Tests Used to Help Diagnose Coronavirus Disease (COVID-19)

There are two types of tests used to help identify the possibility of COVID-19 infection.

The first type of test **can help confirm infection** with the virus.

A second type of test **can show the possibility of previous infection** with the virus.

Testing options will vary based on patient symptoms and goals. Correct sample collection, transportation, and handling of the samples is the key to accurate test results.

Tests used to confirm infection

Tests used to find current infection look for genes or proteins from the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus that causes COVID-19. If the genes are found, it is assumed the patient is infected with the virus. The tests, which are performed as nasal swabs, include:

- Nucleic acid amplification test/real-time polymerase chain reaction (NAAT/RT-PCR) test
- Rapid virus antigen detection point of care (POC) test

Tests used to show the possibility of previous infection (antibody tests)

Tests used to look for the possibility of previous infection with the virus look for the presence of antibodies to SARS-CoV-2 in the blood[1]. There are currently two types of antibody detection tests, which test blood samples, including:

- Enzyme-linked immunosorbent assay (ELISA) test
- Rapid antibody detection POC test

Antibody tests:

- **DO NOT diagnose disease**
- **DO NOT guarantee immunity** to previous infection
- Can possibly provide information about recent or previous infection
- Can possibly provide information about how widespread the infection is
- Can possibly help confirm if new vaccines work against the virus

MDHHS
Michigan Department of Health & Human Services

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[1] https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2#serology

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Tests Used to Confirm Infection

Type of test	Test description	Type of specimen collected	Test results	Test considerations
Nucleic acid amplification test/real-time polymerase chain reaction (NAAT/RT-PCR) test **The NAAT/RT-PCR test is the gold-standard for diagnosing COVID-19 disease.**	The NAAT/RT-PCR test is used to find virus RNA. To test for virus RNA, many copies of the virus' RNA are made. Making copies increases the volume of the virus found in the sample. Increasing the amount of virus RNA in the sample makes finding the virus easier (because there is more to detect). Virus RNA is usually found in samples from patients showing infection symptoms.	Respiratory material taken from the back of the nose (upper respiratory track) using a swab. Blood samples are not used. Collecting enough sample material is important to help avoid false negative test results. Samples should be taken once symptoms begin because the virus is most likely present in high numbers.	**Positive test results** confirm COVID-19 virus infection. However, presence of viral RNA does not always mean the virus is live. **Negative test results** do not always mean the person is not infected. A negative test result could mean there was not enough viral RNA found in the sample. **A negative test result does not mean the patient will be negative tomorrow.**	✓ Timing and technique are very important. The goal is to collect a sample with enough viral RNA to avoid a false negative test result. ✓ The test is complex. It should only be performed by Clinical Laboratory Improvement Amendments (CLIA) certified laboratories. ✓ All results are required to be reported to MDHHS via MDSS within 4 hours of completion.
Rapid virus antigen detection POC test	The rapid virus antigen detection POC test is used to find virus RNA.	Respiratory material taken from the back of the nose (upper respiratory tract) using a swab. Blood samples are not used. Collecting enough sample material is important to help avoid false negative test results. Samples should be taken once symptoms begin because the virus is most likely present in high numbers.	**Positive test results** confirm COVID-19 virus infection. However, presence of viral RNA does not always mean the virus is live. **Negative test results** do not always mean the person is not infected. A negative test result could mean there was not enough viral RNA found in the sample. **A negative test result does not mean the patient will be negative tomorrow.**	✓ Test sensitivity is variable. Finding true infections and avoiding false negatives is difficult due to inadequate sample collection or if the viral load is low at the time of the sample collection[2],[3]. ✓ The test is complex. It should be performed by CLIA certified laboratories or by a patient care site with a CLIA certificate waiver. ✓ All results are required to be reported to MDHHS via MDSS within 4 hours of completion.

MDHHS = Michigan Department of Health and Human Services; MDSS = Michigan Disease Surveillance System

[2] https://www.who.int/news-room/commentaries/detail/advice-on-the-use-of-point-of-care-immunodiagnostic-tests-for-covid-19
[3] https://jcm.asm.org/content/jcm/early/2020/04/03/JCM.00512-20.full.pdf

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Tests Used to Show the Possibility of Previous Infection (Antibody Tests)

Type of test	Test description	Type of specimen collected	Test results	Test considerations
Enzyme-Linked Immunosorbent Assay (ELISA) test	The ELISA test provides information about previous infection. It may determine if antibodies are present. With certain tests, it may also determine what type of antibodies are present. An ELISA test is like many tests used in public health, like those for hepatitis B or HIV. In some instances, ELISA tests can provide quantitative results. Quantitative results may help determine how many antibodies there are and how well a future vaccine will work once it is administered.	**Blood** (serum or plasma) is collected through the vein.	**The presence of antibodies** is considered a **probable** positive result for previous COVID-19 virus infection. Finding antibodies does not mean they were fighting COVID-19 infection. It could mean there was a different (non-COVID-19) infection. For these reasons, to help confirm a positive test, disease risk and protective factors must be considered. Since antibodies can take time to develop, if sample collection was soon after infection, a negative test result may not mean the absence of infection.	✓ Local health departments should investigate positive test results to find additional evidence to confirm as a case. ✓ ELISA tests have been authorized by the FDA under Emergency Use Authorization (EUA). Refer to the FDA to find which EUAs are granted for laboratory tests for SARS-CoV-2[4]. ✓ Special caution should be taken when using non-FDA authorized tests. ✓ All results are required to be reported to MDHHS via MDSS within 4 hours of completion.
Rapid antibody detection point of care (POC) test	The rapid antibody detection POC test provides information about previous infection. These tests provide a positive or negative (or indeterminate) result.	**Blood** (serum or plasma) is collected through a skin prick, like on the finger.	**The presence of antibodies** is considered a **probable** positive result for previous COVID-19 virus infection. Finding antibodies does not mean they were fighting COVID-19 infection. It could mean there was a different (non-COVID-19) infection. For these reasons, to help confirm a positive test, disease risk and protective factors must be considered. Since antibodies can take time to develop, if sample collection was soon after infection, a negative test result may not mean the absence of infection.	✓ Rapid antibody tests have been authorized by the FDA under EUA. Refer to the FDA to find which EUAs are granted for laboratory tests for SARS-CoV-2[4]. ✓ Special caution should be taken when using non-FDA authorized tests. ✓ All results are required to be reported to MDHHS via MDSS within 4 hours of completion.

FDA = U.S. Food and Drug Administration

[4] https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations