



For Immediate Release

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SeraCare Life Sciences Announces Early Access Programs for ctDNA and RNA Fusion Reference Materials

Milford, Massachusetts, Nov 3, 2015 - SeraCare Life Sciences, a leading partner to global *in vitro* diagnostics manufacturers and clinical diagnostics laboratories announces two important development milestones to their growing portfolio of next-generation sequencing (NGS)-based tools for Precision Medicine. Early access programs for the first commercial, novel circulating tumor DNA (ctDNA) reference materials and multiplex RNA fusion reference materials are part of SeraCare's participation at this week's Association for Molecular Pathology (AMP) annual meeting in Austin, Texas, November 5th-7th.

SeraCare's ctDNA reference materials are based upon patent-pending technology previously disclosed as part of the first-ever circulating fetal DNA reference materials developed for [non-invasive prenatal testing \(NIPT\)](#). SeraseqTM ctDNA products are mixtures of size-appropriate fragments of DNA containing key somatic mutations at specific allelic frequencies in a fragmented gDNA background, stabilized in a proprietary synthetic plasma matrix. The first ctDNA product available for early access is a five mutation mixture at varying allele frequencies from 10% down to 1%. The circulating nucleic acid technology is robust and highly amenable to customization, and can support any number of mutations and allele frequencies down to 0.01% quantitated using digital PCR (dPCR). The combination of design and stabilization technology results in a highly precise and reproducible 'ground truth' material suitable for NGS and dPCR assay development and performance monitoring.

The RNA-fusion reference material technology will address a key market need for validated and reproducible oncology gene fusions for the growing list of NGS-based assays detecting these important variants within many solid tumors. The SeraseqTM FFPE RNA Fusion Reference Material will cover twelve fusion RNAs within formalin-fixed, paraffin-embedded cells, suitable as a full process reference material in the development and validation of NGS-based RNA fusion assays. The fusion RNA reference materials are stable and can be adjusted to varying expression levels to suit any assay need and also are customizable to support a variety of assay requirements.

"We are excited to have achieved our development milestones for these two very important products for the clinical oncology assay developer" said Charlie Mamrak, CEO of SeraCare Life Sciences. "The

advances being made in the clinic, driven by the availability of new targeted therapies, are requiring novel tools that support the development of these advanced diagnostics. SeraCare's Seraseq™ Circulating Tumor DNA and FFPE RNA Fusion Reference Materials will provide manufacturers and CLIA-certified laboratories the necessary reagents to hasten the development and characterization of their assays."

SeraCare's Precision Medicine business unit has previously announced novel Seraseq™ reference material technologies for NGS-based assays for [solid tumor profiling](#), [NIPT](#), and [HIV drug resistance](#).

"Our company's goal is to provide developers and testing laboratories Precision Medicine reference materials that are authentic, highly precise and reproducible" said Trevor Brown, Vice President of SeraCare's Precision Medicine business unit. "We have a 30 year history as the leading company developing patient-like materials that enable our customers to gain the most information about their assay's performance, and to trust in the validity of the result."

SeraCare will be presenting preliminary product data along with interim study results from an inter-laboratory study using its previously released Seraseq™ Solid Tumor Mutation Mix-I products on AMP Corporate Workshop Day, [Wednesday, November 4th](#).

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](#)).