

## False-negative COVID-19 test results may lead to false sense of security

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*Source:* Mayo Clinic

*Summary:* A new article calls attention to the risk posed by overreliance on COVID-19 testing to make clinical and public health decisions. The sensitivity of reverse transcriptase-polymerase chain reaction (RT-PCR) testing and overall test performance characteristics have not been reported clearly or consistently in medical literature, the article says.

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As COVID-19 testing becomes more widely available, it's vital that health care providers and public health officials understand its limits and the impact false results can have on efforts to curb the pandemic.

A special article published in *Mayo Clinic Proceedings* calls attention to the risk posed by overreliance on COVID-19 testing to make clinical and public health decisions. The sensitivity of reverse transcriptase-polymerase chain reaction (RT-PCR) testing and overall test performance characteristics have not been reported clearly or consistently in medical literature, the article says.

As a result, health care officials should expect a "less visible second wave of infection from people with false-negative test results," says Priya Sampathkumar, M.D., an infectious diseases specialist at Mayo Clinic and a study co-author.

"RT-PCR testing is most useful when it is positive," says Dr. Sampathkumar. "It is less useful in ruling out COVID-19. A negative test often does not mean the person does not have the disease, and test results need to be considered in the context of patient characteristics and exposure."

Even with test sensitivity values as high as 90%, the magnitude of risk from false test results will be substantial as the number of people tested grows. "In California, estimates say the rate of COVID-19 infection may exceed 50% by mid-May 2020," she says. "With a population of 40 million people, 2 million false-negative results would be expected in California with comprehensive testing. Even if only 1% of the population was tested, 20,000 false-negative results would be expected."

The authors also cite the effects on health care personnel. If the COVID-19 infection rate among the more than 4 million people providing direct patient care in the U.S. were 10% -- far below most predictions -- more than 40,000 false-negative results would be expected if every provider were tested.

This poses risks for the health care system at a critical time. "Currently, CDC (Centers for Disease Control and Prevention) guidelines for asymptomatic health care workers with negative testing could lead to their immediate return to work in routine clinical care, which risks spreading disease," says Colin West, M.D., Ph.D., a Mayo Clinic physician and the study's first author. Victor Montori, M.D., a Mayo Clinic endocrinologist, also is a co-author.

While dealing with the enormity of the growing COVID-19 pandemic, it's important for public health officials to stick to principles of evidence-based reasoning regarding diagnostic test results and false-negatives. Four recommendations are outlined in the Mayo Clinic article:

- Continued strict adherence to physical distancing, hand-washing, surface disinfection and other preventive measures, regardless of risk level, symptoms or COVID-19 test results. Universal masking of both health care workers and patients may be necessary.
- Development of highly sensitive tests or combinations of tests is needed urgently to minimize the risk of false-negative results. Improved RT-PCR testing and serological assays -- blood tests that identify antibodies or proteins present when the body is responding to infections such as COVID-19 -- are needed.
- Risk levels must be carefully assessed prior to testing, and negative test results should be viewed cautiously, especially for people in higher-risk groups and in areas where widespread COVID-19 infection has been confirmed.
- Risk-stratified protocols to manage negative COVID-19 test results are needed, and they must evolve as more statistics become available.

"For truly low-risk individuals, negative test results may be sufficiently reassuring," says Dr. West. "For higher-risk individuals, even those without symptoms, the risk of false-negative test results requires additional measures to protect against the spread of disease, such as extended self-isolation."

At Mayo Clinic, RT-PCR testing is "one of many factors we take into account in deciding whether the patient meets criteria for COVID-19," Dr. Sampathkumar says. If the RT-PCR test is negative but chest X-ray or CT scan results are abnormal, or there has been close contact with a person who has confirmed COVID-19, the recommendation is to continue caring for the patient as if he or she has COVID-19.

"We need to continue to refine protocols for asymptomatic patients and exposed health care workers," says Dr. Sampathkumar.

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**Story Source:**

Materials provided by **Mayo Clinic**. Original written by Jay Furst. *Note: Content may be edited for style and length.*

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**Journal Reference:**

1. Colin P. West, Victor M. Montori, Priya Sampathkumar. **COVID-19 Testing: The Threat of False-Negative Results**. *Mayo Clinic Proceedings*, 2020; DOI: 10.1016/j.mayocp.2020.04.004
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