Cue Health Achieves Groundbreaking Milestone with FDA: First Company to Receive De Novo Authorization for a COVID-19 Home Use Test

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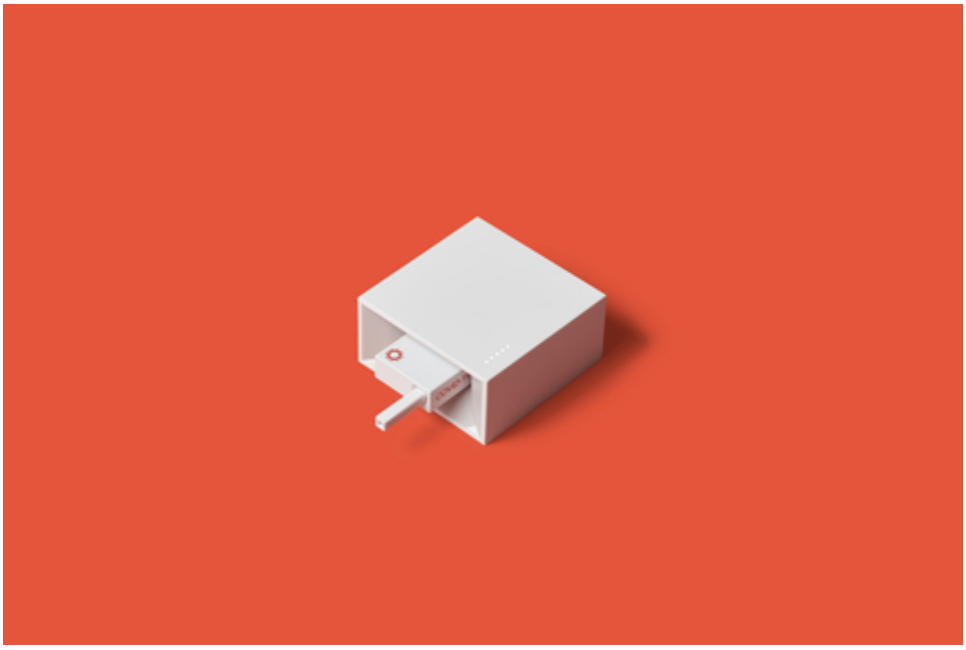
Cue's COVID-19 Molecular Test detects all known variants of concern and seamlessly integrates with Cue Care, the company's innovative test-to-treatment platform

SAN DIEGO--(BUSINESS WIRE)--Jun. 6, 2023-- Cue Health (Nasdaq: HLTH), a healthcare technology company, announces an industry breakthrough as the first company to receive De Novo authorization from the U.S. Food and Drug Administration (FDA) for its Cue COVID-19 Molecular Test, designed for both home and point-of-care use. This sets a new standard as the first FDA De Novo authorization for a home use COVID-19 test and the first De Novo granted for any home use respiratory test.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20230606005936/en/



Cue Reader (Photo: Business Wire)

This significant achievement highlights Cue Health's dedication to empowering individuals with accurate, accessible, and actionable diagnostic tools. The FDA's De Novo authorization signifies that the Cue COVID-19 Molecular Test meets the agency's stringent regulatory standards for safety and efficacy.

Originally made available to consumers without a prescription through a 2021 FDA Emergency Use Authorization (EUA), Cue's COVID-19 test delivers results in just 20 minutes to connected mobile smart devices. With a demonstrated overall accuracy of 98%, the test detects all known COVID-19 variants of concern and integrates into Cue Care, the company's state-of-the-art test-to-treatment service.

Ayub Khattak, Chairman and CEO of Cue Health, said, "We are honored to receive this landmark De Novo authorization from the FDA, which emphasizes the reliability and accuracy of our COVID-19 Molecular Test in home and point-of-care settings. Our integrated test-to-treatment platform, coupled with the recent authorization of our mpox test and several other molecular tests under FDA review or in clinical studies, helps enable faster and better-informed healthcare decisions while making care and treatment more convenient."

This project has been funded in whole or in part with federal funds awarded by the Department of Health and Human Services; Administration for Strategic Preparedness and Response; Biomedical Advanced Research and Development Authority, beginning in June 2018 under contract number HHSO100201800016C.

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's COVID-19 test was the first FDA-authorized molecular diagnostic test for at-home and over-the-counter use without a prescription. Cue has since received Emergency Use Authorization from the FDA for its molecular mpox test at the point of care and, to expand its test menu, the company has a number of other submissions under review by the FDA. 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, 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 March 31, 2023 filed with the SEC on May 10, 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.

The Cue Mpox (Monkeypox) Molecular Test has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA. This product has been authorized only for the detection of nucleic acid from monkeypox virus, not for any other viruses or pathogens. The emergency use of this product 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 infection with the monkeypox virus, including in vitro diagnostics that detect and/or diagnose infection with non-variola Orthopoxvirus, under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

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