



OraSure Technologies, Inc.

OraSure's Oragene®Dx included in EUA allowing at-home saliva collection for use with Phosphorus SARS-CoV-2 test

June 8, 2020

The number of EUAs utilizing OraSure's saliva collection products continues to grow

OTTAWA, June 08, 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, announced today that Phosphorus Diagnostics, a leader in diagnostic and bioinformatic solutions for clinical next generation sequencing (NGS), was granted an Emergency Use Authorization (EUA) by the U.S. Food and Drug Administration (FDA) allowing individuals to self-collect saliva specimens with the Company's Oragene®Dx (OGD-510) collection kit for the detection of SARS-CoV-2 using the Phosphorus COVID-19 RT-qPCR test.

The Phosphorus COVID-19 RT-qPCR test detects nucleic acid from SARS-CoV-2 in the saliva of individuals who are suspected of being infected with COVID-19 by a healthcare professional. Combined with the easy-to-use Oragene®Dx (OGD-510) saliva collection device from OraSure's subsidiary, DNA Genotek, this is an easily deployable testing option for patient or employee populations and for at-home use. Eligibility to receive an Oragene®Dx collection device for in-home self-collection will be determined based on a medical questionnaire reviewed by a healthcare professional before shipment.

This is the third EUA for SARS-CoV-2 testing that utilizes a DNA Genotek collection device and the first that allows a fully at-home, unsupervised collection solution utilizing a DNA Genotek device. Earlier this month, the Company's ORAcollect®RNA kit (OR-100) was included as the collection device for the EUA granted to Biocerna LLC. The Company's OMNIgene®ORAL (OM-505) was included in the EUA recently granted to P23 Labs.

"DNA Genotek continues to find new ways to help patients and healthcare providers fight the COVID-19 crisis through our leading saliva-based collection devices," said Kathleen Weber, Executive Vice President, Business Unit Leader, Molecular Solutions at DNA Genotek. "Our at-home collection kits are designed to make it easier and safer to self-collect samples during this important time. Working with the FDA, regulatory bodies around the world, and laboratories like Phosphorus, we are committed to expanding the availability of saliva-based collection devices to prevent the spread of this disease."

Alexander Bisignano, CEO at Phosphorus said, "We chose to validate our RT-qPCR COVID-19 test with saliva due to its ease-of-use in at-home settings and reliability as a sample type. The Phosphorus COVID-19 RT-qPCR assay, combined with OraSure's Oragene®Dx (OGD-510), makes testing easy, painless and reliable, enabling the widespread usage necessary to combat and contain this disease. In addition to at-home usage, Phosphorus is also partnering with clinicians and employers to provide viral and antibody testing solutions that enable re-opening of workplaces and clinical care."

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

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