COVID-19 Testing

Coronavirus Disease 2019 (COVID-19) is caused by a novel (new) coronavirus that had not been seen in humans. Because people had never been exposed to this virus, people didn't have any natural immunity built up to protect themselves from it. We also didn't have any way to detect if someone had the virus (diagnostic test for COVID-19) or any medical measures available to treat people who were infected (medications) or prevent people from getting infected (vaccines).

The Centers for Disease Control and Prevention (CDC) worked quickly to develop a laboratory diagnostic test for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) or what is more commonly referred to as the virus that causes COVID-19. In order to make this testing available for use, they submitted an Emergency Use Authorization (EUA) to the U.S. Food and Drug Administration (FDA) to speed up FDA approval to use this test in the United States. The EUA approved this new diagnostic test in February and soon laboratories across the country were able to test for COVID-19.

There is a lot of information in the news about testing for COVID-19, types of tests that are available, the limited supply of testing, etc. Below are some answers to some of these commonly asked questions about COVID-19 testing.

What is the Food and Drug Administration's Emergency Use Authorization (EUA)?

The Food and Drug Administration (FDA) is the federal agency which regulates human and veterinary drugs, vaccines and other biological products and medical devices which are intended for human use to ensure they are safe and effective. Typically, the FDA must approve drugs, biological products and medical devices before they can be used to diagnose, treat or prevent diseases and conditions in people and animals.

Under the Emergency Use Authorization (EUA), the FDA may allow unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions when there are no adequate, approved, and available alternatives, such as during a public health emergency.

During the current COVID-19 pandemic, the FDA has used the EUA to authorize the use of tests (and other medical products) to facilitate the ability to detect, track, and prevent the spread of this disease. The EUA has been used to assist with many COVID-19-realted efforts including diagnostic tests, medications, vaccines, and personal protective equipment.

What type of test did the CDC develop to do diagnostic testing?

The CDC developed a Nucleic Acid Amplification Test, or NAAT. A NAAT test is a molecular test that detects the virus's genetic material in a sample that typically comes from a patient's respiratory system. These tests are commonly performed using a method called polymerase chain reaction (PCR). With PCR testing, a small part of the virus RNA sequence is amplified to allow detection with something called a fluorescence measuring instrument. PCR tests require the use of complex instruments in a laboratory setting. These types of tests are highly sensitive and allow for early detection of the virus days after infection and are believed to be highly accurate. This means that a positive or a negative test result from a NAAT test using PCR is likely to be true.

What is an antibody (also called serology) test?

In response to an infection, such as COVID-19, the body develops an overall immune response to fight the infection. One component of the immune system's response is to develop antibodies that attach to the virus and help eliminate it.

An antibody or serology test detects antibodies present in the blood when the body is responding to a specific infection, like COVID-19. This means the test detects the body's immune response to the infection caused by the virus rather than detecting the virus itself. There are several limitations with this type of test. First, detecting “coronavirus” antibodies in a person’s blood does not tell us which coronavirus the person was infected with (there are currently seven known types of coronaviruses that can infect humans, this novel coronavirus that causes COVID-19 is one of those seven types). Second, the antibody test only shows that a person has been exposed to a coronavirus at some point in the past, but it doesn’t tell you when that person was exposed. Third, it takes time for the body to make antibodies in response to an infection. If someone is tested using an antibody test shortly after they are infected, his/her body may not have made enough antibodies to be detected by the test and may give a false negative test result.

These limitations affect the usefulness of antibody testing for diagnosing COVID-19 and demonstrate why antibody testing should not be used to diagnose COVID-19. Antibody tests are more useful for determining if someone has had the infection, recovered, and developed immunity. They may be helpful for identifying people with immunity, guide decision making on when someone can return to work, or for developing antibody-based therapies. If an antibody test is used for diagnosis, anyone with a positive test result will need to get a confirmatory molecular diagnostic test. Any symptomatic individuals with a negative antibody test result should also get a confirmatory molecular diagnostic test.

There is ongoing research to learn more about COVID-19 antibody testing, how best to interpret their results, the usefulness of these tests, and their clinical application.

What is a point-of-care test?

A point-of-care (POC) test is a test designed to be used at the location where the person is receiving care, such as at the bedside in a hospital, urgent care center, emergency room, or alternate setting such as an assisted living facility, drive through testing site, or other testing location. Point of care testing is a way of making testing more accessible to people who need to be tested.

Currently most point-of-care tests used for COVID-19 testing are polymerase chain reaction (PCR) tests that get sent to a lab and results are available within a few days. One POC test with FDA EUA is available for use at the bedside. The FDA is approving more testing including test that will be able to diagnose COVID-19 more quickly.

What kind of testing are we using now?

Most of the diagnostic tests available for COVID-19 are molecular tests using PCR, which is also the type of test used by the County of San Diego Public Health Laboratory and other laboratories conducting

diagnostic testing. Antibody testing should not be used to diagnose potentially active COVID-19 infection as the results are difficult to interpret. Visit the FDA website to see a list of tests that have been approved for COVID-19 testing through the EUA process.

Why aren't more people able to get tested for COVID-19?

There are several reasons why molecular PCR tests have been difficult to get in large numbers. There is a limited supply of the materials needed to conduct the tests, such as the agents, reagents, primers and probes that laboratories need, as well as swabs or RNA purification kits. There is not enough personal protective equipment (PPE) for the healthcare personnel who are conducting the tests to perform the testing safely. There are also testing capacity limits meaning that sites can only perform a set number of tests with the amount of equipment they have that is required for testing or the number of staff able to perform the testing. As a result, just producing more testing material would not solve the issue completely as other logistics are also involved. Solutions to address some of these issues involve more equipment and staff, and developing newer, more rapid tests that can be done in more locations using less equipment.