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Genalyte and Barbara Davis Diabetes Center Collaborate to Advance Multiplexed Antigen Panel for Early Diagnosis of Type 1 Diabetes

Genalyte Launches Multiplexed Biomarker Panel that Measures Seven Autoantigens Associated with the Development of Type 1 Diabetes

SBIR Grant Is Helping Fund Collaboration's Efforts to Profile T1D Autoantibody Responses by Multiple Criteria

SAN DIEGO, AUGUST 15, 2013 – Genalyte, Inc. today announced the launch of its Type 1 Diabetes (T1D) antigen panel that runs on the Maverick™ Detection System. The Genalyte T1D antigen panel is the first multiplexed assay that measures seven autoantibodies associated with the destruction of pancreatic islet cells seen in type 1 diabetes. In a related development, Genalyte reported that it is collaborating with the Barbara Davis Center for Childhood Diabetes (BDC) at the University of Colorado School of Medicine to further develop and test multiplexed antigen panels for the early detection of T1D.

The Genalyte T1D antigen panel was developed as part of the first phase of a Small Business Innovation Research (SBIR) grant awarded to Genalyte to develop multiplexed assays for the early detection and monitoring of type 1 diabetes. The $500,000 grant from the National Institute of Diabetes and Digestive and Kidney Diseases also provides support for expansion of the approach to allow autoantibody response profiling by multiple criteria, which is expected to enhance the ability of researchers and clinicians to detect and monitor the development of the disease.

> Martin Gleeson, PhD, Chief Scientific Officer of Genalyte, noted, "The pioneering work of Drs. George Eisenbarth and Liping Yu at BDC established assays for the measurement of islet autoantibodies. These rogue elements of the immune system eventually destroy the pancreatic islet cells that produce insulin. The unique capabilities of our Maverick detection platform have the potential to provide researchers and clinicians with tools to detect and track this process from an early stage, when interventions to interrupt the disease process may be feasible."

An estimated three million individuals in the U.S. have T1D, an autoimmune disorder that leads to life-long dependence on insulin injections. New disease-modifying therapies may have the potential to reduce or stop the destruction of islet cells in patients at risk of developing T1D. The availability of tools to identify these patients early in the disease process would facilitate the development and use of these preventative therapies.

> "We are pleased to offer our innovative T1D antigen panel to diabetes researchers worldwide at the same time that we are working with Dr. Liping Yu and his lab at the Barbara Davis Diabetes Center to expand the utility of the approach," added Dr. Gleeson. "BDC is a long-time leader in the quest to develop curative therapies for type 1 diabetes, and we are delighted to collaborate with them to develop the tools that may help make this dream a reality."

PRESS CONTACT
media@genalyte.com
858-956-1200

The Genalyte T1D antigen panel requires only a 2 to 5 µL serum or plasma sample and provides results in less than 15 minutes, without the use of dyes, fluorescent probes or radioactive labels. The T1D panel measures autoantibodies to insulin, proinsulin, GAD 65, GAD 67, IA-2 (PTPRN, ICA512), phogrin (PTPRN2, IA-2ß) and ZnT8 (SLC30A8). For more information, visit http://genalyte.com/maverick-type-1-diabetes-t1d-assay-kit/.

Other commercially available tests for the Maverick Detection System include MT-ADA, ENA 4, ENA 6 and ANA 14 assay kits. Additionally, Genalyte offers researchers a Custom Spotting Service that loads proteins supplied by customers, such as antibodies, peptides, biomarkers, cytokines and antigens, on to standard-format Genalyte chips that are ready to be run on the Maverick System.

Maverick assays are currently available for research use only.

About the Barbara Davis Center for Childhood Diabetes (BDC)

BDC specializes in type 1 diabetes research and care for children and adults. It is one of the largest diabetes institutes in the world. Clinicians, clinical researchers and basic biomedical scientists work at the BDC to prevent and cure type 1 diabetes and to find the most effective treatments. The Center is managed as a distinct administrative unit of the University of Colorado School of Medicine and has a dedicated building on the University of Colorado Anschutz Medical Campus in Aurora, Colorado. For more information, visit http://barbaradaviscenter.org.

About Genalyte

Founded in 2007, Genalyte, Inc. is commercializing the MaverickTM Detection System based on the company's revolutionary Microring Sensor Technology™, a new approach to multiplexing that uses a silicon chip containing arrays of photonic ring sensors to reduce or eliminate sample preparation and provide scalable multiplexing for both proteins and nucleic acids. The one-step workflow of the Maverick System can deliver accurate results in as little as 15 minutes from small volume samples of many types. It has a large dynamic range and excellent sensitivity with outstanding reproducibility. For more information, visit www.genalyte.com.

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