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News release

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Idaho Technology, Inc. submits FilmArray® Respiratory Panel to FDA for 510(k) Clearance

SALT LAKE CITY, Utah, (November 3, 2010) - Idaho Technology, Inc. (ITI) announced today that it has filed a submission with the U.S. Food and Drug Administration for 510(k) clearance to market its FilmArray Respiratory Panel (RP) as an in vitro diagnostic product for patients with symptoms of upper respiratory tract infection. The FilmArray RP is a user-friendly multiplex PCR assay designed for the detection and differentiation of a panel of respiratory viruses and bacteria including: adenovirus, bocavirus, corona viruses, human metapneumovirus, influenza A and B viruses, parainfluenza viruses, rhino/entero viruses, respiratory syncytial virus, Bordetella pertussis, and Mycoplasma pneumoniae.

Kirk Ririe, CEO of Idaho Technology stated, "Several hospitals have expressed a strong interest in the FilmArray RP and many have already placed orders for it or are currently evaluating the system. Today's submission to the FDA marks a significant milestone in Idaho Technology's goal to fill the unmet need for user-friendly multiplex PCR in the hospital clinical laboratory." Ririe also said that the company expects rapid and significant adoption of the FilmArray RP partly because of the assay's ability to detect and differentiate the novel influenza A H1 2009 virus. "After last year's pandemic, many clinicians and laboratories are looking for a better solution for influenza A testing" Ririe added.

Beth Lingenfelter, who oversaw the clinical trials for the company said, "Due to the similarity of symptoms caused by many respiratory viruses and bacteria, diagnosis based on clinical symptoms alone is difficult. Existing in vitro diagnostics for respiratory pathogens are time consuming, difficult to run, and often lack appropriate clinical sensitivity. The FilmArray RP provides a robust, rapid, comprehensive, and easy-to-use diagnostic alternative that addresses these issues and brings tremendous value to the clinical management of patients suffering from respiratory infection."

Idaho Technology has several other clinical FilmArray applications currently under development including a GI track panel, a blood culture ID panel, and an STD panel.

About Idaho Technology

Idaho Technology, Inc. is a privately held biotechnology company based in Salt Lake City, Utah. Founded in 1990, Idaho Technology licensed the rapid PCR technology from the University of Utah. Through funds from the United States Department of Health and Human Services and the Department of Defense, the company has created many commercial instruments and reagents for use in research and applied fields. Several of these products, including the LightCycler® Instrument, have been sublicensed to Roche Diagnostics. Researchers, medical technicians, law enforcement officers, and soldiers in the field use the company's devices to detect or study disease-causing organisms. For further information, please visit www.idahotech.com.

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