

Cue COVID-19 Test for Home and Over The Counter (OTC) Use



Cue

Cue™ COVID-19 Test
For Home and Over The Counter (OTC) Use



Includes
Three (3) Cue COVID-19 Test Cartridges
Three (3) Cue Sample Wands

Cue COVID-19 Test for Home and Over The Counter (OTC) Use
No Prescription Required

The Cue COVID-19 Test for Home and Over The Counter (OTC) Use is a molecular diagnostic test for the qualitative detection of nucleic acid from SARS-CoV-2 in anterior nasal (nasal) swab specimens collected with the Cue Sample Wand. It is intended for use in adults (self-swabbing) or children ≥2 years of age (swabbed by an adult).

The test is run using the Cue Health Monitoring System (Cue Cartridge Reader), the Cue COVID-19 Test Cartridge, the Cue Sample Wand nasal swab, and the Cue Health Mobile Application.

Requirements
This product is for use with the Cue Cartridge Reader (not included) and the Cue Health Mobile Application installed on a compatible mobile smart device. Scan the QR code to see a list of compatible mobile smart devices before purchase and download the Cue Health Mobile Application. → 

Questions?
Contact Cue Customer Support at support@cuehealth.com or call toll-free at **(833) CUE-TEST · (833) 283-8378** to request a physical copy of the Instructions for Use and Fact Sheets, free of charge.

REF C1020 **IVD**
LOT For Use Under an Emergency Use Authorization (EUA) Only
Use By: Store Product Between 59°F (15°C) & 86°F (30°C)

The Cue COVID-19 Test for Home and Over The Counter (OTC) Use has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an Emergency Use Authorization (EUA). The Cue COVID-19 Test has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens. The emergency use of the Cue COVID-19 Test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of medical devices 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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 eIFU is available in the Cue Health Mobile Application

 Single Use Only

 Do Not Use if Packaging is Damaged

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Covered by one or more of the following U.S. patents: 9052275, 9207244, 9207245, 9360491, 9522397, 9623409, 9636676, 9718058, 9724991, 9608804, 9962703, 9999889, 10195606, D774407, D821602, D825772, international equivalents. Other patents pending.

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