

Specific Diagnostics Announces CE-IVD Registration of the Reveal Rapid AST System

October 15, 2020 - MOUNTAIN VIEW, California – FOR IMMEDIATE RELEASE

Specific Diagnostics today announced CE-IVD registration of the Reveal rapid antimicrobial susceptibility testing system. European availability of Reveal is now beginning in France, led by 6 distinguished evaluation sites.

“Reveal will provide hospital microbiology laboratories a much-needed option for rapidly obtaining a susceptibility profile directly from positive blood cultures,” said Dr. Paul A. Rhodes, CEO of Specific. “Reveal’s same-shift AST, with an average time to result of 4.6 hours based upon our recent clinical study, is much-needed for time sensitive infections, while the system’s affordable cost, ease of use and high throughput is compatible with the requirements of hard-pressed microbiology laboratories.”

“We have been pleased to work closely with Specific as they have developed manufacturing under the formal quality system appropriate to medical devices in Europe,” said Mr. Maurizio Suppo, co-founder and Partner at Qarad, Specific’s Brussels-based Registered Agent in Europe. “We note that they have also announced completion of a successful ISO-13485 quality system audit as well, indicating a high level of commercial maturity as a medical device manufacturer. We wish them well in bringing their important product to the European markets that we serve.”

Specific intends to offer Reveal for evaluation and clinical use in France and the United Kingdom during Q4 2020 and Q1 2021, with availability in additional markets thereafter.

About Specific

Specific Diagnostics develops *in vitro* microbiology 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 utilizes this fundamental new technology for the rapid, same-shift, determination of antimicrobial susceptibility directly from positive blood cultures. Specific is based in Mountain View, CA.

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