PerkinElmer Receives FDA Emergency Use Authorization for Respiratory SARS-CoV-2 Panel

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RT-PCR test detects and differentiates SARS-CoV-2, influenza A, influenza B and respiratory syncytial virus

WALTHAM, Mass.--(BUSINESS WIRE)--Oct. 7, 2021-- PerkinElmer, Inc. (NYSE: PKI) announced today that the U.S. Food and Drug Administration (FDA) has issued Emergency Use Authorization (EUA) for the PKamp™ Respiratory SARS-CoV-2 RT-PCR Panel assay. Qualified laboratories can immediately begin using this single test for the simultaneous qualitative detection and differentiation of SARS-CoV-2, influenza A, influenza B and respiratory syncytial virus (RSV) isolated from nasopharyngeal swabs, anterior nasal swabs and mid-turbinate swabs.

COVID-19, flu and RSV infections are highly contagious and often cannot be differentiated based on symptoms alone. The U.S. Centers for Disease Control and Prevention encourages COVID-19 testing laboratories to adopt a multiplex method that facilitates detection and differentiation of SARS-CoV-2 and influenza viruses. A multi-analyte test such as the PKamp Respiratory SARS-CoV-2 RT-PCR Panel assay allows laboratories to conserve precious resources by avoiding multiple tests on samples collected from individuals suspected of respiratory viral infection consistent with COVID-19.

"As we enter the flu season, this timely emergency use authorization will be welcome by laboratories that are looking to test for common respiratory illnesses alongside COVID-19," said Arvind Kothandaraman, managing director of specialty diagnostics at PerkinElmer. "The new test will help to alleviate confusion arising from similar symptoms caused by these infections and reduce further strain on the healthcare system during a pandemic."

Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, that meet requirements to perform high complexity tests.

PerkinElmer also has CE marking for a multi-analyte respiratory panel that tests for COVID-19 – the PKamp™ Respiratory SARS-CoV-2 RT-PCR Panel assay has clearance to be marketed as an in vitro diagnostic (IVD) device in more than 30 countries by meeting the requirements of the European In Vitro Diagnostic Directive (IVDD).

PerkinElmer’s comprehensive SARS-CoV-2 portfolio includes high throughput RNA extraction, RT-PCR, workflow automation, ELISA, chemiluminescence, time-resolved fluorescence and lateral flow based antigen as well as 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 15,000 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 $3.8 billion in 2020, serves customers in 190 countries, and is a component of the S&P 500 Index. Additional information is available at www.perkinelmer.com.

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