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 Signs CRADA with NCI to Advance Cancer Diagnostics

Milford, Massachusetts, June 26, 2015 – SeraCare Life Sciences, a leading partner to global in vitro diagnostics manufacturers, today announced that it has signed a Cooperative Research and Development Agreement (CRADA) with the National Cancer Institute (NCI), part of the National Institutes of Health, to create reference materials and positive controls for cancer assays. The CRADA will investigate the development of methods to mix and accurately quantitate control DNA biosynthetics spiked into a genomic DNA background and cell-free circulating tumor DNA (ctDNA) for next-generation DNA sequencing (NGS) applications.

The principal goal of the CRADA is to develop positive control reference materials and mixes to be used to identify clinically relevant somatic mutations from tumors sequenced on NGS platforms. The control materials may provide benefit to the scientific community as they could be used as quality control materials which could help determine an assay's ability to detect multiple oncogenic mutations. These new materials will also be tested to demonstrate that similar results can be obtained between methods, platforms or testing sites.

Under the CRADA, P. Mickey Williams, Ph.D., Director, Molecular Characterization Lab at the NCI, and Russell Garlick, Ph.D., Chief Science Officer at SeraCare, will serve as the lead scientists for the study.

"Together with our NCI collaborator, SeraCare's molecular development and GMP-driven manufacturing capabilities, we believe the research programs under the CRADA have the potential to accelerate the development and widespread use of quality controls to help ensure the correct mutational profiles are reported for patients suffering with advanced stage malignancies. This agreement, along with SeraCare's recent investments to expand laboratory and manufacturing space at our new Molecular Diagnostics Center of Excellence, will help advance our goal of enabling precision medicine." said Dr. Garlick.

There are currently few widely accepted standards for multi-analyte based diagnostic assays such as NGS. The ability to compare the accuracy of different types of NGS assay results and to monitor performance over time and between laboratories is hampered by the lack of data on the utility of such standards. The NCI has developed a number of control DNAs and has tested mixes of 13, 27 or 56 biosynthetic constructs on an R&D scale. This CRADA will explore a number of scientific questions relating to formulating new strategies to develop controls/reference standards for oncology-based assays.

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).