**Specific Diagnostics Commences US Clinical Trials for FDA 510(k) Clearance of its Reveal Rapid AST System**

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Specific Diagnostics announces today the commencement of its US clinical studies for the Reveal Rapid AST System for blood infection. Trials will entail 3 months of data collection followed by submission for FDA consideration of 510(k) clearance of the Reveal test.

In Europe, where the Reveal is launched under CE-IVD registration, 11 studies across France and England comprising over 1,400 clinical positive blood culture samples, yielding overall accuracy of 97.6% have been completed, with 4 of these studies now reported by submitted abstracts, complementing the similar results reported by Henry Ford Health System in Detroit.

Reveal determines the susceptibility of blood infections to antimicrobial drugs in an average of 5 hours, allowing same-shift adjustment of treatment, saving lives while reducing costs and improving the utilization of antibiotics.

Reveal's CE-marked, low cost, high throughput, broad menu, and small footprint are all suited to wide-spread adoption. Modular system design ensures no single point of failure, 100% uptime, and incremental adoption by hospitals of any size. The unique Reveal Dashboard™ provides the lab easy-to-use realtime tools to monitor trends of infection and resistance as well as instrument performance.

"With preclinical data from over 1,400 clinical samples showing accurate, consistent, rapid, and reliable results," said Dr. Paul Rhodes, CEO of Specific, "we believe our system is well-prepared for its US clinical trials, and we look forward to introducing this system to key opinion leaders across the US clinical microbiology community."

**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, with subsidiaries in Ireland, France and the UK.

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