



Screening and Surveillance Testing for COVID-19: Questions and Answers September 3, 2020

1. What are Screening and Surveillance Testing, and how do they differ?

Screening and surveillance are approaches used for disease monitoring in a population or specific group of individuals. Although the terms are sometimes used interchangeably, they are two different approaches and have different indications:

- Screening is performed on an *individual* and
- Surveillance is performed on a *population*.

Screening tests are used to detect asymptomatic carriers who could shed SARS-CoV-2 and infect others. The test result is directly linked to a specific individual and may be used for possible management decisions, including quarantine of individuals with a positive test. Screening occurs at a single time point but can be repeated as necessary. In the United States, testing performed for screening purposes must be performed in a CLIA-certified laboratory because the results are linked to an individual and used for making medical decisions. Most COVID-19 tests in the United States have only received emergency use authorization (EUA) by the US Food and Drug Administration (FDA) for testing of *symptomatic* individuals (ie, for diagnostic testing). Only a few tests have received EUA for screening asymptomatic individuals to date. Fortunately, the FDA has afforded flexibility in that although many tests are not designed for screening asymptomatic individuals, health care providers can request SARS-CoV-2 testing at their discretion, and this could include testing asymptomatic individuals.

Screening is often performed in low prevalence populations where the pretest probability of infection is low. In low prevalence settings, the percentage of positive results that are false positive increases. Care must be taken to determine whether confirmatory testing of a positive screening result should be performed in order to discriminate a false positive from a true positive case of SARS-CoV-2 infection.

Examples of COVID-19 Screening

COVID-19 screening may be indicated for individuals prior to specific events such as a medical procedure (eg, general anesthesia, bronchoscopy) or large gathering (eg, sporting event, wedding). Screening may be also used to limit population mobility between states or countries; a negative test result may be required to enter a region in which the prevalence of infection is low. Screening is also a valuable tool in outbreak investigations for identifying all infected individuals in a certain region or institution. For example, in congregate living facilities, all residents and workers may be tested following identification of a case of COVID-19. Residents with positive test results may be roomed away from uninfected individuals, and infected workers may be required to stay home until they are no longer infectious.

Screening may be repeated in situations where there is an ongoing risk of exposure. For example, some educational institutions require periodic screening of students and teachers. Some employers are also employing periodic screening.

Surveillance testing differs from screening in that it is used to monitor positivity within a community or population, and test results are *not* directly linked to an individual. As such, decisions about the management of individuals are not to be made based on surveillance testing. Unlike screening, surveillance testing can be performed outside of a CLIA-certified laboratory because the results are not linked to a patient or used in the health management of a specific individual.



Examples of COVID-19 Surveillance

COVID-19 surveillance efforts include testing undertaken by public health facilities to monitor prevalence in a specific geographic region over time. Surveillance testing may include a sample of a specific population rather than all members; for example, a state health department may choose to test specimens from 1% of a region's population of on a weekly basis. Tested individuals could include symptomatic and asymptomatic individuals, but results of individual tests are not linked directly to the individuals that were tested or used in directly managing individual patients.

2. Are there any international guidelines on when surveillance or screening testing should be undertaken?

Although there are some general guidelines for screening select populations (eg, CDC guidelines for screening dialysis patients at intake), there are no generally applicable international guidelines. Instead, decisions on when to employ surveillance and screening testing must be made locally, taking numerous variables into consideration such as the local disease prevalence (or positivity rate in symptomatic individuals), availability of testing supplies, and the presence of a well-rationed plan for acting upon test results (including plans for quarantine, isolation, and contact tracing).

Often, multiple stakeholders are involved and may have different and conflicting opinions on optimal screening or surveillance practices. For example, a university may want to screen every student and professor every week, but there may not be adequate testing supplies or health care personnel to collect and test that quantity of specimens.

Testing Strategies for Screening and Surveillance

Because population screening and surveillance can involve testing large numbers of individuals, and performing tests on a recurrent basis, several strategies have been suggested to improve the efficiency and decrease the cost of testing. Examples of these strategies include testing pooled specimens, use of less expensive tests that may have lower accuracy (eg, antigen immunoassays or extraction-free PCR), high frequency testing with low cost and modest accuracy testing devices, and use of easily-collected specimens such as saliva and self-collected nasal swabs. Each of these strategies has pros and cons. The goal of testing should always be clearly defined before designing or implementing a testing strategy because clearly defining the goals will facilitate properly weighting of the variables, and this will enable selection of the appropriate strategy to optimally meet the goal(s). The following is additional information about select testing options:

Testing of Pooled Specimens

Testing of pooled specimens can help to stretch the limited supply of reagents. However, simple pooling (ie, mixing multiple specimens together) can decrease the sensitivity of testing by raising the limit of detection. The degree to which clinical sensitivity is compromised can only be determined by empiric study, and the cost associated with the decreased sensitivity needs to be weighed against the value gained by conserving test reagents. Additionally, pooling is not commonly employed in testing of respiratory specimens, so the pooling and deconvolution of pools containing SARS-CoV-2 is a challenge because of its novelty. Pooling and deconvolution of positive pools can require less reagents but can require more supplies and labor than traditional testing. Please refer to the CAP document on Testing of Pooled Specimens for further information. More information on screening testing, surveillance testing, and pool testing is available from the US Centers for Disease Control and Prevention: <https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/pooled-sample-testing-and-screening-testing-covid-19#surveillance>

Rapid Testing

"Rapid testing" refers to the turnaround time associated with testing. Rapid tests can be serological, NAAT, or antigen-based. Rapid tests can typically be performed while the individual remains on site of the specimen collection location.



Antigen Testing

Testing for SARS-CoV-2 antigen is an emerging method for the detection of SARS-CoV-2. Typically, antigen tests are less sensitive than NAAT, but antigen tests are typically less complex, lower cost, and more rapid than NAAT. The value of these different variables needs to be considered in light of the intended goal of screening or surveilling. The real world clinical performance of antigen testing for SARS-CoV-2 has not been clearly described in rigorous studies as of August 2020. In the coming months, the accuracy of antigen tests will likely be more clearly described, which will enable more insightful determination of their best use cases.

Patient-collected specimens: Saliva and nasal swabs

Traditionally, respiratory viral testing has been performed on nasopharyngeal swabs as the cells in this region contain respiratory viruses and are more accessible than cells from the lungs. Unfortunately, nasopharyngeal swabs are uncomfortable and may not be well tolerated by patients. Patient-collected samples are more pleasant to patients and can encourage more testing, especially if the testing is done frequently on the same patient. Examples of self-collected samples are saliva and nasal swabs. In addition to being more palatable for patients, there is decreased personal protective equipment used for health care personnel in comparison to those collecting nasopharyngeal swabs.

Current literature suggests that saliva and nasal swabs contain about as much virus as nasopharyngeal swabs if collected correctly. As these techniques are used more commonly, we will gain more information on how they compare to nasopharyngeal swabs. Also, most commonly used flu tests are only FDA approved and validated in laboratories for nasopharyngeal swabs, so if testing for both SARS-CoV-2 and flu is requested, a nasopharyngeal swab is necessary unless the laboratory has performed an off-label validation for different specimen types.