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Idaho Technology, Inc. seeks FDA clearance for the expanded FilmArray® Respiratory Panel

SALT LAKE CITY, UT - Idaho Technology, Inc. announced today that it has filed a submission with the U.S. Food and Drug Administration for 510(k) clearance of five additional respiratory pathogens for its FilmArray Respiratory Panel, a user-friendly Multiplex PCR assay currently FDA cleared for 15 respiratory pathogens. The additional five pathogens are; *Bordetella pertussis*, *Chlamydophila pneumoniae*, *Mycoplasma pneumoniae*, Coronavirus 229E, and Coronavirus OC43. There are currently no FDA cleared assays for these 5 pathogens. The *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.

Kirk Ririe, CEO, said, "We have been quite pleased with how well the FilmArray system has been received by the clinical laboratory community and by how quickly it is being adopted. We are very excited about the potential addition of these five respiratory pathogens – particularly the bacterial targets. Many of our potential and current hospital laboratory customers are eagerly anticipating the launch of the expanded FilmArray Respiratory Panel."

A respiratory tract infection can be caused by one of dozens of viral or bacterial pathogens. While the symptoms caused by these pathogens are nearly indistinguishable, how a healthcare provider chooses to treat a respiratory infection may depend greatly on a rapid and accurate diagnosis of the responsible pathogen. The FilmArray RP is designed to aid healthcare providers in making this diagnosis.

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 Idaho Technology Inc.

Idaho Technology Inc. is a privately held biotechnology and 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 and works closely with various governmental agencies including United States Department of Health and Human Services, the Department of Defense and the Food and Drug Administration. 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.

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