Non-Patient Specific Order for
BINAXNOW™ COVID-19 AG CARD COVID-19 Antigen Testing

Purpose: To prevent the spread of COVID-19 through the identification of SARS-Cov-2 antigen leading to appropriate treatment and public health disease control actions and recommendations.

Policy: Under this non-patient specific order as allowed by state law, Registered Nurses (RNs) and trained personnel (volunteers or school employees) may perform a BinaxNOW COVID-19 Ag Card test on adults or children as recommended by the Rensselaer, Columbia and Greene County health departments. All staff performing this test will be trained in specimen collection, administering the test, documentation, and proper personal protective equipment specific to this test and be prepared to perform this procedure under the Questar III BOCES Limited Service Laboratory certification.

Summary and Explanation of Test
The BinaxNOW COVID Ag Card is a point-of-care[1], rapid antigen test[2] that provides results in as little as 15 minutes. This test is designed for use in patients during the acute phase of infection or during the first seven days of symptom onset. The BinaxNOW™ COVID-19 Ag Card test has received U.S. Food and Drug Administration (FDA) Emergency Use Authorization (EUA). This test is authorized for use at the Point of Care (POC) in settings operating under a Limited Services Lab Certificate.

Procedure:
Administering this test does not require prior medical training or experience. Training modules used to train test administrators are available on the Questar III BOCES Abbott BinaxNow™ Covid-19 Ag Card Training Page.

A nasal swab specimen is collected from the patient, six drops of extraction reagent from a dropper bottle are added to the top hole of the swab well. The patient sample is inserted into the test card through the bottom hole of the swab well and firmly pushed upwards until the swab tip is visible through the top hole. The swab is rotated three times clockwise, and the card is closed, bringing the extracted sample into contact with the test strip. Test results are interpreted visually at 15 minutes based on the presence or absence of visually detectable pink/purple-colored lines. Results should not be read after 30 minutes.*Additional resources for health care providers and patients are available on the Abbott BinaxNow™ Covid-19 Ag Card Training Page.

Storage and Stability
Store kits at 2-30°C/35.6- 86°F. The BinaxNOW COVID-19 Ag Card kit is stable until the expiration date marked on the outer packaging and containers. Ensure all test components are at room temperature before use. The temperature should be monitored and recorded periodically, and every time before testing occurs.

Specimen Collection and Handling
Test results are interpreted visually at 15 minutes based on the presence or absence of visually detectable pink/purple-colored lines. Results should not be read after 30 minutes. Inadequate specimen collection or improper sample handling may produce invalid results. Staff performing specimen collection should use personal protective equipment (PPE). Change gloves between handling each person's specimen.

Disposal
Samples, controls, and test cards should be handled as though they could transmit disease. Observe established precautions against microbial hazards during use and disposal,

Required NYS Department of Health/NYS Dashboard Results Reporting
All Abbott BinaxNOW COVID-19 results, both positive and negative, must be reported per NYS Department of Health Guidance.

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Step by Step Process

A. Obtain/Verify Informed Consent for Students and Provide Handout Regarding Testing Information

Testing should only occur after appropriate consent is received form the individual, or if a minor, the parent or guardian. Parents/Guardians (on behalf of students) and other individuals tested will also be provided a copy of the Abbott BinaxNOW™ COVID-19 Ag Card Fact Sheet For Patients.

1. Verify that the individual has been identified as required for testing for COVID-19.
   Inform recipients about the test's risks and benefits by providing the BinaxNOW™ COVID-19 Ag Card Patient Fact Sheet (also available in Spanish).
2. Verify written consent is on file or obtain consent at the point of care before the procedure.

B. Test Procedure for Collecting Specimens

1. Complete Antigen Testing training and complete efficiency review for performing an anterior nasal swab and BinaxNOW COVID 19 Ag Card test as outlined on the attached document in the BinaxNOW™ COVID-19 Ag Card Procedure Card. This training is provided by Questar III BOCES as the LSL and includes the BinaxNOW™ COVID-19 Ag Card training videos.
2. Ensure all supplies, including specimen test kits, PPE, storage and shipment of specimens, and required forms for testing and documentation, are available.
3. Follow test kit directions and precautions as provided on the BinaxNOW™ COVID-19 Ag Card Product Insert and the FDA website. To collect a nasal sample, the swab must be carefully inserted into the nostril exhibiting the most visible drainage or the nostril that is most congested if drainage is not visible. Using gentle rotation, rotate the swab just inside – less than 1 inch – the nostril. The nasal swab must be rotated five (5) times or more against the nasal wall then slowly remove from the nostril. Using the same swab, the sample collection must be repeated in the other nostril. Do not return the nasal swab to the original paper packaging.
4. Document the test was performed by completing the appropriate lab paperwork per the New York State Department of Health regulations and local school district policy. Maintain confidentiality when handling personal health information.
5. All negative and positive test results will be reported to the New York State Electronic Clinical Laboratory Results System (ECLRS) within 24 hours. Positive results will also be immediately reported to the local county health department where the school district is located.
6. Negative test results will be communicated to parents/guardians via e-mail by the end of the day. Positive tests will be shared with parents/guardians via phone to facilitate timely follow-up and contact tracing. Students who test positive will be moved to the isolation room immediately.
7. Results of tests will be submitted by Questar III BOCES through the ECLRS reporting system. School districts must submit testing results via the school COVID 19 Dashboard. Any positive results will also be reported to the local health department.
8. Anyone testing positive will be isolated and managed as directed by the local county health department and school district's COVID management and contact tracing procedure.

This order shall remain in effect 12 months from the effective date stated below or until rescinded.

Health Care Provider Name:	Title: ☐ Physician ☐ Nurse Practitioner
Health Care Provider Signature:	Start Date End Date
NYS License Number:	☐ License on file with School District
This collection site is operating under CLIA (LSL) # 33D2205899 – Questar III BOCES	