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ProPhase Labs Begins Advanced, Saliva-based Viral PCR Multiplex-Testing for COVID-19, Influenza A & B, and Other Viruses After FDA Confirmation of Two Emergency Use Authorizations

Company Integrates Spectrum Solutions™ SDNA-1000 Saliva Collection System for Advanced, Simultaneous Multi-Viral Detection of Infections and Viral Mutations

GARDEN CITY, NY, Feb. 09, 2021 (GLOBE NEWSWIRE) -- ProPhase Labs, Inc. (NASDAQ: PRPH), a diversified medical science and technology company, has begun new saliva-based, viral RT-PCR multiplex-testing as a laboratory developed test (LDT) classification. Emergency use authorization (EUA) applications have been filed and confirmed by the U.S. Food and Drug administration (FDA) for its two new testing methodologies. Testing integrates the Spectrum Solutions saliva self-collection system with a new, advanced multiplex qPCR platform for the simultaneous RNA detection of not only SARS-CoV-2 (COVID-19) but also COVID-19 viral mutations, as well as Influenza A, B, and more.

This new SDNA Viral™ saliva-based testing combo features pain-free self-collection, 100% in-device viral neutralization, removes the need for cold-chain storage of samples, and provides critical sample consistency for optimal accuracy. It additionally offers patients the most intuitive and safest sample collection process while delivering the most robust testing biomaterial for the detection of multiple viral infections or mutations in a single test.

Spectrum Solutions, innovative medical device manufacturer and industry leader in bio-sample collection devices, helped secure the FDA's very first saliva-based testing EUA and continues to lead the charge in saliva-based molecular diagnostic solutions and research. This new, efficient, and cost-effective multi-viral testing product has been engineered to increase testing accuracy and overcome the challenges of limited samples and costly analysis.

This testing provides patients an immediate diagnostic advantage using a single saliva test to quickly detect and identify COVID-19, any of its 17+ current viral mutations, including those first reported in the United Kingdom and now found throughout the United States as well as Influenza A and B. With test processing already underway at both ProPhase New York and New Jersey CLIA certified lab locations, this new, innovative technology ensures optimal assay reliability, offers numerous diagnostic advantages over other testing applications, and delivers the capacity to process more than 60,000 tests per day.

"We are privileged to be working with Spectrum Solutions, one of the leading life-science

companies in the world on innovative testing solutions for detecting dangerous viruses including COVID-19,” said Ted Karkus, CEO of ProPhase Labs. Mr. Karkus added: “This collection device and multiplex testing methodology deliver significant value to testing that other platforms have missed. Not only does our methodology identify the original COVID-19 virus, our assay also has the multiplex capability of identifying Covid-19 viral mutations. With the FDA deciding to limit its review of EUA submissions for COVID-19 laboratory developed tests, receiving confirmation of a formal review from the FDA device division is a great win for all of us. Our new state-of-the-art molecular diagnostic testing equipment from Thermo Fisher not only streamlines testing results but prepares us for additional testing capabilities moving forward.”

“Testing is the purposeful pursuit of understanding a disease and a window into each individual’s personalized response,” said Bill Phillips, Chief Operating Officer at Spectrum Solutions. Mr. Phillips added: “Without testing, patients and medical professionals would not be able to make informed decisions on the proper treatment path. We could not be more excited to partner with industry front-runner ProPhase Labs on the new Spectrum SDNA Viral testing solution. The industry needs more innovative testing collaborations like this, delivering real actionable insights, to help move us all forward.”

This collaboration coupled with other technologies and innovations will continue to provide a wide range of laboratory testing services for the diagnosis, screening, and evaluation of additional diseases. For more information on the RT-PCR multiplex testing, competitive pricing and some of the industry’s fastest testing turnaround times, please contact us at 866-7LAB TEST (866-752-2837) or info@prophasedx.com

ABOUT SPECTRUM SOLUTIONS™ , SPECTRUM DNA™

Headquartered in Salt Lake City, Utah, Spectrum Solutions and its medical device division, SpectrumDNA, focus their industry expertise on engineering innovative end-to-end solutions for clinical diagnostic projects and commercial product plans. A single-source solution provider for medical device development, manufacturing, custom packaging, kitting, and direct-to-consumer fulfillment. Their bio-sample collection devices, patented technologies, and dedicated client services deliver measurable process optimization, unprecedented efficiency, and unmatched global scalability. For more information, please visit spectrumsolution.com/SDNA.

About ProPhase Labs

ProPhase Labs (NASDAQ: PRPH) is a diversified medical science and technology company with deep experience with OTC consumer healthcare products and dietary supplements. The Company is engaged in the research, development, manufacture, distribution, marketing and sale of OTC consumer healthcare products and dietary supplements in the United States. This includes the development and marketing of dietary supplements under the TK Supplements® brand. The Company’s subsidiary, ProPhase Diagnostics, Inc. (“ProPhase Diagnostics”), offers COVID-19 and other Respiratory Pathogen Panel (RPP) Molecular tests. The Company also continues to actively pursue strategic investments and acquisition opportunities for other companies, technologies, and products. For more information visit us at www.ProPhaseLabs.com.

Forward Looking Statements

Except for the historical information contained herein, this document contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements regarding our testing capacity goals. Management believes that these forward-looking statements are reasonable as and when made. However, such forward-looking statements involve known and unknown risks, uncertainties, and other factors that may cause actual results to differ materially from those projected in the forward-looking statements. These risks and uncertainties include but are not limited to the scale, scope and duration of the COVID-19 pandemic, our ability to attract and retain customer accounts, consumer demand for our lab processing services, the competitive environment, attracting and retaining qualified staff, challenges relating to entering into new business lines, our failure to obtain certain regulatory approvals, our ability to ramp up our lab's testing capacity and execute on our business plan, our ability to obtain necessary equipment and raw materials, our ability to execute our business plan in a cost-effective manner, and the risk factors listed from time to time in our Annual Report on Form 10-K and other SEC filings.

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Source: ProPhase Labs, Inc.