The Rhode Island Department of Health (RIDOH) *strongly encourages* testing visitors of long-term care residents for COVID-19. Our COVID-19 unit is now making Abbott BinaxNOW™ COVID-19 antigen card point of care (POC) test kits ("BinaxNOW test kits") available for use at nursing facilities and assisted living residences (both referred to hereafter as "long-term care facilities [LTC]") to test visitors, increase the frequency of surveillance testing for asymptomatic personnel, and test symptomatic personnel and residents. Depending on uptake and test kit availability through RIDOH over time, RIDOH may expand its guidance on prioritizing the use of these tests.

LTC that wish to test visitors for COVID-19 may utilize the BinaxNOW test kits and/or encourage visitors to use traditional PCR testing available at [www.portal.ri.gov](http://www.portal.ri.gov). Facilities may accept PCR test results from visitors if the test was taken within 72 hours before the visit.

This guidance provides information to LTC on how to request BinaxNOW test kits from RIDOH, what facilities must have in place before requesting these test kits, and how to report test results to RIDOH and take actions based on these results.

**Background**

The US Department of Health and Human Services (HHS) and the US Department of Defense (DOD) announced an initiative to deliver BinaxNOW test kits to states. RIDOH is providing these test kits at no cost to LTC to support testing within this setting.

RIDOH has determined that BinaxNOW test kits can be used in specific settings for screening asymptomatic individuals. Although this test likely has a lower percentage of persons correctly identified by the test as having COVID-19 (sensitivity), this is offset by the ability to increase the frequency of testing and reach people who would not otherwise be tested. Note that negative results do not rule out COVID-19 infection and should not solely drive treatment, patient management, and infection control decisions.

While the BinaxNOW test kit was approved for detection of COVID-19 in symptomatic individuals within seven days of onset of illness, it may also be used “off label” in asymptomatic individuals. The US Food and Drug Administration’s (FDA) Emergency Use Authorization (EUA) allows for use of this test in POC settings that are qualified to perform the test and are operating under an appropriate Clinical Laboratory Improvement Amendments (CLIA) certificate.

According to data from a clinical study conducted by Abbott and submitted to the FDA, the BinaxNOW test kit demonstrated sensitivity of 97.1% and specificity (the percentage of persons who do not have COVID-19 who are correctly excluded by the test) of 98.5% in direct nasal swabs from people suspected of having COVID-19 by their healthcare provider *within the first seven days after symptom onset*.
Evaluating the result of an antigen test should incorporate several factors: the performance characteristics of the test such as sensitivity and specificity, the prevalence of COVID-19 in the community, the individual’s exposure, and the history and presence of symptoms consistent with COVID-19. Please refer to Centers for Disease Control (CDC) guidelines, including considerations for utilizing antigen tests in LTC, for further information on interpreting results and determining when confirmatory PCR testing is recommended.

**Use of BinaxNOW Test Kits in Rhode Island LTC**

Guidance on situations in which LTC may opt to use the BinaxNOW test kits follows. This guidance applies to BinaxNOW test kits supplied by RIDOH. It does not apply to POC rapid tests obtained by LTC from other sources. As noted above, depending on uptake and test kit availability through RIDOH over time, RIDOH may modify or expand its guidance on prioritizing the use of these tests.

**Asymptomatic Testing of Visitors and Personnel**

LTC may use these tests for residents’ visitors. They may also use them to *increase the frequency* of routine surveillance testing of asymptomatic personnel, including staff, *beyond the current recommended levels*, or to facilitate testing of contractors, vendors, volunteers, or students, such as those who have missed a test or who visit less frequently.

- Those who test **positive** should be treated as a positive COVID-19 case, denied entry into the facility, and advised to isolate and contact their healthcare provider.

- Those who test **negative** may be allowed to enter the facility if they meet the screening criteria, such as not exhibiting any **COVID-19 symptoms**, and comply with other safety precautions such as wearing a mask. A confirmatory PCR test is not required.

Facilities should **not** implement a testing protocol that delays the entry of those who need immediate access to the facility, such as emergency responders.

**Symptomatic Testing of Personnel and Residents**

Personnel and residents who *have symptoms*\(^1\) consistent with COVID-19 may be tested using the BinaxNOW test kit:

- Treat those who test **positive** as a positive COVID-19 case and manage them in accordance with all infection control procedures. Anyone who tests positive should notify their healthcare provider.

  - Confirmatory PCR testing after a **positive** antigen test result is not recommended in situations where the person being tested has COVID-19 symptoms or had recent close contact with someone with COVID-19.

- Inform those who test **negative** that the negative test is presumptive. The person should follow up with their healthcare provider and get a PCR test for COVID-19.

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\(^1\) Residents *with symptoms* consistent with COVID-19 should isolate. They should not be moved to a COVID-19 unit unless they have a positive test result.
Symptomatic staff should not return to work based on a negative antigen test. If the BinaxNOW test kit result is negative, staff should contact their healthcare provider and continue to isolate until they get the results of a PCR test. If the PCR test result is negative, staff can go back to work once symptoms have improved and they have been fever-free for 24 hours without using a fever-reducing medicine.

Facilities conducting outbreak testing (i.e., at least one new resident or staff case of COVID-19) should ensure they are in communication with RIDOH.

Requirements for Facilities Requesting BinaxNOW Test Kits

LTC must meet the following requirements to request BinaxNOW test kits from RIDOH:

1. Have an approved CLIA certificate of waiver that covers COVID-19 antigen tests
2. Follow manufacturer’s instructions
3. Develop policies and procedures on using BinaxNOW test kits
4. Ensure all staff performing testing have met training requirements
5. Execute a Memorandum of Understanding (“MOU”) with RIDOH
6. Report all test results to RIDOH through the RI Portal

All staff administering BinaxNOW test kits within a LTC must complete all BinaxNOW online training modules before using these tests. Staff should also review the video on proctoring BinaxNow test kits. In addition to the online training videos, facilities should follow package inserts and manufacturer instructions. More information about BinaxNOW test kits can be found at www.fda.gov/media/141570/download.

To access additional support, contact the Abbott Rapid Diagnostics Technical Services Team at ts.scr@abbott.com or 800-257-9525 between 8 a.m. and 8 p.m. EST, Monday through Friday.

Requesting BinaxNOW Test Kits

LTC that meet all requirements outlined above may request BinaxNOW test kits free of charge. **To request these kits, LTC should return the signed MOU and CLIA CMS-116 to James Brennan at jbrennan@hchent.com as soon as possible.** LTC that already have a CLIA certificate to perform COVID-19 waived testing should provide their CLIA number instead of the CMS-116 application.

Once facilities submit the signed MOU and CLIA CMS-116, RIDOH will provide instructions to register for a portal account to report BinaxNOW test kit results and schedule a time for your facility to pick up the tests. Facilities must pick up tests at the Dunkin’ Donuts Center.

Please note that if a facility has not used its prior allotment of tests and properly reported test results to the portal, RIDOH will not fulfill new test kit requests.

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2 The Centers for Medicare and Medicaid provides a [CLIA Quick Start Guide](http://www.cms.gov/medicare/medicare-operations/quality-safety/clia-qsg) for assistance with the CMS-116. Please note there is a $180.00 charge for a CLIA certificate of waiver payable to CMS.
Temperature Controls for BinaxNOW Test Kits

LTC must comply with all manufacturer instructions for BinaxNOW test kits including storage temperature. In accordance with the BinaxNOW test kit instructions for use (IFU), test kits must be stored at temperatures between 35.6°F and 86°F. The IFU requires that test components (antigen card and buffer) are at room temperature (59°F and 86°F) when performing the test.

Reporting Results of BinaxNOW Tests to RIDOH COVID-19 Unit

LTC must enter all positive and negative BinaxNOW test kit results performed during a given day into the RIDOH POC Results Reporting Portal by the end of each day. This is especially important to notify RIDOH of positive test results. LTC should review the training video on reporting test results through the portal.

The portal requires both a phone number and an email address for all people tested. If the person does not have an email address, enter ‘email@example.com.’ For the phone number field, enter the best number to use to reach the person, especially for positive test results.

Those tested should also be given a copy of their test results. You may use the sample letter at the end of this document (Appendix A). Facilities must also follow COVID-19 federal reporting requirements.

Additional Information

- Current CDC guidance does not recommend retesting those previously diagnosed with COVID-19 within three months after the date of symptom onset from the initial COVID-19 infection, unless new symptoms develop, as noted above. For persons who never developed symptoms, the date of first positive PCR or antigen test for COVID-19 should be used in place of the date of symptom onset.

- This guidance should not replace clinical judgment. Facilities should consult with their medical directors or providers for situation-specific considerations and frequently review CDC and RIDOH websites for updates.

- Facilities may also contact the RIDOH COVID-19 Unit with questions at 401-222-8022.
APPENDIX A: Sample Letter

[ORGANIZATION PERFORMING THE TEST]

BinaxNOW Test Kit Results

Name:
Date of Birth:
Date of Test:
Person Performing the Test:

<table>
<thead>
<tr>
<th>Results:</th>
<th>NEGATIVE</th>
<th>POSITIVE</th>
<th>INDETERMINATE</th>
</tr>
</thead>
</table>

The results of your recent COVID-19 test using the BinaxNOW test kit appear above.

You can also access your test result electronically at portal.ri.gov/results. If you need help accessing your test results, call the Rhode Island Department of Health (RIDOH) at 401-222-8022 or email RIDOH.COVID19questions@health.ri.gov.

A negative antigen test does not necessarily mean you are not infected with COVID-19. A person with a negative test result who has symptoms of COVID-19 (or has other risk factors) should isolate and have a PCR-based test to confirm they are negative for COVID-19.

A person with COVID-19 symptoms and a positive antigen test result should be considered infected with COVID-19.

If you test positive for COVID-19, you should isolate right away. Stay home and avoid contact with other people in your home as much as possible. Wear a mask if you must be in the same room with others, or try to stay in another room. Only leave home for essential medical care. Answer the phone when the RIDOH calls you. The caller ID will say “RI COVID Team.” RIDOH staff will provide you with further guidance and ask about your close contacts. Learn more about isolation and quarantine at covid.ri.gov/whattodo.

If you test positive for COVID-19, please also:

- Notify your healthcare provider.
- Let your close contacts know you have COVID-19. Tell them that they may be getting a call from RIDOH. They should stay home for 10 days from the day they were last with you. Learn more at covid.ri.gov/whattodo.
- Have the things you need delivered. Ask friends and family to drop off items at your door. Don’t have any visitors.
• Make sure everyone you live with stays home, too. People you live with cannot go to work or school while you are infected (10 days) and for an additional 10 days.
• If you are having symptoms, especially if you are 65 or older or have underlying health conditions, immediately call your doctor and ask about COVID-19 treatments. Rhode Island has a doctor-recommended treatment for COVID-19, called monoclonal antibody treatment, that is fast, easy, and highly effective.
• Get help if you feel sick. Notify your healthcare provider or urgent care.
• Call 9-1-1 if you think you are having an emergency. Tell them you have COVID-19.

RIDOH COVID-19 Information Line: 401-222-8022
Monday – Friday, 8 a.m. - 5 p.m. | Saturday – Sunday, 8:30 a.m. – 4:30 p.m.
After hours: Call 211
Email: RIDOH.COVID19questions@health.ri.gov
Visit the RIDOH COVID-19 information portal:
When do I need to isolate or quarantine for COVID-19?