

COVID-19 Testing: The Latest Breakthrough

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Possible Resurgence of COVID-19 Cases

As we enter the fall, there is much anticipation about a possible resurgence of COVID-19 cases; especially in schools and on college campuses around the United States. College towns are very much in focus, as they bring in students from around the country and increase the risk of the virus' spread.

Researchers at PolicyLab at Children's Hospital of Philadelphia (CHOP) have warned of increased case counts in Midwestern college towns and large New England cities, such as Boston, Providence, and Hartford.¹

New Testing Guidance from the US Centers for Disease Control and Prevention (CDC)

New guidelines from CDC, issued on August 24th, reverses a previous recommendation that anyone who came into close contact with people known to be infected should be tested. The CDC now recommends, "If you have been in close contact (within 6 feet) of a person with a COVID-19 infection for at least 15 minutes but do not have symptoms, you do not necessarily need a test unless you are a vulnerable individual or your health care provider or State or local public health officials recommend you take one."²

This new guidance would seem to fly in the face of the risks associated with the virus' spread. Indeed, the guidance has come on the heels of a study published by the Journal of Pediatrics that finds that asymptomatic young people could be "silent spreaders" of COVID-19, with higher levels of the virus in their systems than hospitalized adults.³

The reasons for this new guidance are not the focus of this article; however, it is worth noting that the rationale may be political. Brett Giroir, the assistant secretary of health responsible for testing, confirmed on 26 August that the impetus for the change had come from the White House.⁴

Abbott's \$5, 15-Minute Test Gains Emergency FDA Approval

In spite of the new CDC guidelines, universal testing within companies, including Amazon, and on college campuses, has been embraced as a way to mitigate the risk of the virus' spread. Amazon committed to

¹ PolicyLab at Children's Hospital of Philadelphia. "New COVID-19 Projections Raise Continued Concerns for the Midwest, Northeast & Major College Towns". PRNewswire. August 26, 2020. Available at: <https://www.prnewswire.com/news-releases/new-covid-19-projections-raise-continued-concerns-for-the-midwest-northeast-major-college-towns-301119236.html>. Accessed on August 31, 2020.

² Dyer, Owen. "Covid-19: White House told CDC to stop recommending tests for asymptomatic contacts". TheBMJ. September 1, 2020. Available at: <https://www.bmj.com/content/370/bmj.m3386>. Accessed on September 1, 2020.

³ Dunleavy, Brian P. "Asymptomatic young people could be COVID-19 'silent spreaders'". UPI. August 20, 2020. Available at: https://www.upi.com/Health_News/2020/08/20/Asymptomatic-young-people-could-be-COVID-19-silent-spreaders/1121597928494/. Accessed on September 1, 2020.

⁴ Dyer, *op. cit.*

building diagnostic labs to test their warehouse workers months ago. But, now Abbott has gained FDA approval for a quick and inexpensive test that can be more widely adopted.

On August 26th, Abbott announced that the U.S. Food and Drug Administration (FDA) had issued Emergency Use Authorization (EUA) for its BinaxNOW™ COVID-19 Ag Card rapid test for detection of COVID-19 infection.⁵ The card is small (about the size of a credit card), costs \$5, and results are provided within 15 minutes of the time a sample is taken by a healthcare worker.

According to the press release, “[t]he BinaxNOW COVID-19 Ag Card demonstrated sensitivity of 97.1% (positive percent agreement) and specificity of 98.5% (negative percent agreement) in patients suspected of COVID-19 by their healthcare provider within the first seven days of symptom onset.”⁶

Other key points from the press release include the following⁷:

- AdvaMed (The Advanced Medical Technology Association) estimates that test manufacturers are shipping about 1 million tests per day. Abbott will ship tens of millions of tests in September, ramping to 50 million tests a month at the beginning of October.
- The BinaxNOW COVID-19 Ag Card is for use by healthcare professionals and can be used in point-of-care settings that are qualified to have the test performed....[T]he test can be performed by doctors, nurses, school nurses, medical assistants and technicians, pharmacists, employer occupational health specialists, and more with minimal training and a patient prescription.

The NAVICA Mobile App

In addition to the BinaxNOW card, Abbott is also offering a mobile app at no charge “that will allow people to display their results obtained through a healthcare provider when entering facilities requiring proof of testing”.⁸ The app is available in the app stores for both Apple and Android mobile devices.

Robert B. Ford, president and chief executive officer at Abbott Laboratories, explained the relationship between the card and the app: “While BinaxNOW is the hardware that makes knowing your COVID-19 status possible, the NAVICA app is the digital network that allows people to share that information with those who need to know”.⁹

If test results are negative, the app will display a digital health pass via a QR code, similar to an airline boarding pass. If test results are positive, people receive a message to quarantine and talk to their doctor.

⁵ Abbott Labs. “Abbott’s Fast, \$5, 15-Minute, Easy-to-Use COVID-19 Antigen Test Receives FDA Emergency Use Authorization; Mobile App Displays Test Results to Help Our Return to Daily Life; Ramping Production to 50 Million Tests a Month”. PRNewswire. August 26, 2020. Available at: <https://www.prnewswire.com/news-releases/abbotts-fast-5-15-minute-easy-to-use-covid-19-antigen-test-receives-fda-emergency-use-authorization-mobile-app-displays-test-results-to-help-our-return-to-daily-life-ramping-production-to-50-million-tests-a-month-301119289.html>. Accessed on August 31, 2020

⁶ *Ibid.*

⁷ *Ibid.*

⁸ *Ibid.*

⁹ *Ibid.*

With any luck, the scalability of this solution will allow for our businesses and institutions to cheaply and efficiently screen the population for COVID-19 this fall. Tools like this one will be crucial in helping us to ensure that those who need to be quarantined are doing so; whether they are symptomatic or asymptomatic.