



For Immediate Release

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SeraCare Launches Circulating Tumor DNA Reference Materials for NGS and Digital PCR-based Oncology Assays

Milford, Massachusetts, March 7, 2016 - SeraCare Life Sciences, a manufacturer and leading partner to global *in vitro* diagnostics manufacturers, today announces the launch of two new circulating tumor DNA (ctDNA) products at the 2016 Molecular Medicine Tri-Conference in San Francisco. The Seraseq™ Circulating Tumor DNA-I Reference Material and the Seraseq™ Circulating Tumor DNA-I Mutation Mix Kit are designed to assist both oncology assay developers and clinical laboratories in better characterizing the performance and robustness of their ctDNA assays and to monitor the performance across each run. There is currently significant interest in ctDNA for the non-invasive monitoring of tumor dynamics and residual disease after initial therapy. However, the current lack of 'ground truth' reference materials useful for analytical validation and performance monitoring are urgently needed to advance the clinical implementation of these assays.

Trace amounts of circulating tumor DNA may only be present on the order of a few dozen copies in a nominal blood draw. In assays with limit of detection claims down to 0.1% sensitivity, there may only be 5 copies present to detect in that sample. Assay developers need reliable and consistent reference materials to help them establish their assays with the needed level of sensitivity and specificity.

The Seraseq Circulating Tumor DNA-I Reference Material is a 170bp biosynthetic DNA mix of nine actionable mutations titrated to specific mutant allele frequencies, ranging from 5% down to 0.1% in a background of wild-type genomic DNA (gDNA). The mix is stabilized and formulated into a commutable, plasma-like matrix. In this format, this material can be treated like a full-process reference material, going through all of the processing steps that a sample would undergo whether via next-generation sequencing (NGS), real-time quantitative PCR (qPCR) or digital PCR (dPCR).

For assay development and analytical validation needs, where purified nucleic acid is preferable, the Seraseq Circulating Tumor DNA-I Mutation Mix Kit is available as a set of five individual allele frequencies (5%, 1.2%, 0.6%, 0.1% and WT for 'wild-type').

"Given the great interest in detecting and characterizing circulating nucleic acids, there is a definite need for full-process reference materials that can be highly multiplexed for mutations of interest and are also very reproducible," said Dale Yuzuki, Director of Market Development from SeraCare Life Sciences.

"These ctDNA mimetics provide laboratories highly commutable material with which to precisely monitor assay performance. The Seraseq biosynthetic technology is very powerful and flexible, capable

of accommodating any number of mutations and allelic frequencies, providing excellent, high-quality tools for anyone developing, analytically validating or tracking daily performance of a ctDNA assay.”

At the Molecular Tri-Conference in San Francisco, SeraCare will also be presenting the first data from an Inter-Laboratory Study using the Seraseq Solid Tumor Mutation Mix as well as data from an evaluation of the Seraseq HIV Drug Resistance Reference Material on an NGS platform. Launched in 2015, the Seraseq Solid Tumor Mutation Mix is a set of 26 biosynthetic actionable mutations at tunable allele frequencies, representing over 350 independent runs from seven laboratories across enrichment methods and sequencing platforms. “This is the first study of its kind, to use the same ground truth materials at fixed minor allele frequencies, to explore the many variables that can impact the results of these NGS-based oncology panels” said Dr. Russell Garlick, CSO of SeraCare Life Sciences. He presents this work in a plenary session Wednesday, March 9 entitled “NGS-Based Diagnostics: Developing Assays and Monitoring Performance Using Novel Biosynthetic QC Tools”.

More information about these products and SeraCare’s activities at the Molecular Medicine Tri-Conference can be found on SeraCare’s [event page](#) and ‘Precision Genomics’ [blog](#).

About SeraCare Life Sciences Inc.

SeraCare enables the promise of precision medicine by advancing the understanding of disease and providing assurance of the diagnostic result. Our innovative tools and technologies not only provide assurance of the safe, effective, and accurate performance of diagnostic assays but also establish a framework for regulating, compiling, and interpreting data from precision diagnostics. Our portfolio includes a broad range of products such as quality control technologies, disease-state specimens and tissues for research and development, processed biological materials, and immunoassay reagents. For more information, please visit www.seracare.com and follow SeraCare on Twitter ([@SeraCare](https://twitter.com/SeraCare)).