
Background
Testing is an important component of infection control in the COVID-19 pandemic. Real-Time Reverse Transcriptase (RT)-PCR tests have been the standard for testing but have been in short supply in the United States. Antigen tests may increase our capacity to screen and test for COVID-19, particularly in situations where testing can be done regularly and repeatedly. Antigen tests are relatively inexpensive and results are rapidly available. 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 COVID-19 (i.e., false-negatives). In addition, logistical issues of long-term supply, cost and reimbursement policies, and public acceptability must be addressed.

Issues and Considerations
- Antigen tests have been authorized by FDA for diagnostic use, but access to timely RT-PCR testing is needed to confirm negative tests when pretest probability of infection is high.
- In communities where transmission rates are low and mitigation efforts are effective, RT-PCR testing may be a more reliable and manageable approach to screening.
- Antigen tests are most useful as screening tests if screening is performed on a regular and frequent basis every few days.
- Widespread screening using antigen tests has been challenging due to limited availability of a trained workforce to administer tests and low public tolerance for frequent and repeated testing in settings like schools.
- More widespread testing is contingent on an adequate supply of PPE.

Solutions and Ideas for Improvement
- Antigen tests are an important adjunct to expand national testing capacity, but the federal government must take more aggressive steps to assure there is an adequate supply of the more accurate RT-PCR tests for confirmation and for primary use in low prevalence settings. Focus should be on testing platforms with the largest market share.
- The federal government must take aggressive steps to assure an adequate supply of testing supplies and PPE through use of the Defense Production Act. A thorough review of existing investments aimed at strengthening the supply chain for all testing supplies (e.g., reagents, consumables, collection/transport devices, PPE) and equipment should be performed and revised or expanded where necessary.
- The federal government should take steps to assure the quality of expanded point of care testing, including providing or supporting hands-on training for individuals performing tests.
- Create federal rapid response teams that can be deployed to hot spots to provide hands-on training to local groups as well as help with organization of pop-up testing sites.
• The federal government must develop clear communications messages, campaigns, and regulations to reinforce that community screening is a complementary, secondary strategy to mitigation strategies such as face coverings and social distancing.

• The federal government must provide clear guidance to local, state, and territorial health departments on inventory management of laboratory supplies. Specifically, it should improve coordination of laboratory supply deployment, including improved transparency on how allocations are determined.

• CDC should sponsor short- and long-term comprehensive evaluations of the feasibility and success of different testing strategies in the field and in disparate populations and make this information quickly available to all local, state, and territorial health departments.

• FDA should publicly share information about post-market evaluation of all devices authorized under the Emergency Use Authorization process.

Further Resources
• Considerations for Use of Point-of-Care Antigen Testing by State and Territorial Health Agencies
• Considerations for Implementation of SARS-CoV-2 Rapid Antigen Testing

Contact
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