Idaho Technology Receives FDA 510(k) Clearance for Expanded FilmArray Respiratory Panel

SALT LAKE CITY (GLOBE NEWSWIRE) -- Idaho Technology, Inc., a privately held clinical diagnostics company dedicated to providing the world's fastest, highest-quality instruments for pathogen identification and DNA analysis, today announced U.S. Food and Drug Administration (FDA) 510(k) clearance of five additional pathogens for its FilmArray Respiratory Panel (FilmArray RP), a user-friendly Multiplex pathogen detection system. FilmArray RP is now FDA-cleared for 20 viral and bacterial respiratory pathogens.
"We are pleased to offer a more robust and simpler way to test for upper respiratory tract infections," said Kirk Ririe, Chief Executive Officer of Idaho Technology. "Gaining clearance of these additional pathogens for FilmArray RP is an accomplishment long-anticipated by our users in the hospital clinical laboratory community because it improves laboratory testing capacity while providing the fastest way to better results."

With the addition of these five pathogens, the FilmArray RP now includes the first FDA cleared assays for 8 of the 20 organisms on the panel. Furthermore, the FilmArray RP is the only FDA-cleared panel capable of distinguishing between certain bacterial and viral respiratory infections. This represents a significant advancement in the field of infectious disease detection, with the potential to provide clinical laboratories and physicians with more comprehensive, actionable information to guide treatment decisions and improve patient outcomes.

The additional five pathogens are; Bordetella pertussis, Chlamydophila pneumoniae, Mycoplasma pneumoniae, Coronavirus 229E, and Coronavirus OC43. Bordetella pertussis outbreaks in recent months have highlighted the need for an FDA-cleared test that can rapidly and accurately distinguish viral infections from more serious bacterial illness.

Mr. Ririe Continued, "Our expanded respiratory panel highlights the diagnostic potential of our dynamic and innovative FilmArray platform.

After almost one year on the market with FilmArray RP, we have been very encouraged by the market acceptance we've received. We expect, based on current demand for our product and our growing pipeline of additional clinical diagnostic tests, to establish a leadership position in clinical diagnostics, building upon our legacy and expertise in pathogen identification."

Idaho Technology is currently developing additional applications for their FilmArray system including a blood culture ID panel, gastrointestinal pathogens panel, and an STD panel. The Company expects to begin clinical testing its blood culture ID panel later this year.

About FilmArray RP
FilmArray RP is Idaho Technology's first clinical diagnostic test designed to run on the Company's novel FilmArray system, which represents a significant advancement in user-friendliness and multiplex infectious disease testing capability for hospital clinical labs.

FilmArray RP rapidly detects nucleic acids in nasopharyngeal swabs obtained from individuals suspected of respiratory tract infections.

Requiring only two minutes of hands-on time, FilmArray RP has about a 1-hour turnaround time, and simultaneously tests for the following panel of respiratory pathogens: Adenovirus, Coronavirus 229E, Coronavirus HKU1, Coronavirus NL63, Coronavirus OC43, Human Metapneumovirus, Influenza A, Influenza A subtype H1, Influenza A subtype H3, Influenza A subtype H1 2009, Influenza B, Parainfluenza virus 1, Parainfluenza virus 2, Parainfluenza virus 3, Parainfluenza virus 4, Rhinovirus/Enterovirus, Respiratory Syncytial Virus, Bordetella pertussis, Chlamydophila pneumoniae, and Mycoplasma pneumoniae. FilmArray RP has received FDA-clearance for twenty targets and is available for use by hospital and clinical laboratory professionals in the United States. In addition, the European version of FilmArray RP is CE IVD marked for twenty-one targets. Idaho Technology is continuing to develop a broader test menu for its FilmArray system, including a blood culture ID panel, gastrointestinal panel, and an STD panel.

About Idaho Technology, Inc.
Idaho Technology, Inc. is a privately held clinical diagnostics company based in Salt Lake City, Utah. Founded in 1990, the Company currently holds over 70 patents related to polymerase chain reaction (PCR), including rapid PCR cycling. The Company has used its extensive patent portfolio to successfully market nearly 200 products to the clinical, research and military markets. The Company manufactures and distributes its proprietary diagnostic respiratory panel, FilmArray RP, which operates on its user-friendly FilmArray system, to hospital-based clinical laboratories in the U.S. and E.U. The Company also collaborates with various U.S. governmental agencies including the Department of Health and Human Services and the Department of Defense.

Among others, researchers, medical technicians, law enforcement officers, and soldiers in the field use company devices to detect or study disease-causing organisms. For further information, please visit www.idahotech.com [1].

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