



How is COVID-19 diagnosed?

COVID-19 is a disease caused by the virus Sars-CoV-2. Clinicians use several things to determine whether someone has COVID-19, including symptoms, exposure, and testing. None of these pieces of information alone are enough to diagnose COVID, and no single piece of information is perfect. For example, someone with known exposure and classic symptoms might be presumed to have COVID-19 even with a negative test. Someone with no symptoms and no known exposure but a positive test may be diagnosed with COVID-19 anyway because transmission is high enough in that location to assume they have been exposed even without knowing it, and because lots of people who get COVID-19 don't have symptoms.

What tests are available for COVID-19?

The most widely used test to diagnose COVID-19 right now is a molecular test which detects genetic material (ribonucleic acid, or RNA) from the virus. These are sometimes called nucleic acid amplification (NAAT) tests or polymerase chain reaction (PCR) tests based on the method of testing. Sometimes people refer to these tests by the way they are collected, such as nasopharyngeal swab test, nasal swab test, or oropharyngeal swab test. Antigen tests are also being developed but are not yet widely available. These tests detect antigens, which are proteins on the surface of the virus that our immune system recognizes.

Antibody tests are also available, but they are not used to tell people if they have COVID-19 at the moment of the test. These tests are also called serology tests. Antibody tests look for the body's response to an infection instead of looking for the virus itself. Antibodies are proteins that the body makes to fight off infections. They are one part of the immune system response to infection. Because it takes days to weeks for the body to create antibodies, these types of tests are not recommended for initial diagnosis of COVID-19.

Are all these tests approved by the Food and Drug Administration (FDA)?

No. None of the tests for COVID-19 are approved by the FDA. This is because FDA approval is a rigorous process which usually takes months to years. It requires a lot of testing to make sure tests work properly and to prove the quality and accuracy of the tests. However, during a public health emergency like the current pandemic, we cannot wait months for a test to receive approval. The FDA can grant an Emergency Use Authorization (EUA) which allows potentially life-saving products, medicines, and tests which meet certain criteria to be used. Many tests have been granted EUA. A list of tests with EUA is available at

<https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas>

The list includes molecular tests, antigen tests, and serology tests. As of 7/6/20, there are 25 tests with EUA for serology testing, and dozens of manufacturers who have applied for EUA for serology tests. There are many different kinds of serology tests. These tests use different ways of looking for antibodies. They may look for different antibody classes such as IgA, IgM, IgG, or total antibody. They are also looking for antibodies to different parts (targets) of the SARS-CoV-2 virus.

Why aren't we testing everyone?



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There are many reasons that we still don't have enough molecular tests for everyone in this country. Sars-CoV-2 is a new virus which didn't even exist before approximately November 2019. When the virus was recognized, scientists in China quickly sequenced the genome. That information was released in early January and scientists around the world began developing molecular tests for the virus. Some countries used the test provided by the World Health Organization, and others developed their own. In the US, the early tests were not accurate and were delayed. In addition, scientists had trouble getting samples of the virus and getting patient specimens which are used to create tests. When an accurate test was created in the US, there were only a few laboratories which were able to perform the tests. As more companies created tests, approval to use the tests was sometimes slow. When laboratory testing capacity was increased, a shortage of personal protective equipment (PPE) meant that too few health care workers could safely collect a specimen from patients. There are also shortages of nasopharyngeal swabs, viral transport media, and other specimen collection materials. This is in part because many of the factories which make these were shut down temporarily due to COVID, and in part because everyone around the world needs lots more of these than usual. There are shortages of the chemicals used to run the tests in laboratories for the same reason. Although there are more tests available now, we are still seeing shortages of PPE, specimen collection kits, and lab capacity to run tests. We are working very hard to try to increase the tests available in Chester County and Delaware County.

How can I get a test if I need one?

For information about available testing visit <https://www.chesco.org/4460/Coronavirus-COVID-19-Testing-Information> which includes links on testing in Chester County and in Delaware County. Testing is also available by physician referral. If you have symptoms or exposure and need help deciding if you should get tested, consult with your healthcare provider. If you do not have a healthcare provider, call the Health Department at 610-344-6225, select option 4, and a representative can connect you to a healthcare provider to be assessed for testing.

When should I stop isolation if I have tested positive?

For people with a positive molecular test under home isolation:

Those with symptoms may stop home isolation under the following conditions:

- At least 3 days (72 hours) have passed since fever went away without the use of fever-reducing medication
- **AND** improvement in respiratory symptoms (e.g., cough, shortness of breath)
- **AND** At least 10 days have passed since symptoms first appeared.

Those without symptoms may stop home isolation 10 days after the test was collected.

For healthcare personnel (HCP) with a positive molecular test under home isolation:

Follow the above guidance. In addition, after returning to work, HCP should:

- Wear a facemask for source control at all times while in the healthcare facility until all symptoms are completely resolved or at baseline.
 - A facemask instead of a cloth face covering should be used by these HCP for source control during this time period while in the facility.



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- A facemask for source control does not replace the need to wear an N95 or higher-level respirator (or other recommended PPE) when indicated, including when caring for patients with suspected or confirmed COVID-19.
 - Of note, N95 or other respirators with an exhaust valve may not provide source control.
- Self-monitor for symptoms, and seek re-evaluation from occupational health if respiratory symptoms recur or worsen.
- Be restricted from contact with severely immunocompromised patients (e.g. transplant, hematology-oncology) until 14 days after illness onset.

Can I use a PCR test for return to work?

Employers may use the above guidelines, based on symptoms or based on time since diagnosis for people without symptoms, for return to work policies. However, a test-based strategy is also acceptable (but not preferred or required) to decide when employees are safe to return to work. If a test-based strategy is chosen, employees with symptoms need wait until those symptoms are resolved or at baseline, and then have two consecutive negative PCR tests collected at least 24 hours apart. Employees without symptoms need two consecutive negative PCR tests at least 24 hours apart. Note that PCR can be positive for a prolonged period but does not necessarily mean that a person is contagious. Antibody testing may not be used for return to work.

Can I use a PCR test to get out of quarantine early?

No. When a person has been exposed to someone with COVID-19, but they have no symptoms, they need to quarantine. That means staying at home during the time they might become infected. Quarantine is 14 days, because after a person is exposed to COVID-19 germs, it can take up to 14 days (the incubation period) before they are infected. During the incubation period, all testing will be negative because the virus level is not high enough in the body to be detected. If a person has a negative test during quarantine, they must still wait the full 14 days to stop staying home. If a person has a positive test during quarantine, they can follow the above guidelines for when to stop isolation.

Does a negative PCR test mean I am safe to visit someone, travel, or do something else?

No. A negative PCR test only means that you did not have enough virus detected at the time of the specimen collection to have a positive result. PCR tests have a high false positive rate, up to 30% in some studies. Anyone with symptoms but a negative test should consult a primary care provider about the possibility of a false negative test and whether additional testing is needed. Anyone who was recently exposed and is in the incubation period will have a negative test, but could become infected. People with COVID-19 can be contagious even without symptoms and even without knowing they have COVID-19. You should use all available information when you are deciding whether to do a particular activity, such as visiting someone or traveling. For information on travel, visit <https://www.cdc.gov/coronavirus/2019-ncov/travelers/travel-in-the-us.html> and <https://www.health.pa.gov/topics/disease/coronavirus/Pages/Travelers.aspx>. For information on what to consider if you are at increased risk of severe illness, or if you are planning to visit someone at increased risk, visit <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/older-adults.html>.



What kinds of antibodies are there?

The body makes different kinds of antibodies at different times in illness and recovery and in different parts of the body. Antibodies can have different purposes, like signaling other cells or preventing infection. Common classes of antibodies that are used in serology tests include IgA, IgM, and IgG. In general, a majority of the antibodies in your body are IgA, mostly in the intestines and the lungs. Your body usually starts to make IgM during the first few weeks of illness, and usually stops making IgM antibodies after a few more weeks. IgG antibodies may stay in the body for weeks or longer. Antibodies are only one part of the immune system, which has lots of cells and processes for protecting us from infections. For COVID-19 infection, we are still learning about which antibodies are made, when they are made, what they do, and how antibodies might help heal us or protect us from COVID-19 infection. Unlike in many infections, IgM and IgG antibodies seem to appear at the same time in lots of people.

Are all the antibody tests the same?

No, they are very different. There are many different companies making these tests. Some tests require a blood draw and some use a finger stick, like checking your blood sugar. Some look for IgA, IgM, IgG, total antibody of all types, or a combination of these. Some tests measure a level of antibody and some just tell whether it was detected or not (yes/no). Different tests look for antibodies to different pieces of the virus (different targets). Different tests use different ways of detecting antibodies. Overall, the quality of the antibody tests has been really variable, with some tests doing very well and some tests very inaccurate. Even an antibody test (or a molecular test) that has good performance is not perfect.

What are the possible results of antibody testing?

Antibody tests can help decide if someone was exposed to COVID-19. If your body has enough antibodies in your blood for the test to detect, then the test will be positive. Most people appear to make antibodies if exposed to COVID-19, but we do not know if everyone does, especially if you have a weak immune system. A majority of people have made antibodies by the 3rd week after infection. If you have a test too soon after infection started, you might not have any antibodies yet. This might be considered a false negative (when you have a disease but the test doesn't pick it up). An antibody test will not tell you how well your antibodies work, just if they are there or not. Antibody tests might pick up antibodies from a coronavirus that does not cause COVID-19. This is called a false positive (when you don't have the disease but the test says you do). Depending on the antibody test that was done, your results might show positive or negative for total antibodies or positive or negative for one or more specific antibodies, such as IgG or IgM.

How do you know how good a test is? Can I believe the results?

Tests have several characteristics. Stay with me: we are going to talk about some science. Sensitivity is how likely a test can detect a disease that is there. If a test is very sensitive, you will pick up most or all of the cases. You will **not** have a lot of false negatives, when the disease is really there but your test doesn't pick it up. The molecular tests have up to a 30% false negative rate. That is why if a clinician thinks someone has COVID-19, a negative test does **not** mean the person does not have COVID-19. There are lots of reasons that a molecular



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test might have a false negative: the specimen collection wasn't good enough, there is not a high enough amount of virus in the body (viral load) to detect, etc.

Specificity is how likely a test will correctly tell when a disease is not there. If a test is very specific, it will only be positive when the disease is present. You will **not** have a lot of false positives, which is when the test says you have a disease but you really don't. The molecular tests generally have a high specificity, so when a COVID-19 test is positive, it almost always means the patient has COVID-19. But remember: molecular tests only detect virus genetic material. Late in the disease, a person might have dead virus in their body, and they might not be contagious anymore, but they could still have a positive molecular test.

Antibody tests are also being studied to evaluate how well they work. In general, serology tests have a lower sensitivity because of the timing of the tests. Your body makes antibodies between a few days and a few weeks after the start of the illness. When you test for antibodies soon after infection starts, the tests will be negative. That is why they are not recommended for diagnosis of COVID-19. Overall, a low or moderate sensitivity for an antibody test is not very harmful for people or for the community, because we are not using antibody tests to try to detect early infection. But the specificity of antibody tests is very important. If you have low or moderate specificity, then too many of positive tests are false positives. We do not want people to think they are immune when they are not. We do not want counties, cities, or countries to think lots of people have immunity when they have not ever had COVID-19.

Even a very high specificity is not perfect. The chance that your positive result is really a true positive also depends on how much disease is in the community (the prevalence). The chance that your negative result is a really a true negative also depends on prevalence. An example: we use a test with 99% specificity for IgG. We test 100 people (Group A) who have stayed at home, never leaving the house, for the last 6 weeks. All food and household goods have been delivered, and they wash their hands after touching all packages. We also test 100 people (Group B) who went on vacation 6 weeks ago. They flew to Florida, and then went on a cruise for two weeks. For the 4 weeks since they came back, they have worked in a nursing home where there is a known outbreak of COVID-19. In each group, 1 person tests positive for IgG. How likely is the result a true positive? In Group A, it is very likely a false positive! In Group B, there is a much greater chance this is a true positive. Right now in our community, even though lots of people have come down with COVID-19, the prevalence is low. That means even tests with pretty high sensitivity and specificity have a higher risk of inaccurate results. Some people will need another test. The chance that a positive antibody test is a true positive will be higher if another (different) antibody test is also done.

If reported sensitivity and specificity is 100%, then doesn't that mean the test is perfect?

No test is perfect. The studies to get these tests EUA were done in small numbers of people. When we perform these tests in thousands or millions of people across the country, we learn much more about these tests. Also, in studies, tests are performed the exact same way by a small number of trained scientists or clinicians. In the real world, with thousands of people in hospitals, labs, and offices performing these tests, there is much variation in the way the tests are done.

Should people with positive antibody test have a molecular test performed?



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We do not recommend that molecular testing be done for everyone with a positive antibody test. By the time your body makes antibodies, the amount of virus (viral load) is usually decreased and there is a lower chance of the molecular testing being positive. All testing, including molecular and antibody testing, should be used with information from symptoms, exposure, and other lab tests and studies to decide what the test means. In someone who had known exposure and classic symptoms 3 weeks ago, a positive serology is more likely to be a true positive. When there is any doubt, a second serology test, preferably one with a different target, is recommended to confirm a positive antibody test. Consult your primary care provider for further information.

If I need a confirmatory antibody test, how will my primary care physician know which test to order?

The FDA has a website which provides information on antibody tests which have received EUA, including the target, type of test, and performance data. Visit <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/eua-authorized-serology-test-performance>. For confirmation, it is important to choose a test with high positive predictive value (PPV) because the prevalence in our area is estimated to be low (5% or less).

Should people with positive antibody tests be isolated or quarantined?

New information shows that relatively few people make antibodies during the early part of the illness when people are contagious to others. For this reason, it is not recommended to use antibody tests results for restriction from work or school, or for grouping people who live together in congregate settings. If someone with a positive antibody test has symptoms of COVID-19, consider PCR testing for diagnosis, and follow the guidance (above) for stopping isolation.

What does it mean if I have positive antibodies?

Positive antibodies may be a true positive or a false positive. A false positive means the test picked up some other kind of antibody, but it is not COVID-19. The chance that your result is a true positive depends on your symptoms, exposure, and additional tests like labs and x-rays. Consult your primary care provider with questions. Some people need more testing to see if positive antibodies are true positive or false positive. For people with a true positive, antibodies mean that you have COVID-19, or had it in the past. People with IgG might have temporary immunity to COVID-19. When people have immunity to a disease, sometimes it means they cannot get infected again. Sometimes it means they can get infected again, but the disease is usually milder. We do not know if people who had COVID-19 in the past can get infected again. We do not know how long immunity might last. Based on information about other coronaviruses and new information about COVID-19, we think immunity might last for a few months (2 to 3 months). We do not know how other parts of the immune system, such as T-cells, are involved in protecting us from COVID-19. Much more research is needed to know for sure.

If I have IgG, can I donate my plasma?

Some places are doing research on using convalescent plasma, which is taking antibodies from someone who has recovered from a disease and giving them to someone else who is fighting off the disease. This treatment has been used for other infections, such as Ebola, and might help with COVID-19. Potential donors are screened to make sure they have antibodies that would help and no other infections which could be spread to



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the recipient. For more information, or to find a place you might be able to donate, visit <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/donate-covid-19-plasma>.

If I have positive antibodies, can I stop physical distancing or stop wearing a mask?

No. We do not know if people with antibodies who get exposed again might still be able to give the virus to other people who are not immune, even if they don't get sick again themselves. We do not know if having antibodies means you are immune, how strong immunity might be, or how long immunity might last. It is essential that everyone in our community follow all public health guidance to protect everyone else in the community. Healthcare workers should continue to follow guidance on all recommended personal protective equipment (PPE).

What is the purpose of doing antibody testing when there is so much we don't know about them?

Antibody tests may help people who previously had COVID-19 feel some reassurance that their body has made antibodies, even though we don't yet completely understand immunity. Antibody tests may also help people who thought that they had COVID-10 but who didn't get tested find out if they likely did have COVID-19 or not. Finally, widespread testing can help public health experts understand the extent of spread in our communities. This can help us when planning for reopening phases.

What is herd immunity?

Herd immunity means enough people in a population have immunity so that even people without immunity can be somewhat protected. This happens because if the people who are immune do not give the infection to others, the infection will not spread as quickly, or at all. If the infection is not spreading, then the people who are not immune have a smaller chance of getting the infection. Herd immunity depends on how well an infection spreads and how many people are immune. Herd immunity has never been shown before vaccines were invented, even when infections infected millions of people. COVID-19 is a new disease, but it is estimated that around 60% to 80% of a population would need immunity to have "herd immunity." Right now, we estimate that less than 5% of our population has immunity. We also do not know if you could have herd immunity without a vaccine, because people may be able to get COVID-19 more than once, or people who are immune might be able to spread COVID-19 to others if they get exposed again.

I heard that 25% to 50% of people have no symptoms of COVID-19. Doesn't that mean up to half of us have been exposed, and we can go back to normal soon?

No. We estimate that 25 to 50% **of people who have COVID-19** do not have symptoms at the time of diagnosis. Many of them later develop symptoms, but some people never have any symptoms at all. However, only a small number of people have even been exposed to COVID-19. In most areas, including Chester County and Delaware County, we estimate that less than 5% of people have been exposed. In some areas where there was much more transmission, up to 15 or 20% of the people have been exposed. No area anywhere in the world has enough people who were exposed to COVID-19 to be even close to herd immunity.



If young and healthy get exposed, won't that help the people who are more at risk and help us get to herd immunity faster?

No. If you try to get just enough people infected to reach herd immunity, the virus is impossible to stop and many more vulnerable will be exposed than you intended. Young and healthy people have a lot of contact with people who are more vulnerable and can infect them with COVID-19 without knowing it. Also, when many people are exposed, we cannot care for them all at once. Not everyone gets sick enough to be in a hospital or in an intensive care unit (ICU). But when more people are sick at one time, we do not have enough of everything (room in the hospital or ICU, ventilators, medicines, health care workers, PPE, etc.) to care for everyone. Also, when hospitals are full of patients with COVID-19, we do not have ability to care for everyone else with heart attacks, strokes, broken bones, and everything else. This is why we try to "flatten the curve." We also still do not know enough about the virus to know if people who had infections will have problems months or years later. For example, some children are getting very sick with inflammation-related illness several weeks after having a mild or undetected case of COVID-19. Many adults with COVID-19 who didn't need to be hospitalized (a "mild" case) have fatigue or difficulty breathing months later. We do not know how many people might be disabled after recovering.

If we cannot get to herd immunity quickly, how can we ever get back to normal?

Several things are needed to control the virus. Even in the green phase, we are not completely back to normal and need to continue being careful. We will likely need to have public health measures ramp up and back down depending on how much the virus is spreading.

1. The spread of the virus must be slowed. We do this through physical distancing, wearing masks, and other public health measures.
2. We must have lots of rapid tests. We need to figure out who has COVID-19 quickly, to try to stop them from spreading germs to others.
3. We need to be able to isolate people with COVID-19 quickly and safely.
4. We need to track all the contacts of people with COVID-19 quickly. We need lots of trained contact tracers to do this. We need people to be honest about who are their contacts.
5. We need to quarantine contacts of people with COVID-19 quickly and safely.
6. We need treatments and vaccines, so that the way we handle COVID-19 is more like the way we handle influenza.

Getting fully back to normal may not happen for months to years, with tighter and looser restrictions in several steps along the way. Americans have overcome difficult challenges before and we will succeed again.