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Clinical Reference Laboratory Receives FDA Emergency Use Authorization for Best-in-Class Self-Collected COVID-19 Saliva Test

Self-Collected CRL Rapid Response™ Saliva Test is More Accurate Than Widely Used Anterior Nasal Swab Test and Key to the U.S. Safely Getting Back to Work

Lenexa, Kansas - (July xx, 2020) Today, Clinical Reference Laboratory (CRL), one of the largest privately held clinical testing laboratories in the U.S., announced that it received FDA Emergency Use Authorization (EUA) and is scaling up capacity for **CRL Rapid Response™**, a saliva-based COVID-19 RT-PCR test that can be self-collected at home, work or any other setting. The test, shown in CRL's EUA studies to be more sensitive and accurate than the standard COVID-19 anterior nasal swab test, detects the presence of coronavirus in the saliva of the test taker. In addition, the test is more comfortable and easier to administer, is not "technique dependent" and virtually anyone can self-collect an adequate sample for testing, with test results available in 24-48 hours of receipt at CRL. **CRL Rapid Response™** is ready for immediate commercial launch, making it the first large-scale service of its kind focused on the American workforce. *Testing is critical to safely helping America get back to work,* which is why CRL is offering these tests to employers in businesses, universities, government agencies, nursing homes and other organizations. CRL has already lined up several partnerships for **CRL Rapid Response™** testing.

In CRL conducted studies of paired samples required for the FDA EUA, the **CRL Rapid Response™** test had 100% sensitivity and specificity (higher than any other saliva-based COVID-19 molecular diagnostic test) — accurately detecting the presence or absence of the virus in known COVID-19 positive and negative patients as compared to only 55% detection using anterior nasal swabs, the common method of self-collection. The higher sensitivity and accuracy of the **CRL Rapid Response™** saliva test is due to a combination of factors. First, saliva typically contains a larger sample of genetic material than what is usually collected using an anterior nasal swab. Additionally, collection of a CRL sample is not technique dependent and can be easily self-collected. The saliva is collected in a DNA Genotek OMNIgene® ORAL (OM-505) saliva collection device, specifically designed for self collection, stabilization, storage and shipment to the laboratory. Studies conducted by CRL and DNA Genotek, a subidiary of OraSure Technologies, Inc. (NASDAQ:OSUR), demonstrate sample stability of up to twenty-one days post-collection, enabling at-home collection. CRL tests the saliva sample by RT-PCR technology, using

Patented CoPrimer™ probes and primers developed by CRL partner Co-Diagnostics Inc. (NASDAQ:CODX) to detect SARS-CoV-2 viral RNA with high sensitivity and specificity.

"Experts agree that testing is the key to getting America back to work, but concerns about reliability and availability of testing are an impediment for many states, cities and businesses as they consider their re-opening plans," said **CRL CEO Robert Thompson**. "FDA authorization of the **CRL Rapid Response™** saliva test answers the call on both fronts with a convenient, highly accurate test that can be self-collected, supported by a world-class CLIA certified and CAP accredited clinical laboratory accustomed to providing testing on a large scale. Our thirty-year track record of delivering high quality and accurate testing enables us to manufacture, deploy and process the tests very quickly. We currently service employers and insurance companies by processing over 300,000 tests a day and we are aggressively scaling up for mass COVID-19 testing in the next 2-3 weeks, and expect to eventually process over 50,000 tests a day."

"People should not have to choose between comfort or convenience and accuracy. **CRL Rapid Response™** offers convenient self testing with better sample collection, protection and transport, combined with superior testing methodology, which leads to more accurate results and, ultimately, better public health outcomes," said Dr. Heather Fehling, CRL's Chief Scientific Officer, Molecular Diagnostics. "Together with our partners Co-Diagnostics and OraSure DNA Genotek, we are committed to providing the most accurate and user-friendly testing process available. We believe this test will make a meaningful difference in our nation's ability to re-open safely."

CRL Rapid Response™ tests can be purchased by government agencies and businesses for their employees. The test itself is easy to use and simply requires that the individual's saliva be deposited in a collection vial provided and sent back to the CRL laboratories using the company provided prepaid one-day shipping package. Specimens are processed within 24-48 hours of receipt and individuals can access their test results online through a unique two-factor authentication protected portal. Individuals have the option to speak with a licensed physician about their results. Prior to taking the test, individuals will need to give consent for their employers and their local public health departments to receive the test results.

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About Clinical Reference Laboratory:

Clinical Reference Laboratory is one of the largest privately held clinical testing laboratories in the U.S. With dedicated facilities in North America and Europe, and through our global laboratory partners, we perform hundreds of thousands of tests every day for clients large and small. Our staff of more than 600 associates works around-the-clock to process and report results seven days a week for many of the largest retail, transportation, pharmaceutical, healthcare and financial service organizations in the world. Visit us at: https://www.crlcorp.com or call 833-567-8376 for more information.