



OraSure Technologies, Inc.

## OraSure's OMNIgene®-ORAL Device Included in EUA Granted to Clinical Reference Laboratory for Self-Collected SARS-CoV-2 Saliva Test

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BETHLEHEM, Pa., July 31, 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, today announced that its OMNIgene®-ORAL (OM-505) saliva collection device is included in the U.S. Food and Drug Administration (FDA) Emergency Use Authorization (EUA) granted to Clinical Reference Laboratory (CRL), one of the largest privately held clinical testing laboratories in the United States, for SARS-CoV-2 testing. This is the fourth EUA to include a collection device manufactured and sold by the Company's DNA Genotek subsidiary.

The EUA authorizes CRL to use the OMNIgene®-ORAL device with CRL Rapid Response™, its saliva-based SARS-CoV-2 RT-PCR test that can be self-collected at home, work or any other setting, when COVID-19 infection is suspected by a healthcare provider. The saliva sample would be collected with the OMNIgene-ORAL (OM-505) saliva collection device, which is specifically designed for self-collection, stabilization, storage and shipment of samples to the laboratory. The OMNIgene-ORAL device offers improvements over the standard nasopharyngeal swab because virtually anyone can collect a saliva sample at home with no discomfort and return it to the lab for processing, allowing personnel and protective equipment to be saved for when they are most needed.

"As many companies begin the delicate task of lifting stay-at-home orders and allowing businesses to reopen, testing will help keep people safe and help get the economy back up and running," said Robert Thompson, CEO of Clinical Reference Laboratory. "The DNA Genotek OMNIgene-ORAL device was the ideal choice for our CRL Rapid Response test as our studies demonstrated it to be more sensitive and accurate than the standard COVID-19 anterior nasal swab test."

"This EUA highlights the benefits of saliva collected with OMNIgene-ORAL as a sample type for COVID-19 diagnostics in the CRL Rapid Response test kit, due to its performance as well as its safe and easy to use format, suitable for unsupervised home collection," said Kathleen Weber, Executive Vice President, Business Unit Leader, Molecular Solutions at DNA Genotek. "A global challenge like coronavirus requires the commitment and cooperation of everyone who has the ability to help address it. We are pleased to support CRL in their work in expanding the availability of COVID-19 diagnostics."

### 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), UrSure 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](http://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](http://www.dnagenotek.com).

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