




# Routine Antigen Testing Is Not a Substitute for Health Care Worker Vaccination against SARS-CoV-2

Mary Elizabeth Sexton,<sup>a</sup>  Colleen S. Kraft<sup>a,b</sup>

<sup>a</sup>Division of Infectious Diseases, Department of Medicine, Emory University School of Medicine, Atlanta, Georgia, USA

<sup>b</sup>Department of Pathology and Laboratory Medicine, Emory University School of Medicine, Atlanta, Georgia, USA

**ABSTRACT** The utility of rapid antigen testing for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is measured within the context for which it is applied; diagnostic accuracy must be considered in determining if rapid antigen testing is appropriate for the clinical situation. In this issue of the *Journal of Clinical Microbiology*, J. N. Kanji, D. T. Proctor, W. Stokes, B. M. Berenger, et al. (*J Clin Microbiol* 59:e01411-21, 2021, <https://doi.org/10.1128/JCM.01411-21>) evaluate two rapid antigen tests that demonstrate high false-positive rates in asymptomatic health care workers. The assays may not be useful in situations where there is a shortage of staff, such as health care settings, since isolation would occur unnecessarily for these employees.

The efficacy of rapid antigen testing for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has been shown to be an important aspect of managing the pandemic, given the inclusion of such testing in existing algorithms for COVID-19 infection control in health care settings and new guidelines that suggest it as a possible alternative to health care worker vaccination. For example, the Centers for Medicare and Medicaid Services (CMS) guidance for long-term-care facilities requires that unvaccinated staff undergo asymptomatic SARS-CoV-2 testing at a frequency ranging from monthly to twice weekly, depending on local community prevalence of COVID-19 infections (1). Antigen testing for SARS-CoV-2 is an approved testing modality in these facilities, given the advantage of rapid results and the availability of tests. The Centers for Disease Control and Prevention guidelines state that asymptomatic testing of this type could be expanded to health care personnel in other settings if there are sufficient resources (2). More recently, New York City has required that all public hospital employees undergo weekly SARS-CoV-2 testing starting in August of 2021 if they are not vaccinated against COVID-19 (3), and other hospital systems are likely to enact similar policies.

Kanji et al. (4) present an important prospective study of the positive predictive value of two rapid SARS-CoV-2 antigen tests used for weekly screening of asymptomatic health care workers. They found that while there were differences in the performance of the two tests utilized, neither had a positive predictive value of >70%, suggesting that use of rapid antigen testing for screening carries the potential for a significant number of false-positive tests.

Kanji et al.'s findings suggest that these types of rapid antigen use for screening of asymptomatic health care workers will generate false-positive results, and they appropriately highlight the cost of these false positives on already stressed health care systems. Concerns about the financial and staffing burdens associated with false-positive COVID test results for health care personnel are particularly important in light of the new Occupational Health and Safety Administration (OSHA) Emergency Temporary Standard (ETS) enacted on 21 June 2021 (5). The ETS mandates that health care workers who are exposed to COVID-19, either by patients or by their coworkers, must be furloughed for at least 7 days while awaiting negative COVID testing. If a large number of health care workers have false-positive COVID tests,

**Citation** Sexton ME, Kraft CS. 2021. Routine antigen testing is not a substitute for health care worker vaccination against SARS-CoV-2. *J Clin Microbiol* 59:e01564-21. <https://doi.org/10.1128/JCM.01564-21>.

**Editor** Yi-Wei Tang, Cepheid

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Address correspondence to Mary Elizabeth Sexton, [marybeth.sexton@emory.edu](mailto:marybeth.sexton@emory.edu).

For the article discussed, see <https://doi.org/10.1128/JCM.01411-21>.

*The views expressed in this article do not necessarily reflect the views of the journal or of ASM.*

**Accepted manuscript posted online**

1 September 2021

**Published** 19 October 2021

their close contacts will therefore be subject to unnecessary removal from work if they are unvaccinated and were not wearing appropriate personal protective equipment, which could exacerbate existing health care staffing shortages (6).

These considerations highlight the importance of focusing on vaccination of health care personnel, rather than utilizing a test-based strategy for control of COVID-19 infections within health care facilities. The potential costs of false-positive results, coupled with prior data that also raise concerns about false-negative results particularly in asymptomatic patients (7), suggest that mass asymptomatic rapid antigen testing should not be used to ensure safety of patients and health care workers. Kanji et al.'s findings therefore provide additional support for emerging recommendations for vaccine mandates in health care settings (8). These professional society recommendations focus on the potential for vaccines to prevent transmission between and among health care workers and their patients and to preserve safe staffing levels in health care facilities. Given the strong performance of existing COVID-19 vaccines with respect to prevention of both symptomatic illness and severe infection, both health care workers and their patients will be safer following implementation of mandatory vaccination policies, rather than relying on the use of flawed testing modalities that may detect even true positives after exposures have already occurred (8). If health care workers are all fully vaccinated, then testing would only be indicated for those with COVID-19 symptoms, when the test performance characteristics are better given the increased pretest probability (7).

While vaccination can be used to obviate mass testing protocols, there may still be a niche for asymptomatic rapid testing utilization within health care. Kanji et al.'s study was conducted during a time in which overall COVID-19 prevalence was decreasing with increasing vaccination rates, prior to the advent of the delta variant, and so it would be compelling to evaluate rapid antigen screening in the setting of a surge. There may also be a role for rapid antigen testing in outbreak situations, where there may be higher tolerance for false positives given the potential cost of missing cases when there is known to be COVID-19 spread within a health care setting. For example, under the CMS guidance for long-term-care facilities, all staff and residents are required to undergo testing if a COVID-19 case is identified in their facility, with subsequent testing every 3 to 7 days until no further cases are found for at least 2 weeks (1), and this test utilization is likely to be critical for contact tracing efforts.

Rapid antigen screening may also have more of a role in non-health-care settings with either more flexibility to wait on confirmatory testing or lower stakes associated with a false-positive result. Potential uses could include schools, where remote learning may be possible, or community social settings such as restaurants, theaters, and museums, where those who test positive would not be permitted entry, as per recent French regulations (9).

In any situation where rapid antigen testing has a potential role, Kanji et al.'s findings suggest that selecting a test with good performance characteristics is critical. They identified significant differences in the two tests utilized in their study, with one test having a positive predictive value of 24% and the other 70%; similar variability between tests has been documented previously (7). Choosing a well-validated test and deploying it during times of high prevalence will improve diagnostic accuracy. The variability in antigen test results also argues for consideration of rapid molecular testing in high-risk situations, although that would come at significantly increased cost.

The challenges identified by Kanji et al. with utilization of asymptomatic rapid antigen testing for health care workers are substantial, including false-positive results with associated potential for staffing shortages, high cost, and significant differences in test results from different manufacturers. These findings suggest that the routine use of these tests may be counterproductive as an infection control measure in health care settings, although it likely still has a role in responding to an outbreak. Vaccination would remove the need for routine asymptomatic testing and is therefore more reliable for ensuring a safe environment for health care workers and patients.

#### ACKNOWLEDGMENT

C.S.K. is on the scientific advisory board for Rebiotix/Ferring.

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