



OraSure Technologies, Inc.

OraSure's OMNIgene®-ORAL Kit Included in EUA Granted to P23 Labs for At-Home Collection of Saliva Samples for SARS-CoV-2 Test

May 22, 2020

OTTAWA, May 22, 2020 (GLOBE NEWSWIRE) -- OraSure Technologies, Inc. (NASDAQ: OSUR), a leader in point-of-care diagnostic tests, specimen collection devices, and microbiome laboratory and analytical services, (NASDAQ: OSUR), announced today that its OMNIgene®-ORAL saliva collection device (OM-505) was included in the U.S. Food and Drug Administration (FDA) Emergency Use Authorization (EUA) granted to P23 Labs. This EUA permits individuals to self-collect saliva specimens at-home for the detection of SARS-CoV-2.

The P23 Labs' TaqPath SARS-CoV-2 assay, combined with OMNIgene®-ORAL (OM-505), facilitates the detection of nucleic acid from SARS-CoV-2 using oral fluid samples self-collected at-home with telemedicine support or in an assisted living setting, at a doctor's office or at a drive through collection site. A product of OraSure's DNA Genotek subsidiary, OMNIgene®-ORAL (OM-505) is an all-in-one collection kit for the detection of DNA and RNA from viruses.

This is the second EUA that utilizes a DNA Genotek collection device. Earlier this month, the Company's ORAcollect®-RNA kit (OR-100) was included as the collection device for anterior nares (nasal) samples EUA granted to Biocerna LLC for its PCR-based SARS-CoV-2 assay.

"OraSure is on the cutting edge of the fight against the COVID-19 pandemic. Our innovative and non-invasive saliva collection kits are designed to make it easier and safer to test for COVID-19, including use in home settings," said Kathleen Weber, Executive Vice President, Business Unit Leader, Molecular Solutions at DNA Genotek. "P23 Labs was able to leverage the usability studies for our Oragene®-Dx general 510(k) clearance to reduce the time required for submitting their EUA. We are proud of our on-going commitment to regulatory compliance which provides our customers with a high degree of confidence in our medical device products."

At-home self-collection with telemedicine support enables individuals to self-administer sample collection. This reduces the risk of virus transmission to others and lowers the demand for personal protective equipment (PPE) for health care providers, as the test does not require an in-person visit with a clinician.

"P23 is focused on providing testing options to populations that are currently underserved by the testing options available today. This EUA with DNA Genotek's collection device will enable testing for people that do not have the ability to get to a collection center or are at home because they are sick, quarantined, at increased risk for infection or simply concerned about exposing themselves by traveling to a collection site," said Eddie McIntyre, Executive Vice President, Technology and Logistics, at P23 Labs. "The device's intuitive ease-of-use facilitates minimally supervised or in most cases complete self-collection and is a tremendous advance to current COVID-19 sample collection methods."

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, Diversigen, CoreBiome (now operating under the Diversigen brand) 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.

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 P23 Labs

P23 Labs is a high-complexity molecular diagnostics laboratory that specializes in diagnostic testing of infectious disease. P23 Labs offers a full suite of molecular diagnostic tests that also include COVID-19. P23's dedication to the response to the coronavirus pandemic includes respiratory pathogen profiles, and other infectious diseases using our state-of-the-art molecular methods. P23 has created a quality laboratory that focuses on fortifying the relationship of patients and providers by removing barriers to healthcare. P23's staff have a combined 150 plus years of experience in genetics, epidemiology, business, finance, and clinical medical practice. P23 Labs combine innovation, quality, and creativity with science and information technology to emerge as a leader in molecular testing. P23 Labs is in Little Rock, AR. For more information visit www.p23labs.com.

Company contact:

Sam Martin
Argot Partners
212-600-1902

Orasure@argotpartners.com

Jeanne Mell
VP Corporate Communications
484-353-1575

media@orasure.com



Source: OraSure Technologies, Inc.