PRESS RELEASE

CeGaT Obtains CLIA Certification, Final Step Towards U.S. Market Entry

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Tübingen, Germany – CeGaT GmbH, a leading global genetic testing provider focused on large panel and trio-exome diagnostics, has obtained its CLIA certification.

After receiving CAP accreditation in 2016, CeGaT has been granted Clinical Laboratory Improvement Amendments (CLIA) certification by The Centers for Medicare & Medicaid Services (CMS), ensuring compliance with all standards required to process Human DNA samples originating from the United States. Dr. Eva Oberhettinger, Senior Quality Manager at CeGaT, states: “Receiving CLIA certification underscores the high quality standards of our laboratory and confirms the high accuracy and reliability of CeGaT’s proprietary genetic tests.”

The CLIA certification marks an important milestone for the company. CeGaT’s subsidiary B. Braun CeGaT LLC, based in Pennsylvania, will be responsible for U.S. operations. The company’s management expects accelerated growth for the years ahead. Managing Director Dr. Dirk Biskup: “The CLIA accreditation is a recognition and confirmation of our industry-leading quality systems. The whole CeGaT team is aware that we are handling human samples and that a fast and correct diagnosis is of utmost importance for the patient. With CLIA we are now looking forward to expanding our business in the United States.”

Additional to CLIA and CAP, CeGaT is accredited according to DIN EN ISO 15189:2014 since 2011. The company’s portfolio now comprises all important accreditations and certifications necessary to distribute its human genetics services around the globe.

About CeGaT

CeGaT GmbH, Tübingen (Germany), was founded by Saskia Biskup, MD, PhD, and Dirk Biskup, PhD, in 2009. The basis of CeGaT’s success is an established high-throughput process for the use of next generation sequencing (NGS) in diagnostic testing and the up-to-date knowledge of hereditary genetic diseases. CeGaT is a diagnostics company which is renowned for identifying the pathogenic gene variations in patients. Single gene testing (which was state-of-the-art until 2010) would not detect the causative gene variation in 80-90% of all cases. Consequently, CeGaT has invented and established Diagnostic Panels. By simultaneously sequencing all genes associated with a certain disease using next-generation sequencing platforms, the probability of finding the causative gene variation is extremely high. In addition, this approach is much faster and considerably less expensive than classical gene-by-gene sequencing. CeGaT has more than 120 employees and a subsidiary company B. Braun CeGaT, LLC in the United States. CeGaT also is involved in the following companies: CeMeT GmbH (Center for Metagenomics), CAG GmbH (Center for Animal Genetics) and Cenata GmbH (prenatal diagnosis).