



NEWS RELEASE

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Cerilliant Introduces ^{13}C -Labeled Internal Standards for Hormone Analysis by LC-MS/MS

ROUND ROCK, TEXAS – September 29, 2011 – Cerilliant introduces Certified Spiking Solutions[®] of Testosterone-2,3,4- $^{13}\text{C}_3$ for monitoring serum testosterone levels in men, women, and children by LC-MS/MS and Androstene-3,17-dione-2,3,4- $^{13}\text{C}_3$ for newborn screening and doping analysis. These products offer clinical and endocrinology labs additional options in selecting the internal standard most suitable for their hormone testing methods and manufactured under a quality system that is ISO Guide 34 and ISO 17025 accredited, ISO 13485 and ISO 9001 certified, and incorporates FDA's cGMP requirements. These fully certified Snap-N-Spike[®] solutions are provided at a concentration of 100 $\mu\text{g}/\text{mL}$ in acetonitrile.

The Centers for Disease Control (CDC) Hormone Standardization Project address challenges in testosterone testing including lack of data comparison across measurement systems and the lack of appropriate assay performance at the low concentrations observed in women and children.¹ They cite Testosterone-2,3,4- $^{13}\text{C}_3$ as the internal standard of choice for the measurement of steroids at low concentrations in biological fluids by LC-MS/MS. For these analyses, ^{13}C labeled internal standards can eliminate potential issues of isotopic exchange and minimize separation of later-eluting analytes from a higher substituted deuterium-labeled internal standard. Acetonitrile was chosen for its ease of handling and miscibility with water and biological specimens.

According to Dr. Uma Sreenivasan, Cerilliant's Chief Science Advisor, "the introduction of LC-MS/MS has created a new challenge for designing appropriate stable-labeled reference materials. LC-MS/MS transitions and fragmentation must be considered in selection of label location for internal standards. As methods move to lower sensitivity requirements, a viable product is delicate balance between sufficient mass enrichment for use as an internal standard and too much mass enrichment resulting analytical challenges due to chromatographic

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separation of internal standard and parent analyte. At Cerilliant we are committed to continued development of innovative products to support the ever-changing needs of our customers.”

Cerilliant offers a wide selection of Certified Spiking Solutions® for use in clinical testing, endocrinology, toxicology, and therapeutic drug monitoring including Snap-N-Spike® solutions of vitamin D, immunosuppressants, catecholamines, steroids and hormones, pain-management drugs, and ethanol (blood alcohol), from parent drugs and metabolites to internal standards.

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 2,800 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, and certified to ISO 13485 & ISO 9001.

Cerilliant Corporation is a subsidiary of Sigma-Aldrich®. For more information about Cerilliant, please visit www.cerilliant.com.

¹<http://www.cdcfoundation.org/what/program/testosterone-measurement-harmonization>

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