



DNA Genotek Announces FDA General Use Clearance for Oragene®•Dx Family of Products

OTTAWA, ON, January 22, 2020 - DNA Genotek Inc., a leading provider of sample collection kits and end-to-end services and a wholly-owned subsidiary of OraSure Technologies, Inc. (NASDAQ: OSUR), announced today that the U.S. Food and Drug Administration (FDA) has granted a general use 510(k) clearance for its Oragene®•Dx family of products.

Oragene®•Dx is intended for use in the non-invasive collection of saliva samples for in vitro diagnostic testing of human DNA. Oragene®•Dx is now the first and only device with general clearance for collection and stabilization of DNA from saliva for use in genetic testing of human germline DNA, including prescription or over-the-counter (direct-to-consumer) use. Saliva samples collected using Oragene®•Dx are stabilized for use in downstream diagnostic testing applications and can be transported and/or stored long-term at ambient temperatures.

“With this 510(k) clearance, genetic test providers offering diagnostic testing can confidently use our product within their test protocols without having to provide information on Oragene®•Dx devices in their FDA submissions,” says Kathleen Weber, Executive Vice President Molecular Solutions. “This saves time and cost for diagnostic companies that want to leverage an FDA-cleared saliva collection device into their methodologies in addition to, or instead of, collecting blood samples. The clearance reinforces DNA Genotek’s commitment to quality, regulatory compliance – and our customers.”

About DNA Genotek

DNA Genotek Inc., a subsidiary of OraSure Technologies, Inc., focuses on providing high-quality biological sample collection products and end-to-end services for human genomics and microbiome applications. The Company's Oragene®•Dx and ORAcollect®•Dx product lines are the first and only FDA 510(k) cleared saliva-based DNA collection devices 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. 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.

About OraSure Technologies

OraSure Technologies empowers the global community to improve health and wellness by providing access to accurate, essential information. Together with its wholly-owned subsidiaries (DNA Genotek, CoreBiome, Diversigen and Novosanis), OraSure provides its customers with end-to-end solutions that encompass tools, services and diagnostics. The OraSure family of companies is a leader in the development, manufacture, and distribution of rapid diagnostic tests, sample collection and stabilization devices, and molecular services solutions designed to discover and detect critical medical conditions. OraSure’s portfolio of products is sold globally to clinical laboratories, hospitals, physician’s offices, clinics, public health and community-based organizations, research institutions, government agencies, pharma, commercial entities and direct to consumers. For more information on OraSure Technologies, please visit www.orasure.com.