Considerations for Use of Point-of-Care Antigen Testing by State and Territorial Health Agencies

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COVID-19 testing has been one of the most challenging aspects of the pandemic response in the United States due to early issues with test quality and ongoing supply chain management challenges. There is now opportunity to address the demand for testing with new and more plentiful antigen-based point-of-care tests that offer results in as little as 15 minutes versus PCR tests that require several days. Despite these advantages, use of antigen tests in the field has been challenging because they have sensitivity limits and will fail to identify a proportion of people with the disease (false-negatives). Concerns are also emerging about the specificity of these tests. A false positive test can have dire consequences in settings like nursing homes, where a resident who tests positive on an antigen test but is not infected may be moved to an area designated for residents with COVID-19.

If issues of specificity and sensitivity are not managed, they could undermine confidence in our national testing approach. Antigen test manufacturers report sensitivity values of 67-100% and specificity of 92-100% when used according to manufacturer's instructions. The actual performance of antigen tests in the field is now being evaluated by CDC and academic partners, but their use is already becoming widespread. FDA authorized these tests for diagnostic purposes, but they are being widely promoted for screening. Discussions with state health officials and other practitioners have raised several considerations for the field, all of which are discussed below.

Here is a summary of this report's key issues and considerations:

Key Issues:

- Antigen tests have been authorized by the FDA for diagnostic use, but providers should confirm negative results with a PCR test if the pretest probability of infection is high.
- Antigen tests may be useful as screening tests if screening is performed on a regular and frequent basis, every few days.
- Operator errors may have contributed to recent reports of false positives in some settings. Training of personnel and establishing good quality assurance practices is critical.

Key Considerations:

- State health departments may want to discourage use of antigen tests for one-time, asymptomatic screening in doctor's offices, airports, and community settings.
- Public health leaders may want to consider advising facilities against moving nursing home patients to COVID-19 wards until a positive antigen screening test is confirmed with a positive PCR test.
- In communities where transmission rates are low and mitigation efforts are effective, PCR testing may be a more reliable and manageable approach to screening.
- State could consider developing antigen testing device trainings or work with device manufacturers to develop training materials.

False Negatives

Antigen-based tests for COVID-19 have sensitivity limits that are similar to those in antigen-based tests currently in use for influenza, RSV, and rapid-strep. Antigen tests can fail to detect COVID-19 infection when they are used to make or confirm a diagnosis. They are most effective at detecting COVID-19 when viral loads are high, which creates additional challenges when used for screening. They may not detect COVID-19 early in the infection stage when it is useful to identify and isolate individuals before they become infectious. They are more accurate when viral loads are higher and individuals are more likely to transmit the virus to others. The "gold standard" PCR tests are more reliable early in the infection, but their cost, availability, and delayed processing times limit their use in many high-risk settings, particularly when community transmission is high. A recent report indicates that for asymptomatic individuals in high-risk settings (e.g., screening in congregate settings), antigen testing can be useful if testing is repeated frequently and routinely. An early false negative result will likely turn positive if another test is done a few days later; isolating the individual at this point will still be beneficial.

Potential Considerations

- In situations where an individual has symptoms of COVID-19 or has had a significant exposure, a positive test can confirm a COVID-19 diagnosis. However, a negative antigen test could be misleading. Clinicians may want to consider isolating the individual until a confirmatory PCR test can be completed.
- Consider whether antigen tests should be used as screening tests in settings where the test will not be repeated a few days later. State health departments may want to discourage one-time asymptomatic screening testing in doctor's offices, airports, and community settings.
- In communities where transmission rates are low and mitigation efforts are effective, PCR testing may be a more reliable and manageable approach to screening than antigen testing, provided that these tests are readily available. State public health practitioners could consider recommending PCR tests as the preferred screening modality.

False Positives

COVID-19 antigen tests are thought to be very specific, and field-based testing is now confirming the high accuracy of positive antigen results. But concerns and controversy are arising in the field due to the detection of significant numbers of false positives—especially since a false positive test can have dire consequences in some settings. False positive test results may be due to operator error, equipment calibration, or a faulty test batch. It is important to remember that any test will generate some false positives. In the UK, a recent analysis of PCR tests (which are currently considered the gold standard for COVID-19 testing) revealed that false positive rates could translate into a significant number of false-positive results daily due to the current low prevalence of the virus in the UK population.

Potential Considerations

- Confirmation of positive antigen tests with a PCR test may be a best practice in settings where the consequences of a false positive test could be particularly harmful. Public health leaders could advise facilities against moving nursing home patients to COVID-19 wards until positive antigen testing is confirmed.

Long-Term Care Settings

New CMS guidance on long-term care (LTC) facility testing and public pressure to increase visitation in LTC facilities have increased interest in using antigen tests in these settings. The federal government has been providing these testing materials directly to LTC facilities and has taken an aggressive stance in their use as COVID-19 screening modalities.

Potential Considerations

- There are some concerns that inaccurate antigen test results may be the result of operator errors. State could consider developing trainings on proper testing device use, recommending appropriate quality control measures or working with device manufactures to develop training materials.

K-12 Settings

Point-of-care testing is being used in a number of university settings, and we anticipate data and best practices to emerge from institutions that have more extensive resources and capacity. The federal government is distributing new Abbott BINAX Now tests to state governments and has suggested using the tests in K-12 settings. Concerns about widespread implementation of this test in schools include:

- Whether there will be an adequate ongoing supply of tests.
- What the future costs will be.
- Availability of a trained workforce to administer tests.
- Whether frequent and repeated testing will be tolerated by children and parents.
- Feasibility of comprehensive results reporting.

With these concerns in mind, targeted use of antigen tests for screening in K-12 settings may be more manageable.

Potential Considerations

- Several states are using antigen tests in K-12 settings to assess symptomatic children, reduce quarantine periods in children exposed to COVID-19 case, and screen teachers and staff through serial testing.
- Since the greatest K-12 COVID-19 transmission rates appears to occur in extramural settings, states could consider introducing serial antigen testing to regularly screen children participating in sports or other events.

Reporting

Widespread availability of antigen tests in community settings will make accurate reporting of results challenging. Several states are developing manual systems for nursing homes and other settings, but test volume and elimination of duplicates from confirmatory PCR testing have been challenges.

Potential Considerations

- States could provide testing material access in community settings only when they can commit to consistent reporting.
- A number of manufacturers are developing mechanisms for automated electronic reporting through testing equipment or apps.
- The demands of COVID-19 reporting would be significantly reduced if jurisdictions didn't have to report on negative tests results. It may be useful for states to develop alternatives to metrics like percent test positivity for future surveillance, monitoring, and COVID-19 case identification.

Summary

COVID-19 testing is an important component of infection control in this pandemic. Antigen tests may increase our capacity to screen and test for the disease, particularly in situations where testing can be done regularly and repeatedly. The tests are relatively inexpensive and results are rapidly available. However, issues of accuracy, long-term supply, and acceptability must be addressed. Health departments can use these and other considerations to guide decisions on how emerging tests should be introduced and used. Ongoing capacity challenges can be identified to drive advocacy efforts.