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# Proposed Framework for Considering SARS-CoV-2 Antigen Testing of Unexposed Asymptomatic Workers in Selected Workplaces

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**Objectives:** To propose a framework for considering SARS-CoV-2 antigen testing of unexposed asymptomatic workers in selected workplaces.

**Methods:** This is a commentary based on established occupational safety and health principles, published articles, and other pertinent literature, including non-peer-reviewed preprints in medrxiv.org prior to April 16, 2021. **Results:** Not applicable to this commentary/viewpoint article.

**Conclusion:** Antigen testing is a rapidly evolving and useful public health tool that can be used to guide measures to reduce spread of SARS-CoV-2 in the community and in selected workplaces. This commentary provides a proposed framework for occupational safety and health practitioners and employers for considering antigen testing as a method to screen asymptomatic workers in selected non-healthcare settings. When applied selectively, antigen testing can be a useful, effective part of a comprehensive workplace program for COVID-19 prevention and control.

**Keywords:** employees, employer, infectiousness, point-of-care, self-testing

To maintain a workplace free from recognized hazards and for businesses and workers to function safely and effectively, there is a need to prevent or reduce SARS-CoV-2 infection and transmission in the workplace. SARS-CoV-2 workplace prevention and control efforts rely on a hierarchy of controls, including engineering

controls, such as partitions or ventilation, administrative controls, such as physical distancing and hand washing and in some situations, use of personal protective equipment (PPE).<sup>1</sup> Viral testing is another important administrative control that may be used to increase the likelihood of early identification and isolation of infectious workers, thus further reducing exposures to SARS-CoV-2 in the workplace.<sup>2-8</sup> Advances in testing technology and an improved understanding of the frequency of asymptomatic transmission of SARS-CoV-2 have led to consideration of using viral testing to identify workers with current infection.<sup>9-11</sup> Employers can increase the utility of a viral testing program by implementing it as part of a comprehensive plan that includes strategies for communicating with employees and contingencies for modifying operations on the basis of test results, if needed.<sup>4</sup> In this commentary, we provide an overview of antigen testing and a framework for occupational safety and health practitioners and employers for using antigen tests to identify SARS-CoV-2 infection in asymptomatic workers to break the chain of transmission in selected non-healthcare workplaces (see “Whom to test” section).

## Overview of Antigen Tests

Antigen tests for SARS-CoV-2 use anti-viral antibodies as immunological reagents to detect the presence of viral proteins called antigens. Viral antigens are typically structural proteins encoded by the virus genome that can be detected by the host immune system.

## Antigen Tests for Screening or Diagnosis

Screening for SARS-CoV-2 infection with antigen testing is intended to identify persons whose infections would not otherwise be detected because they are asymptomatic or presymptomatic and have no known history of exposure to SARS-CoV-2. Screening tests identify persons who may be infectious so that measures, such as home isolation and removal from work, can be taken to prevent further transmission.<sup>2,9-12</sup> Antigen tests can also be used to diagnose infection with SARS-CoV-2 in individuals with symptoms or asymptomatic individuals with close contact.<sup>6</sup> Some studies have indicated antigen tests can be a test of infectiousness.<sup>11,13,14</sup> Depending on the circumstances, the results of some antigen tests are presumptive until confirmed by a more definitive nucleic acid amplification test (NAAT). However, with guidance, presumptive results can lead to preventive measures, such as home isolation and removal from work.<sup>6</sup>

## Performance Characteristics

SARS-CoV-2 antigen tests detect virus proteins involved in the assembly of viral particles. These tests generally have high analytical and clinical specificity, often better than 95%, but their clinical sensitivities are lower than those of real-time reverse transcription polymerase chain reaction (RT-PCR) tests, ranging from 72.6% to 97.6%.<sup>6,18-22</sup> Sensitivity and specificity are terms used to describe test performance. In the current context, sensitivity

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This manuscript describes using tests for COVID-19 infection to screen asymptomatic working populations. This indication may differ from indications such as evaluating symptomatic individuals authorized by the U.S. Food and Drug Administration.

**Clinical Significance:** This manuscript provides important information for clinicians on how to break the chain of transmission of SARS-CoV-2 virus in workers. It provides guidance on antigen testing as the major focus.

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is the proportion of persons with SARS-CoV-2 infection (ie, true positive condition) that were correctly identified by the test.<sup>23,24</sup> Specificity is the proportion of true negative persons correctly identified by the test.<sup>25</sup>

Although assay results vary, antigen tests often are more likely to be positive when the cycle threshold (Ct) score (in a RT-PCR test on the same person's specimen) is low (<25).<sup>24</sup> NAATs, such as RT-PCR tests, can detect minute quantities of viral genomic material in individual samples which might or might not be infectious. Both types of tests are most likely to be positive in the period just before or just after development of COVID-19 symptoms, when persons have their highest viral load; however, it has been reported that positive antigen tests correlate better with viral culture results and thus perhaps infectiousness.<sup>11,13,14,25–27</sup> Viral load does not appear to differ between asymptomatic and symptomatic infections, but this has not been confirmed.<sup>13,17,28</sup>

For persistently asymptomatic persons, antigen tests can detect when they are most infectious, but test sensitivity for asymptomatic persons is not well established.<sup>29,30</sup> A recent large study compared an antigen test, RT-PCR, and viral culture results for 3419 persons participating in a community screening program. The performance of the antigen test relative to RT-PCR was measured by sensitivity and specificity, which were, respectively, 64.2% and 100% for symptomatic persons and 35.8% and 99.8% for asymptomatic persons. Sensitivity of antigen testing relative to viral culture was 92.6% for symptomatic persons and 78.6% for asymptomatic persons, which was higher than sensitivity of antigen testing relative to RT-PCR results. Thus, antigen test sensitivity appears higher with symptomatic illness and when culturable virus is present; specificity is high for both symptomatic and asymptomatic persons.<sup>31</sup>

### Time to Results

Antigen tests can be designed in many platforms.<sup>32</sup> Lateral flow technologies are inexpensive and can produce test results within a few minutes while the person waits for the results at home or at the testing location; these tests have also been called “point-of-care” testing.<sup>11</sup> It is in this context the term *rapid antigen testing* is sometimes used.<sup>14,15,32–36</sup> Serial testing using rapid-turnaround antigen or other point-of-care tests for SARS-CoV-2 at the workplace, another designated location, or even via self-administration at workers' homes is technically feasible today.<sup>11,17,25,26,37–39</sup>

### Using Antigen Tests to Break the Chain of Transmission

From a public health perspective, antigen testing can also be important for breaking the chain of transmission, by quickly identifying persons with current infection to reduce workplace transmission.<sup>11,15,17,37,39–41</sup>

Data on antigen test performance for asymptomatic persons are limited but increasing.<sup>7,17,22,26,27,29–31,37,42–44</sup> Even though the limit of detection for SAR-CoV-2 is 100 to 1000 times higher for antigen tests than diagnostic RT-PCR testing, antigen testing is likely sufficient for use in serial screening to help break the chain of transmission in a business workforce and thus reduce the workforce incidence.<sup>11,13,17,26,32,40,45</sup> Limited empirical data suggest that asymptomatic antigen-negative workers are unlikely to develop symptoms of COVID-19 or transmit the virus.<sup>15,47,48</sup>

### Antigen Tests in Commerce and Business

As of April 16, 2021, only three SARS-CoV-2 antigen tests (Ellume COVID-19 HomeTest, Abbott BinaxNow, and Quidel QuickVue) have received emergency use authorization from the U.S. Food and Drug Administration (FDA) for home use; some of these are over-the-counter products that can be used by asymptomatic persons.<sup>42,44</sup> The product overview for healthcare professionals states that all results are presumptive for asymptomatic persons.<sup>49</sup>

As of March 2021, CDC recommended that public health jurisdictions consider implementing expanded screening with antigen tests or NAATs of asymptomatic and presymptomatic persons to help prevent silent spread, as an addition to comprehensive mitigation measures and testing of symptomatic persons.<sup>50</sup> Rapid antigen tests are being used extensively in schools, various congregate settings, and by sports organizations.<sup>51–54</sup> For example, the National Collegiate Athletic Association (NCAA) has developed plans to screen asymptomatic participants in NCAA basketball programs with antigen tests, including student-athletes and essential personnel whose job function requires regular, direct access to players.<sup>55,56</sup> Worldwide, nearly 100 companies are developing or manufacturing tests for antigen detection, although not all are approved.<sup>56,57</sup>

### Rationale for Developing an Antigen Testing Program for Workers

Developing an antigen testing program for workers, along with other preventive measures, would help support safe workplace operation.<sup>56</sup> Workers represent a defined, circumscribed population, where COVID-19 preventive programs can be efficiently implemented.<sup>58</sup> Identifying active cases of COVID-19 among workers “not only helps stop virus spread in the workplace but also is a vital component of a larger national effort to stem the pandemic.”<sup>59</sup>

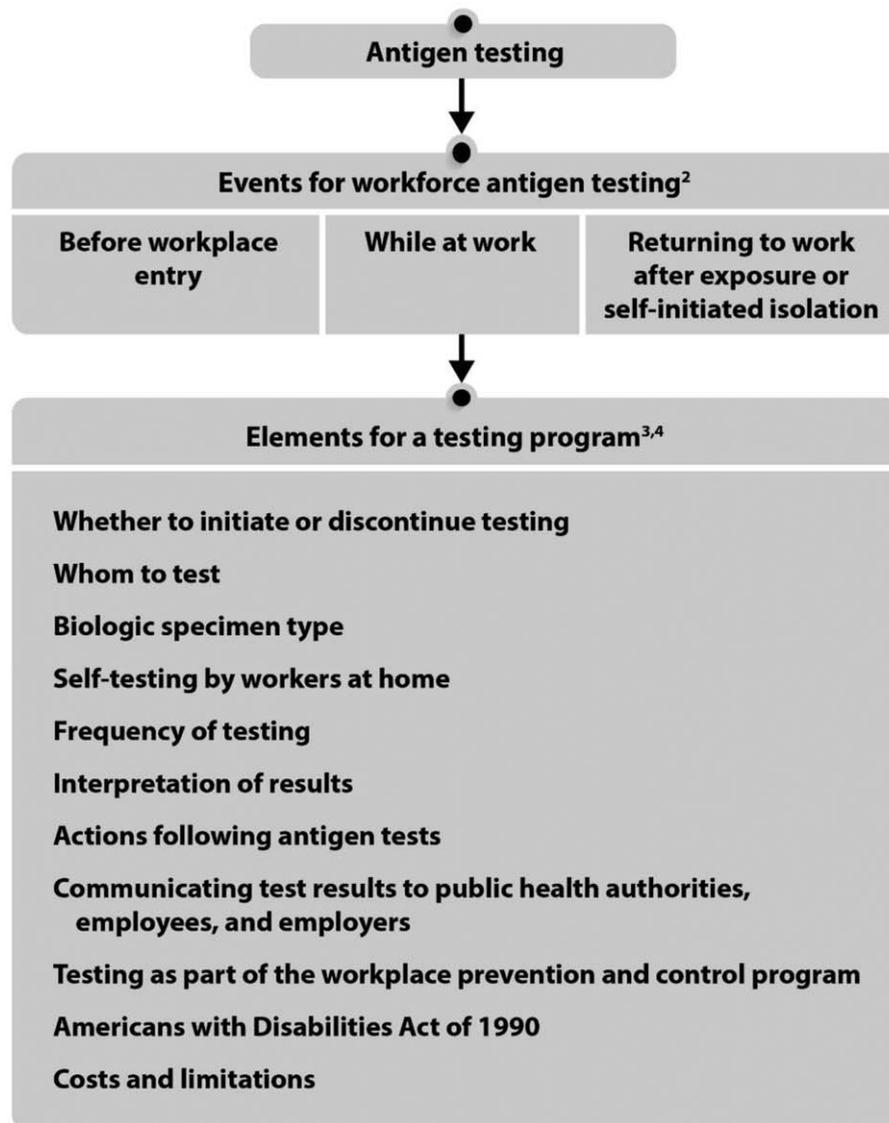
Workers can benefit from clarification of the language used to describe antigen tests used for screening workers, because their primary function in a work setting is not clinical diagnosis; rather, it is detection of infected and thus potentially infectious persons without symptoms and known or suspected exposure to SARS-CoV-2 to control transmission at the workforce population level. Consequently, it may be useful to use the term *screening test*<sup>50</sup> or the even more informative term *workplace outbreak prevention test*.

### Framework Development

This article proposes a framework that employers can consider using when planning an antigen test screening program. It is supported by literature that addresses each factor in a framework of factors generally considered in testing workers.<sup>3,4</sup> In the context of the COVID-19 pandemic, the rapid evolution of laboratory testing and epidemiological findings warranted the inclusion of information that has not been peer reviewed. The literature review was conducted using classic occupational safety and health medical screening literature (such as Halperin et al. 1986,<sup>60</sup> Gochfeld 1992,<sup>61</sup> and Wesdock and Sokas 2000<sup>62</sup>), as well as pertinent literature (publications and preprints) on antigen testing in medrxiv.org prior to April 16, 2021. The medrxiv.org platform indicates that “preprints are preliminary reports of work that have not been certified by peer review (<https://www.medrxiv.org>). They should not be relied on to guide clinical practice or health-related behavior and should not be reported in news media as established information.” As they become available, evaluations of workplace testing and publication of those findings in peer-reviewed journals will be important sources of information.

### Proposed Framework

Employers that require or utilize antigen testing are most likely to be successful if they have the capability and capacity to conduct such testing (either directly or through contractors and consultants).<sup>4</sup> The proposed framework (Fig. 1) addresses important questions about planning and implementation of an antigen testing program for asymptomatic, unexposed workers on a daily or other periodic basis. The framework can be incorporated into a workplace COVID-19 preparedness, response, and control plan before testing a large proportion of asymptomatic workers without known or suspected exposure.<sup>4</sup>



<sup>1</sup>This proposed framework is based on established occupational safety and health practice, currently available literature on SARS-CoV-2, and the authors' professional judgement and expertise by adapting the former to the latter.

<sup>2</sup>Employers may want to conduct testing for any of these events.

<sup>3</sup>All elements should be considered before starting testing; the order of consideration is not consequential.

<sup>4</sup>Elements may pertain to each of the events where testing could occur.

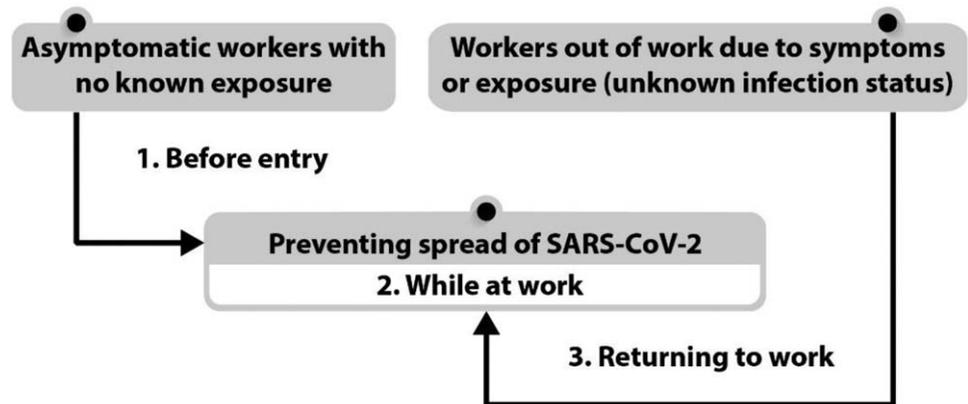
**FIGURE 1.** Proposed framework for consideration of antigen testing of asymptomatic or unexposed workers on a periodic basis.<sup>1</sup>

Although all workers could be the focus of testing for SARS-CoV-2, this framework focuses on asymptomatic and apparently unexposed workers at increased risk (eg, workers who work in close proximity of each other, and with customers and suppliers) who are not in healthcare settings.<sup>4,6</sup> This is in recognition of estimates that 30% to 60% of SARS-CoV-2 infections are due to asymptomatic transmission.<sup>2,42</sup>

Guidance on testing has been developed for workers in critical infrastructure, healthcare, and other businesses.<sup>3,4</sup> There is also guidance for testing asymptomatic workers in various settings, such as schools, after an exposure; for returning to work after a prolonged absence; and for periodic testing of employees.<sup>4,63</sup> This framework applies existing guidance to selected workplaces and provides more details on specific aspects of antigen testing.

Antigen testing as discussed here is not for diagnostic purposes; rather, it is to screen workers and break the chain of transmission of SARS-CoV-2.<sup>11,41</sup> The use of antigen testing specifically for workers is proposed as part of a planned effort of information dissemination and communication (identified in this article) to inform workers that the test result is not a definitive diagnosis but merely a presumption that can be rebutted by subsequent tests. Testing alone is not sufficient to prevent SARS-CoV-2 transmission.

The elements of the framework include: whether to initiate or discontinue testing; whom to test; biologic specimen type; self-testing by workers at home; frequency of testing; interpretation of test results; actions following antigen test results; communicating test results to public health authorities, employees, and employers;



**FIGURE 2.** Workplace events for testing workers for SARS-CoV-2.<sup>1</sup> Three possible scenario events where an employer may want to conduct testing for SARS-CoV-2.

testing as part of a workplace prevention and control program; Americans with Disabilities Act of 1990; and costs and limitations.

### Events for Workplace Antigen Testing

Employers may choose to use antigen testing with regular frequency at one or more of three events—before entry into the workplace, while at work (including travel for work), and returning to work after exposure or self-initiated isolation (Fig. 2).

The first event focuses on preventing SARS-CoV-2 virus entry into the workplace by screening workers before they enter. If workers have symptoms of COVID-19, they should not go to work.<sup>1,4</sup> They should isolate at home and consult a healthcare provider. For workers without symptoms who go to work, antigen testing may be used to identify asymptomatic or presymptomatic COVID-19. Such testing could be conducted daily or as frequently as practical at the workplace, a medical or other designated facility, or at home with a self-testing kit. CDC and other sources suggest that testing with a frequency less often than weekly is not worthwhile.<sup>41,64</sup> No symptomatic workers or workers who tested positive for SARS-CoV-2 (see the “Actions following antigen test results” section) should be permitted to enter a workplace.<sup>1,4</sup>

The second event is using testing to prevent viral spread in the workplace. After one or more persons with SARS-CoV-2 infection are identified in a workplace, periodic testing of part or all of the workforce, even beyond obvious close contacts, can be considered. Adjustments might also be made on the basis of changes in community prevalence potentially affecting the workforce.

The third event of testing is to assess workers who have been out of work, such as for self-initiated isolation due to symptoms or self-initiated quarantine due to exposure to SARS-CoV-2. Employers may choose to have these employees participate in the same antigen screening program as any other employee after they return to work, to prevent workplace transmission.<sup>4</sup> However, for workers with documented SARS-CoV-2 infection, antigen testing does not play a role in determining when to discontinue isolation.<sup>64,65</sup> Once they meet the criteria for discontinuing isolation, workers could return to work. Current CDC guidance states that “for adults previously diagnosed with symptomatic laboratory-confirmed COVID-19 who remain asymptomatic after recovery, retesting or quarantine is not recommended if another exposure occurs or might have occurred within 90 days after the date of symptom onset from the initial SARS-CoV-2 infection.”<sup>64</sup>

### Whether to Initiate or Discontinue Testing

Employers have an opportunity to prevent SARS-CoV-2 transmission in the workplace by adding a screening testing

program to other workplace prevention and control measures such as masks, PPE (where appropriate), physical distancing, hand hygiene, surface cleaning and disinfection, appropriate ventilation, and other engineering controls (such as physical barriers).<sup>1</sup> *Testing alone is not sufficient to prevent SARS-CoV-2 transmission.*

In addition to their readiness to implement testing as part of a comprehensive COVID-19 preparedness, response, and control plan, employers who are considering antigen testing can inform their decision making by taking into account the burden of COVID-19 in the community and other factors such as feasibility and cost.<sup>50,66</sup> Community burden, or prevalence, can be judged by factors such as the number of persons who test positive for SARS-CoV-2 per 100,000 people within the last days; burden can be more grossly approximated by test positivity rates, or the percentage of tests performed that have positive results.<sup>2,50</sup> Community incidence of SARS-CoV-2 infection is a key indicator of the probability that a person seeking workplace entry is infected and will influence how much testing is needed.<sup>2</sup> If the community burden of SARS-CoV-2 infection is low (suggested by low recent incidence [for example, <20 cases per 100,000 persons] or low percentage of positive tests among those tested [for example, <5% test positivity]), the positive predictive value of a positive antigen test will be low.<sup>6</sup> Reviewing the frequency of testing on a regular basis can incorporate changes in community burden, which may result in a more appropriate level of testing.<sup>50</sup> The state, local, tribal, and territorial public health authorities are sources of information on incidence and rates of test positivity.<sup>67</sup>

CDC suggests that the frequency of testing could be informed by current community indicators for COVID-19 such as cumulative incidence in the past 7 days and test positivity rate, as well as other information on the epidemiology of transmission in a particular community.<sup>50</sup> Another tool that may be helpful in deciding to test on the basis of incidence is the listing of new cases in the county risk levels provided in the Harvard Global Institute COVID Risk Levels Map.<sup>68</sup> The number of new cases daily is represented by colors: red (>25 daily new cases per 100,000 people); orange (10–25 daily new cases per 100,000 people); yellow (1–10 daily cases per 100,000 people); and green (<1 daily new case per 100,000 people). Employers might consider testing when the county(s) or other jurisdictions where their employees reside or surrounding the establishment are red, orange, or yellow, but not green. Silcox et al<sup>2</sup> pointed out that aggressive, accurate, efficient testing and contact tracing, paired with continued social mitigation measures, will likely lead to a decline in testing demand over time. As case counts decrease with these measures, fewer close contacts will be identified, which will reduce the need to test them.

Employers may also decide to test, regardless of community prevalence (a) if they are aware of any past or present cases in their workforce; (b) on the basis of workforce characteristics discussed in the “Whom to test” section; or (c) if public confidence in safety of the workplace is critical to business operations (such as for an airline).<sup>4</sup>

### Whom to Test

State or local public health jurisdictions, rather than individual employers, may determine testing priority for non-healthcare employees. CDC has compiled examples of groups to consider for prioritization, such as workers in high-density worksites or worksites with large numbers of close contacts (eg, restaurant workers, transportation workers, grocery store workers).<sup>50</sup> Silcox et al<sup>2</sup> describes three factors that can inform decisions about who receives priority screening tests: (1) whether the workforce is at increased risk of exposure to SARS-CoV-2; (2) whether the workforce has increased risk of SARS-CoV-2 transmission; and (3) whether the workforce is at risk of increased negative impact due to infection. Examples of workers at increased risk of exposure to SARS-CoV-2 include mobile workers and business travelers (especially if traveling in enclosed modes of transportation) and workers who regularly interact with customers, the general public, or persons in their supply chain (delivery workers, for example). Workers at increased risk of transmission include those who work indoors in high-density workplaces or other workplaces where public health measures such as physical distancing, masking, and use of barriers or partitions cannot be optimally implemented; workers who travel together to worksites in shared vehicles; and workers in congregate living settings. Those at risk of increased negative impact from SARS-CoV-2 infection include older workers and workers with underlying medical conditions who are at higher risk of hospitalization and death, workers in remote settings with limited access to healthcare, and critical-infrastructure workers whose absence may impact the safety or health of a community.

Depending on effectiveness and duration of protection provided by current and future COVID-19 vaccines, it is likely that the proportion of the workforce vaccinated for COVID-19 will be an important future consideration regarding whom to test.

### Biologic Specimen Type

Antigen testing can be conducted on nasopharyngeal swabs, nasal swabs, and saliva samples, but the type of specimen is strictly associated with the test used.<sup>27,69–71</sup> To achieve frequent home use, saliva may be the specimen easiest to collect; however, saliva is not listed as a specimen type under the current FDA emergency use authorizations for antigen tests.<sup>37,72,73</sup> At the time of this writing (April 16, 2021), various prototypes of self-administered at-home rapid antigen tests are in development, but only three companies have received FDA authorization.<sup>74</sup> Although several companies have received FDA authorization to sell antigen testing instruments for point-of-care use, only three companies have been cleared to sell tests directly to consumers.<sup>74,75</sup> Whether saliva will be useful in at-home tests is still under investigation.<sup>76,77</sup>

### Self-Testing by Workers at Home

Home testing by workers using antigen tests may be useful as a means to prevent SARS-CoV-2 transmission and may allow for a broad range of businesses to function if employers are confident that workers likely are not infectious (Fig. 3).<sup>11,26,33,35,37</sup> Employers may want to consider some issues before home testing can be accepted. It is necessary to use only tests approved for home use. The tests must be accurate and reliable and the results must be verifiable. Accuracy, which has been addressed elsewhere in this article, is enhanced by serial testing.

Because there are many social and financial pressures for test-takers to misrepresent their results, employers may want tests to be independently validated.<sup>78</sup> One possible means of validation is an app that sends users (employers and employees) a mobile phone indication if a test is negative. It allows people to store, access, and display their test results with date and time information.<sup>79</sup> Despite the possibility of remote test verification, there still may not be complete certainty that a specific test result is linked to a specific worker. Nevertheless, the employer will need to communicate all of these aspects of home testing to the employee and gain their acceptance of it.

### Frequency of Testing

Serially testing workers can improve the likelihood of detecting cases of SARS-CoV-2 infection.<sup>8,10,11,33,41,80</sup> The frequency will depend in part on the community incidence, that is, the incidence in the geographic area where the workers reside, as well as on the workforce risk characteristics of individual companies. Depending on the community and workplace burden of infection, the frequency of testing may vary.<sup>41</sup> To reduce silent spread of SARS-CoV-2, CDC has provided guidance regarding screening testing in select groups, including some groups of workers, with frequency of at least weekly. CDC guidance states that screening frequency could be informed by county-level cumulative incidence over the past 7 days and percentage of viral tests that are positive in the past 7 days are in the “substantial” or “high” categorizations for these indicators.<sup>50</sup>

Viral kinetics also play a role in selecting the frequency of testing. Although the performance characteristics of different brands of antigen tests vary, antigen tests are most sensitive when a worker has a high viral burden and is most likely to be infectious.<sup>11,81</sup> Catching this time window is more likely with regular testing of each worker.<sup>11</sup> Additional factors guiding the frequency of testing include the availability of testing, community burden, size of workplace, employer’s tolerance for missing infections, employees’ tolerance for frequent testing, costs, and history of workplace outbreaks.<sup>10,16,40,45</sup> Some authors have envisioned antigen testing being performed possibly as often as daily, for example, if tests are inexpensive, readily available, and involve less invasive sampling methods, such as saliva-based tests.<sup>45,46</sup> The frequency of testing may vary from consideration of one or more of these factors as well as the concerns of employees.

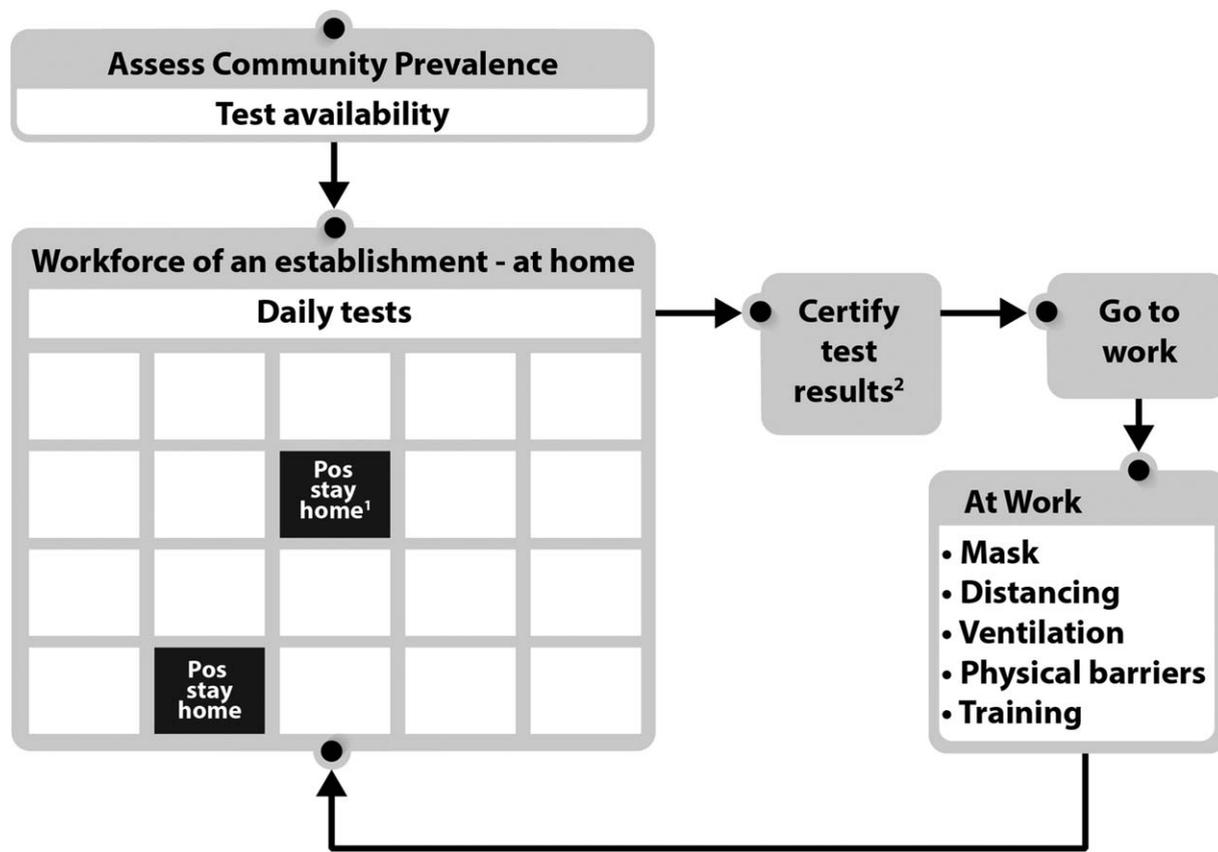
### Interpretation of Test Results

The interpretation of antigen tests should take into account several factors (1) the performance characteristics of the test, (2) the timing of the test and repeat tests, and (3) the incidence of COVID-19 in the workplace and community and the clinical characteristics of the individual being tested.<sup>6</sup> As they do with various occupational safety and health issues, employers may need consultant services to assist in addressing test results.

### Test Performance

All tests have the potential to give an erroneous result: a Type I error is a false-positive result for someone who actually *is not* infected, and a Type II error is a false negative result for someone who actually *is* infected. Ideally, tests would have minimal Type I and Type II error.<sup>82</sup> The value of using tests for screening a population or sub-population depends on the expected prevalence of the disease in the tested population.

In order to use testing to exclude infected workers from entering a workplace, the key would be to have a test with a low false negative (Type II error) rate. This would improve confidence that infected persons could be excluded and not spread the disease among the screened-negative population. However, if the false-positive rate (Type I error) is too high, too many non-infected workers would be limited from being able to perform their duties.



<sup>1</sup>Positive workers should stay at home and self-isolate.

<sup>2</sup>Use of various approaches, such as phone apps, to assure employers that results pertain to a specific worker.

**FIGURE 3.** Process for daily at-home antigen testing of employees of a business establishment.

The performance of antigen tests in asymptomatic persons is under active investigation. One study in a university setting reported sensitivity of 41.2% and specificity of 98.4% among asymptomatic persons.<sup>30</sup> Another study offering free testing in a community with ongoing SARS-CoV-2 transmission showed sensitivity of 81.4% and specificity of 99.9% among asymptomatic persons and persons with symptom onset >7 days before testing (and presumed to no longer have symptoms).<sup>19</sup> On the basis of this information, if a workforce is screened once with an antigen test, it might incorrectly identify 18.6% to 58.8% of those who actually have SARS-CoV-2 infection as uninfected (false negatives), and it might incorrectly identify 0.1% to 1.6% of those who are uninfected as having SARS-CoV-2 infection (false positives). These studies calculated sensitivity and specificity of antigen tests relative to NAATs. However, when compared to symptom and temperature screening, a screening program based on antigen testing has higher sensitivity and specificity.

The performance of antigen tests can be affected if the test components are not stored and handled properly and if the test results are not read at the proper time. Quality assurance procedures should be followed to prevent cross-contamination and inaccurate test results.<sup>6,18,22,83</sup>

**Timing of Testing**

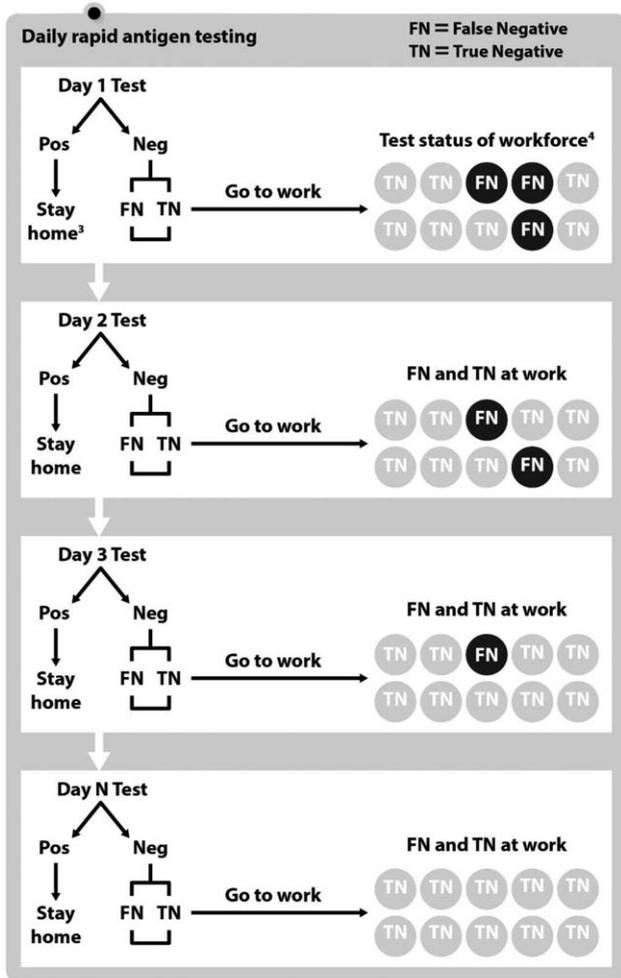
Timing of test administration plays a critical role in interpreting results according to the test’s limit of detection and viral

replication kinetics. A negative test indicates that at the time of testing, viral material is not present or is below the limits of detection for the assay.<sup>11,12</sup> It does not necessarily indicate that the virus is absent in the worker or that it will not be detectable in a few days or even a few hours.<sup>11,12,45</sup> Additional information, such as the incidence of SARS-CoV-2 infection in the workforce and community and any clinical information, can help with interpreting the test result.

**Community and Workplace Incidence and Clinical Characteristics of SARS-CoV-2 Infection**

The pre-test probability for an antigen test is the probability that the worker is infected with SARS-CoV-2 prior to administration of the test. Pre-test probability is based on community incidence of SARS-CoV-2 and clinical presentation. In the testing of asymptomatic workers, and in the absence of additional clinical information such as history of exposure or past infection, pre-test probability is based on the incidence of SARS-CoV-2 infection in the community. When additional information is available, the pre-test probability may be revised upward (such as for history of fever, cough, or shortness of breath) or downward (such as for history of COVID-19 vaccination).

When the pre-test probability is low, such as when a worker is asymptomatic and reports no exposure, and the antigen screening test is administered during a period of low incidence, a positive test result may be a false positive. This result should be interpreted as a



<sup>1</sup>Testing could be at home or at employer-designated site.  
<sup>2</sup>Workers with false negative results could still transmit SARS-CoV-2.  
<sup>3</sup>Positive workers should stay home and self-isolate in accordance with current CDC guidelines (CDC 2020c).  
<sup>4</sup>Each day prevalence of FN would decrease.

**FIGURE 4.** Hypothetical illustration of daily antigen testing reducing false negative results.<sup>1,2</sup>

presumptive positive and should be followed by a highly specific confirmatory NAAT.<sup>6</sup> In the setting of low pre-test probability, a negative antigen screening test result is more likely to be a true negative and does not need to be confirmed by NAAT. If a screening test result is a false negative because it was performed too early in the course of infection to identify viral antigen, then subsequent serial testing may identify infection, still providing early identification and prevention of workplace transmission. It is also useful to consider not conducting screening when community transmission is quite low.

Conversely, when the pre-test probability is high, a positive result from an antigen test is more likely to be a true positive. Persons with positive tests should self-isolate and consult with a medical provider. However, when the pre-test probability is moderate, positive antigen tests should be confirmed by NAAT.<sup>6</sup> When there is a high clinical index of suspicion for COVID-19 (for example, because of symptoms associated with COVID-19), an individual with a negative antigen test should be isolated until the negative test is confirmed with a NAAT.<sup>6</sup>

Because antigen tests are highly effective in identifying infectious persons, particularly for symptomatic ones but possibly

less so for asymptomatic ones, the proportion of falsely negative infectious workers will be lower than the proportion of false negative workers overall. Repeated serial testing may further help identify workers who are infectious but previously tested negative as depicted in Figure 4.<sup>13,26,29,45</sup>

**Actions Following Antigen Test Results**

Employees who test positive with an antigen test, including those who have received a COVID-19 vaccine, should follow CDC recommendations regarding isolation, not reporting to work and contacting their personal healthcare provider for appropriate management.<sup>6,65,84</sup> Depending on the pre-test probability, a confirmatory NAAT may be warranted to exclude a false-positive antigen test, particularly for tests not performed by professionals in a laboratory.<sup>6</sup> Reasons for false-positive tests include contamination or cross-reactivity with other viruses.<sup>85,86</sup> User error is also a concern for tests not performed by Clinical Laboratory Improvement Amendments (CLIA)-certified clinical laboratories. An asymptomatic employee with a positive antigen test should be excluded from work until a confirmatory test is completed.<sup>6</sup> For asymptomatic workers with a confirmed RT-PCR positive test, isolation can be discontinued 10 days after the date of their first positive RT-PCR test for SARS-CoV-2.<sup>64</sup> In rare circumstances when a worker is severely immunosuppressed, consultation with medical experts to determine a strategy for potential return to work that includes RT-PCR testing is recommended.<sup>65</sup> False-positive antigen tests may be a hardship for workers. CDC has encouraged employers to consider implementing flexible, non-punitive paid sick leave and supportive policies and practices.<sup>4</sup> Some employees may be eligible to take leave under the Family Medical Leave Act (29 U.S.C 2601, et seq).

Upon receipt of antigen test results, an employer can allow an asymptomatic and unexposed worker who tests negative to enter the workplace and to work. The employer should also support contact tracing activities by public health professionals for employees who worked near workers who tested positive and were diagnosed with COVID-19.<sup>4,6,87,88</sup>

**Communicating Results to Public Health Authorities, Employees, and Employers**

**Public Health Reporting Requirements**

Point-of-care testing may be performed with a CLIA certificate of waiver, but reporting of test results to state or local public health departments is mandated by the Coronavirus Aid, Relief, and Economic Security (CARES) Act.<sup>90</sup> A CLIA-certified laboratory or testing site operating under a waiver must report antigen diagnostic and screening test results to the local, state, tribal, or territorial health department, in accordance with Public Law 116–136, §18115(a), the CARES Act.<sup>90</sup>

Laboratory and testing professionals should collect and report complete patient demographic information and ensure that they report antigen test results by using the proper LOINC for their FDA-authorized assay.<sup>90,91</sup> A CLIA-certified laboratory or testing site must also report antigen test results to the individual or the individual’s healthcare provider according to the instructions from their assay.<sup>84</sup>

Since workers have contacts and exposures outside the workplace, contact tracing in the community is also important. Employers can collaborate with local public health jurisdictions by sharing test results.<sup>87,88</sup> In some states this may be required.<sup>95</sup> Public health jurisdictions can then conduct contact tracing in the workplace and the community if they have the capacity. Because antigen tests administered serially will generate many test results, it is important to inform jurisdictions prior to testing that an antigen testing program is being initiated.

## Communicating Test Results to Employees

The key to communicating antigen test results to workers is to describe the test and its results as one part of the overall plan to prevent transmission of SARS-CoV-2 in the workplace. The power of the antigen test for workers relies on serial testing, quick return of results, appropriate isolation and quarantine, and contact tracing within the workforce and the community.<sup>90,91</sup> Employers can facilitate employees' understanding of the purpose and limitations of the program by implementing a communication plan in advance of testing in support of ensuring informed consent.<sup>60,84,92</sup> It is important that employers or their designees communicate that a negative test result may not mean that a worker is free of infection nor that the worker will not be infectious in future days, weeks, or months.<sup>93</sup> It only means that, at the time of the test, the worker was unlikely to be infectious. Thus, even if the worker is infected, the viral protein present is insufficient to be detected by the test; but that can change, sometimes within hours.<sup>11</sup>

## Communicating Test Results to Employers

Employers can implement policies describing how and when employees or test providers can communicate SARS-CoV-2 antigen test results to the employer. The employer should have means to keep workers' test data confidential.<sup>84</sup>

## Testing as Part of a Workplace Prevention and Control Program

Antigen testing for SARS-CoV-2 is not sufficient for controlling COVID-19, because a test result can be a false negative or the onset of new infections can occur between scheduled tests, as depicted hypothetically in Figure 4. There is concern that antigen testing may lead to false-negative test results for persons who may infect other people.<sup>94</sup> Thus, there is a need for a comprehensive effort even when all workers have tested negative. Comprehensive efforts should include appropriate ventilation and other engineering controls such as barriers, screening for symptoms, guidance for wearing cloth masks for source control, maintaining physical distancing, hand hygiene, surface cleaning and disinfection, administrative controls, and use of PPE where appropriate.<sup>95–97</sup> Additionally, employers implementing a testing program would benefit by having a worker training program on COVID-19 in general, which covers what their organization is doing to prevent transmission of SARS-CoV-2. Many employers may not feel prepared to do such training, but there are resources to assist them (eg, WHO, 2020).<sup>98</sup>

Figure 4 illustrates conceptually how serial testing could reduce the number of false negatives. The possibility of failing to identify infected persons because the period of peak viral shedding is missed should diminish over time if periodic testing occurs at relatively short intervals.<sup>11,45</sup>

## Americans with Disabilities Act of 1990

State or local laws may relate to worker testing and employers may benefit from considering how such laws may impact implementation of workplace SARS-CoV-2 screening.

At the federal level, the Americans with Disabilities Act of 1990, as amended, (42 U.S.C. §12101–12103; 12111–12117; 12201–12213) (ADA) makes it unlawful to discriminate in employment against a qualified individual with a disability. If developing a SARS-CoV-2 testing program, employers should be mindful of ADA parameters on when and how much medical information an employer may obtain from any job applicant or current employee. For example, the ADA requires that medical examinations or inquiries take place only “after an offer of employment has been made” and must be “job-related and consistent with business necessity” (42 U.S.C. 12112(d)(3)–(4)).<sup>99</sup>

The U.S. Equal Employment Opportunity Commission (EEOC), the federal agency that enforces and advised on the

employment-related portion of the ADA, recently published a technical assistance questions and answers document discussing how the ADA parameters apply to the workplace circumstances of the COVID-19 pandemic.<sup>99,100</sup> The EEOC technical assistance advises that “employers may take screening steps [that are job related and consistent with business necessity] to determine if employees entering the workplace have COVID-19 because an individual with the virus will pose a direct threat to the health of others” and lays out parameters for such screening.<sup>81</sup> Employers may administer “COVID-19 testing to employees before initially permitting them to enter the workplace and/or periodically to determine if their presence in the workplace poses a direct threat to others.”<sup>89</sup> The EEOC notes that any test used by the employer should be considered “accurate and reliable,” for instance by “review[ing] information from the U.S. Food and Drug Administration about what may or may not be considered safe and accurate testing, as well as guidance from CDC or other public health authorities.”<sup>99</sup> EEOC advises that “testing administered by employers consistent with current CDC guidance will meet the ADA’s “business necessity” standard.”<sup>100,101</sup> As with all medical information, testing results need to be kept separate from an employee’s personnel record, “thus limiting access to this confidential information.”<sup>96</sup>

In view of the EEOC’s reliance on CDC guidance, it is important to note that CDC has guidance on testing intended for kindergarten to 12th grade school administrators.<sup>63</sup> In view of this CDC guidance, employers implementing screening testing should use voluntary approaches with incentives to motivate participation. Incentives might include making testing free and convenient. In some situations, as feasible and appropriate, employers might consider providing alternatives to employees who decline testing. One example would be reassignment to jobs with reduced risk for workplace transmission, such as those able to be done via telework.

## Limitations and Costs

The ability to provide rapid antigen testing for employees will depend on the availability of tests. Only a few antigen tests have received FDA authorization, and the number of authorized test kits that have been manufactured and distributed is limited.<sup>71</sup> Critical in the effective use of antigen tests is not only the ability to test and interpret results but also to test regularly. This will be impeded if the supply of test kits is inadequate or inconsistent. Some of the antigen tests in production require proprietary readers, but the supply chains to provide enough of these may not be adequate. There do not appear to be any resource constraints on the raw materials used to manufacture antigen tests, but there may be a limit on production capacity.<sup>46</sup>

Although there are millions of antigen tests purchased worldwide, there are still many issues about antigen tests that may need to be addressed before they are more widely used.<sup>102</sup> Particularly, false negatives could arise as a result of the timing of testing in a person’s infection trajectory.<sup>10,11</sup> These results also need to be seen as presumptive and considered as part of a testing regimen.<sup>11,103</sup>

Another important limitation is whether results of antigen tests self-collected and administered by workers will be provided to appropriate local health authorities and counted in community statistics.<sup>104</sup> Although the American Medical Association has announced a new CPT (Current Procedural Terminology) code ([https://www.aafp.org/journals/fpm/blogs/gettingpaid/entry/covid\\_antigen\\_testing.html](https://www.aafp.org/journals/fpm/blogs/gettingpaid/entry/covid_antigen_testing.html)) for reporting antigen testing results, it is not clear what the implications will be for employees. Procedures for reporting test results to local public health authorities have not been completely developed.

The costs of antigen tests are variable but are generally estimated to be \$5 to \$50.<sup>6,79</sup> Kits that could be used by workers at home might be in the lower cost range. Who pays for the tests and associated costs and when and how to administer tests are not completely resolved questions, and may vary by jurisdiction. Addressing these questions may facilitate an effective testing program for workers.

## CONCLUSIONS

The health of workers and the ability of businesses to function effectively during the COVID-19 pandemic rely on a noninfectious workforce as well as other prevention and control measures. Antigen testing is a useful public health tool that employers can use to address the entry and spread of SARS-CoV-2 in the workplace. Testing can reduce the risk of infected workers spreading SARS-CoV-2 in the workplace, especially when coupled with other prevention and control measures (as well as employee education) and when community burden is moderate or high. As opposed to diagnostic testing of symptomatic or exposed persons for diagnostic purposes, the purpose of screening testing of asymptomatic, unexposed workers is to prevent viral transmission in the workplace. An important trigger for initiating such testing is a high burden of COVID-19 in the community from which the workforce is drawn. Other triggers could include having an outbreak in the workforce, having workers who are at high risk of severe COVID-19 illness, or wanting to ensure public confidence in the safety of the workplace as a critical component of business operations.

Factors such as COVID-19 community incidence and history of workplace outbreaks can influence how frequently an employer chooses to perform periodic screening testing. It is important to have plans for action on positive screening tests and for those plans to be communicated to workers and coordinated with local public health jurisdictions. Because of the potential for false negative results, antigen testing could be conducted as part of a comprehensive workplace program of COVID-19 prevention and control that would provide protection even if an infected worker is present in the workplace.<sup>4</sup> It is important for employers to be aware of current policies of the EEOC under the ADA and of current CDC guidance related to screening workers with antigen testing.

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