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MilliporeSigma Introduces New Calibration Kit for In Vitro Diagnostic Use

- **First CE-marked calibration kit for more sensitive testosterone measurement in men, women and children**
- **Wide analytical range offers increased accuracy at low levels**

Billerica, Massachusetts, January 13, 2017 — [MilliporeSigma](#) today announced the introduction of its new testosterone calibrator kit for in vitro diagnostic (IVD) use. The certified kit allows users to calibrate assays and verify calibrations, and is the first of its kind to receive CE mark approval, indicating compliance with the European Union's Medical Device Directive. The CE mark allows the kit to be marketed and sold in the European Union and in any country recognizing CE mark approval.

The diagnostic range of the new kit encompasses both male and female testosterone clinical reference ranges. The kit's broad reference range enables ample analytical sensitivity for accurate testing using new mass spec-based methods, from the lowest levels needed for testing of women and children to the highest levels used in testing of men. The new calibration kit delivers more accurate and consistent test results for more reliable clinical diagnosis and monitoring. Traditional immunoassays used for measuring testosterone levels in patient samples can be inaccurate and deliver inconsistent results, especially at the low levels present in women and children.

The kit is manufactured and tested under the most stringent international quality standards, assuring calibration accuracy. The calibrator kit includes a set of 10 levels of testosterone serum concentration standards ranging from 2-2,000 ng/dL, along with a blank and internal standard.





News Release

MilliporeSigma's portfolio of Cerilliant® certified reference materials are used to validate analytical measurement methods and calibration, and are manufactured and authorized to ensure the highest level of accuracy. Solutions are used in quantitative mass spectrometry-based applications that range from diagnostic testing and endocrinology to therapeutic drug monitoring, forensic analysis, clinical toxicology and pharmaceutical research. MilliporeSigma manufactures a comprehensive list of parent drug, metabolite, endogenous biomarker and internal standard Certified Spiking Solutions® used for clinical diagnostic test applications of steroids and hormones, biogenic amines, hydroxyvitamin D, bile acids, fatty acids, vitamins, immunosuppressants, antifungals and cardiac drugs.

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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, 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. The company 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.