

Screening for SARS-CoV-2:

Sample Size and Sampling Technique Overview

December 3, 2020

Background

There are three main strategies for testing for SARS-CoV-2, the virus that causes COVID-19: diagnostic testing, screening, and surveillance testing. Each of these is described briefly below. This document focuses on voluntary screening and how it may be used by congregate settings, such as institutions of higher education (IHEs - e.g., colleges, universities), schools, correctional facilities, and businesses (e.g., factories or production plants), as they reopen or remain open during the COVID-19 pandemic. Offering screening to individuals in a community, school, or business can help identify people who have COVID-19 even though they have no symptoms - this can help stop the spread of COVID-19 to others. CDC Guidance on this topic can be found here: [CDC Guidance for Expanded Screening Testing to Reduce Silent Spread of SARS-CoV-2](#).

Diagnostic Testing

Diagnostic testing is conducted to determine if a **person with COVID-like [symptoms](#)** is infected with the virus. Diagnostic testing may also be used to see if a person who had **[close contact with a person known to have COVID-19](#)** acquired the illness. This is typically conducted by a healthcare provider (especially if the person has symptoms), or may be conducted by a local pharmacy (e.g., Walgreens or CVS) or a testing event sponsored by a local health department. Fictional examples include:

- Mr. Smith recently developed fever, cough, and shortness of breath. He goes to his doctor, who performs diagnostic testing to determine if he has COVID-19.
- Mrs. Smith feels fine, but her husband recently tested positive for COVID-19, so she goes to a drive-through testing site to get diagnostic testing.

Screening

Screening is used to identify a **person** who is infected with COVID-19, even though they have **no symptoms** and **have not had close contact with a person with COVID-19**. This is important because many people never develop signs or symptoms of COVID-19, and if they do not know they are infected, they may unknowingly spread the virus to others. Screening tests can be used in a variety of ways:

- **Before or after a specific event.** For example, an employer or school may test all employees and/or students who return to the workplace or school after a holiday.
- **Regular, repeated testing.** For example, if a workplace has difficulty maintaining 6 feet of distance between workers and customers and there is a high risk of infection, the workplace may choose to test all workers every X number of days or weeks.
- **In a specific group of people.** For example, students and teachers in a classroom who have individuals at high risk of severe illness.

Surveillance Testing

Surveillance testing helps identify what is happening in a **community or population**, rather than in an individual person. Examples include:

- **Wastewater surveillance.** Samples of wastewater from a specific area or community (e.g., a city, a dormitory, or a neighborhood) are tested for the virus that causes COVID-19. The results identify if COVID-19 is circulating in that community.
- **Seroprevalence surveys.** De-identified blood samples are tested for antibodies to the virus that causes COVID-19. These blood samples may come from blood that is donated to blood banks, or blood that is collected for routine lab testing. The results provide an estimate of how many people in that sample have been exposed to or infected with COVID-19.

Surveillance testing does not provide information on whether or not a specific individual is infected with COVID-19. For more information on performing surveillance testing, please refer to the [CDC Guidance on Wastewater Surveillance](#) or reach out to your [local health department](#).

Steps for Screening

This document focuses on screening and includes a stepwise approach for implementing it within a population. Keep in mind that every population is different, and determining the appropriate screening plan can be challenging. Facilities will need to consider access to testing, turnaround time for test results, cost, timing and frequency of testing, population acceptance of testing, and logistics, such as the ability to return person-level test results and to take action based on those results. This strategy can be updated over time based on the testing findings, changing scientific knowledge, needs, and available resources. Please see **page 6** for a worksheet that can be used in conjunction with these steps to create a plan for your specific population.

1. **Determine the population of interest.** Who are you interested in screening? Everyone in a particular workplace or school? Just the staff? Just the students? Only students or residents who left the campus for a holiday break? Identify exactly who is included in your “population of interest.”
2. **Determine what percentage of the population you want to test.** In public health, this is called establishing the “sample size.” Some facilities may choose to offer voluntary testing to everyone. In this case, skip steps #2 and #3. In some cases, it is not always feasible to test everyone in your population of interest. By offering voluntary testing to a randomly selected group of people from within your population of interest, you can get a snapshot of what is likely happening in the larger group. Although many methods may be used to determine an appropriate sample size, a good rule of thumb is to test 10 to 20 percent of the population. For example, if you have 50 people in your population of interest, your goal would be to test 5-10 people during each round of screening. These 5-10 people are called your “sample population.”
3. **Determine how you are going to choose the people in your sample.** It is important that these people are chosen randomly, so that you can use the results of your screening to understand what is going on in the population of interest. Several steps go into this process:

- a. Exclude anyone who has already been diagnosed with COVID-19 in the past three months OR who has had known close contact with a person with COVID-19 in the past 14 days. (Remember, the goal is to test people who have no COVID-19 symptoms and no close contact with a person with COVID-19. If we test individuals who are sick or have been exposed to someone who is sick, that is considered diagnostic testing, not screening.)
 - b. Create a list of the remaining people in your population of interest. This does not have to be a list of names, but may instead use a unique identifier. For example, student/staff identification numbers.
 - c. A simple method for choosing random individuals includes the following:
 - i. Randomly choose a number from 1-10. You may want to put the numbers in a hat and pull one out. This number is where you will start on your list of identifiers.
 - ii. Based on the number of individuals you need to select for your random sample, count down the list of identifiers - starting from the point identified above - and choose every nth person. For example, if you have 50 people in your population of interest, and you need 5 people in your random sample, you would choose every 10th person. If you have 50 people in your population of interest and you need 10 people in your random sample, you would choose every 5th person.
 - iii. As an alternative, random samples can be generated using a statistical software package, online tools, or spreadsheets (e.g. Excel).
 - d. If individuals are permitted to opt out of testing if selected, consider selecting additional “backup” individuals as alternates to be used if needed.
4. **Determine the frequency of testing.** Will this be one-time testing only? Will testing be repeated at certain intervals, e.g., every two weeks? Consider the reason you are performing screening when choosing frequency. Are you primarily concerned about a single event? (Example: students returning from a holiday.) Then one-time screening may be reasonable. Is the risk to your students/staff ongoing? Then repeating testing at predetermined intervals may be reasonable. Frequency will also be guided by testing supplies and availability, availability of staff to perform screening, the logistics of conducting screening, and the time required to follow up both positive and negative test results.
5. **Determine the type of test to be used.** A variety of tests are available to test for the virus that causes COVID-19. These include rapid tests (results available in as little as 15 minutes) and PCR tests (results typically available in 2-5 days.) More information on types of tests can be found here:
[VDH: COVID-19 Testing – Coronavirus](#)
[CDC: COVID-19 Testing](#)
[CDC: Test for Current Infection](#)
[FDA: Coronavirus Disease 2019 Testing Basics](#)
6. **Create a plan for performing testing.** Will testing be done at your site? (At your school, workplace, etc.) Will individuals need to go to an established testing site, such as a pharmacy, health department-sponsored testing site, or a healthcare provider? Things to consider:
 - a. If testing on site: Be sure to use a COVID-19 test that has an [Emergency Use Authorization \(EUA\)](#) from the U.S. Food and Drug Administration (FDA). A list of approved tests may be found here: [In Vitro Diagnostics EUAs](#). Moreover, some tests require a laboratory to have a [CLIA](#)

[Certificate of Waiver](#) to perform the test. For example, as of 12/1/2020, all six rapid, point-of-care COVID-19 antigen tests require that a lab have, at a minimum, a CLIA Certificate of Waiver. Please review the test package insert to determine if the test is CLIA waived or not.

[FDA: FAQs on Testing for SARS-CoV-2](#)

[FDA: COVID-19 Test Settings: FAQs on Testing for SARS-CoV-2](#)

- b. If relying on other testing locations: It may be prudent to discuss your plans with the local testing site to ensure they have the capacity to handle the number of individuals you wish to test, and they will test asymptomatic individuals. If you are pursuing repeated screening, note that the capacity at the local testing site might change over time.
 - c. Individuals who are asymptomatic and being screened need to continue to follow every day precautions (wear a mask, maintain social distancing, and wash hands frequently) while awaiting test results. Keep in mind that anyone who is undergoing diagnostic testing (for symptoms, or for close contact with a person known to have COVID-19) should quarantine while awaiting test results.
7. **Create a plan for sharing test results.** Who will notify individuals of their test results and how will they notify them? Who will notify the health department of positive and negative results?
8. **Determine plan for positive results.** Individuals who test positive for COVID-19 need to be isolated immediately. Have a plan in place for sending positive individuals home or isolating them appropriately (if at a residential facility.) It is important to share information on home care and isolation with these individuals. Resources can be found here:

[VDH: What to do if you have confirmed or suspected coronavirus disease \(COVID-19\)? – Coronavirus](#)
[CDC: What to Do If You Are Sick](#)

Facilities that offer housing (such as IHEs, correctional facilities, shelters, boarding schools, etc.) will need to prepare to take further actions to support their testing efforts. This includes isolating confirmed cases, supporting the health department in contact tracing once a case is identified, quarantining the close contacts of people found to be infected, and reviewing infection prevention and control practices. Officials in these facilities should work with health department staff if they plan to do entry testing and/or repeat testing.

Screening for SARS-CoV-2: Sample Size and Sampling Technique Overview

Resources

CDC

- [Interim Guidance for Expanded Screening Testing to Reduce Silent Spread of SARS-CoV-2](#)
- [Interim Guidance for Use of Pooling Procedures in SARS-CoV-2 Diagnostic, Screening, and Surveillance Testing](#)
- [Symptoms of Coronavirus](#)
- [Definition of Close Contact](#)
- [National Wastewater Surveillance System \(NWSS\)](#)
- [Interim Guidance for Rapid Antigen Testing for SARS-CoV-2](#)
- [COVID-19 Testing](#)
- [Test for Current Infection](#)
- [Testing, Screening, and Outbreak Response for Institutions of Higher Education \(IHEs\)](#)
- [Testing Strategy for Coronavirus \(COVID-19\) in High-Density Critical Infrastructure Workplaces after a COVID-19 Case is Identified](#)
- [What to Do If You Are Sick](#)

FDA

- [FAQs on Testing for SARS-CoV-2](#)
- [Coronavirus Disease 2019 Testing Basics](#)
- [COVID-19 Test Settings: FAQs on Testing for SARS-CoV-2](#)
- [COVID-19 EUA Information](#)
- [In Vitro Diagnostics EUAs](#)
- [CLIA Certificate of Waiver](#)

VDH

- [Role of VDH and IHEs in COVID-19 Preparedness and Response Efforts](#)
- [VDH Interim Guidance for Implementing and Defining Roles for Testing Strategies in High-Density Critical Infrastructure Workplaces after a COVID-19 Case is Identified](#)
- [COVID-19 Testing – Coronavirus](#)
- [What to do if you have confirmed or suspected coronavirus disease \(COVID-19\)? – Coronavirus](#)

**Screening for SARS-CoV-2:
Sample Size and Sampling Technique Overview**

Worksheet

1. Determine the population of interest.

Population of Interest

Description (e.g. students who left for holiday.): _____

Estimated Number of People Who Fit This Description (#): _____

2. Determine what percentage of the population you are going to test.

Sample Size

Population of Interest _____ X 0.10 = _____ (10% of population of interest)

Population of Interest _____ X 0.20 = _____ (20% of population of interest)

Sample Population = _____ to _____ people

3. Determine how you are going to choose the people in your sample.

- a. Exclude anyone who has already been diagnosed with COVID-19 in the past three months OR who has had known close contact with a person with COVID-19 in the past 14 days.
- b. Create a list of the remaining people in your population of interest.
- c. A simple method for choosing random individuals includes the following:
 - i. Randomly choose a number from 1-10. You may want to put the numbers in a hat and pull one out. This number is where you will start on your list of identifiers.

Example:

You pull number 3 out of the hat. Start counting from the third name (yellow):

1	Name or Identifier #1
2	Name or Identifier #2
3	Name or Identifier #3
4	Name or Identifier #4
5	Name or Identifier #5

- ii. Based on the number of individuals you need to select for your random sample, count down the list of identifiers - starting from the point identified above - and choose every nth person.

For example, if you have 50 people in your population of interest, and you need 5 people in your random sample, you would choose every 10th person. If you have 50 people in your population of interest and you need 10 people in your random sample, you would choose every 5th person. As an alternative, random samples can be generated using a statistical software package, online tools, or spreadsheets (Excel.)

(# People in Population of Interest) _____ ÷ _____ (# People in Random Sample)
= _____ (n) for every nth person you need to choose.

Example: Starting from the 3rd name or identifier (yellow), if you are choosing every 5th person, the next person chosen for your random sample would be “Name or Identifier #7” (green.)

1	Name or Identifier #1	
2	Name or Identifier #2	
3	Name or Identifier #3	Starting point for counting - 1
4	Name or Identifier #4	2
5	Name or Identifier #5	3
6	Name or Identifier #6	4
7	Name or Identifier #7	5 - First person selected for random sample
8	Name or Identifier #8	
9	Name or Identifier #9	

- d. If individuals are permitted to opt out of testing if selected, consider selecting additional “backup” individuals as alternates to be used if needed.

4. Determine the frequency of testing.

Frequency

- One Time Screening
 Repeated Screening: Every _____ days/weeks/months (circle appropriate choice)

5. Determine the type of test to be used.

Type of Test

- Rapid test. Specific test name: _____ Result expected in: _____ minutes

PCR test. Specific test name: _____ Result expected in: _____ days

6. Create a plan for performing testing.

Plan for Testing

- Testing on Site (at business, school, etc.)
CLIA waiver needed? Yes/No (circle one)
If yes, CLIA waiver obtained? Yes/No (circle one)

- Utilizing Existing Testing Center
Site: _____
Testing Center Agrees to Screen? Yes/No (circle one)

7. Create a plan for sharing test results.

Plan for Sharing Results

- Identified a person to notify individuals of test results? Yes/No (circle one)
Name of Notifier(s): _____
Communication Method: Phone Call / Text Message / Email / Other (circle one)

- Identified a person to notify the local health department of positive and negative results?
Yes/No (circle one)
Name of Notifier(s): _____

8. Determine plan for positive results.

Plan for Addressing Cases of COVID-19 Identified by Screening

- Isolation Plan/Process in Place? Yes/No (circle one)
- Handout/Information Available on "What to Do If You Are Sick?" Yes/No (circle one)

Does your facility offer housing? Yes/No (circle one)

If yes, please consider the following:

- Isolation Plan for Confirmed Cases
- Contact Tracing Plan
- Review Infection Prevention and Control Practices
- Implement Mitigation Efforts
- Consult with Local Health Department if repeat testing or entry testing is planned