

New report examines challenges and implications of false-negative COVID-19 tests

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As communities across the U.S. have struggled to cope with the effects of the COVID-19 pandemic, many have focused on the lack of

widespread testing as a major barrier to safely reopening the country. As progress has been made on this front, concern has shifted to testing accuracy, predominantly with antibody tests, which are designed to identify prior infection.

But according to a new Dartmouth-led paper published in the *New England Journal of Medicine*, more emphasis should be placed on addressing the inaccuracy of diagnostic tests, which play a key role in containing the pandemic.

"Diagnostic tests, typically involving a nasopharyngeal swab, can be inaccurate in two ways," explains lead author Steven Woloshin, MD, MS, a professor of medicine and community and [family medicine](#) at Dartmouth's Geisel School of Medicine, and of The Dartmouth Institute for Health Policy and Clinical Practice. "A false-positive result mistakenly labels a person infected, with consequences including unnecessary quarantine and contact tracing. False-negative results are far more consequential because infected persons who might be asymptomatic may not be isolated and can infect others."

In their paper, Woloshin and his colleagues discuss factors contributing to the current limitations of [diagnostic tests](#)—including variability in [test](#) sensitivity and the lack of a standard process for validating test accuracy—and also cite several large studies whose frequent false-negative results are cause for concern.

The researchers draw several conclusions from their work. "Diagnostic testing will help to safely open the country, but only if the tests are highly sensitive and validated against a clinically meaningful reference standard—otherwise we cannot confidently declare people uninfected," says Woloshin.

The FDA should also ensure that test manufacturers provide details of

their tests' clinical sensitivity and specificity at the time of market authorization. Tests without such information will have less relevance to patient care.

"Measuring the sensitivity of tests in asymptomatic people is an urgent priority," says Woloshin. "A negative result on even a highly sensitive test cannot rule out infection if the pretest probability—an estimate before testing of a person's chance of being infected—is high, so clinicians shouldn't trust unexpected negative results."

This estimate might depend on how common COVID-19 is where a person lives, their exposure history, and symptoms, he says.

More information: Steven Woloshin et al, False Negative Tests for SARS-CoV-2 Infection—Challenges and Implications, *New England Journal of Medicine* (2020). [DOI: 10.1056/NEJMp2015897](https://doi.org/10.1056/NEJMp2015897)

Provided by The Geisel School of Medicine at Dartmouth

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