

## SeraCare and NIST partner, 8/16

**August 2016**—SeraCare Life Sciences and the U.S. Department of Commerce National Institute of Standards and Technology have signed a three-year cooperative research and development agreement (CRADA) to advance the development of circulating tumor DNA diagnostic assay reference standard materials.

SeraCare's ctDNA reference materials are mixtures of size-appropriate fragments of DNA containing highly multiplexed numbers of somatic driver mutations produced at very specific allele frequencies in a defined, fragmented genomic DNA background from a single individual then stabilized and blended into a synthetic plasma-like matrix under proprietary technology. This material can be treated just like a patient sample run through the full extraction and analysis process and can be used to determine analytical performance of a ctDNA molecular assay down to as low as 0.1 percent allele frequency.

Under the terms of the agreement, SeraCare will provide its Seraseq ctDNA Reference Material technology to NIST for development of digital PCR measurement methodologies, and NIST will facilitate a wider distribution of these materials to anonymized laboratories for interlaboratory comparisons. The joint efforts are meant to hasten the development of calibrated reference standards for circulating tumor DNA.

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