Cue Health Confirms COVID-19 Tests Can Detect Omicron Variant

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Cue determines 99.2% of the published Omicron sequences are a perfect match to the primers used in the Company's molecular COVID-19 test

Cue's COVID-19 test provides highly accurate, lab-quality results, including for emerging variants, directly to connected mobile smart devices in about 20 minutes

SAN DIEGO, Nov. 29, 2021 /PRNewswire/ -- Cue Health ("Cue") (Nasdaq: HLTH), a healthcare technology company, today announced it has completed an analysis of the SARS-CoV-2 B.1.1.529 variant, designated by the World Health Organization as Omicron. Using information from the GISAID database, Cue has determined its COVID-19 tests, which uses molecular (NAAT) technology, can detect the Omicron variant. Specifically, Cue found that 99.2% of the available 127 published sequences are a perfect match to the primers used in the Company's tests. Cue's easy-to-use, portable COVID-19 tests provide highly accurate, lab-quality results directly to connected mobile smart devices in about 20 minutes, and it can be used on adults and children (2 years and over), with or without symptoms, wherever they are.

Cue's team of scientists and bioinformatic experts implemented a surveillance program during the early stages of the pandemic to monitor and analyze all relevant SARS-CoV-2 variant sequences globally. These sequences are routinely compared to the primers in Cue's COVID-19 test to determine if any mutations are present that could affect the sensitivity or specificity of Cue's test. Cue's tests work by targeting a region of the nucleocapsid gene (n gene) that is highly conserved, and Company scientists have found that the test's accuracy has remained unaffected by the mutations in the Omicron variant and other variants of concern to date.

"Our molecular test is backed by the science and technology necessary to detect emerging variants, including Omicron, enabling individuals and healthcare practitioners to make better-informed decisions," **said Ayub Khattak, Co-Founder and CEO of Cue.** "Fast and accurate testing that is bolstered by a scientist-led surveillance and monitoring system, which identifies and analyzes variants in real time, will continue to play a critical role in producing actionable health data, preventing community spread and driving better outcomes."

Cue and Helix, a leading genomics company that provides nationwide surveillance of respiratory disease, announced this month a new collaboration to conduct a research study to evaluate variant data. This sequencing effort will allow Cue to contribute to public health sequencing and surveillance efforts by allowing users who obtain positive COVID-19 test results at home to opt in and consent to have their samples rapidly sequenced and shared with public health sequencing repositories like GISAID. Cue's collaboration with Helix further builds on Cue's previously announced real-time variant tracking and sequencing solution, which utilizes AI and ML from Google Cloud to add predictive capabilities to the Cue platform.

Earlier this month, Cue launched its direct-to-consumer (DTC) virtual health platform in the United States, making Cue's first-of-its-kind molecular COVID-19 test available through Cue's new eCommerce site and in-app shop. Cue's new membership offering — Cue+™ — offers members 24/ on-demand access to board certified physicians, e-prescription services, CDC-compliant test results for travel through in-app video proctoring, and

same-day delivery of Cue products in a number of major markets.

In the U.S., the Cue COVID-19 Test for Home and Over The Counter (OTC) Use was the first molecular test to receive FDA Emergency Use Authorization (EUA) for at-home and over-the-counter use without a prescription. This followed an EUA from the FDA in June 2020 for professional point-of-care use.

Internationally, Cue has received the CE mark in the European Union for professional point-of-care use, Interim Order authorization from Health Canada for both professional point-of-care and consumer self-testing, and regulatory approval from India's Central Drugs Standard Control Organisation for professional point-of-care use.

Cue has already delivered millions of COVID-19 tests, which are being used in thousands of settings where a highly accurate, no-compromise testing solution is required, including schools, nursing homes, correctional facilities, hospitals, and community health clinics, as well as in world-class organizations like Mayo Clinic, Google, the National Basketball Association (NBA), and Major League Baseball (MLB).

Cue aims to provide individuals with the ability to proactively monitor and manage their health with actionable information that they can share with healthcare providers in real-time. Cue's planned future care offerings – all of which are intended to be compatible with the Cue Reader – include products and services across the categories of respiratory health (such as for influenza, RSV, and strep throat), sexual health (such as for chlamydia and gonorrhea), cardiac and metabolic health (such as for cholesterol and HbA1c), women's and men's health, and chronic disease management.

About Cue Health

Cue Health (Nasdaq: HLTH) is a healthcare technology company that makes it easy for individuals to access health information and places diagnostic information at the center of care. Cue Health enables people to manage their health through real-time, actionable, and connected health information, offering individuals and their healthcare providers easy access to lab-quality diagnostics anywhere, anytime, in a device that fits in the palm of the hand. Cue Health's first-of-its-kind COVID-19 test was the first FDA-authorized molecular diagnostic test for at-home and over-the-counter use without a prescription and physician supervision. Outside the United States, Cue Health has received the CE mark in the European Union, Interim Order authorization from Health Canada, and regulatory approval from India's Central Drugs Standard Control Organisation. Cue was founded in 2010 and is headquartered in San Diego. For more information, please visit www.cuehealth.com.

Forward-Looking Statements

Statements in this press release about future expectations, plans and prospects, as well as any other statements regarding matters that are not historical facts, may constitute "forward-looking statements". The words, without limitation, "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "will," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these or similar identifying words. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including the factors discussed in the "Risk Factors" section of the Form 10-Q dated November 10, 2021 filed by Cue with the SEC. Any forward-looking statements contained in this press release are based on the current expectations of Cue's management team and speak only as of the date hereof, and Cue specifically disclaims any obligation to update any forward-looking statement, whether as a result of new information, future events or otherwise.

The Cue COVID-19 Test for Home and Over The Counter (OTC) Use and the Cue COVID-19 Test (for professional use) have not been FDA cleared or approved; but have been authorized by FDA under an Emergency Use Authorization (EUA). These products have been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens. The emergency use of these products is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

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