Independent Study Shows Cue Health's Molecular COVID-19 Test is as Accurate as a Lab-Based PCR Test

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In largest-of-its-kind clinical study on asymptomatic people, Cue demonstrated 99.4% accuracy compared to lab-based PCR

SAN DIEGO, Calif., Aug. 17, 2022 /PRNewswire/ -- Cue Health Inc. ("Cue") (Nasdaq: HLTH) announced today the preprint publication of an independent clinical study - the largest of its kind on asymptomatic people - demonstrating that its point of care (POC) molecular COVID-19 test, which produces results in approximately 20 minutes, is as accurate as a centralized lab-based RT-PCR.

The study presents findings from a head-to-head comparison of the Cue COVID-19 test against lab-based RT-PCR on paired samples from 3,037 individuals. The findings revealed a 99.4% match between results from Cue's test and the reference PCR tests, including 100% clinical sensitivity to detect positive cases, yielding no false negatives. Of this testing population, 98.7% was asymptomatic at varying stages of infection and viral load.

"Rapid and accurate COVID-19 asymptomatic screening has been challenging due to the poor sensitivity of antigen testing and the delays with lab-based PCR testing," said Dr. Anu Rebbapragada, D(ABMM) FCCM and Laboratory Director at FH Health, who was responsible for diagnostic testing and the analysis of results for this manuscript. "The findings from our large study indicate that sensitivity of Cue's POC testing may be an excellent proxy for PCR when accurate and fast results are urgently needed to curb transmission."

Dr. Rebbapragada further noted in the paper that due to its high sensitivity and quick turnaround time for results (approximately 20 minutes), screening programs utilizing Cue's COVID-19 test can:

- Reduce the likelihood of spread in gatherings, including workplace settings, providing confidence when testing asymptomatic individuals;
- Facilitate earlier access to treatment, promoting timely clinical management and intervention with antivirals;
- Maintain cost-effectiveness and efficiency by avoiding the logistics and infrastructure needed for lab-based PCR tests and the frequent re-screening needed with lower sensitivity antigen tests.

"We're proud of the results of this study, which further validates that with Cue, you can achieve diagnostic testing that is accurate, fast, and convenient," added Andy Hudak, VP of Research & Development and Program Management at Cue Health. "As the study demonstrates, the high sensitivity of Cue's testing platform can quickly identify asymptomatic cases allowing for large groups, such as in the workplace, to gather safely."

The FH Health analysis included results from 13,848 individuals who accessed the private (fee for service) COVID-19 Express Testing Services at seven FH Health clinics located in urban centers in Ontario, Canada between July 17, 2021 and January 31, 2022. The diverse testing population ranged in age from infants to seniors. Specimen collection and Cue COVID-19 testing was performed by trained registered nurses (RNs and RPNs) at FH Health clinic sites. RT-PCR was performed at the FH Health Laboratory, which is licensed by the Ontario Ministry of Health and accredited under ISO 15189 for COVID-19 diagnostic testing. Cue did not provide funding or any other support of the FH Health Study.

Cue's COVID-19 test has been authorized for use in the United States by FDA under Emergency Use Authorizations (EUA) for professional use at the point-of-care by healthcare providers and certified laboratories as well as for over-the-counter use. It is also authorized for use in Canada through Interim Order authorization from Health Canada.

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, regulatory approval from India's Central Drugs Standard Control Organization, and PSAR authorization from Singapore's Health Sciences Authority. 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 those related to the expected future diagnostic test menu and the factors discussed in the "Risk Factors" section of Cue's Annual Report on Form 10-K for the year ended December 31, 2021 and Quarterly Report on Form 10-Q for the quarter ended June 30, 2022 filed with the SEC on August 10, 2022. 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.

These products 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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