Frequently Asked Questions and Resources
Antigen Tests

Michigan.gov/Coronavirus

What is the antigen test?

The Abbot BinaxNOW™, CareStart™, and BD Veritor™ COVID-19 tests are examples of SARS-CoV-2 antigen tests used by the Michigan Department of Health and Human Services. The test must be administered by a health professional, or staff member who has completed training on its use. The timeline of the test results may vary depending on the type of test. The following documents provide much greater detail on the use of antigen tests:

- CDC Interim Guidance for Antigen Testing for SARS-CoV-2
- CDC SARS-CoV-2 Antigen Testing in Long Term Care Facilities
- CMS FAQ on Antigen Testing in Skilled Nursing Facilities
- CDC Interim Considerations for Testing for K-12 School Administrators and Public Health Officials

When is it appropriate to use an antigen test?

- Antigen tests are effective and quick screening tests, meaning they are good detecting those that are at highest risk at transmitting the virus to others, even for those who do not appear sick (i.e., asymptomatic).
- Antigen tests result in 10-15 minutes and do not need to be sent to a lab to get the results.
    - This means actions can be taken sooner regarding isolation and contact tracing.
    - They are helpful in settings where a large number of people need to get tested quickly and/or regularly, and in community settings.
- Antigen tests are much cheaper, and some are easier to administer than polymerase chain reaction (PCR) tests.
    - Using antigen tests first can save time and resources, leaving PCR tests for the few who need confirmatory testing.
- Antigen tests are most accurate if a patient is symptomatic and/or coming from an area with high disease prevalence.
    - If a person does not fall into one of these categories but has a positive test, confirmatory testing with PCR may be recommended (see testing algorithms below).
    - See this link to view prevalence by county.

Who can order an antigen test?

PA 235 of 2020 specifies who can order COVID-19 testing in Michigan.

The bill provides among other things that a "qualified licensee" may administer COVID-19 testing services and may order a lab test of FDA waived moderate or high complexity for purposes of administering COVID-19 testing services, regardless of scope of practice, supervision, or delegation provisions that would not otherwise allow the qualified licensee to administer the testing services. Qualified licensees are defined as the following:

- An Advanced Practice Registered Nurse (APRN)
- A Registered Nurse (RN)
- A Licensed Practical Nurse (LPN)
- A Physician's Assistant

Additionally, sites that do not have a qualified licensee as listed above may choose to use the State of Michigan's standing order when ordering FDA-authorized SARS-CoV-2 tests, including tests which have received emergency use authorization for COVID-19.

Who can perform this test?

The test can be performed by health care professionals or individuals who have completed training on its use. This can include doctors, nurses, medical assistants and technicians, pharmacists, employer occupational health specialists, and other non-healthcare providers who have completed training.

Can I perform a test on myself?

Yes, for the antigen tests that swab in the nasal region. Abbot BinaxNOW™, CareStart™, and BD Veritor™ COVID-19 tests can all be self-collected with nasal swabs. For instructions on how to self-collect a sample, please refer to the CDC website for complete instructions.

What is the proper handling and collecting of specimens?

For healthcare personnel collecting specimens or working within 6 feet of patients suspected to be infected with SARS-CoV-2, maintain proper infection control and use recommended personal protective equipment (PPE), which includes a N95 or higher-level respirator (or face mask if a respirator is not available), eye protection, gloves, and a gown, when collecting specimens.

For healthcare personnel who are handling specimens but are not directly involved in collection (e.g., self-collection) and not working within 6 feet of the patient, follow standard precautions.

Healthcare personnel are recommended to wear a form of source control (face mask) at all times while in the healthcare facility.

PPE use can be minimized through patient self-collection while the trained healthcare personnel maintains at least 6 feet of separation. Please see the CDC videos in the **How can I get trained to use tests?** section below.

What is the proper disposal method for the test and sample?
The test and sample are medical waste and should be handled as a biohazard.
For more information: EGLE Medical Waste Disposal Website and Michigan Medical Waste Disposal Services.

How can I get trained to use tests?
Personal Protective Equipment (PPE) guidelines are important to follow in order to protect personnel. PPE resources are listed here:

- CDC How to apply PPE
- CDC How to take off PPE

Training materials for the distinct types of tests are listed here and should be reviewed before using any of these testing platforms:

Antigen Test	**Training Resources**
BinaxNOW™	• MDDHS BinaxNOW Training Video • Abbot Training Videos • U.S. HHS BinaxNOW fact sheet • FDA BinaxNOW COVID-19 Ag Card
CareStart™	• CareStart™ Covid 19 Antigen Instructions • CareStart Training Video
BD Veritor™	• BD Instructional Document • Batch Testing Video for BD Veritor • BD Brochures • BD Training Video

Is a laboratory license or certificate needed?

To use this test, a facility or site must receive a certificate of waiver under Clinical Laboratory Improvement Amendments (CLIA), which governs how laboratories operate. To receive a CLIA waiver, facilities should complete the CLIA waiver application and submit it to LARA-BCHS-DHHS-COW-TESTING-APPLICATION@michigan.gov. No specific credentials are required to obtain a CLIA waiver. The site performing the testing must follow the guidelines specified under the waiver. The cost is $180 for two years.

To update a CLIA Waiver, follow instructions on this page.

- Center for Medicare and Medicaid Services How to Obtain and CLIA Certificate
- Michigan Department of Licensing and Regulatory Affairs CLIA Information

How do I interpret test results?

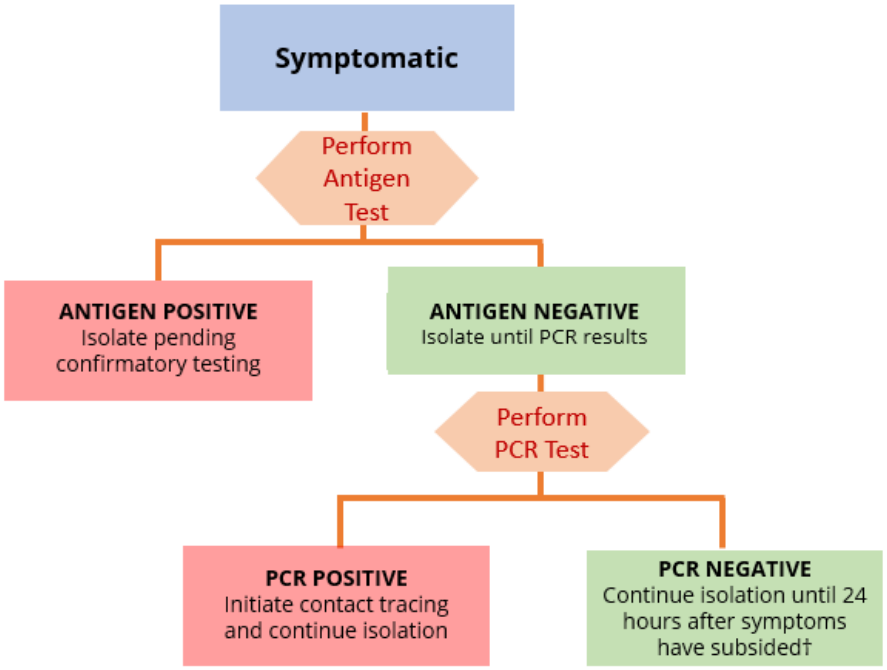
The manufacturer's website has detailed information on how to read the AbbotBinaxNOW™ card results, BD Veritor ™, and CareStart™. Clinical presentation and pre-test probability of COVID-19 should be carefully considered in evaluating results from point-of-care testing. When pre-test probability is low (e.g., no symptoms, limited COVID-19 circulation in the community, patient was not exposed to COVID-19, no outbreaks in the facility), there is an increased likelihood of false positives and an increased likelihood of true negatives. When the pre-test probability is high (e.g., symptoms, COVID-19 circulation in the community is high, patient exposed to COVID-19, outbreaks in the facility), there is an increase likelihood of true positives and an increased likelihood of false negatives. These factors must be considered when interpreting antigen test results. In some circumstances repeat or confirmation testing may be appropriate to ensure accurate results.

When should I retest*?

	Symptomatic (first seven days) or close contact/known exposure	**Asymptomatic and no close contact**
Positive Result	• COVID-19 Case • Prompt isolation	• Presumptive COVID-19 Case • Prompt isolation • Confirm with a PCR test*
Negative Result	• Presume negative • An individual who is a close contact/known exposure must still complete a 14-day quarantine • **Confirm result with a PCR test***	• Negative • No additional follow-up necessary • Reinforce prevention measures

*In the appropriate clinical context (see algorithms below)

Residential Congregate Settings*



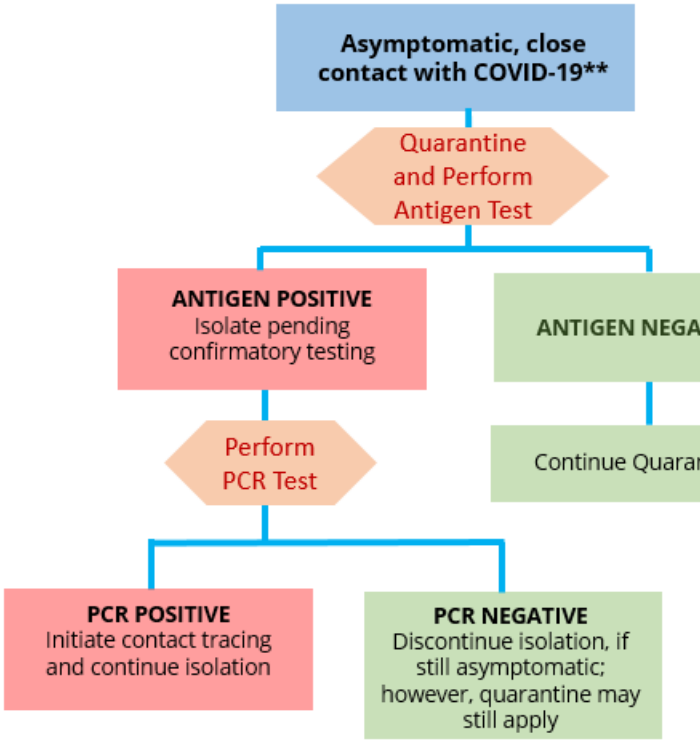
Any of the following symptoms:

- Fever or chills
- Cough
- Shortness of breath or difficulty breathing
- Fatigue
- Muscle or body aches
- Headache
- New loss of taste or smell
- Sore throat
- Congestion or runny nose
- Nausea or vomiting
- Diarrhea

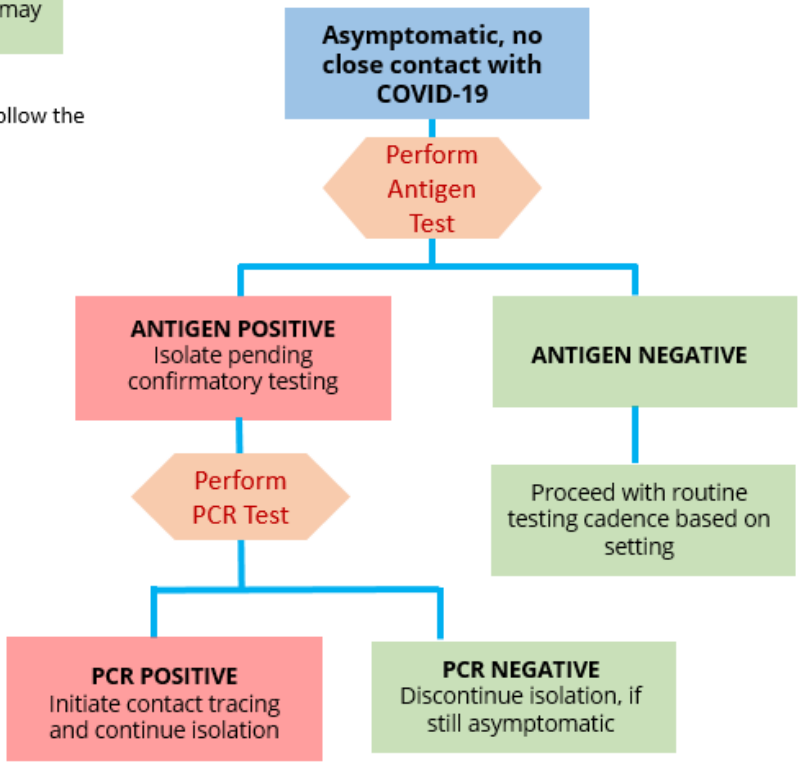
† At least 10 days since symptoms first appeared **and** at least 24 hours with no fever without fever-reducing medication **and** other symptoms of COVID-19 are improving

*e.g. Long term care facilities, skilled nursing facilities, prisons and jails

Residential Congregate Settings*

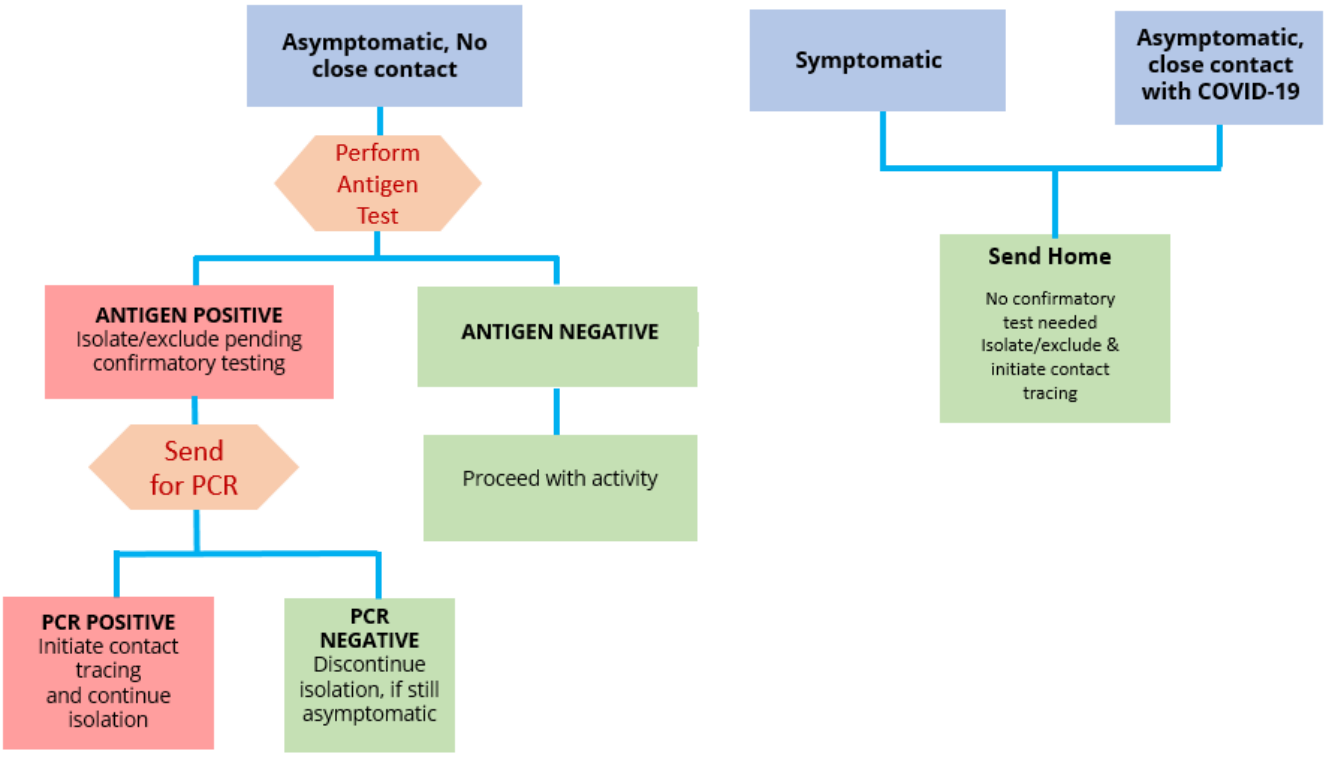


**In an outbreak setting, you may choose to follow the close contact algorithm



*e.g. Long term care facilities, skilled nursing facilities, prisons and jails

Non-Residential Community Settings*



*Schools, athletics, non-residential neighborhood testing

How should I report the results of COVID-19 antigen testing?

Michigan's communicable disease rules are promulgated under the authority conferred on the Department of Health and Human Services by section 5111 of Act No. 368 of the Public Acts of 1978, as amended, being 333.5111 of the Michigan Compiled Laws. Violations of these laws will be reported to the state of Michigan and may constitute a misdemeanor under MCL 333.2261. All positive, negative and inconclusive results of laboratory tests conducted for Novel Coronavirus, SARS-CoV-2, must be reported daily.

To facilitate reporting of antigen testing results, the Michigan Department of Health and Human Services (MDHHS) has developed a form to be used for each daily testing event. Information reported through this portal is accessible by all Michigan Local Health Departments (LHDs) and you are not required to submit additional reports on antigen test results to LHDs.

- Online MDHHS COVID-19 Antigen Test Results Reporting Form

The facility section and the provider section will only need to be completed once per form. The remainder of the form should be completed with individual information for each person that is tested. Ideally, only one form should be completed and submitted by a facility with all the results included for each testing day. Please review and ensure all information is correct before submitting the form.

What if I have more questions?

Please contact MDHHS-COVIDTestingSupport@michigan.gov. There is also more information on Michigan's coronavirus website.