

NEWS RELEASE

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Cerilliant Introduces New Antifungal Certified Spiking Solutions®

ROUND ROCK, TEXAS – December 9, 2013 – Cerilliant introduces new antifungal Certified Spiking Solutions® of fluconazole, itraconazole, voriconazole, posaconazole, 5-fluorocytosine and ketoconazole at a 2.0 mg/mL concentration. These Certified Reference Materials (CRMs) are suitable as Snap-N-Spike® starting materials in preparation of calibrators, controls, or linearity standards for LC-MS/MS testing of antifungals in therapeutic drug monitoring (TDM) or other critical clinical and diagnostic testing applications.

The development of LC-MS/MS methods for TDM of antifungals has increased the need for highly accurate CRMs. Accuracy in concentration of the calibrator or control is dependent on proper certification of the reference material for chromatographic and other residual impurities including water, solvent, and inorganics. Insufficient characterization and/or use of low purity research grade materials in place of CRMs can potentially result in incorrect therapeutic reference ranges and negatively impact clinical outcomes. Lot-to-lot differences in purity of the reference material or its impurity profile can also impact the test's accuracy and reproducibility if not properly accounted for.

Josh Cooper, PhD, Cerilliant's supervisor for Analytical R&D states "calibrators for LC-MS/MS methods are critical to the accuracy of results and must be carefully evaluated. It is important to use fully characterized materials to properly adjust for any chromatographic or residual impurities present. At Cerilliant, we are very sensitive to the intended use of our Certified Spiking Solutions® and characterize our CRMs accordingly."

Cerilliant Certified Spiking Solutions® are prepared and certified to the highest industry standards including ISO Guide 34, ISO 17025, and ISO 13485. Cerilliant reference solutions are manufactured using a validated process that ensures the highest level of accuracy for critical quantitative applications from TDM, diagnostic testing and endocrinology, to toxicology, forensic testing, and clinical chemistry. Cerilliant offers a comprehensive listing of parent drug, metabolite, and internal standard Certified Spiking Solutions® for clinical applications such as immunosuppressants, vitamins including 25-hydroxyvitamin D, steroids and hormones, catecholamines, cardiac drugs, antidepressants, and pain management drugs.

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 over 30 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, natural products, and environmental industries. Cerilliant sustains a modern, robust quality system, which incorporates cGMP, GLP, and ISO requirements. We are accredited to ISO Guide 34 and ISO/IEC 17025, certified to ISO 13485 and ISO 9001:2008, and are compliant with ISO 17511 and ISO 15194.

Cerilliant Corporation is a subsidiary of Sigma-Aldrich[®]. For more information about Cerilliant, please visit <u>www.cerilliant.com</u>.

1.) Marek B, Cooper J, Dilek I, Rettinger M, Kirkovits G, Chen W, Ying Y, Sreenivasan U, Crawford M, Holmquist B, Grant R. Accurate Reference Standards for Accurate Quantitation of Thyroid Hormones: Impact on Clinical Reference Ranges. Presented at Mass Spectrometry: Applications to the Clinical Lab, San Diego, CA, February 2013. Accessed November 5, 2013 from: http://www.cerilliant.com/Shoponline/OpenDocument.aspx?DocumentId=177