UTAH'S

LIFE SCIENCES INDUSTRY

CONFRONTING COVID-19

How BioFire Mobilized to Develop a Comprehensive Testing Solution p. 14

WELCOME LETTER

Welcome to the 2020 BioUtah Life Sciences Magazine. This year's theme, *Taking on COVID-19*, highlights the exceptional efforts of Utah's life sciences industry to combat the virus, protect public health, and mitigate damage to the economy.

Our cover story on BioFire Diagnostics takes an in-depth look at how this Utah company has revolutionized infectious disease diagnostics and is now using their technology to respond to the pandemic. Inside, you'll also see how other life sciences companies in the state are making a difference - from testing supplies and diagnostics, to therapeutics and PPE - they've stepped up.

Importantly, at the heart of this work is our industry's enduring passion for pushing the boundaries of science to improve and save lives. In Utah today, more than 1,000 life sciences companies are engaged in developing and distributing new devices and treatments to address serious illness. To build on this robust ecosystem, Salt Lake City Mayor, Erin Mendenhall, is joining with life sciences leaders to create a distinctly Utah 'Healthcare Innovation Center'. Read on to get the latest on this exciting new initiative.

No doubt, COVID-19 has taken its toll and changed our lives in ways we never could have imagined. But, as our industry takes on the virus and continues to grow and innovate, we remain optimistic for the future. We invite you to turn the page and be inspired.

Sincerely,

Brandi Simpson
Chair, Board of Directors, BioUtah

CONTENTS

On the cover: A BioFire employee wearing PPE holds a component of a reagent panel pouch.

UTAH'S LIFE SCIENCES INDUSTRY

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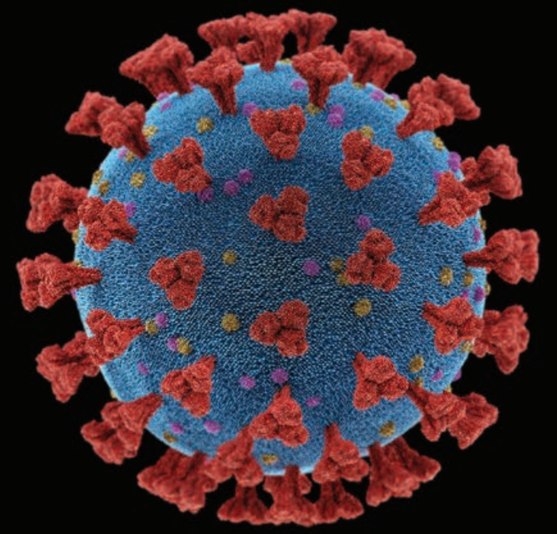


OFF THE CHARTS

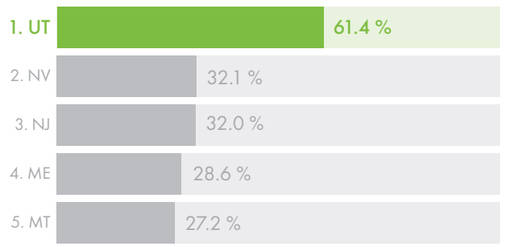
Utah's life sciences industry ranks high on nationwide metrics for growth and innovation.

"COVID-19 PREVENTION AND TREATMENT stands to benefit from many of Utah's more than 12,000 health-related academic researchers and employees at research, testing, and medical laboratories. In times of nationwide economic uncertainty, Utah's life sciences sector has shown remarkable stability. Utahns welcome its support for our livelihoods as we face the economic fallout from the local effects of the global pandemic."

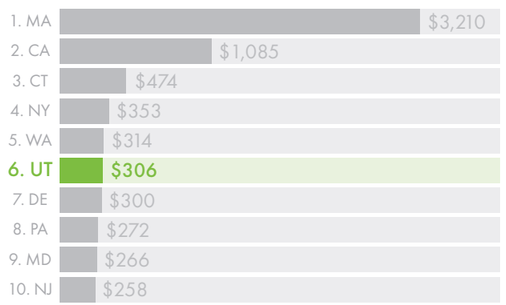
– Levi Pace, Ph.D.
Senior Research Economist, Kem C. Gardner Policy Institute*

*Coronavirus (COVID-19): Economic Commentary, March 17, Kem C. Gardner Policy Institute, University of Utah

TOP 5 ACADEMIC LIFE SCIENCES R&D GROWTH IN U.S. 2016-18



TOP 10 STATES IN LIFE SCIENCES VC INVESTMENTS PER CAPITA



Sources: *The Bioscience Economy: Propelling Life-saving Treatments, Supporting State & Local Communities 2020;* Teconomy Partners, LLC; Biotechnology Innovation Organization; Public Affairs Consultants; 2020.
Pace, L. and Spolsdoff, J., *Economic Impacts of Utah's Life Sciences Industry*, Kem C. Gardner Policy Institute, The University of Utah, 2018.

UTAH LIFE SCIENCES EMPLOYMENT 2018

130,000+
DIRECT AND INDIRECT

UTAH LIFE SCIENCES PATENTS 2019

538

UTAH LIFE SCIENCES NIH AWARDS 2019

IN MILLIONS

$234.3

MEDICAL DEVICE MANUFACTURING

#9
SALT LAKE CITY METRO AREA RANKS NINTH NATIONALLY IN TOTAL MEDICAL DEVICE MANUFACTURING JOBS

UTAH LIFE SCIENCES COMPANIES

TAKE ON COVID-19

Below is a list of more than 45 Utah companies, in the fields of diagnostics, therapeutics, and devices, working on COVID solutions.

ACCUBREATH · ALTERRA MEDICAL · ARCHES RESEARCH · ARUP LABORATORIES · ATL technology · BD Advancing the world of health
BIOFIRE DEFENSE · BIOFIRE A BIOMÉRIEUX COMPANY · BIOPHARM LABORATORIES, LLC · CANARY SPEECH · Cibus Biotechnologies · CO-DIAGNOSTICS INC.
CONSTANT THERAPEUTICS · CONTROL · Curavit Clinical Research · DESERET LABORATORIES INCORPORATED · Dynatronics · Echelon Biosciences
ELITechGroup · exdx EXHALENT DIAGNOSTICS, INC. · GeneSTAT · THE HB GROUP · IDbyDNA · LIPOCINE ENHANCING HEALTH
maxtec · MEDSENTIAL · MERIT MEDICAL · Nelson Labs A Sotera Health company · N8 MEDICAL · NuView Life Sciences
PolarityTE · PREDICTIVE LABORATORIES · QUANSYS BIOSCIENCES · RECURSION · REDDYPORT · RENALYTIX AI
revitale pharma · SIGNPATH Pharma · SINTX Technologies · SDTL Sports Drug Testing Laboratory · SMRTL · SoftCell BIOMEDICAL RESEARCH
SPECTRUM SOLUTIONS · teva · THROUGH THE CORDS Next-Generation Airway Tools · VAREX IMAGING · ZENERCHI

LIFE SCIENCES HUB
- RIGHT HERE

How Salt Lake City is Building a World-Class Healthcare Innovation Center.

By Andrew Wittenberg | Marketing and Research Manager | Salt Lake City's Department of Economic Development

There is no greater gift than good health, and in Salt Lake City some of the world's most innovative healthcare companies are creating products to help people everywhere live better and longer.

And now, in the time of the COVID-19 crisis, we have seen just how important healthcare innovation is for public health and how it will be a key component to economic recovery in the months and years ahead. Salt Lake City's diverse and engaged community is what sets it apart from many places, and will be a key factor that propels us into a solid financial future.

What has been years in the making for the city, Mayor Erin Mendenhall is now leading efforts to build upon the 'Life Sciences Corridor' laying groundwork for a new 'Healthcare Innovation Center' under the 'Tech Lake City' initiative. She says:

"By designating an intentional space, we are achieving Salt Lake City's vision of supporting a local industry that helps grow our economy, creates excellent opportunities for our workforce, and cultivates the creative energy and advancements necessary to produce modern medical solutions for an evolving landscape of needs."

The hub is a new phase, building upon the corridor first developed in 2018 - a planned city effort to build more incubator, office, and wet lab space where startups can grow and scale with ease.

Healthcare innovation encompasses life sciences and digital health sectors of our state economy, including medical devices, biotechnology, biopharmaceuticals, diagnostics, genomics, health tech, digital informatics, and all other services related to, or supporting these industries.

It is no secret that these companies choose Salt Lake City for our favorable business climate, quality of life, and phenomenal tech ecosystem. But what makes the corridor and innovation center plan more intriguing for investors and startups? Available real estate and a specialized concentration in at least three subsectors - medical device, pharmaceutical, and research laboratory sectors.

Opportunity zones were strategically selected with the manufacturing supply chain in mind – from early-stage at the University of Utah and Research Park development to innovation happening in Class A and co-working office space downtown, to late-stage manufacturing west toward Salt Lake International Airport for seamless distribution. Each area allows for the capital stacking of many available financial tools. You could call it 'doubling incentives' – where opportunity zones overlap with Redevelopment Agency project areas, New Market Tax Credits, and Community Development Block Grant eligibility.

The downtown area of the corridor is a priority for Salt Lake City Mayor Erin Mendenhall's Healthcare Innovation 'Tech Lake City' initiative, building upon what is shaping up to be already incredible biotech work happening in the area. Called to lead the effort in the city's Department of Economic Development is Clark Cahoon, technology and innovation advisor, who will support and carry out the vision of the Healthcare Innovation Charter. By organizing subcommittees and coordinating industry leaders and city resources, the charter is developing the groundwork for the Healthcare Innovation Center.

The goals set forth by the Healthcare Innovation Charter include: developing a central downtown facility for innovation, inclusive workforce development, better public/private partnerships, business friendly zoning policies, and national awareness campaigns, among others.

In Salt Lake City, we are attracting leaders and innovators that are committed to the Life Sciences Corridor, staying in Salt Lake City, and all of the benefits of being here. Here they can operate with the same innovative spirit you might find in larger cities but without the inflated expense. The amount of new venture capital flowing to the life sciences industry, even over the past year, has been staggering. In Salt Lake City alone, more than $500 million has been invested since 2016.

In collaboration with the industry trade group, BioUtah, as well as Salt Lake County, and the State of Utah, Salt Lake City is about that culture of pulling together and figuring it out. This is how we will rethink our current economic landscape and emerge from this crisis in the strongest possible position.

With the University of Utah as a Tier 1 research institution and our unique combination of subsectors, we're honored to support, assist, and lead the next decade of innovation.

Deseret Laboratories lends its expertise to fight COVID-19.

Matt Toone, CEO, Alterra Medical

An ATL employee assembles a COVID-19 viral collection kit.

THE PIVOT

When COVID-19 Hit, These Utah Companies Got Out Front Fast.

"When the going gets tough, the tough get going," is apropos of Alterra Medical, ATL Technology, Deseret Laboratories, PolarityTE, and Soft Cell Laboratories, all of whom quickly pivoted operations to respond to COVID-19. Here, in their own words, company executives explain their timely actions.

Alterra Medical: Rapidly Responding to the Critical Need for PPE—*Matt Toone, CEO*

Alterra Medical was founded on the vision of building a preeminent brand that is synonymous with integrity, ingenuity, and impactful products that improve the lives of both patients and healthcare providers. Combining the agility of a startup with the acumen gained from decades of experience in the medical device industry, our mission is to serve as a trusted partner to innovators, from concept to exit. As a commercialization engine for early- and growth-stage life sciences companies, we leverage our deep clinical expertise and nationwide sales network to de-risk the development life cycle and extract maximum value from the market.

Established in February 2019, Alterra rapidly scaled up a portfolio of differentiated electrophysiology products. When the COVID-19 pandemic began, all elective procedures—including electrophysiology interventions—were halted, putting our core business in jeopardy. Given our global sourcing capability and manufacturing relationships, we were able to mobilize a rapid response to the critical need for personal protective equipment (PPE). We executed a quick pivot to focus on securing and distributing PPE products from reliable, certified suppliers. Among the first steps we took was identifying an FDA-certified, U.S.-based manufacturing facility and converting it to a hand sanitizer plant. Since the emergence of the novel coronavirus, we have supplied over a quarter million gallons of hand sanitizer—along with millions of face masks, gloves, and other PPE—to government agencies, healthcare systems, and frontline personnel across the U.S. And, we accomplished this all while continuing to vet and validate new products for commercialization.

Having experienced exponential growth over the past six months, Alterra has emerged an even stronger, more efficient organization. As we continue to support the safe reopening of the country, we remain committed to executing on our founding vision. Incorporating lessons learned from the COVID-19 pandemic, we believe that, now more than ever, "Made in the USA" matters. We also believe that the ongoing pandemic-related supply chain challenges have revealed an unprecedented opportunity for Utah to lead the repatriation of medical manufacturing. The availability of skilled talent, logistics expertise, and industrial space makes the Beehive State a perfect headquarters for Alterra as we prepare for the next evolution in our business, which includes the development and launch of additional manufacturing capabilities, and a Utah-based 3PL subsidiary.

ATL Technology: "How Can We Help?" The Story of ATL's COVID Response—*Brad Brown, CEO*

At ATL Technology, we use an engineer-to-engineer approach to develop custom interconnect and other critical solutions for eight of the top 10 medical device companies in the world.

When the pandemic struck, we asked a simple question: Given our resources in the medical space, how can we help? This led to our pivot, greatly expanding our diagnostic business and securing critical personal protection equipment (PPE).

ATL operates four manufacturing facilities globally, including in China. Our engagement with COVID-19 began in late January 2020, when our Chinese employees became stranded in various provinces throughout China due to the lockdown during Chinese New Year as COVID-19 spread. During the New Year shut down, our management team remained in constant contact with our local Chinese management and together developed a plan to ensure: 1) the safety of our employees and, 2) the continuous supply to our customers.

This experience, among many things, taught us the need for testing and the use of masks.

While testing was available in China at that time, it was not in the U.S., where we are headquartered, or in Costa Rica, where we have operations. So, ATL set up its own laboratory to screen employees for possible COVID-19. We also prepared each site with PPE.

When the virus began to spread within the U.S., we learned of shortages of both PPE and testing supplies. So, ATL took action again, and dipped into our inventory to help Utah bridge the gap until the state could acquire more PPE and expand testing capacity.

Utah continued to buy supplies from us and our laboratory was ultimately acquired by the state and moved to a local hospital. Our support has now expanded to other states, cities, and countries.

In the end, we couldn't have made this timely pivot without the hard work and dedication of ATL employees. They have worked many long days to redirect their focus and make sure people received necessary supplies. We are also grateful to the State of Utah whose collaboration has contributed to ATL's ability to swiftly respond to COVID-19. And, we won't rest until the job is done.

Deseret Laboratories: Fighting to Keep Utah Safe—*Mark Gubler, COO*

If you would have told me years ago while a student in the MBA program at the University of Utah, that a biotechnology company that I would help to found with my brother, and for which I serve as COO, would one day enter the trenches on the front lines of a battle against a worldwide pandemic, I would have wondered about your sanity. Yet, when I received a call from BioUtah and subsequently a member of the Utah Senate asking if we could assist in responding to the pandemic, that is exactly where I, and our company, Deseret Laboratories, Inc., located in St. George, found ourselves.

As a long established Contract Manufacturing Organization and Contract Development and Manufacturing Organization servicing the nutraceutical, pharmaceutical, and medical device industries, Deseret Laboratories was perfectly poised to quickly identify and pur-

PolarityTE's research and laboratory facilities support COVID-19 public health efforts.

A Soft Cell Laboratories' scientist pipetting a patient saliva sample to prepare for an extraction.

chase needed equipment. To this purchased equipment, we combined a portion of our repurposed production capacity to begin provisioning transport kits, extraction kits, and PCR testing kits to be used in the diagnosis of COVID-19.

Working closely with our neighboring company, GeneSTAT Molecular Diagnostics, and two other Utah companies, it was just a few weeks before supplies and equipment were assembled, protocols written, equipment and raw materials qualified and validated, batch sheets issued, and transport kits began rolling off the production lines by the thousands. While such a pivot could have potentially caused a devastating distraction from our core business, Deseret Laboratories' talented and dedicated team amazingly produced a 50%-60% increase in demand for our core nutritional supplements and pharmaceutical products during this same time frame.

It has been an honor for all of us at Deseret Laboratories to support our state, communities, the life sciences industry, and our fellow citizens in mounting a defense against this devastating virus.

PolarityTE: No Time to Sit on the Sidelines—*David Seaburg, CEO*

PolarityTE, Inc., headquartered in Salt Lake City, is focused on transforming the lives of patients by discovering, designing, and developing a range of regenerative tissue products and biomaterials for the fields of medicine, biomedical engineering, and material sciences. PolarityTE came to Utah in 2016 because of the biotech-friendly environment and large biological sciences talent pool in the Salt Lake Valley, and developed a state-of-the-art laboratory and manufacturing facility. Today, our company employs over 70 individuals, including physicians, researchers, engineers, manufacturing, and clinical personnel dedicated to the advancement of PolarityTE's initial product, SkinTE. SkinTE is a human cellular and tissue-based product derived from a patient's own skin intended for the repair, reconstruction, replacement, or supplementation of skin tissue. SkinTE is created from a small piece of the patient's skin that is flown to Salt Lake City and manufactured into a unique, personalized SkinTE treatment for each individual patient. SkinTE has been used to treat wounds that are difficult to treat with conventional therapies.

Watching the COVID pandemic unfold and not wanting to sit on the sidelines, Arches Research, the contract research subsidiary of PolarityTE, obtained its CLIA registration through the efforts of Nikolai Sopko, MD, PhD, chief scientific officer and laboratory director. PolarityTE's talented R&D team and patient-focused organization rapidly adapted our company's state-of-the-art laboratory and manufacturing facility to perform high-throughput molecular testing to detect COVID-19. PolarityTE's goal is to help the country keep its vulnerable populations safe and to facilitate a healthy working environment for businesses by offering affordable and rapid testing with same day turn around to nursing homes, businesses, and organizations across the U.S.—all while pursuing our passion to provide SkinTE for patients in need.

Soft Cell Laboratories: Getting Nimble to Test for COVID-19—*Gregory Prince, CEO*

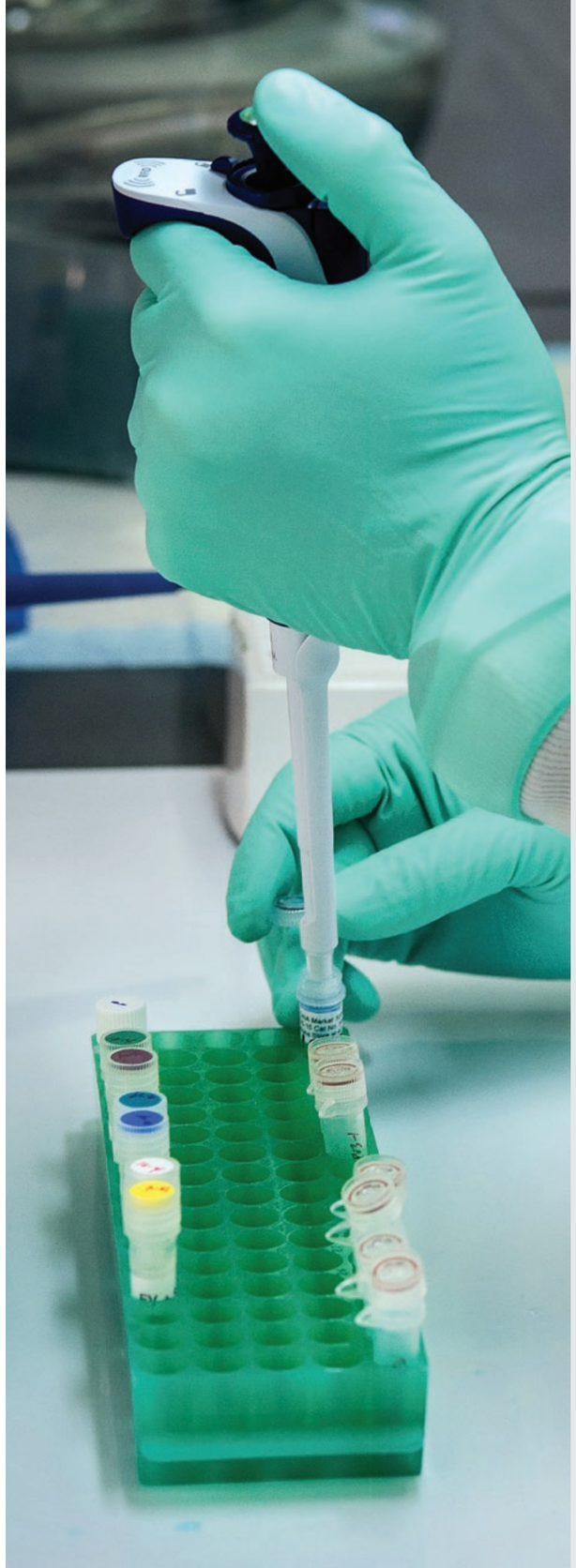
Soft Cell Founder, John "Brent" Hunt, was a medical visionary whose unique intuition opened the door to an entire frontier of medicine: "dark bacteria." These unusual microbes, whose existence had first been described over 80 years ago, remained of unknown importance because no one was able to culture them in the laboratory. Brent "cracked the code," and established Soft Cell Laboratories in St. George, Utah, to diagnose potential connections between these hidden bacteria and chronic diseases, such as autoimmune conditions.

Then, COVID-19 hit, and Soft Cell knew it had to draw on its talents and rapidly adapt to make a difference. The company became a CLIA-certified, high-complexity laboratory with a single aim, to accurately diagnose COVID-19. Tragically, shortly after the laboratory received certification, Brent died unexpectedly. His death was a blow to the team, but his spirit and two-fold mission for Soft Cell lives on. Mission one: in the midst of the pandemic, devote all available resources to provide as much COVID-19 testing capacity as possible to meet the high demand for testing in Utah and nationwide.

Soft Cell occupies 13,000 square feet of new laboratory space in St. George's Fort Pierce Industrial Park. Our workforce of bright and highly motivated scientists and technicians is drawn almost entirely from our local communities, most notably students and graduates of Dixie State University. Our "Utah first" attitude extends to a crucial piece of our testing protocol, the FDA-approved saliva collection kit manufactured in Utah by Spectrum Solutions. The saliva test is quickly gaining popularity, given the ease of collection, safety, and stability that it affords—all of which make it superior to the painful and often unstable nasopharyngeal swab.

As word of our operation spreads, particularly with a goal of returning results to clients within 24 hours, we are seeing our throughput double or triple each month as we work toward an ultimate capacity of 10,000 tests per day.

If and when the pandemic subsides, and that's hard to predict, we'll continue to pursue mission two: Brent's enduring vision to decipher harmful, hidden bacteria to better identify and treat serious chronic diseases.



A BioFire® FilmArray® Pouch is inserted into the BioFire® FilmArray® Torch.

CONFRONTING COVID-19

How BioFire Mobilized to Develop a Comprehensive Testing Solution.

By Wade Stevenson | VP of North American Clinical Marketing | BioFire Diagnostics

Early in the year, leaders at BioFire Diagnostics, a bioMérieux company, were monitoring the news coming out of China about a new and deadly respiratory virus. Executives were naturally concerned about the evolving humanitarian crisis in China and about the possible spread of the novel coronavirus into countries around the world. But the news about the virus was particularly relevant for BioFire—a Salt Lake City-based company that offers cutting-edge infectious disease testing instruments and reagent panels.

BioFire's diagnostic reagent panels test for a whole menu of pathogens associated with a particular disease syndrome, an approach called "syndromic testing." For instance, the BioFire® FilmArray® Respiratory 2 Panel can detect and identify 21 pathogens that cause respiratory illnesses like influenza, whooping cough, or the common cold—all with one test, and with results in about 45 minutes.

The syndromic approach maximizes the chances of finding out what's making a patient sick. Fast and accurate diagnostic results help physicians quickly provide appropriate treatment. BioFire currently offers diagnostic panels that tackle five infectious disease syndromes: respiratory infections, bloodstream infections, gastrointestinal infections, meningitis/encephalitis, and pneumonia.

"We knew in February that the novel coronavirus was spreading very fast and that we needed to help our customers identify it. Infectious disease diagnostics is what we do, and our respiratory products clearly needed to be updated to include the ability to detect this new emerging virus," said Stephanie Thatcher, vice president of molecular systems at BioFire.

That moment was a jumping-off point for an extraordinary, company-wide effort to develop the test, gain regulatory authorization, and meet unprecedented customer demand for BioFire's respiratory testing solutions—all while battling supply shortages, manufacturing capacity limits, and the necessity of keeping the workplace safe for BioFire's essential workers.

Focusing on the science

The first challenge for BioFire scientists was to develop a test that could accurately detect and identify the novel virus, called Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2). This virus causes the disease we know as COVID-19.

To begin with, BioFire Diagnostics' teams supported their colleagues at BioFire Defense in its efforts to develop a targeted test for SARS-CoV-2. "Then we looked at what it would take to implement SARS-CoV-2 in our syndromic testing systems for respiratory infections, to distinguish it from other pathogens that cause colds, flu, or pneumonia," Thatcher said. "Our goal was to streamline the development effort as much as possible to get a product out to our customers ASAP."

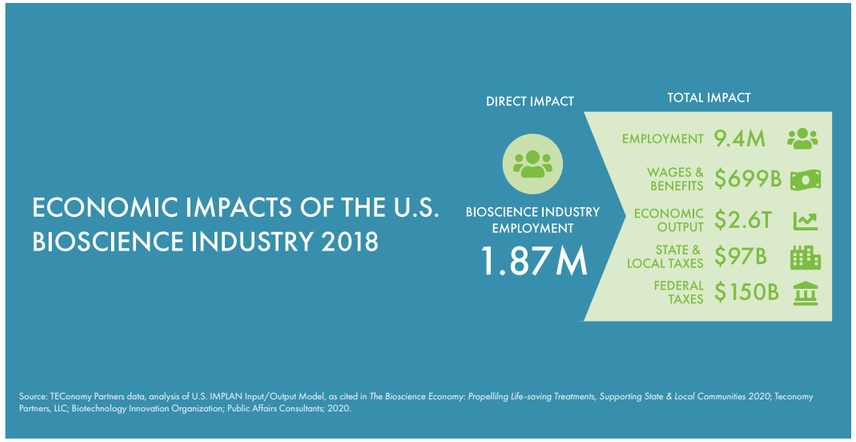
As the pandemic worsened globally, materials like swabs and sample transport media became scarce for testing facilities and laboratories. "Testing centers have to buy these materials to run any test, including ours," Thatcher explained. "Our team has been busy verifying that the variety of swabs and transport liquids commercially available are compatible with our system. Limited sampling materials is an evolving challenge that we are trying to keep ahead of and prepared for in the upcoming flu season."

For Andrew Hemmert, vice president of molecular biology, "The biggest obstacle we faced was time." He added, "We wanted to work as fast as possible and took many risks. Because of our expertise we felt comfortable taking these risks to respond to the pandemic. Our approach paid off and the test was developed and ready for FDA submission in record time."

Hemmert said the experience "awoke a fire in the Molecular Biology department. We came up with clever strategies to lower risk and worked efficiently, not only within the team, but also across the broader company. This experience helped BioFire create a new roadmap of how to respond in a crisis."

> Infectious disease diagnostics is what we do, and our respiratory products clearly needed to be updated to include the ability to detect this new emerging virus."
>
> —Stephanie Thatcher, Vice President of Molecular Systems at BioFire

Andrea Kendell, BioFire ad interim CEO, thanks employees for their tremendous efforts.



Working with regulators

Developing the test was just the first step. The next was obtaining emergency use authorization (EUA) for the test from the FDA and seeking approval from various international regulatory agencies.

This is a daunting hurdle in normal circumstances, but "we had the challenge of an uncertain regulatory environment in the early days of this public health emergency, with the FDA's expectations for EUA evolving along with the pandemic," noted Kevin Bourzac, vice president of regulatory and clinical affairs.

The effort was also complicated by the fact that half of the department's staff were working from home so onsite staff could maintain social distancing. "Obviously we did not have the luxury of our normal development cycle and really came together as a team to not only validate this panel, but to prepare and submit the EUA request to the FDA. There were a lot of very long days and weeks and I'm sure a few sleepless nights," Bourzac said.

"We are extremely grateful for the laboratory teams who came in to work to perform the testing necessary to support the submissions despite the overhanging fear and unknowns of being at work during the early days of this global pandemic," he said. "Their ability to be flexible, to adapt to new cleaning, mask, and social distancing measures very quickly, and still produce superior testing results and reports to support this product was nothing short of amazing."

Bourzac additionally praised the hardworking personnel within the FDA. "We are extremely thankful to our reviewers at the FDA for their open interactions with us during the review process of our EUA," he said. "Notably, we received our EUA after midnight on a Friday (which indicates how hard the FDA has been working as well!)."

Ramping up production

Even before the new panel that includes testing for SARS-CoV-2 was available, demand for BioFire's existing respiratory testing panels was on the rise. "In March, shipments for our products increased over 200% within a matter of weeks," said Meghan Kuehn, vice president of reagent manufacturing at BioFire. And once the new panel was available, customer demand was immediate and overwhelming. Additionally, BioFire faced tremendous demand from new customers for the instrumentation necessary to run the testing.

"We have an essential workforce of nearly 1,000 employees dedicated to manufacturing BioFire reagent kits who continued to report to work throughout the pandemic. We had to quickly review our normal operations and enact new protocols and workflows to help keep our employees safe at work," she said.

During all of this activity, Reagent Manufacturing was in the process of moving into a new, state-of-the-art manufacturing facility. "While an unplanned pandemic added significant complexity and urgency to these efforts, we were well positioned to leverage these resources to help us respond," Kuehn said.

Meanwhile, the company significantly stretched its instrument production capacity, according to Ben Smith, vice president of engineering. This was accomplished in part through a hiring mandate that helped nearly double the number of direct labor personnel. Other departments also stepped forward to supply personnel. "We coordinated with multiple other departments to support this increased capacity," said Smith.

The research and development team assisted with production part shortages. It also changed or delayed development plans to free up resources and space to support production.

Procuring vital materials

In the midst of all this activity, the Purchasing department proved to be a key ally for the scientists, the Regulatory and Clinical Affairs department, the manufacturing teams, and many other areas.

"We have needed to work very closely with our Purchasing department to coordinate strategically based procurement of raw materials and supplies to support our increased capacity," Smith said.

While trying to ramp up production to meet demand, manufacturing was challenged by material shortages and supply chain disruptions. "Our purchasing and procurement teams have been relentless in ensuring they could source and provide this necessary material," Kuehn said. "And our procurement and materials logistics teams adapted quickly to find new channels and alternative solutions."

Communicating with transparency

The Marketing department at BioFire faced a unique challenge—marketing leaders found themselves working to launch the new respiratory panel while being careful to manage customers' expectations about availability. "We tried to mitigate these challenges by not over-promising or under-delivering," said Mari Hoidal, director of marketing.

Hoidal said that frequent communication and transparency have been key. "We want our customers to know that we are working hard to support them in the fight against this global pandemic," she said. "We want them to stay updated on our ramp-up progress and manufacturing expansion plans as we continue to deliver our high-quality testing globally."

Adapting to change

"No one at BioFire started the year planning to combat a global pandemic," noted Andrea Kendell, ad Interim CEO. "Nonetheless, the executive leadership team is impressed and amazed with our team's ability to mobilize, strategize, adapt, and execute on unprecedented goals in difficult circumstances."

"During our response to SARS-CoV-2, we were reminded of our strengths such as collaboration, trust, and working in unison toward a shared meaningful purpose," Thatcher said. "During this difficult time, it gave our teams something to focus on that can really help physicians and patients around the world. Historically, we have worked in a fast-paced environment—this was just a reminder of how capable we are of adapting quickly to new challenges and how successful we can be when we all focus on a common goal." ■

FIND A NEW PATH

LIFE SCIENCES IN SLC

We are leading through crisis, together. Salt Lake City is building a world-class Healthcare Innovation Center -- intentional space for more incubator, office, and wet lab locations where startups can grow and scale with ease. For more information reach out to Technology and Innovation Advisor Clark Cahoon at clark.cahoon@slcgov.com or visit slc.gov/ed.

1
FIRST IN NATION FOR ACADEMIC LIFE SCIENCES R&D GROWTH

2
SECOND IN NATION FOR MEDICAL DEVICE EMPLOYMENT CONCENTRATION

3
UTAH IS 1 OF ONLY 4 STATES WITH 3 LIFE SCIENCES SUBSECTORS—MED DEVICE, PHARMACEUTICALS, AND LABORATORIES

"The life sciences industry is critical to fueling healthcare innovations, which will, in turn, strengthen our public health and local economy."
—Salt Lake City Mayor Erin Mendenhall

SLC.GOV/ED

SALT LAKE CITY

Sources: TEConomy Partners analysis of National Science Foundation (NSF), National Center for Science and Engineering Statistics, Higher Education Research and Development (HERD) Survey; TEConomy Partners analysis of U.S. Bureau of Labor Statistics, QCEW data; enhanced file from IMPLAN;
TEConomy, Biotechnology Innovation Organization, PMP Public Affairs Consulting, Inc., The Bioscience Economy: Propelling Life-Saving Treatments, Supporting State & Local Communities 2020, 2020

Co-Diagnostics' test kits have been deployed to nearly 50 countries and over 25 U.S. states.

PUTTING COVID TO THE TEST

Utah Companies Provide a Range of Tests with State, National, and Global Reach.

These Utah diagnostics companies are manufacturing innovative tests for COVID-19. They're hard at work to increase testing capacity and meet the needs of healthcare providers, communities, employers, and in the case of Spectrum Solutions, Major League Baseball!

Co-Diagnostics: On the Scene Early with a COVID-19 Test

Co-Diagnostics, Inc. is a Salt Lake City-based molecular diagnostics company with a unique, patented platform for the development of diagnostic tests. Co-Diagnostics has approximately 40 employees working from its Utah manufacturing and R&D facility and another 50 employees working in India with the company's joint venture, CoSara.

Co-Diagnostics began taking a role in the coronavirus response early, completing the design work for its COVID-19 test in January 2020, then receiving its CE Marking in February (the first U.S. company to do so), which made it possible for its tests to be used by countries in the European Union (EU) and by those honoring the EU's regulatory process. In early April, the company received its emergency use authorization from the FDA.

Co-Diagnostics differentiates itself from the marketplace in several ways, including a unique compassionate pricing business model that allows the high-quality diagnostics it produces to be competitively priced to markets in the developing world.

Its diagnostic platform is underpinned by its patented CoPrimerTM molecule that has been shown to enhance the output of PCR molecular diagnostic tests by dramatically minimizing false positive test results. The company's tests are designed to operate in high-throughput, quick turnaround environments, enabling laboratories to get results back to patients quickly. Rapid turnaround and high-volume processes is a key to keeping the country open and providing COVID-safe schools and COVID-safe workplaces, a focus of Co-Diagnostics testing.

In August 2020, Co-Diagnostics was announced as the diagnostic partner for Clinical Reference Laboratory's CRL Rapid ResponseTM saliva-based COVID-19 test that can be self-administered from home or work. Clinical Reference Laboratory is one of the largest private CLIA laboratories in the U.S. The laboratory is able to return results to patients in 24-48 hours.

Clinical Reference Laboratory has also been announced as one of two laboratories chosen to process the Los Angeles Unified School District's tests for its 700,000-member student body.

The CoPrimer platform includes an AI-powered design process that identifies a genetic target based on its likelihood of being "conserved" through mutations and performing optimally with the patented CoPrimer molecule. The Logix Smart COVID-19 test genetic target of the RdRp gene has been proven over time, present in all known mutations of the Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2), which causes the COVID-19 disease.

Now, the company has announced it is leveraging its CoPrimer molecules' strengths once again, developing a multiplex respiratory test that will find and differentiate between Influenza A, Influenza B, and COVID-19, referred to as their "ABC" test. As schools return to face-to-face instruction and the world descends into flu season, Co-Diagnostics' respiratory panel will be a key to keeping schools and local economies open and safe.

GeneSTAT Molecular Diagnostics: Driven by a Global Need

As we all do our part to mitigate the effects of the global COVID-19 pandemic, St. George-based GeneSTAT Molecular Diagnostics has been active in their response by providing precise and timely testing. The company develops and manufactures testing options for many disease agents, but their real-time, one-step RT-PCR tests for Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) (COVID-19) offer a noteworthy combination of efficiency, user-friendliness, and disease differentiation.

GeneSTAT tests are lyophilized, which allow them to be stored at temperatures between 36-77°F. "Many labs are concerned about the logistics of shipping and storing these tests because the reagents must be kept frozen," says David Taus, CEO of GeneSTAT. "Lyophilized or freeze-dried tests allow labs to store larger quantities in ambient temperatures, so there's no concern about freezer space, or the expense of keeping reagents frozen."

Aside from lyophilization, there are other factors that make GeneSTAT's test significant. It's also specific for two different genes, the N gene and the S gene for SARS-CoV-2, allowing the patent-pending assay to rapidly identify and differentiate not only COVID-19, but also other coronaviruses. This means the tests are definitive without culture, offering quick, conclusive results for samples from both symptomatic and asymptomatic patients.

Adding to this efficiency is the fact that the GeneSTAT test is mul-

tiplexed, requiring only one test well per sample being tested. Current methods require the use of two or three test wells for each sample, so a 96-well cartridge can run just 32 to 48 tests simultaneously. By using just one test well per sample, the GeneSTAT test enables a 96-well test cartridge to test 96 patients at once.

While COVID-19 is on everyone's mind right now, GeneSTAT's agile business model allows them to create a variety of molecular testing options designed around the needs of customers. "Rather than offer a rigid set of products, we work to understand the testing needs, and then consult with customers to provide the best solution, with all supplies and equipment needed," says Taus. This includes solutions for robotic-controlled automation for high-throughput testing and low-throughput point-of-care testing, plus test kits, extraction kits, transport kits, and the assays themselves. "We format and develop entire testing platforms and validate the system. Our goal is to provide turn-key solutions for every part of the testing process," Taus says. "We believe this agility is crucial to helping healthcare workers identify, diagnose, and treat COVID-19 and other diseases."

Quansys Biosciences: Antibody Testing—A Roadmap to a Safe Reopening

Quansys Biosciences, Inc., based in Logan, Utah, specializes in developing and manufacturing multiplex ELISA assays that measure specific immune response biomarkers called cytokines, chemokines, and antibodies. The Q-Plex™ Array Technology, developed by Quansys, allows the simultaneous measurement of up to 18 different biomarkers without compromising assay performance. A customized combination of relevant biomarkers provides researchers, clinical laboratories, and pharmaceutical companies a fast, cost-effective way, to a more comprehensive disease profile or treatment efficacy.

As researchers and problem solvers with a mission to improve health around the world, scientists at Quansys understand the necessity of accurate data. As COVID-19 rapidly transitioned into a pandemic, Quansys scientists knew that they could provide a useful tool in the fight against the Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) (COVID-19). Researchers and developers at Quansys quickly went to work developing a new assay to detect antibodies against the SARS-CoV-2 virus, the Q-plex SARS-CoV-2 Human IgG (4-Plex) Assay. Quansys utilized their proprietary multiplex ELISA technology, known as Q-Plex, to develop an antibody test that separately detects both the S1 and S2 subunits of the spike protein of the SARS-CoV-2 virus. Simultaneously analyzing antibodies against both subunits allows for higher clinical sensitivity and specificity.

To determine whether individuals have mounted an immune response to SARS-CoV-2, indicative of an infection, Quansys has established a CLIA laboratory to test individuals throughout the State of Utah and across the U.S., using the Q-plex SARS-CoV-2 Human IgG antibody test. Additional laboratories across the U.S. have adopted the Quansys platform to assist in antibody studies.

Studies show that SARS-CoV-2 antibodies are an essential tool in fighting COVID-19. Accurate antibody testing can provide valuable insights for researchers and pharmaceutical companies by screening blood that can be used for convalescent serum to treat severe cases of COVID-19, population studies to better understand the spread of the disease in a community, and monitoring the immune response in regards to the level of antibodies present in an individual. COVID-19 antibody testing, together with cytokine assays provided by Quansys, can be used to elucidate the immune system reaction to COVID-19 and experimental treatments. Having access to this information to make better data-driven decisions is crucial in successfully and safely reopening the economy. With well over 99% accuracy, the Q-plex SARS-CoV-2 Human IgG Assay is critical in providing that information.

RenalytixAI: Pioneering AI-Driven Diagnostic Solutions for Kidney Disease and COVID-19

RenalytixAI is a developer of artificial intelligence-enabled clinical in vitro diagnostic solutions for kidney disease, one of the most common and costly chronic medical conditions globally. The company's products are being designed to make significant improvements in kidney disease diagnosis, transplant management, clinical care, patient stratification for drug clinical trials, and drug target discovery.

RenalytixAI's lead product, KidneyIntelX™, is an artificial intelligence-enabled in vitro diagnostic platform designed to enable risk prediction of progressive decline in kidney function in patients with chronic kidney disease (CKD) and type 2 diabetes. With licensed CLIA commercial clinical laboratories in Salt Lake City, Utah, and New York, RenalytixAI commercially launched its KidneyIntelX test in 2020 and is currently scaling commercial operations in the U.S. and globally.

RenalytixAI has emerged as a key leader in the fight against COVID-19, employing its scientific resources and technology to improve patient outcomes, both in CKD and beyond.

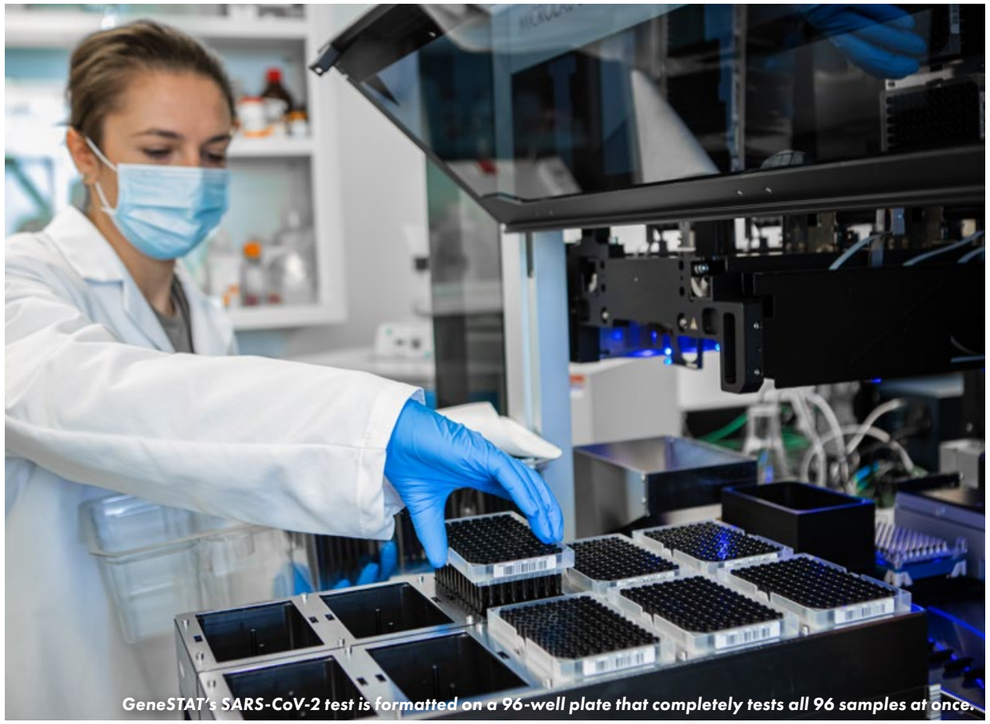
RenalytixAI has recently announced multiple large-scale initiatives to help mitigate the impact of the current COVID-19 pandemic. These initiatives include two new studies launched in conjunction with the Icahn School of Medicine at Mount Sinai to assess both the short- and long-term risk of adverse kidney events in patients diagnosed with COVID-19. Both of these studies will use the KidneyIntelX platforms to analyze clinical features and several biomarkers as predictors of major adverse kidney events in patients hospitalized with COVID-19.

The first of these studies, announced in April 2020 and being conducted at the Icahn School of Medicine at Mount Sinai, is using KidneyIntelX to assess the risk of adverse kidney events in patients diagnosed with COVID-19 and focuses on the impact of COVID-19 in the acute hospitalized setting. The second study, announced in July 2020, is a multi-center study to conduct in-depth investigations into kidney-related complications and long-term outcomes linked to COVID-19. RenalytixAI's KidneyIntelX platform will be used to assess the risk of kidney disease progression and kidney failure, among other kidney complications, in patients surviving COVID-19 from multiple centers in the U.S., including the Icahn School of Medicine at Mount Sinai in New York, Yale School of Medicine, University of Michigan Medical School, Johns Hopkins University Medical School, and Rutgers New Jersey Medical School. Data from these studies will be used to foster research projects to improve the knowledge of COVID-19 and augment clinical operations with machine intelligence.

Additionally, RenalytixAI announced in May 2020 the launch of Kantaro Biosciences, a joint venture with the Icahn School of Medicine at Mount Sinai to develop and scale production and distribution of a high-performance test kit for Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) antibodies. The underlying technology was created by Mount Sinai's internationally recognized team of virologists and pathologists and is designed for use in any laboratory without the need for proprietary equipment. The test will deliver valuable information regarding the level of potentially neutralizing antibodies in previously infected individuals, information which is expected to be critical to the development of vaccines and therapeutics, as well as assessment of workplace personal protection programs and population vaccination programs.

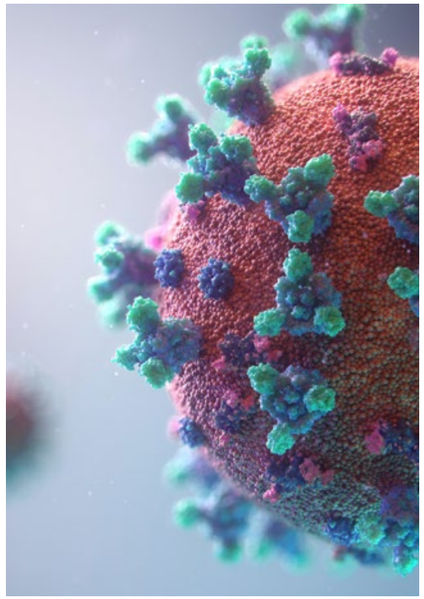
Spectrum Solutions: Put It to the Spit Test

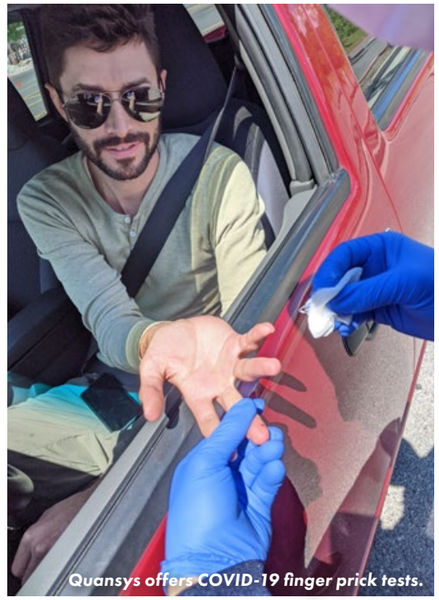
Sometimes a fresh perspective on something we thought we understood can open the door to new possibilities we hadn't even considered. Take saliva. We know it is a watery liquid secreted into the mouth by glands, it provides lubrication for chewing, swallowing, and



GeneSTAT's SARS-CoV-2 test is formatted on a 96-well plate that completely tests all 96 samples at once.

RENALYTIXAI





Quansys offers COVID-19 finger prick tests.

Stephen Fanning, CEO of Spectrum Solutions, displays saliva collection kit, first to receive FDA EUA authorization for saliva-based COVID-19 testing. | ©Spectrum Solution 2020

aids in digestion. We can produce enough saliva in one day to fill five soda cans. That's over 60 ounces. Still, saliva is often considered one of the most overlooked components of our overall health. Discoveries are only now shedding light on its importance to modern medicine.

The COVID-19 pandemic caused immediate shortages in testing supplies and personal protective equipment (PPE) as well as an increase in anxiety, fear, and isolation. It propelled us all to look at systems and processes differently. It was through this that Spectrum Solutions wondered if saliva could be the game-changing testing innovation the world needed. As it turns out, it was.

In March 2020, Spectrum initiated a study with Rutgers University to use its SDNA-1000 saliva collection system for COVID-19 detection. This study resulted in securing a groundbreaking FDA Emergency Use Authorization for the first COVID-19 saliva-based testing solution.

Saliva's recent MVP status is a new development even though saliva's been used in diagnostics for more than 2000 years. Analyses of the properties in saliva using biochemical and physiological methodologies are traced back to at least a century ago. The gold standard biosample for viral detection has previously always been blood or the painful nasopharyngeal or oropharyngeal swabs. Ever ask why? Unlike blood, saliva analysis looks at the cellular level (the biologically active compounds), making it a better representative of what is clinically relevant. Years from now, the medical community will look back on March 2020 as a pain-free diagnostic turning point in favor of saliva. Studies and validation from around the world will continue to echo the Spectrum/Rutgers findings turning first to saliva for the diagnosis and prevention of diseases.

FDA authorization hailed the proven process of Spectrum's saliva system over painful swabbing for its ability to deliver sample consistency, increased sensitivity, and routinely better testing accuracy throughout the infection. Central to these early discoveries was the SDNA-1000 saliva collection device and its patented preservation chemistry.

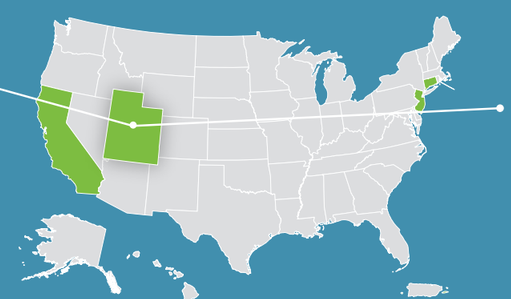
Pioneering a new era of at-home sample collection for viral diagnostic applications beyond COVID-19, the SDNA-1000 is engineered to eliminate self-collection errors and provide 100% live virus inactivation. This single collection device and proven process stabilize and preserve saliva samples for transport, offering over ten days of post-collection stability with no degradation of sample efficacy. Spectrum's proprietary collection method provides the safest and most robust testing biomaterial mitigating exposure risks for families at home, healthcare professionals, laboratory staff, and sample transport providers. It offers more than a 90% reduction in PPE usage as well as a noticeably better patient experience. Only with saliva can it be measured where a patient who tests positive sits in the virus's lifecycle. Understanding how clinically informative saliva truly is, opens the door for exciting applications in early disease diagnosis, point-of-care tests, clinical monitoring of disease progression, liquid biopsies, enhanced physician decision-making regarding patient care, and even drug development and personalized medicine.

Saliva and Spectrum's patented collection system is rewriting viral testing protocols and leaving its most memorable mark on 2020 history. Manufacturing over 30 million saliva collection kits a month, Spectrum is helping businesses and schools reopen as well as organizations like the PGA, NHL, and Major League Baseball (MLB) get back in the game through safer, pain-free testing. In August, the MLB named Spectrum Solutions a top-tier league partner integrating its saliva collection system into their COVID-19 testing program supplying all MLB staff, players, and family members with SDNA-1000 saliva collection kits.

The status quo has been challenged in several ways recently. We don't have to blindly turn to blood, urine, or nasal swabs as a primary source of biomaterial when a safer, more accurate, and pain-free solution is here.

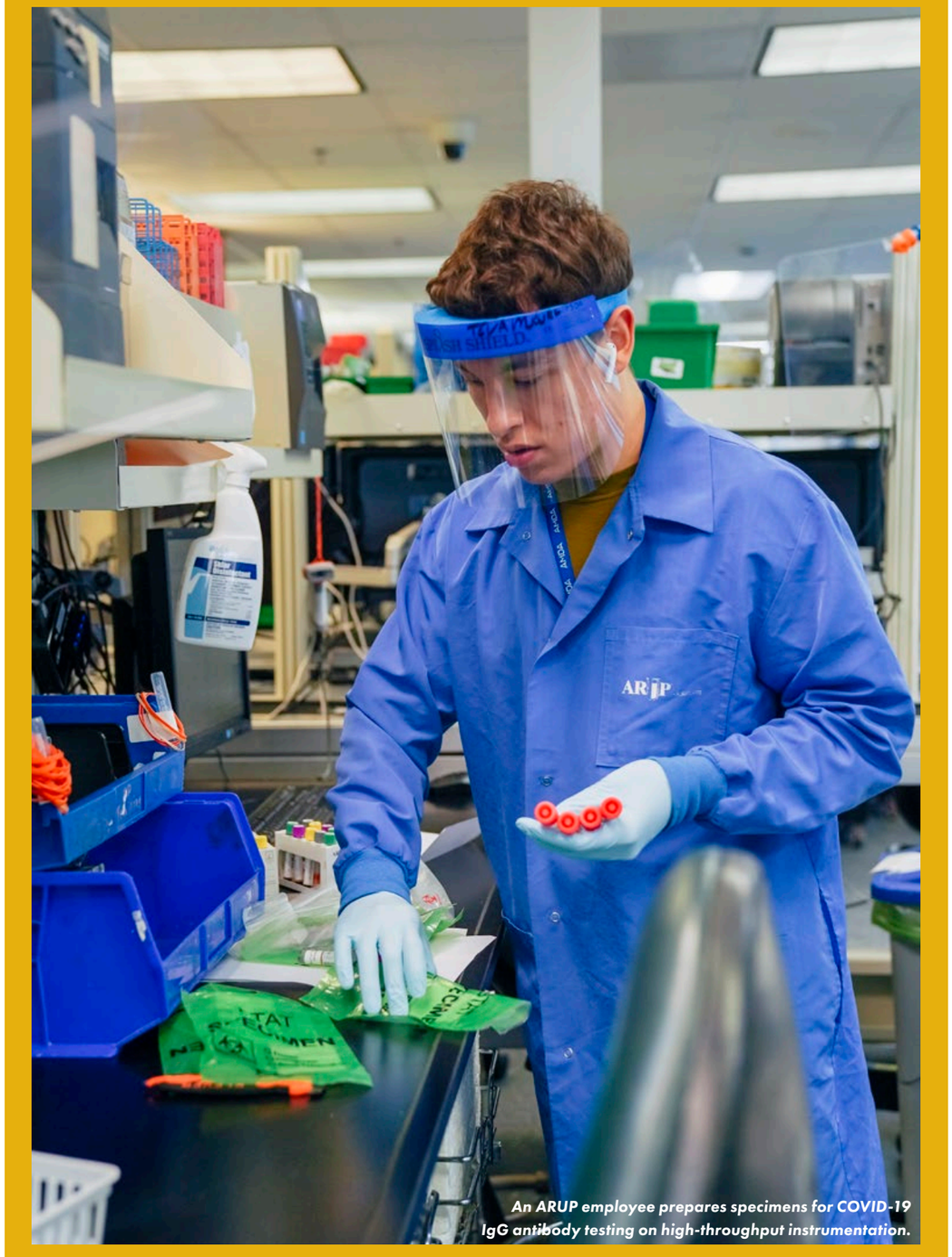
EMPLOYMENT CONCENTRTION
SPECIALIZED CONCENTRATION OF JOBS

#2
IN MEDICAL DEVICE EMPLOYMENT CONCENTRATION



1 OF 4
STATES WITH CONCENTRATION IN PHARMACEUTICALS, MEDICAL DEVICES & RESEARCH, TESTING AND MEDICAL LABORATORIES

Source: *The Bioscience Economy: Propelliing Life-saving Treatments, Supporting State & Local Communities 2020*; Teconomy Partners, LLC; Biotechnology Innovation Organization; Public Affairs Consultants; 2020



An ARUP employee prepares specimens for COVID-19 IgG antibody testing on high-throughput instrumentation.

RESULTS

MATTER

ARUP and Nelson Labs Play Key Roles in Trusted Testing for Patients and PPE Validation.

Results matter when it comes to testing for COVID-19 and ensuring that PPE is, in fact, protective. Highly skilled laboratories, such as ARUP, perform a range of COVID-19 diagnostic and antibody tests, and Nelson Labs is recognized worldwide for its PPE barrier testing.

ARUP Laboratories: A Nationwide Leader in Test Development for COVID-19 and Other Infectious Diseases

Well before the World Health Organization (WHO) declared the COVID-19 outbreak a pandemic on March 11, 2020, laboratory scientists at ARUP Laboratories in University of Utah (U of U) Research Park were already hard at work developing a diagnostic test to detect Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2), the virus that causes COVID-19.

ARUP's test was the first molecular test for COVID-19 available in Utah, and one of the first available nationwide. ARUP, a not-for-profit enterprise of the U of U and its Department of Pathology, also validated the first COVID-19 IgG antibody test available in Utah to test for previous exposure to the virus.

As an academic reference laboratory with clients nationwide, ARUP develops dozens of new tests each year, drawing on the expertise of its medical directors, all of whom are also U of U faculty members. ARUP developed tests for the Zika virus in 2016 and for H1N1 in 2009, so its experts were already well versed in the FDA Emergency Use Authorization process that all laboratories must follow to get COVID-19 tests approved for use in the U.S.

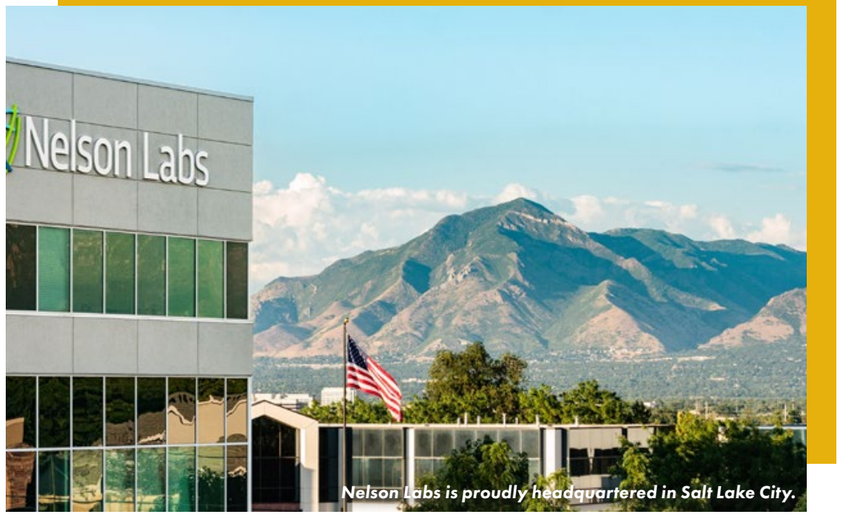
"We were able to work on an accelerated schedule while maintaining rigorous standards that ensure accurate results for every individual tested," said ARUP CEO Sherrie L. Perkins, MD, PhD.

In addition to COVID-19 diagnostic and antibody testing, ARUP's menu of more than 3,000 tests includes other assays useful when treating patients with COVID-19. For example, the laboratory offers cytokine testing that identifies a serious hyperimmune reaction that affects some patients with COVID-19.

Through its Clinical Trials team, ARUP is participating in numerous clinical trials underway at the U of U and Intermountain Healthcare, as well as nationally, to investigate treatments for COVID-19. ARUP is collaborating with the Utah Department of Health on a study of SARS-CoV-2 genetics to understand how the virus has spread in Utah. It also is performing all testing for the Utah Health and Economic Recovery Outreach (HERO) project, an initiative that aims to help keep Utahns safe at work and at school.

"Through our academic affiliations and many healthcare partnerships in Utah and nationwide, ARUP is uniquely positioned to respond to COVID-19 from many angles," Perkins said. "We are proud to lead our industry as a trusted source of COVID-19-related testing."

> We are honored to be playing an important role in supporting our customers in this fight against the coronavirus with the ongoing validation of PPE and other critical healthcare supplies."
>
> —Jeffery R. Nelson, President, Nelson Labs



Nelson Labs is proudly headquartered in Salt Lake City.


Nelson Labs performs a sodium chloride aerosol challenge for a medical respirator.

Nelson Labs: Safeguarding Global Health During the Pandemic

As the COVID-19 pandemic began to spread worldwide during the first quarter of this year, it became evident that the supply of face masks, respirators, and other personal protective equipment (PPE) would not be sufficient for the surge in demand that this pandemic was creating. In many parts of the world, including the U.S., face masks were not commonly worn, and most people did not know the difference between a face covering, a face mask, and a respirator—an N95 respirator was an entirely new concept for most people.

However, as healthcare experts and government leaders began stressing the importance of wearing a face mask to help reduce the spread of COVID-19, people around the world rushed to buy whatever they could find and the supply of surgical and respirator-type face masks became stressed.

It was evident that even if existing manufacturers significantly increased their production, there was a need for a greater number of new companies to help fill this growing demand. In response, many companies—not generally associated with PPE—switched their manufacturing efforts towards making face masks and other protective gear. To encourage this, the FDA authorized the emergency use of certain masks and respirators intended for a medical purpose during the COVID-19 pandemic. This emergency use authorization (EUA) allowed companies to get their products on the market quickly.

Though this EUA helped to streamline the requirements for face masks to enter the market, it did not eliminate the testing required before a mask could be offered to the public. This is where Nelson Labs, a Utah-based provider of laboratory testing and expert advisory services, comes in.

Nelson Labs, a business unit of Sotera Health, is considered an innovator and the industry leader in offering full-service testing for face masks, respirators, and other PPE. Therefore, many of these companies hoping to get their products quickly to market, turned to Nelson Labs for help. Nelson Labs' mission statement is "Safeguarding Global Health" and they take that mission seriously; therefore, to meet this increased demand, it was vital that they protect their critical, on-site laboratory staff while also increasing their testing capacity.

Nelson Labs knew that it could not take any risk of having its testing compromised and quickly instituted proactive steps to protect its employees. Theses steps included moving all non-laboratory staff offsite (working from home), restricting travel, daily symptom checking and isolation, social distancing which included closing the cafeteria and removing chairs from the lunchroom and meeting rooms, spreading staff throughout the buildings into offices vacated by those working remotely, wearing face masks where social distancing is not possible, daily calls/updates, moving most meetings online, and continuous education on how to remain virus free, etc.

These steps helped to keep Nelson Labs up and running through the pandemic, but the next challenge was how to meet this increased demand for mask testing. The rush of new manufacturers entering the face mask market to meet the needs of the COVID-19 pandemic caused an increase of over 3,900% in protective barrier testing for Nelson Labs in the first half of this year alone. The pandemic combined with the FDA EUA for face masks created a quickly evolving environment for Nelson Labs. To meet demand, they needed to increase their PPE testing from one shift to three, working essentially 24/7 to keep up with the unprecedented demand. Laboratory staff needed to be flexible as headcount in this area increased by almost 400% in a matter of a few months. Individuals working in other parts of the laboratory, who had experience working in PPE testing, were being asked to switch back to the Protective Barriers group and everyone was being asked to work additional shifts, nights, and weekends. According to Jeffery R. Nelson, president of Nelson Labs, "It was essential that our team had an adapt, adjust, and overcome mentality to try to meet the need, and I was blown away by our team's willingness to dig in for our customers."

Not only was additional staff needed, Nelson Labs had to install additional equipment which then needed to be tested and validated before being used. There was also an increase in the need for greater communication and education with their customers who were often new to the requirements of the FDA and especially the FDA's EUA.

However, even with the increased number of manufacturers creating masks and respirators, demand for protective equipment was still outpacing what could be manufactured in the short run. The shortages of PPE caused by the COVID-19 pandemic left hospitals and healthcare facilities with few options but to reuse equipment that was never intended to be reused. This created a call from industry and government to find ways to disinfect single-use PPE so it could be reused. Nelson Labs, along with its sister companies Sterigenics, and Nordion, joined with industry leaders and government agencies and took up the call to work together to identify effective possible decontamination options.

This was a new challenge for Nelson Labs as regulations and guidelines didn't exist for reprocessing single-use PPE and regulators weren't prepared for the urgent demand the pandemic created. This is a highly regulated industry and putting the development of a new process on a very accelerated time frame was a new challenge for everyone involved.

Shared learnings and collaboration between Nelson Labs, its sister companies, industry, end users, and regulatory organizations was key as they worked together to identify possible decontamination approaches for the reuse of PPE. The working relationships that developed among the various organizations worked very well because everyone was working together toward a common goal.

The result of this collaboration was that Nelson Labs created a test plan that allows innovators trying to reprocess their PPE a way to validate their reprocessing solutions. This potentially allows many face masks and respirators, which were previously single use, to be reprocessed and reused—increasing the total number of protective masks available to end users.

When asked about the many challenges the coronavirus has created for Nelson labs, Nelson said, "We are honored to be playing an important role in supporting our customers in this fight against the coronavirus with the ongoing validation of PPE and other critical healthcare supplies. We are also very proud of the adaptability of our teams and the tireless effort our employees are making to meet the needs of our customers and the world."

During this time of unprecedented challenges, Nelson Labs knows that the products they test for all their customers are as important as the patients they represent. That is why they are committed to doing all that they can to continue to "Safeguard Global Health." ■

THE POWER OF NEXT-GEN SEQUENCING

How IDbyDNA's Explify Platform Addresses the Pandemic and On-Going Infectious Disease.

By Ivy Estabrooke | Executive Director for Corporate Affairs | IDbyDNA

Photo by IDbyDNA

The emergence of COVID-19 has brought the fields of infectious disease and public health to the forefront of everyday life. Outside of the halls of the CDC, NIH, and research laboratories in the halls of academia, outbreaks of emerging and novel viruses, like swine flu (H1N1), SARS (Severe Acute Respiratory Syndrome), and MERS (Middle East Respiratory Syndrome) did not enter the public conscious in the U.S. However, the acute pandemic caused by the Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2), the virus that causes COVID-19, has elevated awareness around the challenges of detecting, diagnosing, and treating a novel, highly contagious virus.

While PCR and antibody tests have become the discussion of socially distanced happy hours, new technologies, such as Next-Generation Sequencing (NGS), provide new and innovative tools for detecting and understanding more about COVID-19. Decades of research and development investment laid the groundwork for these innovative technologies that are positioned to detect both known viruses, such as flu, but also emerging viruses, like SARS-CoV-2.

The NGS method – coupled with powerful bioinformatics and machine learning – allows scientists to rapidly and affordably decode the sequence of nucleotides that make up an organism's DNA. Once decoded, advanced data analytics can be applied to provide clinically relevant insights into the pathology that is making someone ill – from mutations causing cancer in humans, to the pathogens causing the flu or an infection. This technology leverages the work of the Human Genome Project, which sequenced the entire human genome and paved the way to developing new approaches to detecting not only human or host genome sequences, but also that of pathogens and microorganisms.

Today, with the evolution of automation and analytics, the diagnostics industry has seen costs and turnaround time for sequencing decrease, beating the exponential decline dictated by Moore's law. These changes have opened the doors to new applications for use of NGS, and new companies to make that technology available to laboratories, clinicians, and public health experts.

IDbyDNA, Inc., is a leader in the development and commercialization of big data analytics that exploit NGS data with its Explify® platform. Once a sample is collected, it is processed, removing the human genetic material, and sequencing all the remaining DNA. Once sequenced, the data is rapidly analyzed identifying all of the microorganisms present. Collecting the entire sequence of each organism in the sample allows for the detection of novel and emerging pathogens. Unlike PCR where the test targets specific pathogens, Explify will detect any organism in the sample. Another advantage of obtaining the entire sequence of the organism allows for the tracking of mutations in the pathogen. Mutations provide important information for public health surveillance and guiding clinical treatment.

Molecular epidemiologists use point mutations to track the spread of infectious diseases. For example, during the COVID-19 pandemic, the use of whole sequence data provided insights into the patterns of viral spread. Tracking individual mutations in the virus augmented contact tracing, allowing epidemiologists to determine patterns of spread. In addition to identifying the pathogen present when sequencing the entire organism, Explify is able to detect antimicrobial resistance (AMR) markers. These AMR markers provide clinicians with insight into what treatments will be effective, reducing treatment time.

If COVID-19 is going to be controlled, we must look to advancing technologies like NGS and advanced software applications, such as those available through the Explify Platform, to help lead the fight. If used broadly, it could be a huge step forward for not only detecting COVID-19, but all infectious disease as a whole, and it will continue to transform public health surveillance as well, contributing to the prevention of the next pandemic. ■

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