EUA for personal PCR device for COVID-19 testing

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November 2020—The FDA has issued an emergency use authorization for Visby Medical's single-use personal PCR device, a rapid test 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.

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

Visby Medical, 833-468-4729

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