

October 13, 2016

## **MilliporeSigma Introduces First Certified Spiking Solution<sup>®</sup> of Heavy Labeled Thyroglobulin Protein**

- **First to represent Cerilliant<sup>®</sup> portfolio in reference standards of endogenous protein biomarkers**
- **Suitable for critical diagnostic testing applications by liquid chromatography, mass spectrometry**

Billerica, Massachusetts, October 13, 2016 — [MilliporeSigma](#) today introduced the first Certified Spiking Solution<sup>®</sup> of intact, heavy labeled Thyroglobulin (Tg) in SigMatrix<sup>®</sup>, a synthetic surrogate serum. The matrix-based reference material is suitable as an internal standard for the quantification of Tg levels by LC-MS/MS methods to ensure accurate, identifiable and quantifiable clinical diagnostic testing. MilliporeSigma's solution-based product is the first endogenous protein biomarker of the extensive Cerilliant<sup>®</sup> portfolio.

Measurement of patient Tg levels is primarily performed to monitor differentiated thyroid carcinoma recurrence following therapy.<sup>1</sup> Quantification of Tg levels is also useful in determining the cause of hyperthyroidism and for monitoring treatment effectiveness in Graves disease.<sup>1</sup>

Anti-Tg autoantibody (TgAb) is present in about 25 percent of thyroid cancer patients and can interfere with Tg immunoassays (IA), causing false-negative results.<sup>2,3</sup> Quantitative mass spectrometry-based analysis of Tg concentrations in serum is the preferred assay for measuring Tg in TgAb positive patients.<sup>2,3</sup> Recent studies suggest that reflex testing of Tg levels by LC-MS/MS following a positive IA test for TgAb can lead to substantial cost savings as a result of improved test utilization.<sup>2</sup>



## News Release

Cerilliant® Certified Spiking Solutions® are manufactured using validated processes to ensure the highest level of accuracy for critical quantitative mass spectrometry-based applications. The portfolio spans from therapeutic drug monitoring, diagnostic testing, clinical chemistry and endocrinology to pharmaceutical research, clinical toxicology, and forensic analysis. MilliporeSigma offers parent drug, metabolite, endogenous biomarker and internal standard Certified Spiking Solutions® for clinical and diagnostic testing applications which includes omega-3 and omega-6 fatty acids, bile acids, catecholamines, vitamins, immunosuppressants, cardiac drugs, antiretrovirals and antifungals to hormones including male, female, neonatal, thyroid and hydroxyvitamin D.

### References

1. <https://labtestsonline.org/understanding/analytes/thyroglobulin/tab/test>
2. [http://arup.utah.edu/media/shortTopics/aacc15\\_straseski/Straseski-AACC2015-Tg%20by%20MSv11.pdf](http://arup.utah.edu/media/shortTopics/aacc15_straseski/Straseski-AACC2015-Tg%20by%20MSv11.pdf)
3. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4016991/>

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### About the Life Science Business of Merck KGaA, Darmstadt, Germany

The life science business of Merck KGaA, Darmstadt, Germany, which operates as MilliporeSigma in the U.S. and Canada, has 19,000 employees and 65 manufacturing sites worldwide, with a portfolio of more than 300,000 products enabling scientific discovery. Udit Batra is the global chief executive officer of MilliporeSigma.

Merck KGaA, Darmstadt, Germany completed its \$17 billion acquisition of Sigma-Aldrich in November 2015, creating a leader in the \$125 billion global life science industry.

Merck KGaA of Darmstadt, Germany is a leading company for innovative and top-quality high-tech products in healthcare, life science and performance materials. The company has six businesses – Biopharmaceuticals, Consumer Health, Allergopharma, Biosimilars, Life Science and Performance Materials – and generated sales of €12.85 billion in 2015. Around 50,000 employees work in 66 countries to improve the quality of life for patients, to foster the success of customers and to help meet global challenges.

Merck KGaA, Darmstadt, Germany is the world's oldest pharmaceutical and chemical company – since 1668, the company has stood for innovation, business success and responsible entrepreneurship. Holding an approximately 70 percent interest, the founding family remains the majority owner of the company to this day. Merck KGaA, Darmstadt, Germany holds the global rights to the name and the trademark "Merck" internationally except for the United States and Canada, where the company operates as EMD Serono, MilliporeSigma and EMD Performance Materials.