OraSure's Oragene®•Dx Saliva Collection Kit Included in Industry's First FDA Authorization for a Whole Exome Sequencing Platform

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BETHLEHEM, Pa., Jan. 21, 2021 (GLOBE NEWSWIRE) -- OraSure Technologies, Inc. (NASDAQ: OSUR), a leader in point-of-care diagnostic tests, specimen collection devices, and microbiome laboratory and analytical services, today announced that its Oragene®•Dx (OGD-610) saliva collection device was included as a component in the De Novo authorization granted by the U.S. Food & Drug Administration (FDA) to Helix for their Helix® Laboratory Platform[1], a whole exome sequencing platform. This is the first exome sequencing-based platform authorized by the FDA. Oragene®•Dx is a product of OraSure's DNA Genotek subsidiary.

Oragene®•Dx (OGD-610) was also included as a component in the 510(k) clearance Helix received for its Helix® Genetic Health Risk App[2] for late-onset Alzheimer's Disease for over-the-counter use – the first test to be cleared on the Helix® Laboratory Platform.

"The inclusion of our Oragene®•Dx saliva collection device in the FDA authorization granted to Helix for the first and only whole exome sequencing platform highlights how genetic test providers offering diagnostic testing can confidently use our product within their protocols," 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 for both supervised (i.e. prescription) and unsupervised at home collection. The team at DNA Genotek congratulates Helix on this important work."

In 2020, Oragene®•Dx received U.S. Food and Drug Administration (FDA) general use 510(k) clearance and remains the first and only device with general clearance for collection and stabilization of DNA from saliva for use in genetic testing, 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.

"Now, more than ever, it's important to offer non-invasive, at-home sample collection for clinical testing," said Marc Laurent, VP of Operations and Partnerships, Helix. "DNA Genotek's product and support were an important part of our efforts to obtain FDA authorization. We are proud to have worked with the team at DNA Genotek and to include the Oragene®•Dx saliva collection device in our FDA authorization."

This FDA Authorization makes it possible for Helix and its partners to develop and obtain market authorization for future tests using subsets of sequencing data generated from the Helix® Laboratory Platform, including for cancer, cardiovascular disease, and carrier screening.

About OraSure Technologies
OraSure Technologies empowers the global community to improve health and wellness by providing access to accurate, essential information. OraSure, together with its wholly-owned subsidiaries, DNA Genotek, Diversigen, and Novosanis, 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 about OraSure, visit www.orasure.com

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 Helix
Helix is the leading population genomics company operating at the intersection of clinical care, research, and genomics. Its end-to-end platform enables health systems, life sciences companies, and payers to advance genomic research and accelerate the integration of genomic data into clinical care. Powered by one of the world's largest CLIA / CAP next-generation sequencing labs and the first and only FDA authorized whole exome sequencing platform, Helix supports all aspects of population genomics including recruitment and engagement, clinically actionable disease screening, return of results, and basic and translational research. In response to the COVID-19 public health crisis, Helix has launched a sensitive and scalable end-to-end COVID-19 test system to meet the needs of health systems, employers, governments, and other organizations across the country. Learn more at www.helix.com.

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[1] The Helix® Laboratory Platform is a qualitative in vitro diagnostic device intended for exome sequencing and detection of single nucleotide variants (SNVs) and small insertions and deletions (indels) in human genomic DNA extracted from saliva samples collected with Oragene®•Dx (OGD-610).

[2] The Helix® Genetic Health Risk App uses qualitative genotyping to detect clinically relevant variants in genomic DNA isolated from human saliva collected from individuals ≥18 years with Oragene®•Dx OGD-610 for the purpose of reporting and interpreting Genetic Health Risks (GHR).



Source: OraSure Technologies, Inc.