



OraSure Technologies, Inc.

## OraSure's ORAcollect®-RNA Device Included in EUA Granted to MiraDx Inc. for SARS-CoV-2 Test

September 3, 2020

BETHLEHEM, Pa., Sept. 03, 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 ORAcollect®-RNA (OR-100) collection device was included along with other devices in the U.S. Food and Drug Administration (FDA) Emergency Use Authorization (EUA) granted to MiraDx Inc., a Los Angeles-based molecular genetics company. This is the fifth EUA to include a collection device from the company's DNA Genotek subsidiary.

MiraDx will utilize ORAcollect®-RNA to collect oropharyngeal samples in their COVID-19 testing program for essential workers and first responders to help slow, and hopefully prevent, the spread of COVID-19. Samples are collected under the supervision of a healthcare professional.

MiraDx is performing COVID-19 PCR-based viral detection testing in their CLIA-certified, high-complexity molecular diagnostics laboratory that can provide 24-48 hour turnaround time. The MiraDx SARS-CoV-2 assay, combined with ORAcollect®-RNA, facilitates the detection of nucleic acid from SARS-CoV-2 using highly sensitive quantitative PCR technology.

"There's an urgent need for COVID-19 testing so that people who are infected can be easily and quickly identified," said Joanne Weidhaas, Founder, MiraDx Inc. "Reliable, high-quality testing is essential to help healthcare systems overcome this pandemic. We are focused on delivering the highest quality, most sensitive and dependable testing possible."

"Making rapid and accurate diagnostic tools available is critical for early detection and control of COVID-19," said Kathleen Weber, Executive Vice-President, Business Unit Leader, Molecular Solutions at DNA Genotek. "Our global leadership in molecular collection devices has enabled MiraDx to utilize a highly accurate collection device to detect genetic material from SARS-CoV-2. With our legacy of innovation and unique capabilities in molecular diagnostics, we're in a strong position to help provide a diagnostic tool for the COVID-19 public health challenge."

MiraDx was spun out of Yale University in 2009 by scientists and clinicians seeking advances in the field of personalized medicine and treatment based on microRNA-based genetic testing.

### 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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Source: OraSure Technologies, Inc.