Visby Medical's personal PCR device for COVID-19 testing gets EUA

Oct. 23, 2020—The FDA has issued an emergency use authorization for Visby Medical's single-use, personal PCR device for detecting COVID-19.

The Visby Medical COVID-19 test is a palm-size device that provides results in less than 30 minutes. It has been authorized for the qualitative detection of SARS-CoV-2 RNA in nasopharyngeal, nasal, or mid-turbinate swabs collected by a health care provider, or nasal or mid-turbinate swabs self-collected in a health care setting from individuals who are suspected of having COVID-19 by their health care provider.

"We are humbled by the FDA's decision," Adam de la Zerda, PhD, founder and CEO of Visby Medical, said in a press statement. "The COVID-19 crisis has shown that we don't just need more testing; what we really need are accurate results delivered quickly. If you care about accuracy, PCR is the right way to test for COVID. We are excited that Visby Medical's Personal PCR device will now provide rapid and accurate testing to lab personnel fighting the pandemic at the frontlines."

Emergency use of this test is limited to authorized laboratories that meet requirements to perform high or moderate complexity tests.