

# Genalyte Streamlines Immunogenicity Testing With Launch of MT-ADA™ Assay For Real-Time Detection of Anti-drug Antibodies

Automated MultiTier ADA Test Combines Screening,  
Confirmatory and Isotyping Steps in a Single Assay

Learn More about MT-ADA and the Maverick™ Detection System  
at PEGS 2013, AAPS National Biotechnology Conference  
and Next Generation Protein Therapeutics Summit

**SAN DIEGO, APRIL 3, 2013**– Genalyte, Inc. today announced the launch of its MT-ADA™ anti-drug antibody (ADA) immunogenicity assay designed to run on the Maverick™ Detection System. This test combines screening for the presence of ADAs and the characterization of each detected ADA with a full isotype profile. With minimal required sample preparation and its combination of detection and characterization in a single assay, the MT-ADA assay streamlines ADA testing for both mouse and human samples, providing real-time detection without the use of dyes, fluorescent probes or radioactive labels. Immunogenicity is triggered when the body generates an unwanted immune response to a drug. The resulting anti-drug antibodies can reduce the efficacy of the drug and cause a variety of harmful effects. As a result, clinical testing of drug candidates to identify potential immunogenicity issues arising from anti-drug antibodies has become common. The new MT-ADA assay is designed for rapid, efficient and accurate ADA testing.

“Immunogenicity testing currently requires multiple steps and significant hands-on effort,” said Martin Gleeson, PhD, Chief Scientific Officer of Genalyte. “MT-ADA simplifies and speeds up this process, combining the screening, confirmatory and isotyping steps in an automated assay that is efficient to develop and uses standard sample preparation methods. Early feedback from drug developers has been positive and we are pleased to now make the MT-ADA assay widely available to Maverick System users.”

The MT-ADA chip provides simultaneous ADA detection and confirmation for eight anti-body classes/isotypes. The Maverick System’s multiplex capacity and kinetic measurement capability streamline assay development by enabling simultaneous assessment of assay sensitivity and free drug tolerance for total ADAs and for each antibody class. The MT-ADA assay is compatible with commonly accepted sample preparation methodologies.

Genalyte’s Maverick Detection System uses a silicon chip containing arrays of photonic ring sensors that simultaneously analyze multiple antibodies and other proteins from a single small sample. The one-step workflow of the Maverick Multiplex System can deliver accurate results in as little as 15 minutes from small volume samples of many types. The Maverick platform has a large dynamic range and excellent sensitivity with outstanding reproducibility.

Current commercially available tests for the Maverick Detection System include MT-ADA, ENA 4, ENA 6 and ANA 14 assay kits. Assay kits for SLE, Sjogren's syndrome and type I diabetes research are available under Genalyte's Technology Access Program. 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.

**Learn more the Maverick Detection System and its multiplexed assays at the following upcoming conferences.**

**PEGS 2013: The Essential Protein Engineering Summit,**  
Boston, MA, April 29–May 3, 2013, Booth 115

**American Assoc. of Pharmaceutical Scientists  
(AAPS) National Biotechnology Conference,**  
San Diego, CA, May 20-21, 2013, Booth 704

**Next Generation Protein Therapeutics Summit,**  
San Diego, CA, June 25-27, 2013, Booth 6

For more information, visit [www.genalyte.com](http://www.genalyte.com).  
Maverick assays are currently available for research use only.

**About Genalyte**

Founded in 2007, Genalyte, Inc. is commercializing the Maverick™ detection platform based on the company's revolutionary Microring Sensor Technology™ a new approach to multiplexing that leverages advances in silicon photonics to reduce or eliminate sample preparation, provide scalable multiplexing for both proteins and nucleic acids from a single small sample, and achieve excellent sensitivity and up to eight logs of dynamic range.