue is established. Specifically, notes Wark, some participants in the Ovation Research Network are generating money from several multimillion-dollar whole-genome sequencing projects while also justifying acquisition and implementation of new instruments that will help them reduce cost and increase throughput in the rest of their diagnostic business.[29]

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Chapter 4:

The Role of LIMS in Biobanking

As mentioned earlier in this white paper, questions often surround the value of a sample:

- *How was the sample collected from the patient?*
- *How was it stored?*
- *Is the label still secure?*
- *When will the sample expire and no longer be considered valuable for research?*

When the answers are not readily available, the easy choice is to transfer the samples to biohazard waste.

For labs trying to organize their samples and have at-a-glance answers to questions about them, a proper laboratory information management system (LIMS) or laboratory information system (LIS) streamlines the process. Platt of BRIDGenomics notes that because research and development is increasingly on the minds of lab leaders, particularly those who are coming around to seeing themselves as information providers, those lab managers and directors are looking at how they can strengthen their quality systems to validate and verify their samples and tests.[30]

When diversifying into biobanking, check that the LIMS built-in consent process means **"universal consent"** —that a specimen has sufficient permissions on it for others to perform research testing and to recontact the patient at a future date yet to be determined.

Whether a LIMS, with the capacity to run batch data, or an LIS, often better for single tests or individual records, an automated information system helps labs manage electronic medical records, revenue cycles, clinical interpretation, and importantly for biobanking, patient consent. As Wark defines it, a LIMS "supports the full cycle of lab functions to take a sample from order to diagnostic report to delivery of that report reimbursement and all of the operations that support that cycle within the lab, including operational intelligence and quality management."[31]

"Labs with R&D capabilities and with informatics capabilities are poised much more beneficially in this space," Platt says of labs

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participating with biobanks. "I think they have an advantage to be able to leverage the information—and the skills they have—to work with drug developers to run biomolecular and biomarker studies …. We've already seen that around next generation sequencing and variant detection."[32]

Wark adds that the best specimens are those that are linked to a patient's clinical journey. "That linked record is worth far more than the sum of its clinical and biomarker measurement components to a researcher because it allows [the researchers] to answer a complete question," he explains.[33]

To be clear, linking doesn't necessarily invade patients' privacy rights. Linking can be performed in a privacy-preserving manner, he says, that uses only de-identified data through tokenization.[34] Tokenization is an algorithm-generated process that protects sensitive data and doesn't identify the patient. The right LIMS can make tokenization possible, while also tracking samples, thereby making it easier to determine which ones can be successfully biobanked.

"We encourage labs to use our LIMS system," Wark says. It works seamlessly with the Ovation Research Network by automatically handling sample determination. "The LIMS knows the lifetime of the sample, knows whether it's still viable, knows what kind of testing has been performed on it, knows how it was labeled—the LIMS can very quickly tell labs which samples to put in the shopping container to the Ovation Research Network."[35]

That said, the Ovation LIMS is not required to participate in the ORN. It is easier for the lab if the lab uses Ovation's LIMS, but they don't have to. "We've worked with institutions that have particularly valuable samples or particular strategic interests to connect their LIS to our network, so it's as easy for them as possible to participate."[36]

Biobanking is possible without a LIMS, but with one, molecular lab directors and administrators will find it easier to share samples of value—and reap the financial rewards and greater impact that may come from biobanking.

MINIMUM REQUIREMENTS ARE BASED ON

A fully consented sample

Patient information— first and last name, date of birth, sex, valid zip code

Sufficient contained evidence of the disease (the reason a sample was taken)

Sample integrity —quality

Sample airtight chain of custody

Biobanking is not the only part of the ORN that would be facilitated by the LIMS.

All research testing of de-identified samples performed is documented in the Ovation LIMS.

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Conclusion

The healthcare industry—notably molecular laboratories and life sciences companies, including biopharma, all working collaboratively—is positioned to improve patient outcomes significantly, unlike at any other point in recent medical memory. COVID has put clinical and molecular labs and researchers in the spotlight.

Agencies and venture capitalists are throwing funding behind the research, which is all well and good, as long as scientists and drug developers have the samples they need to run diagnostics and test therapies.

Labs testing for COVID-19 and other diseases hold those samples. They have the gold, as it were, and if they think strategically, automate their information systems, and share their samples through biobanks, they may be able to generate new revenue streams while also doing their part to contribute to potentially high-impact health research networks. It's important to note that while COVID was the catalyst, the research and need for samples will be ongoing even as the urgent response to COVID wanes.

People like Bustamante are not going to quit. There are still too many unknowns about SARS-CoV-2 and other infectious diseases and illnesses that plague the world. For COVID alone, Bustamante is following for two years 10,000 adults and children who tested positive for COVID-19. He's interested in researching how their genetic makeup affects their response to the virus.[37]

He's also interested in using specimens to better understand how the virus impacts the nervous system. "COVID-19 is a once-in-a-lifetime opportunity to study post-infectious sudden onset neuropsychiatric disease," Bustamante says.[38]

There is no understating the value of biosamples in today's medical climate. The public wants answers as much as scientists do.

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Biospecimens play a crucial role in public health research and population health. Labs are at the front end of the process.

The Ovation Research Network makes subsequent revenue and new health research partnerships for molecular laboratories possible.

When laboratories participate, the network is able to aggregate data and specimens, and enable labs to service non-interventional studies across a broad range of therapeutic areas, explains Wark.[39] "Ovation Research Network enables those studies to happen 10 times faster than traditional trials that create a primary repository," he says.

Adds Platt,[40] "I would challenge lab leaders to think about that specimen in the lab as being information—and information that's valuable to vaccine developers, therapy developers, as well as those doing surveillance and those looking to validate other methodologies that help us get to answers more quickly."

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Ovation is a scientific data company that provides a cloud-based LIMS for molecular diagnostic laboratories. Beyond standard sample and workflow tracking, Ovation addresses challenges in the critical functional areas of Relationship Support, Laboratory Operations, and Business Analytics. Using a modern infrastructure with seamless integrations of best-in-class partners and consultants, Ovation provides labs with an out-of-the-box laboratory management experience that scales with each individual lab's needs.

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