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Media Contact: Robin Embry
robin@lovell.com
615-297-7766

DIATHERIX Laboratories Receives Second Research Contract from FDA and HHS

Innovative research will support tools for the detection of potential bio-defense agents

Huntsville, Ala. (December 16, 2014) – DIATHERIX Laboratories, Inc., has been awarded a second federal contract to continue its groundbreaking work in the development of research methodologies designed to support the development of diagnostic tools to detect certain low prevalence pathogens. The contract is a joint award from the Food and Drug Administration (FDA) and the Department of Health and Human Services (HHS) to support the development of diagnostic devices/platforms to detect high priority pathogens, as classified by the National Institute of Allergy and Infectious Diseases (NIAID).

Diatherix's research focuses on three NIAID pathogens: *Francisella tularensis*, *Escherichia coli*, and *Babesia microti*. Though not prevalent in the natural environment, the pathogens are prioritized by NIAID because of the ease with which they can be disseminated or transmitted; the mortality rates and public health impact they can generate; their potential to cause public panic and social disruption; and the special actions that are required for public health preparedness. For instance, *F. tularensis* has a low infectious dose, is highly virulent, and is easily spread by aerosol; as such, it is classified by the NIAID and the U.S. Department of Homeland Security as a Category A Priority pathogen/biological agent that poses high risk to national security and public health.

The low prevalence of these pathogens complicates the development of diagnostic tools to aid in their detection, as sufficient clinical samples may not be available to conduct the clinical sensitivity studies required for Food and Drug Administration (FDA) clearance. To address this regulatory and scientific challenge, the FDA is exploring the use of "spiked" clinical samples – special lab samples in which the pathogen being studied is introduced at increased or enriched levels – to support

sensitivity studies for the evaluation of diagnostic devices.

Diatherix's expertise in developing highly sensitive tools used in molecular analysis allows detection of pathogens in ranges as low as 10 organisms per milliliter. The company's proprietary Target Enriched Multiplex Polymerase Chain Reaction (TEM-PCR™) technology will be deployed on spiked clinical samples in this research effort as Diatherix builds on protocols established by a collaborative project between the FDA Center for Biologics Evaluation and Research/Division of Emerging and Transfusion Transmitted Diseases (CBER/DETTD), Center for Devices and Radiological Health/Office of In Vitro Diagnostics (CDRH/OIVD) and NIAID. The contract award is for one year.

"Diagnostics are a crucial component of the public health strategy to reduce the burden – and potential threat – of infectious diseases," said Diatherix Vice President for Research and Development Elena Grigorenko, PhD, who serves as principal investigator on the effort. "We are honored to work with the federal government on this important project, and are pleased that our TEM-PCR™ technology can be applied for detection of low prevalence pathogens."

ABOUT DIATHERIX

Diatherix Laboratories, Inc. is located in the HudsonAlpha Institute for Biotechnology in Huntsville, AL. Diatherix operates as an independent high complexity CLIA-certified clinical laboratory providing advanced multiplex molecular diagnostic services to assist healthcare providers in the detection of infectious diseases – providing one-day results and single sample collection. For more information, please visit the company's website at www.diatherix.com.

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