PathogenDx Launches Breakthrough Clade Variant Testing and Secures Phase Two Funding as NIH Aims to Increase Capabilities for Viral Mutation Screenings

SCOTTSDALE, Ariz., March, 2021 -- PathogenDx, Inc., an Arizona based technology company which has developed a multiplexed microarray DNA-based pathogen testing platform, announced today the launch of their Clade Variant Adaptive Surveillance (CVAS) technology to identify SARS-CoV-2 variants in as little as four hours. PathogenDx has also entered phase two funding under the Rapid Acceleration of Diagnostics (RADx) Tech program. The additional funding will be used to support Clade Variant Array screening nationally, initially as an RUO (research use only) release, as well as expand pooled COVID-19 testing with its Detect-Rv test kits for schools, businesses and communities nationwide.

Genetic variations in the SARS-CoV-2 virus have caused new variants to arise across the globe, diversifying into numerous lineages such as the UK B.1.1.7 variant, South Africa B.1.351 variant and the Brazil P.1 variant. Such mutations in a patient sample can alter the performance of COVID-19 tests, risking an increase in false negative results. PathogenDx's Clade Array tests for all variants to quickly identify if positive samples tested from an EUA authorized platform are from the South African, Brazilian or UK variant within only four hours. The innovative multiplex array technology can fit around 150 different probes to test for multiple viruses and its mutations, thereby mitigating the chance for false negatives. Meanwhile, current testing technology is costly, unable to identify between variants and requires next generation sequencing, which takes 2-3 weeks to receive results. In contrast, PathogenDx's Clade Variant technology is highly affordable. The system is 1/15th the cost of a sequencer and sample testing costs 50%-90% less than the testing on sequencing. With this cutting-edge technology, PathogenDx can help the U.S. increase its current variant testing capacity of 0.3% of samples to the goal of 15% of samples.

PathogenDx's Clade Variant test does not require immediate FDA approval as it will be launched in its own kit as an RUO for clinical labs, universities, pharmaceutical companies, and research institutions to canvas the test's capabilities in identifying the myriad of SARS-CoV-2 variants as well as to expand genomic surveillance. The company's ultimate goal is to receive FDA Emergency Use Authorization (EUA) in order to increase capabilities for Clade Variant screening nationally.

"Every one of us wants to return to normal, open the economy fully and go back to work or school. To do so safely, we need testing technologies that are affordable and can accurately and rapidly detect virus variants so any risk can be quickly isolated. Currently available sequencing systems cost roughly $1M and charge between $400-$1,000 per sample, which is unrealistic for nationwide testing of millions of samples," said Milan Patel, CEO of PathogenDx. "We are deeply appreciative to the National Institute of Health for their confidence in our technology and for bringing our Clade Variant Array to the frontlines of the pandemic. This test will provide the U.S. with the information necessary regarding Clade variants to effectively address the COVID-19 pandemic in a much faster and more affordable manner than other technologies."

RADx Tech is managed by the National Institutes of Health (NIH), working in collaboration with the Biomedical Advanced Research and Development Authority (BARDA), with the aim of rapidly scaling-up and manufacturing new COVID-19 testing technologies. PathogenDx received initial funding from the program in April to complete development and validation of their DetectX-Rv Microarray Assay for COVID-19. This second round of funding includes a contract

to scale the DetectX-Rv testing nationally as the U.S. aims for 25 million tests per month in an effort to get children back in school.

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To learn more, please visit www.pathogendx.com.

About PathogenDx

Headquartered in Scottsdale, Arizona, PathogenDx's mission is to become the new standard in DNA-based testing through widespread adoption of its advanced microarray testing platform for the human diagnostics, food and agricultural industries. PathogenDx's technology can rapidly identify and detect up to 50 pathogens all in a single test, in 6 hours providing triplicate data per analyte for certainty in results with a simple and easy process. The company's DNA-testing products – DetectX™, QuantX™, and EnviroX™– are disrupting conventional microbial and molecular technologies to identify, detect and quantify pathogens that are a threat to human health, their ecosystem and the environment. This technology will help growing businesses deliver safer products and healthier lives, while preventing billions of dollars in losses from infection and contamination. For more information on how you can utilize this simple, powerful and inexpensive DNA-based pathogen testing, visit www.pathogendx.com.

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