



DNA Genotek Inc. Receives CE-IVD Mark for its OMNIgene®•GUT Microbiome Collection Kit

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OTTAWA, ON, July 7, 2015. DNA Genotek, a leading provider of sample collection kits and end-to-end services and a subsidiary of OraSure Technologies, Inc. (Nasdaq: OSUR) today announced that its OMNIgene®•GUT microbiome collection kit has received CE-IVD marking through completion of a comprehensive technical validation and self declaration under the European Directive for In Vitro Diagnostic Medical Devices.

The CE-IVD marked OMNIgene•GUT is an all-in-one system designed to enable an individual to easily self-collect high quality microbial DNA from feces/stool for gut microbiome profiling for use in clinical laboratory and research use settings. The product ensures that the fecal sample is fully stabilized immediately upon collection and maintains an accurate and reliable profile for weeks at room temperature. Current methodologies for gut microbiome profiling have distinct shortcomings due to the introduction of bias, leading to a lack of reproducibility in the field. OMNIgene•GUT will transform current microbiome testing to provide a more efficient and accurate system for optimizing patient testing.

"Receipt of the CE-IVD mark is indicative of the quality of the design and development of the OMNIgene•GUT collection kit," said Ian Curry, President, DNA Genotek Inc. "Achieving this regulatory milestone is a major step forward in assuring labs and clinicians that they can rely on OMNIgene•GUT to stabilize the sample at point of collection, resulting in optimal assessment and classification of the gut microbiome."

The CE-IVD marked OMNIgene•GUT collection kit is available in the European market immediately. The product is for research use only applications in the United States.

About DNA Genotek

DNA Genotek Inc., a subsidiary of OraSure Technologies, Inc. (NASDAQ: OSUR), focuses on sample collection kits and end-to-end services for human genomics, microbiome and infectious disease. The company's Oragene®Dx product line is the only U.S. FDA 510(k) cleared salivabased collection kit for in vitro diagnostic use. DNA Genotek also offers Research Use Only products to collect and preserve large amounts of DNA or RNA from multiple sample types for use with humans, animals or livestock. The reliability and ease-of-use of the company's products have resulted in rapid adoption at top-tier health research institutions globally, including Harvard, Stanford, Cambridge, and Johns Hopkins. DNA Genotek markets its products worldwide and has a global customer base with thousands of customers in over 100 countries. For more information about DNA Genotek, visit www.dnagenotek.com

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