PerkinElmer COVID-19 Test Kit Receives FDA Emergency Use Authorization for Sample Pooling

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Latest testing strategy to increase the sample processing efficiency

WALTHAM, Mass.--(BUSINESS WIRE)--Oct. 29, 2020-- PerkinElmer, Inc. (NYSE: PKI) announced today that the U.S. Food and Drug Administration (FDA) has issued Emergency Use Authorization (EUA) to allow sample pooling with PerkinElmer® New Coronavirus Nucleic Acid Detection Kit to increase the number of individuals who can be tested without increasing resources. This validation of batch testing using the industry's most sensitive assay to date according to the FDA Reference Panel leverages its proven ability to detect low amounts of viral genetic material.

Laboratories certified under the Clinical Laboratory Improvement Amendments (CLIA) can now use PerkinElmer's real-time RT-PCR in vitro diagnostic assay for COVID-19 to pool multiple samples together using the resources needed for a single test. If a pooled test is negative, all the individual samples are considered negative. If the pooled test is positive, each of the individual samples in that pool should be tested again separately to determine which of the samples are positive. For sample pooling to be effective, screening using a highly sensitive test is integral.

From comparative data released by the FDA, the PerkinElmer New Coronavirus Nucleic Acid Detection Kit has the lowest Limit of Detection (LoD) among the authorized COVID-19 molecular diagnostic tests reported, deeming it the most sensitive assay that can detect 3-fold less viral material in samples compared to the assay in second place, and over 90-fold times less viral material in samples compared to the industry average.

"The FDA has recognized that there is great interest in sample pooling to test for COVID-19," said Masoud Toloue, Ph.D., Vice President and General Manager, Diagnostics, PerkinElmer. "The ability to pool samples using a highly sensitive RT-PCR test offers diagnostic labs an efficient and accurate way to increase testing capacity."

PerkinElmer has been on the front lines of improving COVID-19 test turnaround times enabled by increasing production capacity of viral RNA extraction, RT-PCR tests and live streaming availability status to meet evolving public health needs.

PerkinElmer is actively working with specialty and reference diagnostic labs, clinics, hospitals, pharmaceutical and biopharmaceutical labs, academia, and governmental and research institutes to battle the pandemic. PerkinElmer's comprehensive SARS-CoV-2 offerings span high throughput RNA extraction, RT-PCR, automation, ELISA, chemiluminescence, time-resolved fluorescence and lateral flow based serology testing.

About PerkinElmer

PerkinElmer enables scientists, researchers, and clinicians to address their most critical challenges across science and healthcare. With a mission focused on innovating for a healthier world, we deliver unique solutions to serve the diagnostics, life sciences, food, and applied markets. We strategically partner with customers to enable earlier and more accurate insights supported by deep market knowledge and technical expertise. Our dedicated team of about 13,000 employees worldwide is passionate about helping customers work to create healthier families, improve the quality of life, and sustain the wellbeing and longevity of people globally. The Company reported revenue of approximately $2.9 billion in 2019, serves customers in 190 countries, and is a component of the S&P 500 index. Additional information is available through 1-877-PKI-NYSE, or at www.perkinelmer.com

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