PerkinElmer SARS-CoV-2 RT-PCR Assay Receives FDA EUA for Asymptomatic Testing

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Gold-standard testing of individuals without COVID-19 symptoms key to controlling the spread

WALTHAM, Mass.--(BUSINESS WIRE)--Jan. 14, 2021-- PerkinElmer, Inc. (NYSE:PKI) announced today that its PerkinElmer® New Coronavirus Nucleic Acid Detection Kit received Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA) to test individuals without symptoms or other reasons to suspect COVID-19 infection.

According to a new model from The Journal of the American Medical Association's Open Network developed by researchers from the Centers for Disease Control and Prevention, close to 60% of total COVID-19 transmissions come from those who have no symptoms, signaling that silent spreaders are the ones most often passing the virus around without knowing it.

For asymptomatic carriers, diagnostic testing is essential to identify infected individuals, and thereby provides a better chance of getting infectious individuals into isolation to avoid spreading the disease further. The ability to quickly identify asymptomatic individuals provides significant public health value. Moreover, based on comparative data released by the FDA, the PerkinElmer test kit has the lowest Limit of Detection (LoD) among the authorized COVID-19 molecular diagnostic tests reported, deeming it the most sensitive assay. PerkinElmer's RT-PCR assay originally obtained FDA EUA in the spring of 2020.

"The data is clear – it's imperative we have reliable and accurate testing for asymptomatic individuals, especially as we're seeing new strains of the virus appear that are even more contagious," said Masoud Toloue, Ph.D., Vice President & General Manager, Diagnostics, PerkinElmer. "PerkinElmer is in a unique position to help this cause, as we're one of the few suppliers to have an EUA for asymptomatic testing, maintain the most sensitive test on the market along with a strong supply chain, and have the capability to do sample pooling to save time and resources for diagnostic laboratories."

Previously, the FDA issued EUA to allow sample pooling with the PerkinElmer New Coronavirus Nucleic Acid Detection Kit to increase the number of individuals who can be tested without increasing resources. Additional testing mechanisms, including the use of saliva as a sample type, are also on the horizon. SARS-CoV-2 testing using saliva is less invasive, reduces the risk of exposure to healthcare workers involved in sample collection, and lessens the need for frequent replacement of personal protective equipment.

PerkinElmer continues to work on the frontlines of improving COVID-19 testing. The Company'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 14,000 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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