



Cue Health Named one of Fierce Medtech's "Fierce 15" Companies of 2020

March 8, 2021

SAN DIEGO, Jan. 19, 2021 /PRNewswire/ -- Cue Health Inc. (Cue) announced today that its molecular, point-of-care COVID-19 Tests are being distributed to five additional states, including Colorado, Minnesota, Pennsylvania, Rhode Island and Utah, as part of the joint \$481 million program with the U.S. Department of Health and Human Services (HHS) and the Department of Defense (DOD). This expansion doubles the number of states participating in the program. Cue expects to deliver six million tests by the spring. Cue's COVID-19 Tests are being used in point-of-care settings to provide molecular confirmation to antigen tests that yield positive and suspicious negative results, eliminating the need to send results to a central lab and thereby enabling healthcare providers to respond immediately.

The Cue COVID-19 Test is being used in a variety of applications by the departments of public health in each state. The tests are being distributed for use in high-concern populations and congregate care settings, such as long-term care facilities, nursing homes, and hospices, as well as in public health and safety screenings such as mobile testing units, drive-through clinics, K-12 schools, and hospitals. Tests are also being sent to tribal nations and rural communities where access to laboratories is minimal and results are not received for several days. In some states, tests are being provided to essential businesses, fire and police departments, and front-line workers. Correctional facilities and juvenile detention centers are also using Cue tests to monitor and prevent outbreaks.

"Cue is proud to expand this important program, scale our manufacturing, and deploy our test to make a positive impact on the health of communities alongside HHS and DOD," said Ayub Khattak, CEO of Cue.

Cue's easy-to-use, fast, molecular test provides lab-quality results directly to connected mobile phones. "Cue's COVID-19 Test is an efficient solution at the point-of-care, and is a critical part of our strategy to deliver the right test, for the right person, at the right time," said Assistant Secretary for Health and COVID-19 Testing Coordinator, Admiral Brett P. Giroir, M.D. "While this program is in the pilot phase, we have already seen a significant impact in communities across the country. It is our goal to deploy millions more of these tests that help improve infection control."

While each state has autonomy over how to best deploy the Cue test, notable use cases include the following: in Pennsylvania, the Children's Hospital of Philadelphia is using the tests for teachers and staff in K-12 schools in five counties. In Minnesota, Cue's tests are being deployed to assist underserved homeless populations and correctional facilities. In Utah, the test is being used in schools, long-term care facilities, drive-through clinics, and community testing centers to identify hot-spots and prevent community spread after the holidays.

In November 2020, Cue announced its COVID-19 Tests had been deployed to five states as part of the program's launch: Alaska, Florida, Louisiana, New Jersey, and Texas. The tests have been utilized in various ways, including at Veteran Affairs Medical Centers in New Jersey, fish processing plants in hard-to-reach regions of Alaska, and nursing homes in Louisiana.

Cue's COVID-19 Test is a portable, compact, easy-to-use, molecular test that detects the RNA of SARS-CoV-2 using a nasal swab (the Cue Sample Wand) taken from the lower part of the nose. Specimen collection and execution of the test is simple, requires no training, and is completely automated in its process of sample to result. Cue's molecular assay and connected platform, which provide results to a mobile smart device in about 20 minutes, is an efficient solution for frequent, fast, and reliable testing at point-of-care.

The Cue COVID-19 Test received Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA) on June 10, 2020. The test is authorized for use in point-of-care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

On October 13, 2020, HHS and DOD announced an award to Cue that will enable the company to expand its industrial base and U.S. production capacity to deliver six million COVID-19 Tests and 30,000 Monitoring Systems to the U.S. government, to support the domestic pandemic response. This effort is being led by the DOD's Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND), in coordination with the DOD's Joint Acquisition Task Force (JATF), and funded through the HHS' Office of the Assistant Secretary for Health, to enable and support domestic production of critical medical resources.

About Cue Health

Cue Health Inc. ("Cue") is an ISO 13485-certified company focused on developing and manufacturing professional and consumer medical diagnostic products that can be used in clinical or at-home settings. Cue's mission is to create tools that empower healthcare providers and consumers by increasing their access to actionable health data. Cue's first product, the Cue Health Monitoring System with the Cue COVID-19 Test Cartridge, is a platform that provides diagnostic information to clinicians and patients seeking to benefit from a connected healthcare delivery ecosystem. The company is based in San Diego, CA. For more information visit www.cuehealth.com

This test has not been FDA cleared or approved; this test has been authorized by FDA under an EUA for use by authorized laboratories; this test has been authorized only for the detection of nucleic acid from SARSCoV-2, not for any other viruses or pathogens; and this test 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 Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

SOURCE Cue Health Inc.

