Peer-Reviewed Independent Study Published in Microbiology Spectrum Finds 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--(BUSINESS WIRE)--Oct. 4, 2023-- Cue Health (Nasdaq: HLTH), a healthcare technology company, announced today the peer-reviewed publication of an independent clinical study - the largest of its kind on asymptomatic people - finding that Cue's molecular COVID-19 test provides comparable accuracy to centralized lab-based RT-PCR with the advantages of convenient use at the point-of-care or home settings and fast results in 20 minutes.

The study, published in Microbiology Spectrum, a journal produced by the American Society for Microbiology, 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 from paired testing revealed a 99.4% match between results from Cue's test and the reference PCR tests with 100% clinical sensitivity to detect positive cases, yielding no false negatives. The finding of high test sensitivity in the primarily asymptomatic patient population (98.7%) highlights Cue's accuracy for detection at varying stages of infection and viral load, a critical diagnostic feature that supports early identification and robust risk mitigation.

The publication also presents analysis of Cue COVID-19 testing and operational metrics for 13,848 individuals who accessed the direct to consumer (private pay) COVID-19 Express Testing Services at seven clinics located in urban centers in Ontario, Canada between July 17, 2021 and January 31, 2022, under the Health Canada emergency use authorization framework. The diverse testing population included patrons with ages ranging from under 1 year to over 60 years. Specimen collection and Cue COVID-19 testing was performed by trained registered nurses (RNs and RPNs) and 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.

"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, Lead Investigator, Laboratory Director & VP Diagnostic Services at FH Health. "The findings from our large testing population 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 the combination of high sensitivity and quick turnaround time for results (20 minutes) offer critical benefits to screening programs utilizing Cue's COVID-19 test:

- 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.

"COVID-related hospital admissions are on the rise across the U.S., demonstrating the ongoing need for vigilance, especially to protect high risk individuals such as the elderly and immunocompromised, and that begins with access to highly accurate, fast, and reliable testing," said Dr. David Tsay, Chief Medical Officer at Cue. "This study finds Cue's test has accuracy comparable to that of central laboratory PCR, while being fast and easy-to-use in the point-of-care setting."

Cue recently received De Novo authorization from the U.S. Food and Drug Administration (FDA) for its COVID-19 test, which became the first home use respiratory test to receive this FDA approval. To further expand its diagnostic test menu for at-home and point-of-care use, Cue has made a number of other submissions with the FDA.

Cue did not provide funding or any other support of the study.

About Cue Health
Cue Health Inc. (Nasdaq: HLTH) is a healthcare technology company that uses diagnostic-enabled care to empower people to live their healthiest lives. The Cue Health platform offers individuals and healthcare providers convenient and personalized access to lab-quality diagnostic tests at home and at the point-of-care, as well as on-demand telehealth consultations and treatment options for a wide range of health and wellness needs. Cue's customers include federal and state public sector agencies and the private sector, which includes healthcare providers, enterprises, and individual consumers. Cue received De Novo authorization from the U.S. Food and Drug Administration (FDA) for its COVID-19 test, which became the first home use respiratory test to receive this FDA approval. Cue also received Emergency Use Authorization from the FDA for its molecular mpox test at the point-of-care. To further expand its test menu, Cue has made other submissions that are now under review by the FDA, including for the Cue® Flu A/B + COVID-19 Molecular Test and the Cue® RSV Molecular Test, both of which are designed for at-home and point-of-care use. Cue, founded in 2010, owns over 100 patents 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, including those regarding Cue's diagnostic platform, its partnership with BARDA, and statements made by Cue's CEO, 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, 2022 filed with the SEC on March 16, 2023 and Cue's Quarterly Report on Form 10-Q for the quarter ended June 30, 2023 filed with the SEC on August 9, 2023. 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.

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