



For Immediate Release

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SeraCare Launches Industry's First Recombinant Virus Technology-based AccuPlex™ Zika Reference Material

Milford, Massachusetts, May 09, 2016 - SeraCare Life Sciences, a manufacturer and leading partner to global in vitro diagnostics manufacturers, today announces the launch of [AccuPlex Zika Reference Material](#) to fast track the development and validation of PCR-based Zika virus assays. Based on SeraCare's patent-pending AccuPlex recombinant virus technology, AccuPlex Zika Reference Material provides a safe, non-replicative, and fully-extractable positive material which covers the entire Zika virus genome.

In the spring of 2015, an outbreak of the mosquito-borne Zika virus occurred in Brazil. Since that time, the virus has gained global attention due to its rapid spread through at least 21 countries. Within infected areas, Zika has been linked to microcephaly, a neurological birth defect, as well as the possible cause for an increase in adult Guillain-Barré syndrome cases. In response to this outbreak, diagnostic laboratories and test developers have an accelerated need to develop and validate molecular diagnostic assays, which require stable and reproducible manufactured positive reference materials.

Utilizing [AccuPlex recombinant virus technology](#), SeraCare's Zika reference material contains the entire RNA genome of the ZIKV 2007 strain in four separate overlapping virus constructs. This product is formulated at $\sim 1.0E+05$ copies/ml in 0.25ml of defibrinated human plasma; the copy number is assigned based on results from a digital PCR assay developed in-house. As a recombinant virus product, AccuPlex Zika Reference Material utilizes a mammalian RNA virus that closely mimics the Zika virus in both size and complexity. Ongoing accelerated and real-time stability studies indicate that AccuPlex recombinant viruses are stable at room temperature for at least 20 months and at 4 °C for at least two years.

"We have developed and manufactured this plasma-based product in just a matter of weeks by leveraging our scalable, recombinant virus technology," says Dr. Bharathi Anekella, Vice President of Research and Development at SeraCare Life Sciences. "As a result, we have provided assay developers, such as [Siemens Healthineers](#), a reliable source of safe, positive material to aid in the development of their Zika virus assays." Siemens developed their PCR assay (RUO) to test for the presence of the Zika virus prior to the development of antibodies.

In addition to assay development, [AccuPlex Zika Reference Material](#) is an ideal product for public health agencies around the globe to implement training, interlab studies, and proficiency programs. As a safe,

non-infectious, positive reference material, this product is part of an ever growing portfolio of critically important products from SeraCare for better validation and characterization of emerging molecular 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 provide assurance of 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)).