

Visby POC COVID-19 PCR test gets CLIA waiver

March 2021—Visby Medical announced FDA authorization of the company's rapid PCR COVID-19 test for use at the point of care by organizations with a CLIA certificate of waiver.

"This latest authorization will have a dramatic impact on COVID-19 testing, especially in situations when an accurate result is needed quickly," Gary Schoolnik, MD, chief medical officer at Visby, said in a press release. "Visby's test can now be used directly at the point of care with our most vulnerable populations, including nursing homes; for frontline health workers; to maintain patient care at places like cancer and dialysis treatment centers; and to the many schools and institutions that have undertaken the process to become CLIA-waived environments."

The test 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. The palm-size device provides results in less than 30 minutes.

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