Nuclein Receives Dual FDA 510(k) Clearance and CLIA Waiver for DASH® SARS-CoV-2 & Flu A/B Test for use on the DASH® Rapid PCR System

Rapid PCR Made Simple™: DASH® Delivers Lab-Quality Results in 15 Minutes

AUSTIN, Texas, Jan. 6, 2025/PRNewswire/ – Nuclein, a leader in rapid, point-of-care molecular diagnostics, today announced it has received U.S. Food and Drug Administration (FDA) 510(k) clearance and a Clinical Laboratory Improvement Amendments (CLIA) waiver for its DASH® SARS-CoV-2 & Flu A/B Test for use on the DASH® Rapid PCR System.

The DASH® Rapid PCR System delivers lab-quality, point-of-care PCR results in 15 minutes. With a speed that is typically only available with antigen tests, the DASH® Rapid PCR System was designed to offer low-cost, highly sensitive and specific results, with robust multiplexing across various sample types, and requires less than one minute of hands-on time. Nuclein is working to expand its test menu to include other upper respiratory infections, STI testing, and many other tests that will be uniquely valuable when run on a rapid, low-cost, point-of-care, PCR testing platform.

The DASH® Rapid PCR System's ease of use and fast turnaround time make it ideal for a wide range of healthcare settings, especially urgent care, student health, physician offices, pharmacies, and emergency rooms. The DASH® SARS-CoV-2 & Flu A/B Test, which runs on the DASH® Rapid PCR System, seamlessly integrates into existing workflows and delivers actionable, lab-quality results for COVID-19, influenza A, and influenza B within a single patient visit.

With its 15-minute runtime, the DASH® SARS-CoV-2 & Flu A/B Test utilizes a single, patient-friendly, anterior nasal swab to simultaneously test for COVID-19, influenza A, and influenza B using a single shelf-stable cartridge. Providers also benefit from DASH® Rapid PCR System's Wi-Fi and cloud connectivity to further support clinical workflow integration.

"Nuclein was founded with a vision to enable simple, affordable, rapid, and accurate testing for everyone," said Alan Blake, CEO and co-founder of Nuclein. "FDA 510(k) clearance and a CLIA waiver for the first of many anticipated tests for our DASH® Rapid PCR System marks an exciting step towards realizing this vision."

Nuclein plans to begin shipping its DASH® Rapid PCR System and DASH® SARS-CoV-2 & Flu A/B Test later this month.

To learn more about Nuclein and the DASH® Rapid PCR System, visit www.nuclein.com.

About Nuclein

Nuclein, LLC is an Austin, Texas-based company founded in 2017 with a vision to enable simple, affordable, rapid, and accurate testing for everyone. Its DASH® Rapid PCR System runs the FDA-cleared and CLIA-waived DASH® SARS-CoV-2 & Flu A/B Test and delivers lab-quality, point-of-care PCR results in 15 minutes. With a speed that is typically only available with antigen tests, the DASH® Rapid PCR System was designed to offer low-cost, highly sensitive and specific results, with robust multiplexing across various sample types, and requires less than one minute of hands-on time. Nuclein has raised approximately $50 million to date, led by private equity firm Trinity Investors. In 2023, Nuclein merged with Minute Molecular Diagnostics, Inc., a Northwestern University spin-out that initially developed the DASH System.[i]

Contact: media@nuclein.com

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