

Considerations for Implementation of SARS-CoV-2 Rapid Antigen Testing

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Rapid antigen tests directly detect the presence or absence of an antigen. These tests are relatively inexpensive, offer a short turnaround time and are commonly used to diagnose patients in point-of-care settings such as doctors' offices. Currently available antigen tests for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), have reported significantly lower sensitivity than most nucleic acid (i.e., molecular tests) but have also reported high specificity.

Rapid antigen tests are commonly used in the diagnosis of other respiratory pathogens including influenza virus and respiratory syncytial virus (RSV). Rapid antigen tests for these pathogens have proven challenging to interpret, commonly producing false negative results due to their low sensitivity, as well as false positive results when disease prevalence is low. CDC recommends the use of rapid antigen tests for influenza primarily to inform treatment decisions (i.e., prescription of antivirals), aid in ongoing outbreak investigations, or to direct infection control actions¹. Based on experience with rapid influenza diagnostic tests (RIDTs), the following considerations are offered to assist public health officials and other healthcare providers in making decisions on the appropriate use of rapid antigen tests for SARS-CoV-2.

Overview of SARS-CoV-2 Rapid Antigen Tests

- Antigen tests are typically performed on nasopharyngeal, nasal or oral swab specimens directly or after the swabs have been added to viral transport media. Refer to Table 1 for a list of authorized specimen types for each available test.
- Antigen tests target specific proteins of the virus of interest to detect the presence of SARS-CoV-2 antigen, indicating viral infection. Currently available, SARS-CoV-2 antigen tests with emergency use authorization (EUA) target the nucleocapsid protein from SARS-CoV-2.
- Antigen tests produce rapid qualitative results for the detection of SARS-CoV-2. They do not provide a quantitative result.
- In settings experiencing high SARS-CoV-2 positivity rates, positive test results indicate that SARS-CoV-2 antigens were detected and that the individual is infected and presumed to be contagious. However, despite high specificity, false positive results can occur and are most likely in populations where the prevalence of SARS-CoV-2 infection is low.
- Currently available SARS-CoV-2 antigen tests are considerably less sensitive than molecular tests and may therefore generate false negative results. They should only be used to test symptomatic patients in populations with a high prevalence of disease. However, false negative results can occur regardless of the overall prevalence of disease.
- Negative results obtained with existing tests for SARS-CoV-2 antigen tests are considered presumptive according to the Instructions for Use (IFU). Presumptive negative results should be confirmed using a molecular test.

Scenarios Where SARS-CoV-2 Antigen Tests May Be Considered for Use

Due to the rapid time to result of antigen tests, SARS-CoV-2 antigen tests have utility in symptomatic patient populations with high pre-test probability that the patient has COVID-19 (i.e., symptomatic patients in high

prevalence populations). Use of these tests should be reserved for instances where a positive result would direct immediate clinical decisions or infection control measures. Negative results in this scenario should be confirmed with a laboratory-based molecular test and downstream costs of that confirmatory testing should be considered when making implementation decisions. Below are some example scenarios in which SARS-CoV-2 antigen tests may reasonably be used.

- Deployed with strike teams to provide targeted testing in emergency or outbreak situations.
- Triaging individuals with respiratory symptoms in an Emergency Department or similar setting.
- In correctional facilities, long-term care facilities or other high risk, congregate settings where cases have been confirmed.
- Off hour testing in hospital settings when the patient will benefit from a rapid result and the laboratory will repeat the test by another method when staff are available.
- Symptomatic individuals in remote populations such as small rural hospitals, tribal nations or other jurisdictions with known high prevalence and limited alternative access to testing.

Scenarios Where SARS-CoV-2 Antigen Tests Should NOT Be Considered for Use

Due to the lower sensitivity of antigen tests relative to molecular test, SARS-CoV-2 antigen tests should only be considered for use in situations where a positive result would indicate immediate, specific clinical action and **should not be used** under the following circumstances:

- Screening of asymptomatic individuals.
- Screening of healthcare workers, emergency responders and other essential personnel.
- Population-based surveillance studies.
- Testing underserved or marginalized populations where access to testing is limited.
 - In these scenarios, efforts to improve access to molecular testing should be explored rather than implementing an antigen test — antigen tests should not be considered a “better than nothing” alternative as the results for asymptomatic populations could be falsely positive or negative.
 - Alternatives, such as courier services and public service testing resources should be sought, with transfer of specimens to a laboratory for molecular testing.

Considerations for Public Health Laboratories When Deploying SARS-CoV-2 Rapid Antigen Tests in CLIA-Waived Settings

When public health laboratories are asked to deploy instruments and tests to non-laboratory settings in support of the COVID-19 response, they should consider providing assistance to support or ensure that the following are in place when feasible:

- A public health reporting mechanism when testing is not connected to a laboratory information system, preferably electronic reporting.
- Automatic reflex processes and a pathway for follow up testing for specimens with negative antigen test results.
- Adequate training of staff that will be performing testing.
- Appropriate biosafety risk assessments and adequate biosafety procedures.
- Quality assurance processes including quality control schedules and proficiency testing, as applicable.

Table 1: Currently Available SARS-Cov-2 Antigen Tests

Test Name	Separate Instrument Required	Authorized for Use in Waived Settings	Specimen Types	Time to Result	Test Performance*	More Information
Quidel Sofia 2 SARS Antigen FIA	Yes Sofia 2 FIA Analyzer	Yes	NP or Nasal Swabs Directly or After Transport in VTM	15-30 minutes	Sensitivity: 80% Specificity: 100%	IFU HCP

*Test performance data taken from assay's IFU

ⁱ https://www.cdc.gov/flu/professionals/diagnosis/clinician_guidance_ridt.htm



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