



DNA Genotek's ORAcollect®-RNA kit included in EUA granted to Biocerna SARS-CoV-2 test

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OTTAWA, May 04, 2020 (GLOBE NEWSWIRE) -- 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 its ORAcollect®-RNA kit (OR-100) was included as the collection device for anterior nares (nasal) samples under a U.S. Food and Drug Administration (FDA) Emergency Use Authorization (EUA) granted to Biocerna LLC for its PCR-based SARS-CoV-2 assay.

The Biocerna assay, combined with the ORAcollect®-RNA collection kit, is designed to allow for self-collection of nasal samples for the purpose of detecting the SARS-CoV-2 genome using the ThermoFisher Scientific TaqPath COVID-19 Combo Kit under the supervision of a healthcare provider. ORAcollect®-RNA is an all-in-one system for the collection, stabilization and transportation of human, microbial and viral RNA.

"We are pleased with the recognition our ORAcollect®-RNA collection kit has received as part of this Emergency Use Authorization granted to Biocerna," said Kathleen Weber, Executive Vice President, Business Unit Leader Molecular Solutions at DNA Genotek. "We believe our collection kits can be a valuable tool for use in conjunction with a variety of SARS-CoV-2 assays and are proud that we can be a part of Biocerna's efforts in bringing new testing solutions to the fight against COVID-19."

"It was important for us to offer innovative specimen collection options to our clients which will help minimize the exposure of their healthcare providers to the SARS-CoV-2 virus and reduce use of PPE. ORAcollect®-RNA allows for us to provide an easy-to-use and minimally invasive collection kit that provides excellent performance in detecting the virus, works seamlessly with our automated laboratory workflow and allows for shipping of specimens to our laboratory without the use of cold packs," said Chris Sanders, Founder and CEO, Biocerna.

OraSure Technologies, Inc., DNA Genotek's parent company, is developing a pan-SARS-coronavirus antigen rapid in-home self-test that uses oral fluid samples, and a lab-based oral fluid microplate coronavirus antibody enzyme-linked immunosorbent assay (ELISA). "We are proud to bring our experience with sample collection and infectious disease diagnostics to bear in the battle against COVID-19. Improving and increasing the capacity of COVID-19 testing is crucial to controlling the pandemic and restarting the global economy," said Stephen S. Tang, Ph.D., President and CEO of OraSure.

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.

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