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KCAS Bioanalytical and Biomarker Services Now Offers Ultra-Sensitive Validated Assay for Nicotine Studies

KCAS Bioanalytical and Biomarker Services, a leading functional service contract research organization (CRO) has validated a 0.2 ng/mL lower limit (LLOQ) assay for nicotine and two key metabolites cotinine and trans-3'-hydroxycotinine in plasma. Previously having validated a 0.5 ng/mL LLOQ assay, the ultra-low trace nicotine assay meets additional needs of tobacco industry that need to detect trace levels to evaluate risk of tobacco products in development. Sample contamination from the environment presents a major concern since nicotine is ubiquitous. To be able to accomplish the assay sensitivity, KCAS customized a secondary location lab space on a smoke-free campus approximately 15 minutes from our Headquarters. This permits lowering the background levels of nicotine to trace levels. "The ability to quickly respond to industry's growing needs for this service is further evidence of KCAS' commitment to investment in capabilities and expertise," stated John Bucksath CEO. "Our recent expansion of a new laboratory site and increasing our team of experts has positioned KCAS well to serve customers in this space."

KCAS has formed clinical partnerships that have established relationships with both tobacco and e-cigarettes companies to provide clients with a one-stop shop to alleviate bottleneck issues resulting from an insufficient capacity and ability of labs able to validate these assays and measure nicotine at low levels without ongoing contamination. Time is of critical importance to clients. The FDA's Center for Tobacco Research (CTR) has mandated every product on the market including e-cigarettes, pipe and hookah tobacco, dissolvable tobacco projects, cigars, smokeless tobacco and 'novel and future tobacco products' conduct clinical studies and submit exposure data to the FDA in order to be able to continue to sell products after August 2018. Beyond the FDA, regulatory requirements for reduced exposure and modified risk tobacco products (MRTPs) are evolving globally.

"KCAS has been approached multiple times to help support nicotine studies, we then evaluated the business case before launching into this market. We knew it wouldn't be easy, but were confident that our experience with endogenous and high-sensitivity assays would lead to our success. We're ready to do business to both tobacco and e-cigarette companies to help them meet the timelines mandated by the FDA. We're flexible and excited to present a new, affordable option for companies who have had limited choices in the past." stated Gene Ray, Senior Scientific Advisor.

About KCAS

KCAS Bioanalytical & Biomarker Services is a contract laboratory with 37+ years of bioanalytical expertise. Centrally located in Kansas City, KCAS provides small- and large-molecule PK, immunogenicity, and biomarker analysis operating a variety of equipment platforms to service a wide range of therapeutic areas. KCAS' team leverages a highly scientific staff with an average tenure of 14 years at the company to provide clients of all sizes with expertise in robust assay development, validation, and sample analysis under fit-for-purpose Non-GLP or regulated (GLP/GCP) conditions for discovery, preclinical and clinical studies. Our teams have developed and validated more than 5,500 bioanalytical assays and have undergone 16 FDA inspections.

Learn more at: http://www.kcasbio.com