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PerkinElmer launches highly sensitive PoC antigen test for mass screening

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Company expands portfolio of SARS-CoV-2 testing solutions with rapid antigen test benchmarked against gold standard RT-PCR



PerkinElmer, Inc, has launched the PerkinElmer® COVID-19 Antigen Test for the qualitative detection of SARS-CoV-2 nucleocapsid protein antigen in nasal (NS) or nasopharyngeal (NP) swab specimens.

The lateral flow immunoassay test can be used to screen or to aid in diagnoses of COVID-19 in asymptomatic or symptomatic individuals. A positive or negative result can be obtained in as little as 15 minutes to facilitate immediate isolation or treatment decisions.

This latest addition to the Company's portfolio of SARS-CoV-2 testing solutions is available in more than 30 countries that accept the CE mark. The in vitro diagnostic device is ideally suited for professional use point-of-care (POC) clinical and non-clinical settings such as healthcare centers, travel hubs, businesses and educational institutions.

Clinical studies in symptomatic and asymptomatic populations, including individuals with low viral load, have shown sensitivity of greater than 97% amongst all NS and NP samples. Specificity of the test across 202 negative samples was 100%, which means no false positives were identified.

"While RT-PCR tests remain the gold standard in COVID-19 diagnostics, there is an unmet need in the market for a highly reliable antigen test that can support the reopening strategies of organizations worldwide," said Masoud Toloue, Ph.D., Senior Vice President, Diagnostics, PerkinElmer. "Sensitivity and reliability matters, especially in this challenging environment. Just like with our RT-PCR test, significant talent and effort was put behind developing a lateral flow antigen test that sets the benchmark for rapid testing, and may help facilitate the safe return of in-person education, commerce and everyday life."

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.

Based on comparative data released by the U.S. Food and Drug Administration, the PerkinElmer® New Coronavirus Nucleic Acid Detection Kit has the lowest limit of detection among authorized COVID-19 molecular diagnostic tests reported, deeming it the most sensitive assay. This RT-PCR assay originally obtained FDA EUA in the spring of 2020 and recently received EUA to test individuals without symptoms or other reasons to suspect COVID-19 infection.