

Below is guidance for the allocation, distribution, use and reporting of **Abbott BinaxNOW™ COVID-19 Antigen (Ag) Card tests**. The Vermont Department of Health may modify this guidance based upon availability, outbreak surges or other factors during the response to COVID-19.

## Background

The BinaxNOW™ COVID-19 Ag Card is a rapid antigen test with a nasal swab that gives results in as little as 15 minutes. It is intended for use in people who are suspected to have COVID-19 by their health care provider within the first seven days of symptom onset. It is a screening tool used in conjunction with established mitigation procedures and does not replace any prevention measures.

Through December 2020, the federal government will provide Vermont with BinaxNOW™ COVID-19 Ag Cards. The distribution of these test cards to designated high-risk, vulnerable populations is in coordination with federal, state, and local agencies.

## Allocation

These facilities are prioritized to receive allocations as long as supplies last:

- Long-term Care Facilities
- Federally Qualified Health Centers (FQHC)
- Correctional Facilities
- Rural and Critical Access Hospitals

## Laboratories

Only laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C § 263a, that meet the requirements to perform moderate, high or waived complexity tests and Point of Care (POC) settings operating under a CLIA Certificate of Waiver, Certificate of Compliance or Certificate of Accreditation are authorized to use this test.

## Requirements

Facilities requesting BinaxNOW™ COVID-19 Ag Cards must meet the following requirements and agree to follow the Department of Health's policies for use and reporting results:

- Train staff to administer the BinaxNOW™ COVID-19 Ag Card test.
- Staff training must be documented per agency protocols.
- Report all positive and negative results through established reporting systems.
- Be able to dispose properly the BinaxNOW cards and related materials as biohazardous waste.

## Training Resources

- Train the Trainer: The Department of Health and Department on Aging and Independent Living will coordinate with Abbott to schedule virtual BinaxNOW™ COVID-19 Ag Cards train-the-trainer courses. People will be invited to scheduled classes through established distribution lists.
- Training: [Abbott has videos, modules, guidance documents and FAQs for the BinaxNOW™ COVID-19 Ag Cards.](#)<sup>i</sup>

## Requests & Distribution

- To submit a request for the BinaxNOW™ COVID-19 Ag Card test, complete the [Resource Request Form](#)<sup>ii</sup>.
- The Department of Health will distribute tests through UPS to facilities that have been approved through Resource Request process. Shipments will continue until further notice.

## Storage Requirements

- Facilities must store test cards between 35.6°F - 86 °F. The test cards are stable until the expiration date marked on the outer packaging and containers. All test components must be prepared at room temperature before use.

## Specimen Collection & Testing

- Testing personnel:
  - must be employed by a facility-type listed above.
  - must be trained with periodic assessment of their ability to perform quality tests.
  - should administer tests under the direction of a trained health care professional, if they are non-healthcare personnel.
- Specimens should be tested immediately after collection. Inadequate collection or improper handling, storage or transport may lead to inaccurate results. [Read the CDC Guidance.](#)<sup>iii</sup>

## Disposal

All parts of this test should be discarded as biohazard waste according to federal, state, and local regulatory requirements.

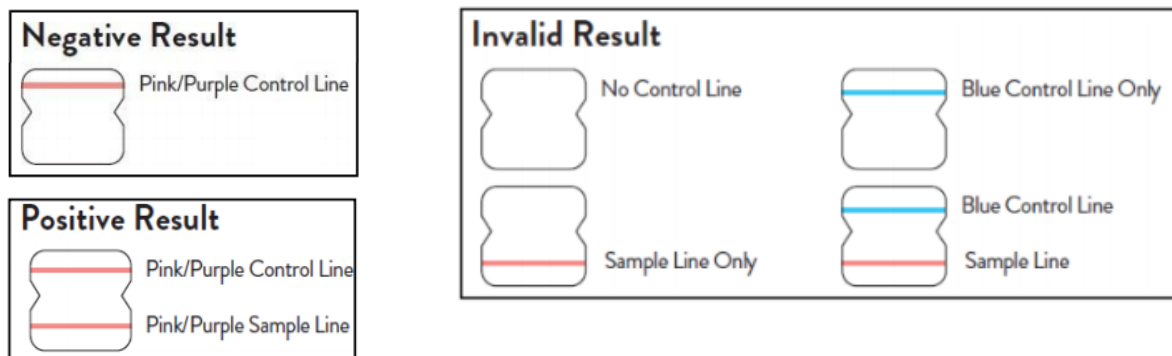
## Interpreting Results

**Antigen Testing Guidance:** [Refer to the Use of SARS-CoV-2 Antigen Testing in Vermont](#) Health Update<sup>iv</sup>

**Negative Result:** Look for a pink/purple colored Control Line in the tip half of the window. This line means that the detection part of the test was performed correctly, but no COVID-19 antigen was detected.

**Positive Result:** Look for two pink/purple lines, the Control Line, and the Sample Line. This means the COVID-19 antigen was detected. Any visible pink/purple Sample Line, even faint, designates a positive result.

**Invalid Result:** If there is no Control Line and Sample line, only the Sample Line or the Blue Control Line does not turn pink/purple the assay is invalid. Repeat the test if the result is invalid.



## Reporting Requirements

All test results (positive, negative, and inconclusive) shall be reported to the Health Department within 24 hours. There are several reporting options. Learn more at [healthvermont.gov/LabReporting](https://healthvermont.gov/LabReporting). If you have a situation that requires prompt public health follow-up, an epidemiologist is available 24/7 at 802-863-7240 or 800-640-4374 (within Vermont only).

## Contacts

- CLIA Contact: Suzanna Leavitt, Department of Aging and Independent Living, [Suzanne.Leavitt@vermont.gov](mailto:Suzanne.Leavitt@vermont.gov)
- BinaxNOW™: 1-800-257-9525 or [ts.scr@abbott.com](mailto:ts.scr@abbott.com)
- Allocation or Distribution: [Resource Request Form](#)
- Reporting System: [healthvermont.gov/LabReporting](https://healthvermont.gov/LabReporting)

<sup>i</sup> <https://www.globalpointofcare.abbott/en/support/product-installation-training/navica-brand/navica-binaxnow-ag-training.html>

<sup>ii</sup> <https://forms.office.com/Pages/ResponsePage.aspx?id=05001K26PE0cAnDtzHVZxnYHsES1qh9Hs2EGYmwc2tBURDVPSDJDS1hUTzdJMFixVDZHQ1JHS1cxViQIQCNOPWcu>

<sup>iii</sup> <https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html>

<sup>iv</sup> <https://www.healthvermont.gov/sites/default/files/documents/pdf/COVID-19-HAN-AntigenTesting.pdf>