

PreAnalytiX GmbH, NuGEN Technologies and Rutgers University Cell and DNA Repository Infinite Biologics partner to develop clinically validated RNA-Seq workflow for Whole blood samples

Hombrechtikon, Switzerland, San Carlos, CA, Piscataway, NJ, January 8, 2015 – PreAnalytiX GmbH, NuGEN Technologies, Inc. and Rutgers University Cell and DNA Repository Infinite Biologics (RUCDR), today announced a joint project to validate an end-to-end workflow for the reproducible collection and processing of whole blood for RNA sequencing (RNA-Seq) in clinical studies. The multi-site validation study involves three independent laboratories processing samples collected, stored and transported in the PAXgene® Blood RNA System from PreAnalytiX to prepare strand-specific RNA-Seq libraries using NuGEN's Ovation Human Blood RNA-Seq System prior to NGS sequence analysis. RUCDR will oversee all sample collection, processing and data analysis for the purpose of validating the PreAnalytiX and NuGEN offerings in a combined workflow. Results of the study are expected to be published later in the year.

Whole blood samples are used for a myriad of clinical genomics applications, due in part to the ease of collection as compared to other clinical sample types. However, there are challenges associated with preparation of human whole blood samples for analysis by RNA-Seq. Post collection changes of RNA molecules amounts in blood caused by gene inductions and down regulations as well as by degradation of nucleic acids, can occur during handling and processing, resulting in unreliable results, and apparent bias in transcript abundance. Whole blood also contains high levels of uninformative ribosomal RNA and reticulocyte globin RNA which reduces sequencing efficiencies and compromises the cost-effectiveness of the analysis.

“Sample quality has a direct effect on data integrity and is, therefore, critical to molecular diagnostic testing”, said Lynne Rainen, Scientific Director, PreAnalytiX GmbH. The PAXgene Blood RNA System was developed by PreAnalytiX to address the issue of sample handling variability and is considered the gold standard for whole blood collection intended for RNA based tests. The generic, FDA cleared system provides an integrated process for standardized blood collection, stabilization, transport, storage and purification of RNA from human specimens producing samples of superior quality. “We are very pleased to partner with NuGEN and RUCDR to validate our technology in combination with NuGEN's sample preparation solution for human blood RNA-Seq”.

The Ovation Human Blood RNA-Seq System was developed specifically to address the issues associated with preparing human whole blood for RNA-Seq analysis. The core technology employed in the kit, NuGEN's novel and proprietary Insert Dependent Adaptor Cleavage (InDA-C) technology, provides targeted depletion of human ribosomal RNA and adult human reticulocyte globin. Alan Dance, Vice President of Marketing and Business Development at NuGEN commented, “Our expertise lies in the development of robust sample preparation technologies that enable molecular diagnostic testing in streamlined and automatable workflows. The importance

of RNA-Seq data quality for clinical applications cannot be over-emphasized, and we are delighted to undertake this impactful study to expand the value and utility of RNA-Seq in the clinical setting”.

RNA-seq is useful for a range of applications, such as discovery and analysis of disease-related biomarkers, identification of new therapeutic targets and monitoring disease progression and treatment. “Full adoption of RNA-Seq using whole blood samples in a clinical setting requires workflows that are validated and standardized to ensure that the data generated is accurate and highly reproducible”, stated Dr. Andy Brooks, Chief Operating Officer of RUCDR Infinite Biologics. “As a CLIA laboratory and provider of clinical genomics services, RUCDR Infinite Biologics is proficient in the validation of molecular assays for clinical utility and translational medicine. We look forward to initiating the study and reporting on the results”. The study will be conducted across multiple sites and will evaluate the workflow for reproducibility, accuracy and sensitivity.

About PreAnalytiX

PreAnalytiX, a joint venture between BD and QIAGEN, develops, manufactures and sells integrated and standardized systems for sample collection, stabilization and purification of high-quality RNA, microRNA and DNA from human blood, bone marrow, or tissue specimens. The Company serves healthcare institutions, academic researchers, clinical laboratories and the pharmaceutical industry with a broad array of manual and automated products. Read more at www.preanalytix.com

About NuGEN

NuGEN Technologies is the leader in providing solutions which make biological samples accessible for genomic analysis, enabling scientists to capture the truest biology achievable, independent of the quantity or quality of the samples. The company has commercialized numerous proprietary DNA and RNA sample preparation products for use in research and diagnostic applications. Founded in 2000, NuGEN Technologies, Inc. is privately held and headquartered in San Carlos, CA. For more information please visit www.nugen.com

About RUCDR Infinite Biologics

RUCDR offers a complete and integrated selection of biological sample processing, analysis and biorepository services to government agencies, academic institutions, foundations and biotechnology and pharmaceutical companies within the global scientific community. RUCDR provides DNA, RNA and cell lines with clinical data to hundreds of research laboratories for studies on mental health and developmental disorders, drug and alcohol abuse, diabetes and digestive, liver and kidney diseases. RUCDR completed an \$11.8 million expansion and renovation of its facilities in May 2013. Read more at www.rucdr.org

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