

PerkinElmer receives CE mark for multi-analyte respiratory panel including COVID-19

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PerkinElmer, Inc. has announced that its <u>PKampTM Respiratory SARS-CoV-2 RT-PCR Panel</u> has received 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). This test is currently under review by the U.S. FDA for Emergency Use Authorization (EUA). The multi-analyte panel enables labs to detect and differentiate between SARS-CoV-2, influenza A viruses, influenza B viruses and respiratory syncytial virus (RSV) in a single test, which will be critical to manage the surge in test demand during the flu season as the targeted pathogens have some similar signs and symptoms.

Rather than running multiple tests on samples, the PKamp Respiratory SARS-CoV-2 RT-PCR Panel is designed to conserve resources by testing a single nasopharyngeal, oropharyngeal or nasal swab sample collected from individuals suspected of respiratory viral infection consistent with COVID-19, the flu and RSV. Building off the <u>most sensitive SARS-CoV-2 test kit</u> in the market according to the FDA's reference panel comparative data, the multi-analyte panel is designed to be used with PerkinElmer's automated viral nucleic extractor to detect smaller amounts of viral material in samples.

"In the next few months, it will be vital for health professionals to detect and differentiate between COVID-19, the common flu and RSV infection," said Masoud Toloue, Ph.D., Vice President and General Manager, Diagnostics, PerkinElmer. "By offering an automated multi-analyte testing solution, we are equipping diagnostics labs with the right toolset to tackle the additional pressure the season may have on this pandemic."

PerkinElmer continues to work with specialty and reference diagnostic labs, clinics, hospitals, pharmaceutical and biopharmaceutical labs, academia, and governmental and research institutes to battle the pandemic. PerkinElmer's