Frequently Asked Questions and Resources

BD Veritor™ Antigen Test

Michigan.gov/Coronavirus

What is the BD Veritor™ antigen test?

The BD Veritor Plus™ for rapid detection of COVID-19 is authorized for use using nasal swab specimens collected from individuals who are suspected of COVID-19 by their healthcare provider within the first five days of the onset of symptoms. This test may be used for asymptomatic individuals as well.

FDA Fact Sheet – BD Veritor Antigen Test

Who can order a BD Veritor ™ antigen test?

The Governor signed PA 235 of 2020 that went immediately into effect.

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:

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

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 individuals who have completed training.

Can I perform a test on myself?

Yes. For instructions on how to self-collect a sample, please refer to the CDC website for complete instructions.

How can I get trained to use BD Veritor™ tests?

Brochures regarding the BD Veritor™ test can be found on BD's website. The resources are designed to provide the training necessary to successfully test individuals using the BD Veritor™. BD has posted a short training video on how to collect the sample and test for COVID-19.

BD Veritor™ training materials

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 BCHS-CLIA@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.

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

When is it appropriate to use an antigen test?

- Antigen tests are most reliable when used on symptomatic individuals in populations with a high prevalence of disease go to https://www.michigan.gov/coronavirus/0,9753,7-406-98163_98173---,00.html to view case counts by county.
- The goal is to quickly identify and isolate contagious individuals. A positive result would inform immediate clinical, infection control or public health action. In this setting, there is less concern about false positive results.
- Antigen tests are also useful in environments with a high prevalence of disease, in which repeated testing may be performed (e.g., congregate living settings, high-risk essential workers, work settings, particularly anywhere in health care, and in outbreak investigations).
- Antigen tests are well suited for areas with limited access to testing.
- Results from antigen tests should always be interpreted in the context of the exposure history and clinical presentation. Asymptomatic individuals may have a higher likelihood of a false positive or false negative result. This group has not yet been studied and therefore clinical discretion from medical professionals is invaluable in decision making for the asymptomatic group.

How do I interpret test results?

The manufacturer's website has detailed information on how to read the BD Veritor™ results.

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.

Potential for False Positive Results with Antigen Tests for Rapid Detection of SARS-CoV-2

When should I retest*?

	Symptomatic (first 7 days) or close contact/known exposure	**Asymptomatic: Facility with an outbreak (Resident and HCP serial testing every 3-7 days##)**	**Asymptomatic: Facility without an outbreak (HCP serial screening testing#)**
Positive Result	• Classify as COVID-19 case • **No confirmatory test needed.** • Isolate/exclude from work. • If index case, initiate outbreak response.	• **No confirmatory test needed.** • Isolate/exclude from work.	• Perform confirmatory RT-PCR test within 48 hrs. • Exclude from work/isolate patient pending confirmatory test result. • **Confirm result with a PCR test and initiate outbreak response plan. Consult with LHD.**
Negative Result	• Presumptive negative • An individual who is a close contact/known exposure must still complete a 14-day quarantine • **Confirm result with a PCR test****	• Presumptive negative • **Continue serial testing until no new positives for 14 days.^^**	• Presumptive negative • **No additional follow-up necessary** • Reinforce prevention measures • **Continue serial testing**

* Asymptomatic individuals who have recovered from SARS-CoV-2 infection in the past 3 months and live or work in a nursing home performing facility-wide testing do not need to be retested. If an individual has recovered from SARS-CoV-2 infection in the past 3 months and develops new symptoms suggestive of COVID-19, alternative diagnoses should be considered prior to retesting for SARS-CoV-2.

** Some antigen platforms have higher sensitivity when testing individuals within 5 days of symptom onset. Clinical discretion should be utilized to determine if retesting by RT-PCR is warranted.

CMS recommendations for testing asymptomatic HCP in facilities without a case

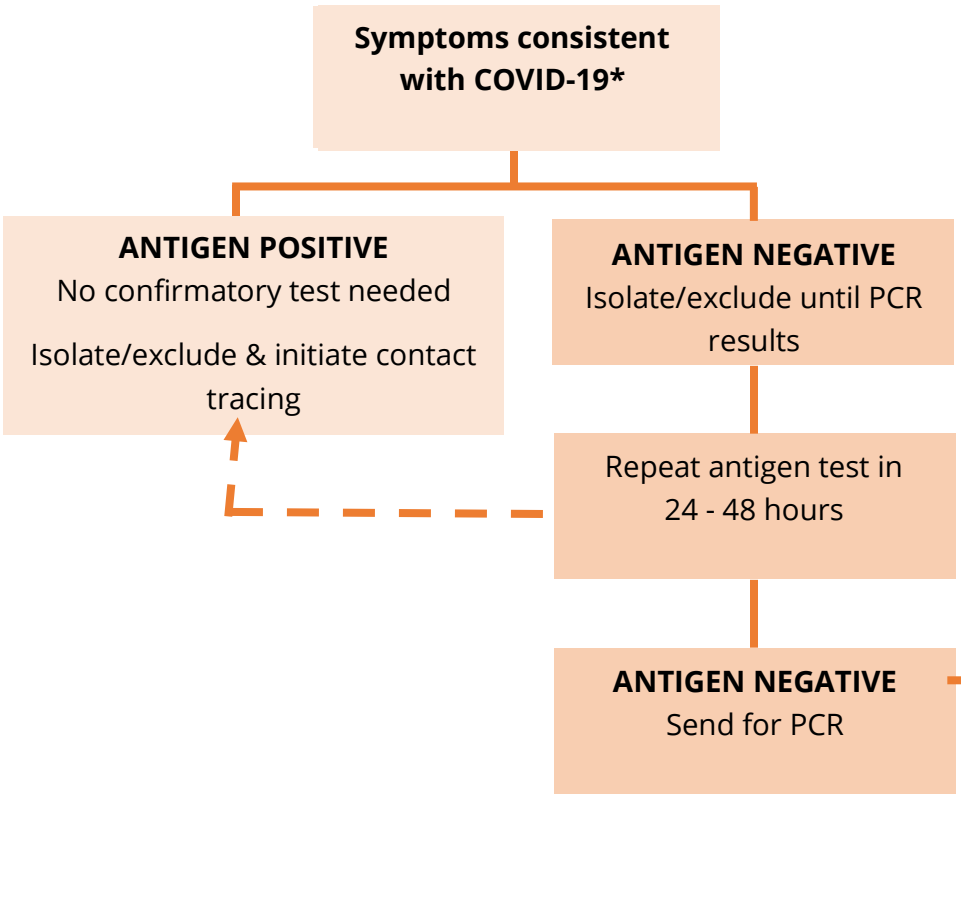
CDC guidance on testing residents of nursing homes. CDC guidance on testing HCP

^ In discussion with the local health department, community incidence and time between antigen test and RT-PCR test can be utilized to interpret discordant results and determine when HCP can return to work.

^^ If an antigen test is presumptive negative in a facility with an outbreak, residents should be placed in transmission-based precautions or HCP should be allowed to continue working while monitoring for symptoms.

Source: https://www.cdc.gov/coronavirus/2019-ncov/downloads/hcp/nursing-home-testing-algorithm-508.pdf

Antigen Testing Flow Chart for Symptomatic Individuals

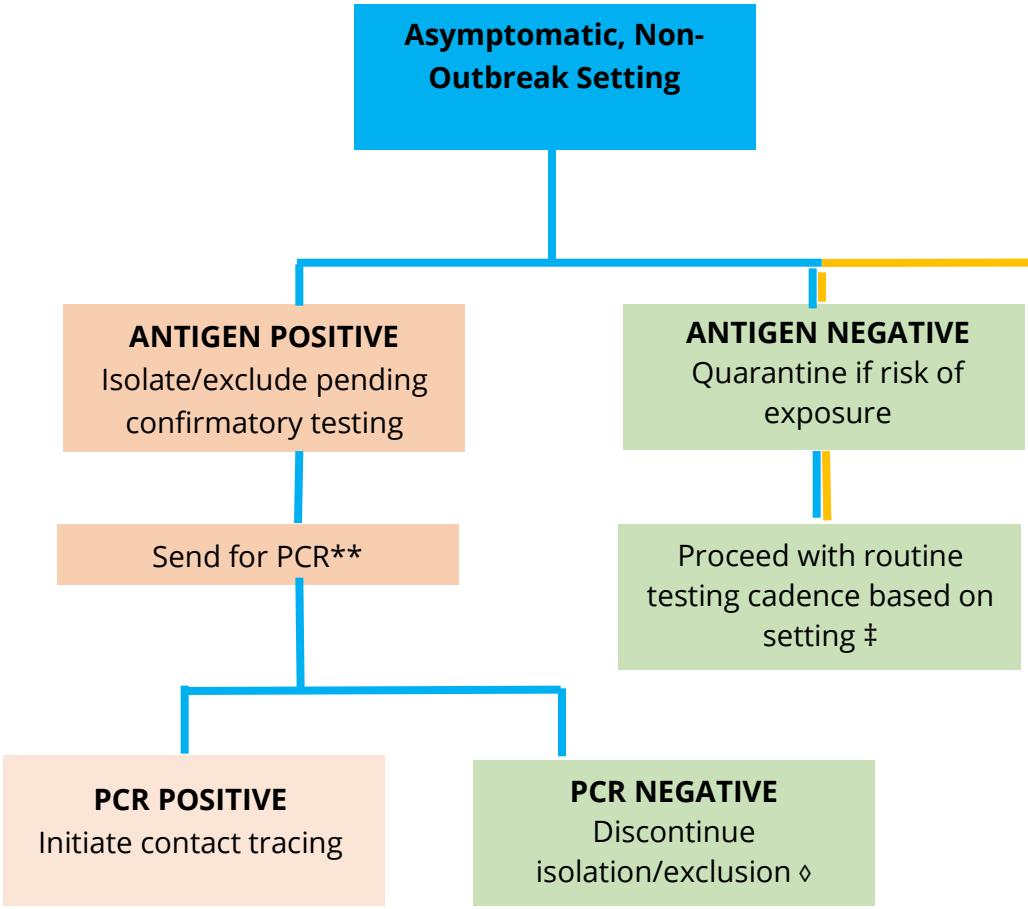


*Any of the following symptoms:

- 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

† When symptoms have resolved for 24 hours without fever reducing medications.

Antigen Testing Flow Chart for Asymptomatic Individuals



*Outbreak: Two or more laboratories confirmed, linked cases in that setting.

** If the initial antigen test was done for purposes of visitation only, the individual may be sent to their medical provider for symptom evaluation and further testing if required.

†Send for PCR confirmatory testing if cohorting is planned.

‡Repeat tests every 48-72 hours in an outbreak setting. In settings without routine testing cadence, consider repeating antigen test at least once.

◊Monitor for symptom development and repeat test if symptoms develop.

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. The 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.
Antigen Testing Reporting Form
https://www.michigan.gov/documents/mdhhs/Facility_Antigen_Reporting_Form_706039_7.pdf

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. Forms should be faxed to the local health department where the facility resides.

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 facemask 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.

What is the proper disposal method for the BD Veritor™ and sample?

The BD Veritor™ tester and sample are medical waste and should be handled as a biohazard.
For more information: EGLE Medical Waste Disposal Website

What if I have more questions?

Please contact checcdeptcoor@michigan.gov with questions.
There is also more information on Michigan's Coronavirus Website.