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Quanterix and Beth Israel Deaconess Medical Center Publish Study on the Development and Validation of Digital ELISAs for Ultrasensitive Detection and Quantification of *C. difficile* toxins in Stool

Lexington, Mass. – August 5, 2015 — Quanterix Corporation, a leader in high definition diagnostics, today announced that the *Journal of Clinical Microbiology* has published a new study in which its Simoa (single molecule array) technology was used to develop a rapid, simple tool to allow diagnosis of *Clostridium difficile* infection (CDI) with both high analytical sensitivity and clinical specificity. The study was supported by the National Institute of Allergy and Infectious Diseases (NIAID) and the National Institute of Health (NIH) and was a collaboration between Beth Israel Deaconess Medical Center (BIDMC) clinician-scientists (Drs. Nira Pollock and Ciaran Kelly) and Quanterix.

To date, the optimal method for diagnosis of CDI remains controversial. Disease caused by *C. difficile* is due to the effects of two large protein exotoxins: toxins A and B. While the presence of toxin is necessary for disease, current methods for the detection of toxin are inadequate; conventional toxin immunoassays are insufficiently sensitive and cytotoxicity assays are too complex. Assays that detect toxigenic organism [toxigenic culture (TC) and nucleic acid amplification testing (NAAT)] are confounded by asymptomatic colonization with toxigenic *C. difficile*. Drs. Pollock and Kelly worked with Quanterix to develop ultrasensitive "digital ELISA" assays for toxins A and B using single molecule array technology and validated the assays using culture filtrates from a panel of clinical *C. difficile* isolates, as well as 149 adult stool specimens already tested routinely by NAAT.

"Within the controversial, complex and rapidly shifting *C. difficile* diagnostic landscape, one major theme is emerging: that the detection of toxins, rather than of bacteria capable of producing those toxins, is central to the accurate diagnosis of CDI," said Dr. Pollock, the PI of the study and a faculty member both at BIDMC (Division of Infectious Diseases) and Boston Children's Hospital (Department of Laboratory Medicine). "We're extremely motivated to do further research using this new tool and hope that it will lead to improved approaches to diagnosis and management of this important disease."

"Despite mounting evidence that toxin detection is paramount in CDI diagnosis, current methods continue to have limitations," said Dr. Kelly, a faculty member of the BIDMC Division of Gastroenterology and *C. difficile* expert. "NAAT, while ultrasensitive, can lead to false positive diagnoses of *C. difficile* infections, and sensitive and quantitative toxin immunoassays could be better indicators of disease."

"Until now, no highly sensitive assay existed that could rapidly detect and quantify both toxins A and B in stool samples at the time of diagnosis," said Kevin Hrusovsky, CEO and Executive Chairman, Quanterix. "We are delighted to find that our Simoa technology was used to develop assays that have both high analytical sensitivity and high clinical specificity, and thus could provide higher diagnostic accuracy compared to existing assays."

To read the full study published in the *Journal of Clinical Microbiology*, please visit: http://jcm.asm.org/content/early/2015/07/16/JCM.01334-15.abstract.

About Quanterix

Quanterix is a developer of ground-breaking tools in high definition diagnostics. Its Simoa platform uses single molecule measurements to access previously undetectable proteins. With this unprecedented sensitivity and full automation, Simoa offers significant benefits to both research and clinical testing

applications. Quanterix was established in 2007 and is located in Lexington, Massachusetts. To learn more about Quanterix and Simoa, please visit: www.quanterix.com.

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