Specific Diagnostics Announces Successful Completion of Audit for Certification as an ISO-13485-Compliant Medical Device Manufacturer

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Specific Diagnostics today announced that it has successfully completed a 4-day onsite audit confirming the completion and implementation of its ISO-13485-compliant quality management system, the final milestone required for designation as an ISO-13485 certified manufacturer of medical devices. As defined by the International Organization for Standardization, a QMS conforming to ISO-13485 meets the highest FDA standards applicable to businesses operating in the medical device sector.

Specific, which manufactures the Reveal rapid antimicrobial susceptibility testing system and associated disposables, will be on-market in Europe this month. While not required for European sales, the ISO-13485 quality management system certification will give European hospital customers the added assurance that Specific's instruments and disposables have been manufactured under the highest standards applicable to medical devices.

"I am proud of our team for their successful completion of the 2-year process to build and implement an ISO-13485-compliant quality system. It has made us a better engineering and manufacturing organization, and will continue to positively impact the Company's operations as we begin to supply the Reveal rapid AST system to our customers in Europe," said Dr. Paul A. Rhodes, Specific's CEO.

Specific's Reveal furnishes a phenotypic MIC directly from a positive blood culture sample in an average of less than 5 hours, as reported in a to-be-published preclinical study of 104 patient samples conducted at the Henry Ford Health System in Detroit, Michigan. Based upon arrays of printed sensors responsive to the volatiles emitted by growing microorganisms, the Reveal system has the high throughput, low cost, antibiotic menu, and ease of use to prompt wide adoption. As described by a Reviewer of one of Specific's recently awarded NIH grants: "The high biomedical significance and public health impact of [Reveal] is in its potential to provide novel, rapid, and improved phenotypic diagnostic platform for AST that can create a paradigm shift in management of patients and healthcare providers in hospitals, especially for bloodstream infections."

"As we move to make Reveal available to clinics in Europe, we were determined to complete the ISO-13485 certification process to ensure we meet the highest standards applicable to medical device manufacturers, and we have done-so," said Specific COO Raymond Martino. "The Reveal system, which will be available in Europe next month, will rapidly make an impact on clinical best practice for bacteremia and other time-sensitive infections."

About Specific

Specific Diagnostics has developed *in vitro* diagnostic systems based upon a unique, patented metabolomic signature technology that enables rapid detection and identification of microorganisms as they grow in culture. Its first commercial application applies this fundamental new platform to the rapid determination of antimicrobial susceptibility directly from positive blood cultures, as well as isolate dilutions. Specific is based in Mountain View, CA.

For press inquiries, please contact: press@specificdx.com