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Shiga toxin Rapid Diagnostic Assay Earns USU-HJF Third Consecutive Tech Transfer Award

Bethesda, Md. — A joint effort by the Uniformed Services University of the Health Sciences (USU) and The Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc. (HJF) to license assays that allow for the rapid detection of Shiga toxin has received the 2015 Federal Laboratory Consortium Award for Excellence in Technology Transfer. This marks the third consecutive award for the University, which is aided in its technology transfer efforts by HJF through the USU-HJF Joint Office of Technology Transfer.

The award is for work on Shiga toxin-producing *Escherichia coli* by Alison O'Brien, Ph.D., professor and chair of USU's Microbiology and Immunology Department, and her colleagues. The Federal Laboratory Consortium, a nationwide network of federal laboratories that seeks to develop strategies and opportunities for linking technologies and expertise with the marketplace, will present the award in April.

Two strains of the Shiga toxin are responsible for approximately 265,000 intestinal infections each year in the U.S. The strains have caused multiple food-borne outbreaks prompted by the consumption of undercooked meat, raw milk, lettuce, spinach and other foods. Such infections can result in acute diarrhea, hemorrhagic colitis, and in 5 percent to 10 percent of cases, life-threatening hemolytic uremic syndrome.

The research done by Dr. O'Brien and her colleagues addressed a key challenge in diagnosing the disease. Previously, such diagnoses were hampered by the slowness of culturing methods, which could take 24 hours or more to complete, and the difficulty of diagnosing certain strains by culturing. Further, existing detection kits did not provide the sensitivity necessary for rapid same-day testing of samples or diagnosis at physicians' offices and clinics.

These issues were addressed when USU researchers developed two assay formats that can detect Shiga toxin produced by multiple strains of *E. coli*. The first is a detection technology used in food and clinical samples, while the second is a diagnostic assay that uses monoclonal antibodies, developed at USU, to detect Shiga toxins. As a result of the research, rapid tests are now able to detect and differentiate the toxins in about 30 minutes, allowing timely diagnosis of Shiga toxin-producing *E. coli* and the implementation of appropriate treatment plans.

"We're extraordinarily proud of the accomplishments of Dr. O'Brien, Dr. Teel and the USU-HJF technology transfer team, and their ability to develop products that directly benefit our warfighters and their families," said USU President Dr. Charles L. Rice. "The continued presentation of these awards to USU personnel demonstrates the outstanding quality of our research and faculty and the successful relationship between USU and the Henry M. Jackson Foundation for the Advancement of Military Medicine."

The Shiga toxin diagnostic technology was successfully transferred under a license to Alere, a company with a focus on innovative rapid diagnostic products. The products have been licensed as Shiga Toxin Chek and Shiga Toxin Quik Chek. To further the development of the Shiga toxin technology into a commercial product, a cooperative research and development agreement with Alere and TechLab®, a sublicensee of Alere, was executed by the USU-HJF Joint Office of Technology Transfer. The efforts of Dr. O'Brien, lead USU inventor of the technology, and Louise Teel, Ph.D., principal investigator on the agreement and an

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inventor of the technology, as well as representatives from USU's Office of the General Counsel and HJF's Technology Transfer team, were key to the successful negotiation of the agreement for transfer of the technology. Dr. Teel is an associate professor in USU's Microbiology and Immunology Department.

The Foundation and the University created the USU-HJF Joint Office of Technology Transfer in 2000 to help scientists at the University and Foundation move their novel inventions, devices and technologies to possible patenting and commercialization. The office serves as the technology transfer office for USU and supports University research through agreement negotiation and management, patent filings, and licensing and marketing of technologies.

The Federal Laboratory Consortium's Award for Excellence in Technology Transfer recognizes employees of its member laboratories and non-laboratory staff members who have accomplished outstanding work in the process of transferring federally developed technology to the commercial marketplace. A panel of experts from industry, state and local government, academia, and the federal laboratory system judge the nominations.

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The Uniformed Services University of the Health Sciences (USU), founded by an act of Congress in 1972, is the academic heart of the Military Health System. USU students are primarily active duty uniformed officers in the Army, Navy, Air Force and Public Health Service who receive specialized education in tropical and infectious diseases, TBI and PTSD, disaster response and humanitarian assistance, global health, and acute trauma care. A large percentage of the university's more than 5,200 physician and 790 advanced practice nursing alumni are supporting operations around the world, offering their leadership and expertise. USU also has graduate programs in biomedical sciences and public health committed to excellence in research, and in oral biology. The University's research program covers a wide range of clinical and basic science important to both the military and public health. For more information, visit www.usuhs.edu.