



For Immediate Release

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SeraCare Launches Expanded Offering of Biosynthetic Somatic Tumor Reference Materials for NGS-based Tumor Profiling Assays

Broader array of 'hard-to-sequence' mutations at challenging allelic frequencies for assay validation and daily performance monitoring

Milford, Massachusetts, April 18, 2016 - SeraCare Life Sciences, a manufacturer and leading partner to global *in vitro* diagnostics manufacturers, today announces at the American Association for Cancer Research the launch of an expanded product line to support Next-Generation Sequencing (NGS)-based somatic tumor profiling assay development, validation, and QC performance monitoring. The Seraseq™ Solid Tumor Mutation Mix family of products is the [latest offering](#) of SeraCare's biosynthetic reference material technology meant to provide an even wider breadth of actionable mutation types for laboratories that are in the midst of validating or running comprehensive gene panels.

The eight (8) new [Seraseq Solid Tumor Mutation Mix-II \(STMM-II\)](#) products now contain 40 total 'hard-to-sequence' somatic variants with increases in the number of insertion-deletion mutations (INDELS) from 4 to 13 to challenge both the sequencing and variant calling algorithms. There is also the addition of 2 DNA-level structural variants of actionable gene fusions.

In addition to the wide variant coverage, SeraCare has provided the STMM-II at 4%, 7% and 10% allelic frequencies making it an ideal format for labs looking to test a nominal assay limit of detection (LOD) set at 5%. Moreover, due to the inherently flexible nature of the technology, SeraCare is now providing a single-tube blended reference material format containing all 40 variants in a tri-level configuration with mutations at one of 10%, 7% or 4% allelic frequencies. This innovative configuration will enable labs to gain much more detailed performance tracking information when running their genomic sequencing panels or for interlab proficiency testing. The Seraseq STMM-II products are available in two concentrations to facilitate laboratories' input DNA requirements.

"Highly multiplexed assays like NGS-based gene panels require highly multiplexed reference materials", says Russell Garlick, CSO of SeraCare Life Sciences. "The Seraseq Solid Tumor Mutation Mix-II offers laboratories the broadest array of actionable variants at assay relevant allelic frequencies on the market today. With increasing industry focus on validation and characterization data, laboratories have told us they want better options for their analytical validation and performance monitoring needs. "

The new [Solid Tumor Mutation Mix-II](#) products are part of an ever growing portfolio of critically important products for better validation and characterization of NGS-based assays from SeraCare Life Sciences.

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 ensure 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)).