13.0 GUIDANCE ON MEDICAL TESTING FOR DIAGNOSIS AND SCREENING

The following section shares background information and guidance for implementing COVID-19 testing programs at Camps. Given the high proportion of individuals, particularly children, that are either pre- or asymptomatic for SARS-CoV-2 infection, screening campers and staff for symptoms may not be sufficient to reduce the likelihood of infections in a camp setting.[1] If a testing program is implemented, Camps will need to determine the locations for testing or develop testing relationships and will need to create protocols for how and when testing programs will be employed for incoming campers and staff. In addition, having access to testing for symptomatic individuals can help to identify cases and contain outbreaks.

Availability of tests, testing programs, and technologies have been changing rapidly throughout the course of the pandemic.

FUNDAMENTALS OF TESTING OPTIONS

Background

There are several medical tests to determine if a camper or staff member is currently infected with the SARS-CoV-2 virus (diagnostic tests) and at this time only one to identify past infection. To determine if an individual is infected with the SARS-CoV-2 virus, typically "molecular" testing will be completed on viral ribonucleic acid (RNA) collected from a nasal or throat swab or saliva collected in a sampling tube.[2] These tests typically return results in 1 to 5 days. In addition, there are other diagnostic tests that use "antigens," which are immune markers associated with the virus to aid in assessing current infection. These can be done more rapidly, typically resulting in 10 to 15 minutes. Both types of tests are known as diagnostic tests. To test for past infection, an antibody test on blood collected from a finger stick or venous blood draw is used.[3]

Testing to determine the presence of SARS-CoV-2 entails measurement of RNA or other unique markers of the virus. These samples can be collected using several methods:

- A nasopharyngeal sample entails inserting a swab deep into the nasal cavity.
- Mid-turbinate swab is inserted into the nostril and is spun while in contact with the nasal wall.[4]
- For oropharyngeal samples, a swab is used to sample material at the back of the throat.

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[1] Gostic K, et al. 2020. Estimated effectiveness of symptom and risk screening to prevent the spread of COVID-19. eLife, 9:e55570. https://doi.org/10.7554/eLife.55570.

[2] U.S. Centers for Disease Control and Prevention. *Coronavirus Disease 2019, Test for Current Infection*. https://www.cdc.gov/coronavirus/2019-ncov/testing/diagnostic-testing.html

[3] U.S. Centers for Disease Control and Prevention. *Coronavirus Disease 2019, Test for Past Infection*. https://www.cdc.gov/coronavirus/2019-ncov/testing/serology-overview.html

[4] Rush Medical Center. *Swab Differences for POC and Standard COVID Testing*. https://www.rush.edu/sites/default/files/coronavirus-swab-differences.pdf

- Anterior nares swabs entail swabbing the inside of each nostril.
- Saliva samples are also used and entail spitting into a vial. [5]

Material collected on the swabs or in saliva sampling tubes is then extracted, and a molecular test, typically reverse transcriptase polymerase chain reaction (RT-PCR), is conducted in a laboratory. The test determines if a person is currently infected with the virus that causes COVID-19. In addition, antigen tests can also be used to determine current infection, but these tend to be less sensitive than RT-PCR tests so can require additional confirmation testing.

Table 13.1 lists the factors related to the use of molecular, antigen, and antibody tests for use in health screening of campers and staff for infection with SARS-CoV-2. While antibody testing is included in the table, it is not a test that can be used to identify potential infection and cannot be used to ascertain that a person cannot become re-infected.

The number and type of available tests and criteria for their use are continuing to evolve due to the rapid reviews being conducted by the U.S. Food and Drug Administration (FDA) under their Emergency Use Authorization (EUA) program and developments in testing technology. A limitation of the rapid approval process for the tests (as of January 2021) is that it allowed many varieties of the same test into the marketplace and does not necessarily require rigorous review of real-world performance.[6] At all times, only tests with FDA EUA approvals and well-documented performance should be used if a testing program is planned for camps.[7]

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[5] U.S. Food and Drug Administration. *Coronavirus (COVID-19) Update: FDA Authorized First Diagnostic Test Using At-home Collection of Saliva Specimens*. https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-first-diagnostic-test-using-home-collection-saliva

[6] U.S. Food and Drug Administration. *Emergency Use Authorizations*. https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations

[7] U.S. Centers for Disease Control and Prevention. *Coronavirus Disease 2019, Viral Testing Data in the US*. https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/testing-in-us.html

Table 13.1 Adapted from U.S. Food and Drug Administration Coronavirus Testing Basics Fact Sheet

	Molecular Test	Antigen Test	Antibody Test
Synonyms	PCR, RT-PCR diagnostic test, viral test, NAAT, LAMP	Rapid diagnostic test	Serological test, blood test, serology test
Sample collection	• Nasal or throat swab • Saliva	Nasal or throat swab	Finger stick or blood draw
Time for results	Same day (some locations) or up to a week	One hour or less	Same day (many locations) or 1-3 days
Follow-up testing	Not usually	Without symptoms: • Positive requires PCR • Negative – none With symptoms: • Positive – varies by state may require PCR • Negative – requires PCR	• Most states require positive antibody tests be followed up with PCR to rule out current infection. • Sometimes a second antibody test is needed for accurate results.
Test results	• Active coronavirus infection. • Past infection as much as 3 months ago.	Active coronavirus infection.	Infected by SARS-CoV-2 in the past.
Test does NOT do	Show past SARS-CoV-2 infection.	Detect low viral loads which may occur during early stages of infection.	• Diagnose active SARS-CoV-2 infection • Cannot confirm that you did or did not have SARS-CoV-2
Note	Tests can remain positive weeks after infection due to continued shedding of viral RNA.	• Tests approved by FDA generally are for use on symptomatic people, who likely have high viral loads. • Use on asymptomatic people as a screening tool is essentially "off-label" application of the test.	Does not diagnose infection.
Examples of tests	• Lab Corp • Quest Diagnostics • Abbott IDNow • Broad Institute	• Quidel Sofia 2 • BD Veritor	• Thermo Fisher OmniPATH COVID-19 Total Antibody ELISA Test

FDA U.S. Food and Drug Administration
PCR polymerase chain reaction
RT-PCR reverse transcription polymerase chain reaction
NAAT nucleic acid amplification test
LAMP loop mediated isothermal amplification

Source: Adapted from U.S. Food and Drug Administration

IMPLEMENTATION OF TESTING STRATEGIES AT CAMPS

Camps should determine the process by which they will screen campers and staff and the protocols for management of campers and staff who screen positive. It is important to screen everyone in camps determined to be in close proximity with the camp community including kitchen staff, grounds crews, and office staff.

Diagnostic testing (molecular and rapid antigen) is most valuable to camp scenarios as this type of testing indicates current infection. Four testing scenarios are relevant to camp programs. They include:

- Prescreening testing carried out within 7 days (or preferably 72 hours or less) prior to arrival at camp.
- On-site screening conducted upon arrival to residential camps or prior to day camp sessions.
- Diagnostic testing carried out in response to potential cases and close contacts.
- Surveillance testing carried out at regular intervals during the camp season.[8]

Considerations

Key factors to consider in developing a testing program are:

- Background infection rate in the nearby community as well as in the home communities of campers and staff.
- Status of community spread in the areas from which campers and staff are drawn. Examples of factors to evaluate:
  - Case rate per 100,000 people over previous 7-days (increasing trend for more than one to two weeks)
  - Percent positivity of testing
  - Daily incidence of cases
- The time from sample collection to results should be as short as possible, preferably within 24 hours; however, this may be difficult to obtain during periods of high laboratory demand. The amount of time between sample collection and reporting of results ranges from 15 minutes to several days.
- Sensitivity and specificity of the test being used. The minimum recommended sensitivity of a test is dependent upon the frequency of administration of the test. A less sensitive test that can provide results within an hour or as much as 24 hours would be preferable if the test will be administered frequently, such as multiple times per week. Most tests are highly specific to SARS-CoV-2 because they test for multiple genes or regions of genes to ensure results pertain only to SARS-CoV-2.
- The frequency of testing for campers and staff should be related to their relative risk of infection. For example, campers at overnight programs using cohorts could be tested less often than staff commuting in and out of camp on a daily basis.
- Plans and resources to implement, support, and monitor additional NPIs to control the spread of COVID-19.

The potential for false positive results among low risk, asymptomatic individuals is recognized by clinicians and organizations that perform large amounts of regular testing for entire populations or communities, like camps, work forces, and schools. To address this limitation, a

[8] Note the use of "surveillance" to reference to ongoing regular screening of campers differs from the CDC definition, which generally applies to community-wide testing programs to determine disease prevalence in a community.

growing number of organizations employ a strategy known as serial or orthogonal testing.[9,10] Here, an initial positive result is followed by at least one more test. This approach is effective because the probability of two consecutive false positives is very low. Repeat testing for positive cases is particularly effective for populations like camps, which are at lower risk of infection and are asymptomatic.

Note that any procedure for identifying false positives must be carried out in accordance with local and/or state guidance.

Prescreening Testing

Testing prior to travel to camp is considered "prescreening" testing. If prescreening testing is conducted, results should be reported to the camp Health Center or administration before the first day of camp to allow for confirmation of test type and negative result. Tests must be scheduled with sufficient turnaround time to allow for results to be assessed prior to travel (note that some test results can be delayed by several days).

Numerous camp, school, and university examples from Summer and Fall 2020 indicate that pre-screening using RT-PCR tests while still in the home location prior to arrival at camp is an important way to reduce potential cases from entering the camp. Pre-camp testing of all campers and staff is strongly recommended for overnight camps.

When available and results can be obtained quickly (i.e., less than 72 hours), RT-PCR tests are considered the most sensitive for identifying cases early in infection, so are generally used in most screening programs.

- Good practice: Campers and staff are tested at home within 7 days of travel to residential camp. Low-risk behaviors are advised after testing and prior to camp.
- Better practice: Campers and staff are tested within 72 hours of arrival at camp, where available. Low-risk behaviors are advised after testing and prior to camp.
- **Best practice**: Campers and staff are tested within 24 hours of arrival at camp, where available. Low-risk behaviors are advised after testing and prior to camp.

Note: Some states may require a 14-day post travel quarantine period based on several factors including the community status of the area that the camper is traveling from.

On-site Screening

Testing taking place upon arrival at camp is on-site screening. On-site screening is recommended for overnight camps if resources allow. Camps may be able to obtain testing supplies and

[9] Daniel Griffin, MD. Interview on This Week in Virology, August 30, 2020, Episode #658, Minutes 12:45 – 17:00.
[10] Briefing by NFL Chief Medical Officer Allen Sills, MD, August 24, 2020.

laboratory relationships that make on-site RT-PCR and/or rapid antigen testing feasible. If camps develop these capacities, the following best practices may be achieved:

- **Best practice:** For overnight camps lasting more than three days, campers and staff could undergo RT-PCR testing on site after approximately three to five days with results obtained within 24 to 48 hours to allow for identification of potential travel-related exposures.
- **Best practice:** For overnight camps lasting more than three days, campers and staff could undergo rapid screen testing, such as antigen tests, on-site or using mail-in samples after approximately three days with results obtained within 48 to 72 hours to allow for evaluation of campers and staff with symptoms that could be consistent with COVID-19.
- **Best practice**: Staff at overnight programs who leave camp for weekend trips or other off-facility activities should be tested after three to five days upon arriving back at camp.
- Camp programs that choose to conduct testing after arrival alone (e.g., no pre-testing) should use all recommended NPIs and quarantine campers and staff (ideally in small groups or "cohorts") until test results are obtained.
- If a camper or staff member reports any symptoms consistent with COVID-19 upon arrival, they should remain in an isolation location until testing can be conducted and confirmed.
- All campers and staff must wear masks while waiting to be tested and keep physically distanced from all individuals, except for healthcare staff wearing PPE.

Mitigation Testing

Mitigation testing is conducted on an as-needed basis to contain spread related to a potential case by testing anyone who is either symptomatic or is asymptomatic but had close contact with a confirmed or suspected case. Testing can be conducted at an individual's healthcare provider (relevant for day camps) or on site at the camp facility.

For a symptomatic camper or staff member, laboratory-based RT-PCR test should be done. The COVID-19 positive individual must remain in isolation until ten days have passed since symptoms first appeared; the individual has not had a fever for at least 24 hours without fever-reducing medication; and symptoms have improved. For an asymptomatic case, the camper can leave isolation after 10 days without symptoms.

Those identified as close contacts of a camper or staff person should be tested and must immediately go into quarantine for 10 days. In some states, a close contact can be tested on day 5 and released from quarantine as early as day 8 after exposure. Close contact is defined as being within 6 feet of a COVID-19 case for 10 to 15 minutes, including up to two days prior to the person developing symptoms per CDC or state guidance.

- Better practice: Be prepared to conduct mitigation testing when individuals display symptoms or are in contact with a confirmed or suspected case.

- **Best practice**: Camps can be prepared to provide mitigation testing by maintaining on-site swab kits and making arrangements with a local laboratory to carryout same-day RT-PCR analysis. Being prepared to provide testing on-site also signals that the Camp will respond quickly to potential cases.

Surveillance Testing

Surveillance testing is carried out on a semi-regular basis during the camp session on populations without symptoms, not just within the first few weeks of arrival of each camp session. This type of testing can be used to assess effectiveness of controls and quickly identify cases to contain potential spread. Recommendations regarding testing schemes are not available from regulatory agencies at this time.

Recent research indicates that the effectiveness of viral testing for control of SARS-CoV-2 transmission is primarily influenced by the frequency that tests are administered and turnaround time for results.

Regular surveillance testing may have value if used to test staff who are present for multiple sessions or campers with programs lasting over two weeks. Surveillance testing a subset or all of the community on a less frequent basis may provide some indication of prevalence in the community but is unlikely to identify or contain outbreaks. Camps should continue to monitor SARS-CoV-2 testing options and new lower cost methods as they evolve and are approved for use by the FDA.

SELECTION OF TESTING PRODUCTS

The testing landscape is changing daily. In general and where possible, EH&E recommends RT-PCR testing for staff and campers in advance of arrival at camp, followed by RT-PCR, other molecular testing, or antigen testing upon arrival or within several days of arriving at camp. When possible, it is also recommended that camps have a supply of rapid tests available for campers or staff who develop symptoms or are in contact with a confirmed or suspected case. A low-cost example is the Abbott BinaxNow test, which has been made widely available to K-12 schools.

Tests that have been approved via EUA are listed on the FDA's website. The current approval process relies on company-provided, non-peer reviewed studies, making interpretation of performance difficult. EH&E recommends selecting a test that has already been widely used until more thorough evaluation of newer options is complete.

TESTING IN DAY CAMP SETTINGS

- Testing in a day camp setting can be difficult and costly. Like day schools or workplaces, all attendees commute and return home each day, making testing representative only of the current status at the time the test is carried out. Modeling studies in 2020 indicated that to

control outbreaks, twice weekly testing would be needed. However, during Fall 2020, many colleges and universities implemented weekly testing, which was shown to be effective on many campuses.

- **Best practice:** On-site screening for day camps can be considered if resources allow. Given potential future availability of rapid screen testing, testing at least weekly and up to several times per week would be an effective way to contain outbreaks in a day camp setting. Once such testing devices are readily available, they could be added to a day camp program of NPIs.
- Good practice: Day camps can be prepared to provide mitigation testing by maintaining on-site swab kits, such as the Abbott BinaxNow and making arrangements with a local laboratory to carryout same-day RT-PCR analysis for symptomatic campers or staff. On-site testing capability may reduce delay that could arise from relying on parents to identify testing through their family healthcare practice or other testing centers.

LESSONS LEARNED FROM 2020 SUMMER CAMP SEASON

A CDC report released in September 2020 shares insight into four overnight camps in Maine that were successful in reducing the spread of COVID-19 during their summer 2020 programs. The key testing-related strategies implemented by all four camps are outlined below.

- Five to seven days before arriving at camp, almost all campers and staff were tested near their home locations for the virus using a RT-PCR test.
- Campers and staff were screened by Health Center team members at least daily, through temperature-taking and questions related to symptoms.
- Approximately every 4 to 9 days, RT-PCR testing was conducted on nearly all campers and staff.
- Individuals with symptoms or a positive test result were placed in isolation, and their cohort was quarantined.

Of the 1,022 attendees, four individuals tested positive before traveling to camp. Those campers stayed home for the isolation period. While at camp, two staff members and one camper tested positive (all were asymptomatic). After retesting, none of the 30 members of the single infected camper's cohort tested positive. This successful example emphasizes the significance of medical testing when used in a multilayered approach with additional controls such as masks, hand hygiene, and physical distancing.

TESTING IN CAMP 2021

Many advances in testing are expected over the coming months (Winter 2021). Several technologies are in development to increase the availability, reduce cost, and/or shorten

turnaround times for SARS-CoV-2 testing. The ideal test for widescale screening would have the following characteristics:

- Highly sensitive
- Only indicates active infection
- Does not require a testing instrument
- Easy and not painful to collect (e.g., nares swab or saliva)
- Provides results in less than an hour
- Widely available
- Inexpensive

A rapid screen RT-PCR test by Visby Medical, Inc. (San Jose, CA) was approved by FDA and meets many of these conditions.[11] This highly sensitive portable, low cost test could be deployed readily at day and overnight camps with CLIA certification or exemption during Summer 2021.

Saliva-based rapid antigen tests are being developed by several companies. These lower sensitivity testing methods could be used at high frequency (e.g., daily) to assess staff and campers. While lower sensitivity, repeated use may identify cases earlier than laboratory-based RT-PCR testing (given the long turnaround times) and allow for more rapid control of outbreaks. The Abbott BinaxNOW is an example of such a test recently approved for symptomatic cases and administered by a CLIA-certified or exempt provider.[12] In addition, the Ellume COVID-19 home test was approved in Fall 2020, and it is an at-home rapid antigen test.

Pooled testing of RT-PCR samples has been approved by FDA, and several commercial testing providers have begun using this method. Extensive pooled testing programs for elementary schools are underway. Most use a self-collected swab sample that is pooled on-site for example in a classroom, then it is transported to a laboratory for RT-PCR testing. Further development of pooled testing methods will reduce costs for screening programs using RT-PCR.

In some camp settings, wastewater testing can be a cost-effective strategy for monitoring in a residential camp setting. Despite being primarily a respiratory illness, SARS-CoV-2 has been shown to be shed by the fecal route by both symptomatic and asymptomatic infected individuals and transported through wastewater. SARS-CoV-2 has been detected in the sewage of municipal and communal living spaces before cases within the served population were otherwise apparent, potentially providing an early means of detection and control. Some evidence suggests SARS-CoV-2 can be detected by this method up to a week earlier than by population testing alone. Wastewater testing for SARS-CoV-2 can be implemented as part of a suite of testing and has not been shown to be effective in replacing health-based screening tests. Subsequent to SARS-CoV-2 detection in wastewater, the served population should undergo individual swab or saliva testing to identify and isolate active cases. Wastewater testing for SARS-CoV-2 may be an effective

[11] https://www.fda.gov/media/142228/download
[12] https://www.fda.gov/media/141567/download

complement to a comprehensive testing program, which may allow for reduced frequency of surveillance testing.

SUMMARY

Testing and surveillance for COVID-19 is a complex and changing landscape with a myriad of protocols currently in use and under evaluation. We recommend camps seek counsel from knowledgeable health care and public health providers as they consider and develop their Summer 2021 testing plans.

REFERENCES AND RESOURCES

U.S. Centers for Disease Control and Prevention. *Isolate If You Are Sick.* https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/isolation.html

U.S. Centers for Disease Control and Prevention. *Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens for COVID-19.* https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html

U.S. Centers for Disease Control and Prevention. *Overview of Testing for SARS-CoV-2.* https://www.cdc.gov/coronavirus/2019-ncov/hcp/testing-overview.html

U.S. Food and Drug Administration. *FAQs on Testing for SARS-CoV-2.* https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-testing-sars-cov-2

U.S. Food and Drug Administration. *Coronavirus Testing Basics.* July 2020. https://www.fda.gov/media/140161/download

Infectious Diseases Society of America (ISDA). *Guidelines on the Diagnosis of COVID-19.* IDSA, 5/6/2020. https://www.idsociety.org/practice-guideline/covid-19-guideline-diagnostics/

Rush Medical Center. *Swab Differences for POC and Standard COVID Testing*. https://www.rush.edu/sites/default/files/coronavirus-swab-differences.pdf

U.S. Food and Drug Administration. *Emergency Use Authorizations*. https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations

World Health Organization. *Advice on the use of point-of-care immunodiagnostic tests for COVID-19 - Scientific Brief*, 8 April 2020. https://www.who.int/news-room/commentaries/detail/advice-on-the-use-of-point-of-care-immunodiagnostic-tests-for-covid-19

SECTION 13.0 APPENDIX – BACKGROUND ON TESTING METHODS FOR SARS-COV-2

Molecular Testing

Molecular testing to determine the presence of SARS-CoV-2 entails measurement of RNA or other unique markers of the virus. These samples are typically collected using a swab sample from the upper respiratory system, usually from the back of the nasal passage or the back of the throat. For a nasopharyngeal sample, a swab must be inserted deep into the nasal cavity. A mid-turbinate swab is inserted into the nostril and is spun while in contact with the nasal wall.[13] For oropharyngeal samples, a swab is used to sample material at the back of the throat. Anterior nares swabs entail swabbing the inside of each nostril. Saliva samples are also used for some tests, but nasal swabs are most commonly used. The U.S. Centers for Disease Control and Prevention (CDC) and state public health agencies generally require RT-PCR based testing, including as confirmation following antigen, antibody, or other screening methods. Revised infectious disease guidance[14] defines laboratory confirmation by antigen test as "presumptive" not confirmed, and states are reporting those separately often as "probable" until confirmed by RT-PCR. Given these federal and state requirements, EH&E recommends choosing tests analyzed by RT-PCR over other molecular options, when feasible.

Challenges related to this type of sample collection and testing include:

- Test result represents exposures from 3-5 days prior to testing day.
- False negative results reported due to improperly collected sample material or post-testing exposure.
- Shortages of sampling supplies and personal protective equipment (PPE) for healthcare workers who collect the samples.
- Patient discomfort with collection of samples, typically worse with nasopharyngeal swabs.
- Turnaround time for the sample results is usually 2-5 days or longer depending on laboratory used.
- Cost for sample analysis alone is typically in the $35 to $100 range as of January 2021.
- Often screening for those without symptoms or potential exposures is not covered by health insurance and will not be ordered by health care providers.

At the time of development of this *Field Guide*, all approved viral RNA tests must be conducted under the supervision of a qualified healthcare professional. Some nasal swabs can be self-collected, but analysis must be conducted by a certified laboratory.

[13] Rush Medical Center. *Swab Differences for POC and Standard COVID Testing*. https://www.rush.edu/sites/default/files/coronavirus-swab-differences.pdf

[14] Council of State and Territorial Epidemiologists. 2020. Update to the standardized surveillance case definition and national notification for 2019 novel coronavirus disease (COVID-19), Interim-20-ID-02.

Several researchers have developed tests using saliva samples instead of upper respiratory swabs.[15] These tests are easier to conduct, more comfortable for patients, and may provide greater detection sensitivity, although some children may have difficulty with the collection method. Saliva-based tests may be a preferable indicator for infection with less variability in results and could enable sample collection for SARS-CoV-2 by non-professionals or by a health professional via a video telehealth visit to ensure proper sample collection. This would eliminate the risk of person-to-person exposure and minimize costs associated with sample collection by a healthcare professional.

Several barriers exist to the use of viral RNA testing as a routine screening tool. Some of these include the limited availability of the RNA/PCR test kits, reagents used for laboratory analysis, and the number of RT-PCR laboratory platforms available. Rapid-screen RT-PCR tests are also in development, and one received an EUA approval in September 2020.

Rapid Antigen Testing

Some rapid diagnostic tests for the presence of antigens associated with SARS-CoV-2 are available for use in health care, and increasingly other settings. Antigens are viral proteins that are expressed while a virus is rapidly replicating, which is generally the case in earlier stages of infection. These tests use nasal or throat swabs and results are available within 30 minutes. Some of these devices are widely used for screening and are commonly used for other diagnoses, including influenza (e.g., the Quidel Sofia 2 Antigen test). Antigen tests tend to have lower sensitivity, meaning they are less able to detect cases with low viral loads or may not be able to detect cases until later in their infectious course. Some testing programs using these devices use repeated or frequent rapid screening supplemented by RT-PCR for symptomatic cases that report negative antigen tests and for confirming positive antigen tests. Developments in these methods should be monitored and testing strategies adjusted based on approval and availability of these tests. Considerations for testing using antigen tests are provided by the CDC.[16]

Other rapid screening tests, employing various antigens or enzymes related to SARS-CoV-2, are under development. These tests have potential broad appeal for surveillance monitoring, if they perform well in the real-world. In addition, most rapid screen antigen tests have been approved for use on symptomatic individuals and their sensitivity is known to be lower than for RT-PCR.

Antibody Testing

Serology, or antibody testing, for SARS-CoV-2 is conducted by collecting a blood sample from a small finger prick to see if a person's immune system demonstrates a response to the virus. Typically, the body's immune system develops antibodies when they are exposed to a pathogen

[15] U.S. Food and Drug Administration. *Coronavirus (COVID-19) Update: FDA Authorized First Diagnostic Test Using At-home Collection of Saliva Specimens*. https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-first-diagnostic-test-using-home-collection-saliva

[16] U.S. Centers for Disease Control and Prevention. *Interim Guidance for Rapid Antigen Testing for SARS-CoV-2*. September 4, 2020. https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html

(such as a virus) to destroy or neutralize it. The immune system will then recognize this pathogen if it is encountered in the future and mobilize a response, generally providing some level of immunity against the virus. A positive antibody test indicates that an individual was exposed to SARS-CoV-2 at some point in the past, and their immune system was able to launch an antibody-forming immune response. A positive antibody test does not signify that an individual is not currently infected with the virus. Most public health agencies require follow-up RT-PCR testing if an antibody test is positive.

Currently, it is unknown whether a positive antibody test can affirm that a person has immunity and will be protected from infection or reinfection with COVID-19. Other unknowns include how long antibodies to SARS-CoV-2 stay in the body; what level of detected antibody determines immunity; and how long immunity might last. The antibody test alone is not useful as a screening tool to determine potentially infective people, or those that have long-term immunity. The application of antibody testing in camp settings is not recommended. Antibody testing can be effective in certain clinical settings and in wide-scale population studies, but not for screening to identify potentially infectious cases.[17]

[17] GeurtsvanKessel CH, et al. 2020. An evaluation of COVID-19 serological assays informs future diagnostics and exposure assessment. *Nature Communications*, 11(3436). https://www.nature.com/articles/s41467-020-17317-y.