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## Cerilliant Introduces New Multi-Component Reference Solutions for Drug Interference Testing

ST. LOUIS – September 15, 2015 – Sigma-Aldrich Corporation (NASDAQ: SIAL) today announced that the Cerilliant<sup>®</sup> brand within its Applied Diagnostics and Testing business segment now offers the first-ever reference solutions for qualitative evaluation of drug interferences in a testing laboratory's analytical methods. These seven multi-component solution mixes contain more than 50 of the most routinely monitored over-the-counter (OTC) and prescription drugs. Cerilliant offers the seven mixes separately or as a kit for added convenience.

Regulations for drug bioanalysis, including the Clinical Laboratory Improvement Amendments (CLIA), as well as the US FDA Bioanalytical Method Validation Guidance, state that manufacturers of laboratory-developed tests (LDTs) must determine the effect of interfering substances during design, development, and validation of an analytical method.<sup>1,2</sup> The presence of interfering substances, which often includes drugs and their metabolites, impacts measurement accuracy of the analyte of interest.<sup>1,2</sup> Interfering compounds originate from many sources including sample matrix, contaminants inadvertently introduced during handling or sample preparation, and samples from patients on multiple drug regimens.<sup>1,2</sup>

The importance of identifying interfering substances is critical for numerous testing applications ranging from therapeutic drug monitoring (TDM), confirmatory drug testing, and forensic analysis to bioavailability (BA)/bioequivalence (BE) and pharmacokinetic (DMPK) studies.

To learn more about this new offering, visit Cerilliant Reference Materials.

**About Cerilliant:** Cerilliant Corporation, located in Round Rock, Texas, is a global leader in providing certified reference standards for critical applications. The company has been providing Certified Reference Materials for more than 35 years. Cerilliant offers more than 3,000 catalog products and a full range of custom products and services that address the stringent and complex requirements of the pharmaceutical, clinical diagnostic, clinical/forensic toxicology, and natural products industries. Cerilliant sustains a modern, robust quality system, which incorporates cGMP, GLP, and ISO requirements. The company is accredited to ISO Guide 34 and ISO/IEC 17025, is certified to ISO 13485 and ISO 9001, and is compliant with ISO 15194. Cerilliant Corporation is a subsidiary of Sigma-Aldrich.

For more information about Cerilliant, please visit www.cerilliant.com.

**About Sigma-Aldrich:** Sigma-Aldrich, a leading Life Science and Technology company focused on enhancing human health and safety, manufactures and distributes 250,000 chemicals, biochemicals and other essential products to more than 1.4 million customers globally in research and applied labs as well as in industrial and commercial markets. With three distinct business units - Research, Applied and SAFC Commercial - Sigma-Aldrich is committed to enabling science to improve the quality of life. The Company operates in 37 countries, has approximately 9,700 employees worldwide and had sales of \$2.79 billion in 2014.

For more information about Sigma-Aldrich, please visit its website at <a href="www.sigma-aldrich.com">www.sigma-aldrich.com</a>.

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- 1. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2901657/
- 2. <a href="http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm368107.pdf">http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm368107.pdf</a>