

For Immediate Release**Company Contact:**

Kimberly Anderson
SeraCare Life Sciences, Inc.
508.244.6429
KAnderson@seracare.com
www.seracare.com

Agency Contact:

Shannon Meirzon
Pyxis Communications
203.550.5978
Shannon@pyxiscommunications.com
www.pyxiscommunications.com

SeraCare Life Sciences' Precision Medicine Unit Launches New Product to Ensure Accuracy of NGS Assays

Milford, Massachusetts, July 8, 2015 – SeraCare Life Sciences, a leading partner to global in vitro diagnostics manufacturers, today announced that the company's new precision medicine business unit has launched its first product, the [Seraseq™ Solid Tumor Mutation Mix—I \(AF20\)](#); a biosynthetic reference material designed to evaluate the performance of next generation sequencing (NGS)-based tumor profiling assays. This product contains a mixture of mutations in key oncogenes and tumor suppressor genes and is intended as a quality material for translational and disease research testing. In addition, it permits laboratories to monitor library preparation, sequencing and variant allele detection under a given set of bioinformatics pipeline or parameters. It is currently for research use only.

Clinical laboratories that have adopted next-generation sequencing for somatic mutation detection typically maintain their own pre-diluted mixtures of characterized cell-line DNA, which is labor intensive, inconsistently characterized and of unknown stability and variability. A well-designed quality control program is critical for providing reliable results obtained for unknown specimens. The use of independent reference products may provide valuable information concerning assay sensitivity and bioinformatics pipeline analysis.

“SeraCare’s extensive background and experience with the manufacture of quality reference and validation materials under cGMP ISO® standards has enabled us to develop the Seraseq™ Solid Tumor Mutation Mix,” says Russell Garlick, Chief Scientific Officer at SeraCare. “This technology allows almost unlimited breadth of mutations and can be accurately ‘tuned’ to specific allelic frequencies because we’ve incorporated digital PCR in the manufacturing. With this product, we can partner with *in vitro* diagnostics developers and clinical labs to offer a powerful performance tracking tool for their NGS tumor profiling assays.”

Seraseq™ Solid Tumor Mutation Mix is a mixture of biosynthetic target genes with specific engineered mutations in a wild-type background of well-characterized genomic DNA, and is compatible with all major cancer hotspot oncology panels and NGS platforms on the market today. With a novel internal quality marker, Seraseq™ Solid Tumor Mutation Mix makes it simple to analyze and monitor potential laboratory contamination levels over time. This first version includes 26 major cancer ‘hotspot’ genes, all at 20% allelic frequency and quantitated using digital PCR to ensure highest accuracy. It is stable for two

years under recommended storage conditions, and can undergo ten freeze-thaw cycles without any degradation of performance.

“We are fully dedicated to building on our investments in precision driven diagnostics through technology developments and strategic partnerships. The Seraseq™ Solid Tumor Mutation Mix is just the first of many [precision medicine products](#) that SeraCare has in development and we look forward to continuing our commitment to bringing new technologies and tools to our customers,” says Charlie Mamrak, CEO, SeraCare.

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](#)).

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