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PACE ANALYTICAL GROWS THROUGH INNOVATION IN AIR, PFAS AND WASTEWATER COVID SURVEILLANCE — EXPANDS NETWORK WITH 21 NEW LOCATIONS IN 2020

Pace Analytical Services LLC provides trusted environmental and life sciences testing and analysis capabilities as well as onsite services for client laboratories to include scientific staffing, regulatory compliance support, instrumentation and clean room services, and relocation. More than 3,500 employees work collaboratively to provide an exceptional experience for Pace customers, delivering accurate, timely data and services for those making the critical decisions that benefit us all. Pace delivers science better to businesses, industries, consulting firms, government agencies, and more through the largest, American-owned and nationally certified laboratory network.

Johnny Mitchell is the Vice President of Operations at the Pace Analytical National Center for Testing and Innovation where he has applied over 32 years of experience in laboratory science to bring proprietary and patented solutions to Pace customers. Mr. Mitchell's deep knowledge spans the areas of environmental analytical field work and data validation where he is proficient in both organic and inorganic methods.

Pace Analytical innovations led by Mr. Mitchell include ezHerbicide™ and ezSoil™ testing and analysis services that were developed to reduce environmental impact and waste. ezCans™ is a proprietary, ready-for-sampling air canister that virtually eliminates field sampling errors. Most recently, Mr. Mitchell partnered with Pace Life Sciences to develop a quantitative method for identifying RNA fragments in wastewater for SARS-CoV-2 surveillance.

EBJ: Congratulations on becoming the first commercial laboratory to test and monitor wastewater treatment systems for SARS-CoV-2, the virus that causes COVID-19! Can you tell us more about this project?

Mitchell: Wastewater testing for viruses has been a topic of discussion since the AIDS epidemic in the 80s. The idea was never developed due to social resistance. Then, the prospect resurfaced with the first SARS outbreak in 2001 and then again with MERS in 2008. The discussions again never developed as the outbreaks were brought under control relatively quickly.

The COVID-19 pandemic has been quite different, both in terms of its impact on the U.S. and its duration. Of course, back in April, when we started developing this methodology, none of us knew we would still be dealing with COVID-19 twelve months later. All we knew was that we were in a pandemic, so we needed to scale quickly. Collaborating with Pace Life Sciences, we were able to progress from initial idea to commercial availability in about eight weeks.

The target audience for SARS-CoV-2 wastewater surveillance overlaps with our client base for other services. For example, we do a lot of testing for environmental contaminants for municipalities and industry. Right now, we are pursuing projects involving large industrial sites, like petroleum refineries, and institutions, such as prisons. Anywhere you can isolate a wastewater stream, you can do a quantitative analysis for SARS-CoV-2.

Wastewater testing is a powerful weapon in the fight to lessen the impact on people in a congregate living setting and on workforce productivity. Identifying an increase in viral RNA levels can give you an extra 3-5 days to prepare for a potential spike in cases. It doesn't provide information on who is infected, but that also means you don't have to deal with some of the privacy issues that crop up when testing employees or residents individually. It's also a lot less expensive and intrusive way of gauging COVID-19 levels than daily, or even semi-daily, nasal swab testing.

EBJ: What qualities / advantages did Pace had prior to achieving this that enabled you to move fast and obtain such a success? And what challenges did you experience along the way? How were you able to solve them?

Mitchell: Our partnership with Pace Life Sciences was crucial. Our experts in Boston have significant experience and familiarity with the tools we needed, primarily qPCR, or quantitative Polymerase Chain Reaction. However, we needed to develop qPCR a bit because the test method is usually used to analyze DNA. With SARS-CoV-2 wastewater surveillance, we're analyzing the levels of RNA fragments in a sample. We had to develop a way to transcribe the RNA into DNA to use qPCR to magnify the signal and quantify the concentration of particle resent.

Once Pace Life Sciences solved that challenge, we took their work and brought it into our environmental labs to address the challenges of dealing with wastewater, a complex matrix with a lot of interferences. Specifically, we needed to determine how we separate the RNA and purify the sample to produce a reliable matrix for analysis.

Once we made SARS-CoV-2 wastewater testing commercially available, we realized we also had some market education to do. The initial press coverage on wastewater surveillance had many thinking you could catch COVID-19 from infected wastewater. I think, by now, the word has

gotten out that the virus doesn't survive the digestive track intact and that we're only testing for RNA fragments.

We also needed to educate the market on the importance of conducting a quantitative analysis. There are other labs offering wastewater testing commercially, but the majority are only offering pass/fail testing. That doesn't add much value because there will almost always be evidence of SARS-CoV-2 in wastewater. Only a quantitative analysis tells you whether the infection rate is climbing or falling.

A lot of the universities are doing quantitative testing, and they're making a significant contribution to our overall understanding of how wastewater testing can be used to predict and pre-empt outbreaks. That said, there's a pretty big difference between research and commercial testing. Most universities don't have the resources to offer this at a commercial level.

EBJ: What other New Practice Areas or Innovative Solutions have come out from Pace over the past couple of years?

Mitchell: We've developed two methods that are worth noting. ezSoil™ allows us to test for volatile organics in soil using methanolic extracts only. This is a much more reliable way to test for contaminates of interest. ezHerbicide™ uses new developments in Liquid Chromatography Tandem Mass Spectrometry for faster, more accurate, and more reliable testing of the presence of herbicides in the environment.

On the PFAS front, we're also rolling out a method called TrueTOF™ to measure total organic fluorine. This method improves on the standard AOF method because it doesn't require any extraction. This allows for a quicker, often less expensive, and more reliable analysis.

EBJ: How does the future look? At what pace will laboratories and environmental companies will have to innovate to keep up with all the changes that we see in the world and our society?

Mitchell: We believe the environmental industry is at the beginning of what will be a dramatic era of innovation. Technology in general is developing rapidly as well. Advancements in Tandem Mass Spectroscopy and liquid chromatography provide more techniques for reliable analysis of a large class of compounds. One area you will see this is in the analysis of primary personal care products, also known as PPCPs, and potentially in the analysis of pharmaceutical materials in the environment.

We're also seeing sensitivity improvements in existing analytical tools that allow for better measurement and discovery of contaminants, such as PFAS. These contaminants are not new to the environment, but the industry is developing ways to more closely monitor them and measure their presence at increasingly lower levels.

EBJ 2020 Project Merit Award: SARS-CoV-2 Testing Accreditation

Pace Analytical (Minneapolis, MN) became the first commercial laboratory to test and monitor wastewater treatment systems for SARS-CoV-2, the virus that causes COVID-19. Pace Environmental Sciences, in collaboration with Pace Life Sciences, leveraged combined strengths to quickly develop a process for monitoring wastewater for changes in the level of RNA from the SARS-CoV-2 virus over time.

Wastewater testing falls into the surveillance testing category in that it does not detect an infection in a specific individual, but it can help determine if additional testing or precautionary measures are needed. Wastewater testing also has several advantages over other testing programs. It is less intrusive at the individual level, accounts for the presence of the virus in asymptomatic individuals, and allows for spot testing, as long as an isolated wastewater stream is available. By monitoring quantitative data over time, versus ubiquitous wastewater pass/fail tests, Pace has helped municipalities, universities, correctional facilities, businesses, and more with actionable data they can monitor and use to anticipate and prepare for outbreaks and make efforts to contain spreading.

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EBJ: What opportunities do you see for innovation? Where do you think that the environmental industry should focus their efforts?

Mitchell: Historically, the environmental analytical process has been driven primarily by regulation. With increasing levels of environmental awareness across the globe, we are confident that progress will continue at an even greater pace. The advances in technology we have discussed are also driving the industry in a new way. A focus towards developing more environmentally sustainable solutions to address existing issues allows us to proactively improve the techniques we use to meet existing regulations while expanding our capabilities towards compounds of emerging concern.

EBJ: How has busines been for Pace Analytical over the past couple of years?

Mitchell: Pace Analytical® has experienced growth organically, through innovation, and by expanding its lab network and services through acquisitions. The company's focus on service delivery and in creating a unique experience for its customers has engendered loyalty. Innovations in our Air labs, PFAS methods, and quantitative COVID-19 wastewater surveillance programs, as well as proprietary, low-impact solutions for water, soil, and herbicide residue testing have provided great benefit to our Environmental Sciences customers.

Pace Life Sciences has expanded to a full-service contract development and manufacturing organization (CDMO), adding sterile and non-sterile clinical trial manufacturing services, proprietary spray-drying techniques, and specialty ophthalmic formulation development and manufacturing expertise.

The addition of these capabilities allows Pace Life Sciences to support pharmaceutical, biopharmaceutical, and gene therapy customers from early-stage research and development through clinical trial materials production to GMP central lab testing services. For these customers, flexibility and turnaround times are critical, and they appreciate the project continuity Pace can provide in bringing new drugs and therapies to market.

Similarly, with its focus also on the pharmaceutical and biopharmaceutical markets, Pace Scientific Professional Services has experienced growth across its services to customers with internal labs. While instrument repair/maintenance, clean room services, and regulatory compliance support remains strong, Pace scientific staffing services have been particularly important to customers experiencing workforce fluctuations due to the pandemic.

Pace customers value laboratory and service center proximity for convenience, quick turnaround times, and deployment of service technicians. This, coupled with expanding and adding service capabilities, has driven the expansion of the Pace lab network through acquisitions. In 2020, the company added 21 locations.

Deemed an essential business for public health under CDC guidelines, Pace Analytical has remained fully operational during the pandemic. The company has instituted safety protocols and services to protect both its customers and employees. Pace has also worked to contribute in other ways. Due to advanced capabilities in the development and testing of gene therapies and other complex therapeutic modalities, Pace Life Sciences proudly supported several of the leading biotechnology and pharmaceutical companies in their development of COVID-19 vaccines and therapies.

In collaboration with Pace Life Sciences, Pace Environmental Sciences implemented the COVID-19 wastewater surveillance program to provide quantitative data for analysis. Regular monitoring of quantitative data allows for non-obtrusive monitoring of populated areas for increases in RNA levels, providing advanced notice of infection spikes. Pace has provided these services to local governments and communities, universities, prisons, manufacturers, industry, and others.

EBJ: What can you comment in regards to Pace's geographic strategy? Why does this strategy make sense?

Mitchell: Pace customers value laboratory and service center proximity for convenience, quick turnaround times, and deployment of service technicians. Our localized level of service backed with our broad capabilities, provides great customer value. As such, we continually analyze customer and market opportunities against our laboratory footprint.

EBJ: In which ways has Pace differentiated from other laboratories?

Mitchell: At Pace, we work to honor our commitments so that our customers can honor theirs. Our customers rely on our ability to deliver accurate data when and where they need it. As such, we believe we differentiate in customer experience and the ability to make doing business with us easy, convenient, and personalized.

We offer all the laboratory capabilities, credentials, and expertise you would expect from a large lab services company, but with a different level of commitment. Pace has developed innovative technologies to dramatically improve turnaround times, embarked on acquisitions to provide convenient locations for samples, and we provide customers easy, online access to their data. It's not the company, but Pace people that make the difference.

Our Environmental, Life Sciences and Scientific Professional Services divisions allow us to help clients on multiple fronts. As you will see when we dig into the specifics of wastewater testing for COVID-19, there's also a synergy between these divisions that allows us to move faster than most commercial labs. □

Pace Analytical Divisions

Environmental Sciences – Pace offers full-service environmental laboratory capabilities supporting routine and specialty testing and analysis services. Pace Environmental Sciences provides services to communities, businesses, industry, consulting firms, government agencies, and others through the largest, American-owned laboratory network. Pace Environmental Sciences has been in business for over 40 years and holds several patents related to process innovations and instrumentation.

Life Sciences - Pace Analytical Life Sciences, LLC. is a full-service contract development and manufacturing organization (CDMO) with a network of laboratories. Capabilities span from early-stage research and development to clinical trial materials production and GMP manufacturing. Pace Life Sciences continually invests in its facilities, technologies, and experts to provide exceptional, full-project support to the pharmaceutical, biopharmaceutical, and gene therapy manufacturing industries.

Scientific Professional Services – Pace Scientific Professional Services provide on demand solutions to support in-house biopharma and pharmaceutical laboratories. Services are managed to the customer's requirements and may include:

Managed Staffing Services. Fully-managed lab staffing services that provide highly-trained, performance-based Pace professionals to fill any need from short-term gaps to longer-term project leaders.

Regulatory Services. Pace provides expertise in the areas of hazard communication, product stewardship, and raw material data management.

Instrument Support Services. Onsite maintenance and repair, cleanroom and pharmacy regulatory specification testing, and laboratory relocation services are delivered by qualified Pace experts.

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