



OraSure Technologies, Inc.

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OraSure's OMNIgene®·ORAL Device Included in EUA Amendment Granted to 3B BlackBio Biotech India for SARS-CoV-2 Test

OTTAWA, ON, December 23, 2020 – 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/OME-505) collection device was included in the U.S. Food and Drug Administration (FDA) Emergency Use Authorization (EUA) amendment granted to 3B BlackBio Biotech, one of the leading suppliers and developers for RT-PCR diagnostic assays in India. This is the seventh customer EUA that includes a collection device from the company's DNA Genotek subsidiary.

This EUA amendment will allow 3B BlackBio Biotech's North American distributor, Genophyll Enterprises, to expand saliva COVID-19 PCR-based viral diagnostic testing across the U.S. as well as from their upcoming New Jersey-based laboratory.

This EUA amendment granted to 3B BlackBio Biotech includes the addition of qualitative detection of nucleic acid from SARS-CoV-2 in saliva specimens that are collected with the assistance of a healthcare provider (HCP) using the OMNIgene·ORAL (OM-505/OME-505) saliva collection device by individuals suspected of COVID-19. The 3B BlackBio Biotech SARS-CoV-2 assay, combined with OMNIgene·ORAL, facilitates the detection of nucleic acid from SARS-CoV-2 samples using highly sensitive quantitative PCR technology. A product of OraSure's DNA Genotek subsidiary, OMNIgene·ORAL saliva collection devices are intended for use by individuals to collect and immediately stabilize saliva specimens suspected of containing SARS-CoV-2 ribonucleic acid (RNA) at ambient temperature for transport.

"A saliva-based collection method for COVID-19 laboratory tests is a valuable addition to our testing portfolio for helping diagnose SARS-CoV-2 infection," said Aditi Luthra, CEO, Genophyll Enterprises. "Now, Genophyll Enterprises has access to a robust and safe biomaterial collection approach for the detection of COVID infections. This expansion of testing methods is critical to informing patient management decisions and containing the spread of COVID-19."

"As the pandemic evolves, the need for testing continues to grow," said Kathleen Weber, Executive Vice-President, Business Unit Leader, Molecular Solutions at DNA Genotek. "The addition of OMNIgene·ORAL to 3B BlackBio Biotech's EUA expands access to saliva-based collection to more individuals, which will result in more testing and help provide the confidence we need to help get back to living with more normalcy."

“3B BlackBio Biotech aims at fulfilling the current demand of higher testing and has stepped up its production capacity for RT-PCR kit for SARS-CoV-2 detection. Our kit coupled with the Saliva Specimen Collection Device of OraSure’s DNA Genotek will make the sampling easier for the healthcare service provider (HCP) and will also reduce the patient’s discomfort,” said Dharendra Dubey, Managing Director, 3B BlackBio Biotech India Limited.

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.

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 3B BlackBio Biotech

3B BlackBio Biotech, a subsidiary of Kilpest India Limited (a publicly traded company), is a leading Indian manufacturer of molecular diagnostic kits. 3B BlackBio Biotech produces the FDA EUA authorized TRUPCR SARS-CoV-2 kit. The TRUPCR SARS-CoV-2 kit is a highly sensitive, comprehensive three gene detection assay (E, RdRp, N genes). In addition to its FDA Emergency Use Authorization, the kit has also been validated by the Indian Council of Medical Research, Government of India.

In addition to infectious diseases and virology, its portfolio of assays include blood-borne diseases, vector borne diseases, oncology, sexually transmitted infections and coagulation panels. 3B BlackBio Biotech’s in-house enzyme production, bulk procurement and India-based operations ensure substantial cost advantages. The Company is ISO 13485:2016 certified and GMP compliant. 3B BlackBio Biotech has supplied over 5.5 million tests to over 400 satisfied customers all across India. For more information about 3B BlackBio Biotech, visit www.3bblackbio.com.

About Genophyll

Genophyll is a woman and minority owned small business based in New Jersey. Genophyll is proud to partner with 3B BlackBio Biotech, the manufacturer of FDA EUA authorized TRUPCR SARS-CoV-2 kit, to broaden its ability to serve the North and South America. The TRUPCR SARS-CoV-2 kit is the only Indian-made RT-PCR for the novel coronavirus that has received Emergency Use Authorization from the FDA. 3B BlackBio Biotech’s production capacity is 100,000 tests per day. This fact, coupled with hands-on technical customer service support and lower supply costs in India, uniquely positions Genophyll to offer a high-quality, easy to use, cost-effective solution. For more information about Genophyll, call, text, or email us at 732-945-0190 and mail@genophyll.us.