

New Clinical Study Demonstrates Feasibility of Performing Multiplex ANA Testing on Whole Blood via Finger-Stick in Physician Office Near-Patient Setting

Genalyte's Maverick™ Detection System illustrates potential to improve turnaround time for diagnosis

SAN DIEGO, NOVEMBER 12, 2016 – [Genalyte Inc.](#), an emerging clinical diagnostics company, today released the first-ever clinical abstracts for the Maverick™ Detection System, demonstrating the potential for the diagnostics system to be used in a near patient setting to improve the turnaround time for test results.

Genalyte sponsored two pilot studies incorporating the Maverick™ platform into rheumatology offices. The combined studies tested more than 750 patients over a span of four months, comparing the real-time results of the Maverick™ with those of standard lab procedures and patient diagnosis.

Both studies (abstracts can be found [here](#) and [here](#)) were presented at the 2016 American College of Rheumatology/ Association of Rheumatology Health Professionals ([ACR/ARHP Annual Meeting](#)) in Washington, DC. Key conclusions included the following:

- Successful demonstration of the feasibility of performing multiplex ANA testing on whole blood in a near patient setting
- Extremely high correlation between positive and negative results comparing whole blood tested on the Maverick™ system with serum tested using previously approved devices
- Extremely high correlation of test results between venous draw and finger-stick blood samples
- Potential for use of the Maverick™ system in the outpatient setting to improve turnaround time for diagnosis, increase proximity of patient testing (near-patient in the physician office)

“Genalyte’s goal is to put a rapid and powerful suite of diagnostic tests in every physician’s office, and these initial trials illustrate that our team has made significant strides in that direction,” said Dr. Cary Gunn, Genalyte’s founder and CEO.

“The 2016 American College of Rheumatology meeting marks a major milestone in Genalyte’s clinical development program,” said Dr. Rick Hockett, Genalyte’s Chief Medical Officer. “Dr. Reddy’s presentation of in-office clinical trial data as well as independent validation data from Dr. Miyara’s group at le Pitié-Salpêtrière Hospital demonstrate Genalyte’s commitment to engaging in the clinical peer review process for the evaluation of our novel diagnostic platform.”

Dr. Smitha Reddy, medical director of the Arthritis Care and Research Center of San Diego, said the company-sponsored study demonstrated, “the feasibility of performing multiplex ANA testing on whole blood in a near patient setting in an outpatient clinic.” Added Dr. Reddy, “There is high correlation between venous blood and finger-stick blood, and between positive and negative results on the Maverick and comparative devices.”

Dr. Cary Gunn is available to discuss the results and the Maverick system. Interested members of the media should contact media@genalyte.com to set up an interview or request more information.

About Genalyte

Genalyte’s vision is to transform the doctor-patient relationship by bringing the doctor, the patient, and the lab together to provide results when they matter: Now. Genalyte’s platform is being designed with the goal of providing test results from a whole blood sample within fifteen minutes in the physician’s office. Providing diagnostic results at the time and place they are needed – when the patient is sitting in front of the doctor—has the potential to empower physicians, improve quality of care for patients, and reduce resource utilization across the healthcare system. Genalyte’s technology is based on a proprietary silicon biosensor design that is currently in use by pharmaceutical companies, contract research organizations and academic researchers. For more information, visit www.genalyte.com.