Frequently Asked Questions and Resources for State Supported Testing Sites

Point of Care Antigen Test Use Information

Michigan.gov/Coronavirus

This document outlines requirements for the use of COVID-19 tests provided by the State of Michigan to state supported sites. This includes details about who can perform testing, specimen collection, proper disposal of tests and samples, reporting requirements and other pertinent information.

What is a Point of Care antigen test?

The Abbot BinaxNOW™ Professional, CareStart™ and BD-Veritor COVID-19 tests are examples of SARS-CoV-2 Point of Care (POC) tests distributed by the Michigan Department of Health and Human Services (MDHHS). A POC Antigen test must be administered by someone who has completed training on its use and can be self-administered with the supervision of a trained individual. The timeline of the test results may vary depending on the brand of test. The following documents provide much greater detail on the use of antigen tests:

- Interim Guidance for Antigen Testing for SARS-CoV-2 - CDC
- SARS-CoV-2 Antigen Testing in Nursing Homes - CDC
- Interim Considerations for Testing for K-12 School - CDC

When is it appropriate to use an antigen test?

- Antigen tests are effective and quick screening tests, meaning they are good at detecting COVID-19 in individuals that are at highest risk of transmitting the virus to others, even for those who do not appear sick (i.e., asymptomatic).
- Antigen tests results are ready in 10-15 minutes and do not need to be sent to a lab.
  - This means actions can be taken sooner regarding isolation and contact tracing.
  - They are useful 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 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 when 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 algorithm below)*
  - Prevalence of COVID-19 by county.

What types of medical professionals can order a point of care antigen test?

PA 235 of 2020 states 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
- A Physician
- A Dentist

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 physicians, nurses, medical assistants, technicians, pharmacists, employer occupational health specialists, and other non-healthcare staff who have completed training.

What is the proper procedure for collection and handling of specimens?
For 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 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. Personnel are recommended to wear a form of source control (face mask) at all times while in the testing facility/area.

PPE use can be minimized through patient self-collection while the trained personnel maintain at least 6 feet of separation. **Please see the CDC videos as outlined in the section on training below.**

What is the proper disposal method for the test and sample?
MDHHS recommends that used antigen tests be disposed of as biohazardous waste materials in an appropriately labeled biohazard bag in compliance with manufacturer's disposal instructions. Pick-up of these materials (final disposition) can be contracted through a site's existing waste pick-up programs (as an extension of their current solid waste management agreements or in addition to any biohazardous pick-up already in place for sharps/used diabetic test materials/etc.) or can be autoclaved.

MDHHS cannot provide biohazard pick-up or disposal. An organization may be able to work with local police, fire, local health department or a local health care provider to share biohazard pick-up and disposal contracts. A list of Michigan-based medical waste disposal services can be found online.

Where can training materials be found?

Personal Protective Equipment (PPE) guidelines are important to follow in order to protect personnel. PPE use resources are listed below:

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

Training materials for the specific brands 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 BinaxNOW Pro Training Videos • FDA BinaxNOW COVID-19 Ag Card
CareStart™	• CareStart™ Covid 19 Antigen Instructions *(Includes visuals and technique tips for administering nasopharyngeal or anterior nasal specimen collection)* • CareStart NP Swab 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 perform point of care testing?

To use any of the tests listed in this FAQ document, 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.

- Instructions to update a CLIA Waiver page
- Center for Medicare and Medicaid Services How to Obtain a 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, COVID-19 circulation in the community is low, 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, individual 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 an individual retest*?

<table>
<tr><th></th><th>Symptomatic or close contact/known exposure</th><th>Asymptomatic and no close contact</th></tr>
<tr><td>Positive Result</td><td colspan="2">• PCR testing is not required for confirmation but may be required in certain settings*
• Testing again at day 5 is recommended. If testing is positive, or they still have symptoms on day 5, continue to isolate for a total of 10 days.</td></tr>
<tr><td>Negative Result</td><td>Please see What to Do If You Were Exposed to COVID-19 (CDC)</td><td>• Negative
• No additional follow-up necessary
• Reinforce prevention measures</td></tr>
</table>

*In long-term care settings, see Considerations for Interpretation Of SARS-CoV-2 Antigen Tests In Long-Term Care Facilities (CDC) and Testing Algorithm for Community Settings (CDC) algorithms.

How should results of COVID-19 antigen testing be reported?

Antigen test results should be reported daily by the site performing the testing. To facilitate reporting of antigen testing results, the Michigan Department of Health and Human Services (MDHHS) has developed an online portal to be used for each daily testing event. Information reported through this portal is accessible by all Michigan local health departments (LHDs) and are not required to submit additional reports on antigen test results to LHDs.

- Online MDHHS COVID-19 Antigen Test Results Reporting Form
- Negative results are to be entered in aggregate and should be done within 24-hours of testing.
- Positive results are to be individually entered within 4-hours of testing.
- This training resource can help individuals understand how to use the Antigen reporting form.

Skilled Nursing Facilities and other Long Term Care sites that report their test results through the National Healthcare Safety Network (NHSN) system should continue to report through the NHSN system and do NOT need to report results through the MDHHS Antigen Reporting Portal. Reporting through NHSN satisfies both State and Federal COVID-19 test reporting requirements.

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.

What if there are more questions?

Please contact **MDHHS-COVIDTestingSupport@michigan.gov**

There is also more information on Michigan's Coronavirus Website.