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.¹

Requests & Distribution

- To submit a request for the BinaxNOW™ COVID-19 Ag Card test, complete the Resource Request Form.²
- 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.³

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 Updateiv

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. 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
- BinaxNOW™: 1-800-257-9525 or ts.scr@abbott.com
- Allocation or Distribution: Resource Request Form
- Reporting System: healthvermont.gov/LabReporting

ii https://forms.office.com/Pages/ResponsePage.aspx?id=O5001K26PE0cAnDtzHVZxnYHsES1qh9Hs2EGYmwc2tBURDVP5D8S1hUTzDJMFxVD2HZ1HS1oxViQJCNOPwcu