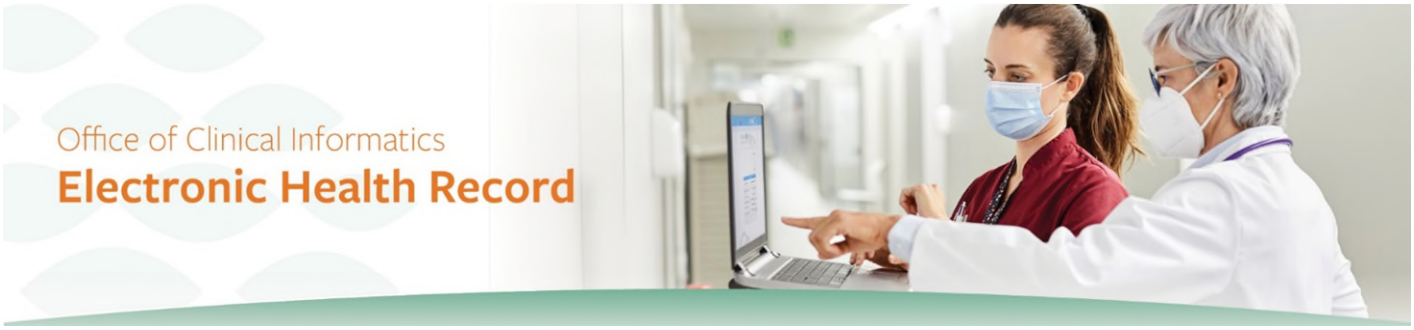


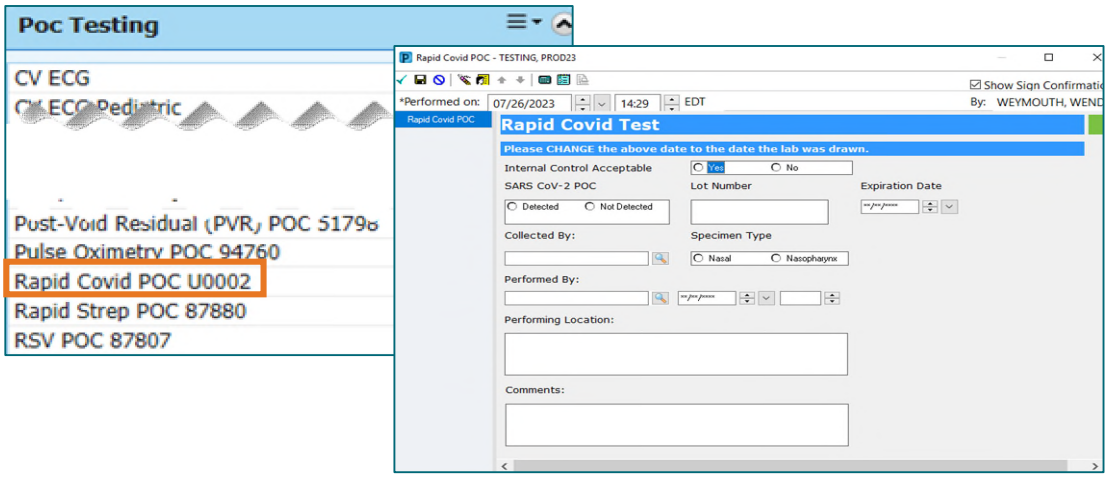
Rapid COVID Antigen Point of Care (POC) Testing

On **Tuesday, September 5**, a new point of care order, **Rapid COVID POC**, will be made available at all **Ambulatory** and **Walk-In-Care** locations. The update allows for point of care testing and results at the time of the patient's visit.

Rapid COVID POC results are documented using the **Single Patient Task List** or **LaunchPoint** and corresponding PowerForm.

The **Rapid COVID POC U0002** order has been added the POC Testing **Quick Orders Component** for all **Primary Care**, **Pediatric**, and **Walk-In-Care** locations. If the POC test is not in your Quick Orders, it can be searched as Rapid COVID POC.

The results will post to the patients banner bar.



NOTE: Clinical team members may begin this POC testing as soon as training has been completed and competency has been documented. Documentation of competency is required for each performing team member.

See **attachments** for MA Competency Procedure Instructions, Checklist and Exam, these are up to date as of 8/31/23.

Performing the POC

Testing may be performed on nasal swab specimens collected from patients 2 years of age and older. Specimens must be collected by a trained healthcare professional wearing appropriate PPE (a respirator such as a PAPR or a fit tested N95 or elastomeric half-facepiece respirator, **and** eye protection, **and** gloves).

Ordering COVID-19 Test Kits

COVID-19 test kits can be ordered through **Infor** using item **#545638.**

From Infectious Disease

Negative results mean that SARS CoV antigen was not detected in the sample.

A **NEGATIVE** result:

- Is presumptive and should be considered in the context of the patient's recent exposures, history and the presence of signs and symptoms consistent with COVID-19. Confirmation with a molecular (e.g., PCR) test may be considered as deemed necessary for patient management.
- Does not rule out infection and should not be used as the sole basis for treatment and/or patient management decisions, including infection control decisions.
- May occur when the level of antigen in the sample was below the detection limit of the test at the time of specimen collection.

Positive results indicate that SARS-Co-V antigen was detected in the specimen.

A **POSITIVE** result:

- Is considered a presumptive. Clinical correlation with patient's history and other diagnostic information is necessary to determine the patient's infection status. The agent detected may not be the definite cause of disease.
- Is a reportable condition*.

Reporting Positive Results to the State *

Positive results must be reported to the Maine CDC within 24 hours via the **REDCap Portal.**
NOTE: The mandatory COVID questions are no longer required for reporting.

Click here for instructions on how to register for the REDCap Portal and report the positive results.

Practice Leadership

To implement POC SARS-CoV-2 antigen testing at practices.

- Ensure the facility has at least a CLIA Certificate of Waiver.
- If the facility does not have a CLIA certificate, follow these instructions to apply: How to obtain a CLIA Certificate of Waiver (cms.gov)

Clinical Informatics – Please share this information with **All Ambulatory and Walk-In-Care Clinical Staff and Providers** and make this a topic of discussion in upcoming rounding.

Behavioral Health: *This information* ***does*** *affect behavioral health caregivers.*

Please direct any questions to the Clinical Informatics team using this link.

BinaxNOW COVID-19 Ag Card – Quick Reference Guide

NOTE: INFORMATION MAY BE UPDATED BY MANUFACTURER. ALWAYS CONSULT PROCEDURE CARD INCLUDED IN THE KIT.

Abbott

BinaxNOW™
COVID-19 Ag CARD

Technical Support Advice Line
Further information can be obtained from your distributor, or by contacting Technical Support on:
US +1 800 257 9525 ts.scr@abbott.com

PROCEDURE CARD

For Use Under an Emergency Use Authorization (EUA) Only.

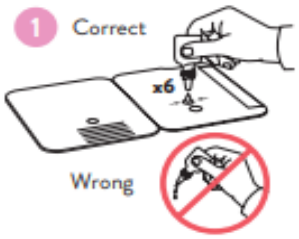
The BinaxNOW COVID-19 Ag Card is a lateral flow immunoassay for the qualitative detection of the nucleocapsid protein antigen to SARS-CoV-2 directly from anterior nasal (nares) swab specimens collected from individuals who are suspected of COVID-19 by their healthcare provider within seven days of the onset of symptoms.

IMPORTANT: See Product Insert, including QC section, for complete use instructions, warnings, precautions and limitations. **False negative results may occur if specimens are tested past 1 hour of collection. Specimens should be tested as quickly as possible after specimen collection.** Open the test card just prior to use, lay it flat, and perform assay as follows.

Part 1 - Sample Test Procedure

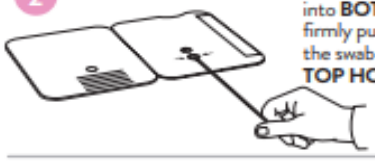
Patient Samples require 6 drops of Extraction Reagent.

1 Correct



Hold Extraction Reagent bottle vertically. Hovering 1/2 inch above the **TOP HOLE,** slowly add **6 DROPS** to the **TOP HOLE** of the swab well. **DO NOT** touch the card with the dropper tip while dispensing.

2



Insert sample or control swab into **BOTTOM HOLE** and firmly push upwards so that the swab tip is visible in the **TOP HOLE**.

3

Rotate (twirl) swab shaft 3 times **CLOCKWISE** (to the right). Do not remove swab.

4

Used test cards should be discarded as Biohazard waste according to Federal, State and local regulatory requirements.

Peel off adhesive liner from the right edge of the test card. Close and securely seal the card. Read result in the window 15 minutes after closing the card. In order to ensure proper test performance, it is important to read the result promptly at 15 minutes, and not before. Results should not be read after 30 minutes.

Part 2 - Result Interpretation

A **negative specimen** will give a single pink/purple colored Control Line in the top half of the window, indicating a negative result. This Control Line means that the detection part of the test was done correctly, but no COVID-19 antigen was detected.
Negative results should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management, may be performed.

Negative Result

A **positive specimen** will give two pink/purple colored lines. This means that COVID-19 antigen was detected. Specimens with low levels of antigen may give a faint Sample Line. Any visible pink/purple colored line is positive.

Positive Result

If no lines are seen, or if just the Sample Line is seen, the assay is invalid. Invalid tests should be repeated.

Invalid Result

Procedure for External Quality Control Testing

External Controls require 8 drops of Extraction Reagent

1. Hold Extraction Reagent bottle vertically. Hovering 1/2 inch above the **TOP HOLE**, slowly add **8 DROPS** to the **TOP HOLE** of the swab well. **DO NOT** touch the card with the dropper tip while dispensing.
2. Follow Steps 2 – 4 of the Test Procedure shown.

In the USA, this product has not been FDA cleared or approved; but has been authorized by FDA under an EUA for use by authorized laboratories; use by laboratories certified under the CLIA, 42 U.S.C. §263a, that meet requirements to perform moderate, high or waived complexity tests. This test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation. This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens. In the USA, - this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the virus that causes COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

Abbott Diagnostics Scarborough, Inc.
10 Southgate Road
Scarborough, Maine 04074 USA
www.globalpointofcare.abbott

℞ Only
IVD

IN195001 Rev. 2 2020/12

Northern Light Health
POINT-OF-CARE TESTING

BinaxNOW COVID-19 ANTIGEN CARD TEST

PURPOSE AND SCOPE

The BinaxNOW COVID-19 Ag Card is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in direct nasal swabs from symptomatic individuals within the first 7 days of symptom onset, serial testing of an individual who has been exposed to a confirmed COVID-19 person, surveillance testing, or are part of a surveillance testing plan.

This test is intended for use by medical professionals or trained operators who are proficient in performing rapid lateral flow tests.

Testing is limited to testing locations that meet the requirements to perform moderate, high, or waived complexity tests. This test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance or Certificate of Accreditation.

INTRODUCTION

Coronaviruses are a large family of viruses which may cause illness in animals or humans. SARS-CoV-2 is an enveloped, single-stranded RNA virus of the β genus. The virus can cause mild to severe respiratory illness and has spread globally, including in the United States.

The ability to rapidly identify individuals with COVID-19 both supports clinical decision-making regarding initiation of antiviral therapy in appropriate patients and provides an opportunity to promote recommended infection prevention and control practices.

Because SARS-CoV-2 antigen is typically detectable in nasal swab specimens during the acute, symptomatic phase of COVID-19**,** testing should be limited to symptomatic individuals who are within the first 7 days since symptom onset and COVID-19 is suspected.

PRINCIPLE

The BinaxNOW COVID-19 Ag Card is an immunochromatographic membrane assay that uses highly sensitive antibodies to detect SARS-CoV-2 nucleocapsid protein from nasal swab specimens. SARS-CoV-2 specific antibodies and a control antibody are immobilized onto a membrane support as two distinct lines and combined with other reagents/pads to construct a test strip. This test strip and a well to hold the swab specimen are mounted on opposite sides of a cardboard, book-shaped hinged test card.

REAGENTS AND MATERIALS

Materials provided in test kit:

- Test cards (40)
- Extraction Reagent (10mL)
- Nasal swabs (40)
- Positive Control swab (1)
- Procedure Card

Materials required but not provided in the test kit:

- Timer, clock, or stopwatch

Optional Materials (purchased separately):

- BinaxNOW Plastic Swab Transport Tube

Storage Requirements:

- Store Kit at 2-30°C (35.6-86°F)
- Kit is stable until expiration date marked on the outer packaging.
    - **NOTE:** In December of 2022, Abbott extended the expiration dates of current lot numbers from 15 months to 22 months. Please contact Abbott for a list of the current affected lot numbers @ 1-800-257-9525. Not applicable on kits that expire after January 27, 2024.
- DO NOT mix or interchange components from different kit lot #s
- Ensure that all test components are at room temperature prior to using.

SPECIMEN COLLECTION AND HANDLING

Collection Process

1. Appropriate personnel protective equipment (PPE) must be worn by the healthcare professional during the specimen collection process. Prior to specimen collection, the healthcare professional must don:
    - A respirator (in the form of either a fit tested N95 or elastomeric half-facepiece respirator or a PAPR)
    - AND eye protection
    - AND gloves.
2. Ensure the swab has come to room temperature.
3. Carefully insert the absorbent tip of the swab into the nostril that is exhibiting the most drainage or is the most congested.
4. Using gentle rotation, push the entire absorbent tip of the swab into the nostril until resistance is met (½ - ¾ of an inch)
5. Rotate the swab against the nasal wall 5 times or more, for a total of 15 seconds.
6. Slowly remove the swab.
7. Using the same swab, repeat steps 4 and 5 above in the other nostril.

TRANSPORT AND STORAGE

1. For best results, test direct nasal swabs as soon as possible after collection. NOTE: Testing must occur within 60 minutes of collection.
2. If a delay in testing is going to occur:
   a. Place the nasal swab specimen in a clean, unused plastic transport tube.
   b. Label the tube with the patient identifiers and the time of collection.
   c. Cap both ends tightly.
   d. Hold the tube containing the swab at room temperature for no more than 60 minutes.

PATIENT TEST PROCEDURE

NOTE: Ensure all test kit components are at room temperature prior to patient testing.

1. Turn a specimen biohazard bag wrong side out and place it on the surface where testing will occur.
2. Remove the BinaxNOW Covid-19 Ag Card from its packing and **confirm a blue line is present at the control line position.**
   NOTE: If blue line is **NOT** present at the control line position, **DO NOT** use and discard
3. Write patient identifiers (*at least 2*) on the outside of the test card before opening.
4. Open the test card just prior to use and lay it flat on the biohazard bag.
   NOTE: The card must remain flat during the testing process.
5. Hold *Extraction Reagent* bottle **vertically**:
   a. Hover ½ inch above the **TOP HOLE**.
   b. Slowly add:
      - **6 DROPS** if performing a **Patient test.**
      - **8 DROPS** if performing a **Control test**.
6. Collect the patient swab sample (refer to above Specimen Collection section)
7. Insert the patient sample swab tip into the **BOTTOM HOLE** and firmly push it upwards so the swab tip is visible in the **TOP HOLE**.
8. Rotate (twirl) the swab shaft **3 times CLOCKWISE** (to the right). **DO NOT** remove the swab from the card.
9. Peel off the adhesive liner from the right edge of the test card.
10. Close and press to securely seal the card.
11. Set a timer for **15 minutes** immediately after closing the card.
    a. Read results immediately after the 15 minutes.
    b. DO NOT read results prior to 15 minutes or after 30 minutes.
12. When testing is complete:
    a. Discard all used kit components, the used patient or control swab, and used gloves onto the specimen biohazard bag.
    b. Put on clean gloves.
    c. Turn the bag right-side out and seal it closed.
    d. Wipe all testing surface with a disinfectant wipe and allow to air dry.
    e. Dispose the sealed biohazard bag and disinfectant wipe into a biomedical waste container.
    f. Remove and discard PPE per facility policy.
    g. Perform hand hygiene.

TEST RESULT INTERPRETATION

Positive Test Result

- Indicated by:
  - The presence of TWO pink/purple colored lines. This means COVID-19 antigen was detected.
  - Specimens with low levels of antigen may give a faint sample line. **ANY visible pink/purple colored line is positive.** ALL POSITIVE RESULTS:
    - Should be treated as a presumptive diagnosis of COVID-19.
    - Reported to the appropriate public health authorities (see *Reporting Results* section for further guidance).

Negative Test Result

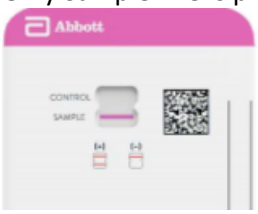
- Indicated by:
  - The presence of a SINGLE pink/purple colored control line in the top half of the window.
  - The control line means the test was performed correctly and COVID-19 antigen was NOT detected.

Valid/Invalid Test Result

- A test is **VALID** when the blue line washes away and a pink/purple line appears. This confirms the sample has flowed through the test strip and the reagents are working.
- A test is **INVALID** when any of the following are observed:

  - No lines are present:

  - Only Sample line is present:



  - Blue Control Line remains Blue:

NOTE: INVALID TESTS SHOULD BE REPEATED USING A NEWLY COLLECTED SAMPLE AND NEW TEST CARD

REPORTING RESULTS

1. Record the following information on the *BinaxNOW COVID-19 Ag Card QC and Patient Log:*
   - Date test was performed.
   - Initials of test performer
   - Patient name and 2nd identifier
   - Test result
   - Control Line present? (Y/N)
2. Enter results in patient's electronic medical record.
3. **Positive tests must be reported** to the Maine CDC, within 24 hours, using the **REDCAP** or another approved reporting tool.

PROCEDURE LIMITATIONS AND INTERFERENCES

- This test detects both viable (live) and non-viable SARS-CoV and SARS-CoV-2. Test performance depends on the amount of virus (antigen) in the sample and may not correlate with the viral culture results performed on the same sample.
- The performance of the BinaxNOW COVID-19 Ag Card was evaluated using the above procedures only. Modifications to these procedures may alter the performance of the test.
- Positive test results **DO NOT** rule out co-infections with other pathogens.
- Positive test results **DO NOT** differentiate between SARS-CoV (the cause of SARS) and SARS-CoV-2 (the cause of COVID-19). If the differentiation of specific SARS viruses and strains is needed, additional testing, in consultation with the state or local public health department is required.
- Negative results are not intended to rule in other non-SARS viral or bacterial infections.
- The presence of nasal mupirocin may interfere with the BinaxNOW COVID-19 Ag test and may cause false negative results.

PERFORMANCE CHARACTERISTICS

- The BinaxNOW COVID-19 Ag Card test has demonstrated a 97.1% sensitivity rate and 98.5% specificity rate when used as intended and proper collection, storage, handling and testing instructions are followed.
- No high dose hook effect was observed when tested with up to a concentration of 1.6×10^5 $TCID_{50}$/mL of heat inactivated SARS-CoV-2 virus.

QUALITY CONTROL

Internal Quality Controls

- BinaxNOW COVID19 Ag cards have a built in internal/procedural control for daily quality control.
- These must be recorded on the *BinaxNOW COVID-19 Ag Card QC and Patient Log.*

External Quality Controls

- Used to ensure the test reagents are working and the test is performed correctly.
  - Positive Control
    - A positive control swab is included in the kit.
  - Negative Control
    - A sterile, unused swab included in the kit.

- Testing personnel must perform QC, **using both a positive and negative control** in the following circumstances:
  - When opening a new kit.
  - With each new test kit shipment.
  - When training new operators.

External QC Procedure:

1. Remove 2 test cards from the kit.
2. Confirm a blue line is present at the Control Line position on both cards.
3. Write *Positive Control* on one card and *Negative Control* on the 2nd card.
4. Follow STEPS 1-11 of the Patient Test Procedure, using:
   - An unused nasal swab from the kit for the negative control test card
   - A Positive control swab included in the kit for the positive control card.

   NOTE: Must use **8 DROPS** of extraction reagent when testing controls.
5. Record both control results on the top section of the *BinaxNOW COVID-19 Ag Card QC and Patient Log.*
6. If one or both of the control results are **NOT ACCEPTABLE**:
   - Repeat testing steps 1-5 above. If repeat testing is still not acceptable:
   - Notify Clinical Lead.
   - Sequester the kit. DO NOT use for patient testing until the problem is resolved.
   - Document all corrective actions taken on the QC log.
   - For further assistance, contact the Point of Care Department @ 973-6951 or NLLabPointofCare@northernlight.org

SAFETY PRECAUTIONS

- **Treat all patient specimens and used patient test cards as potentially infectious materials:**
  - Solutions used to make the positive control swab included in the kit are non-infectious.
  - Patient samples and used test cards should be handled as though they could transmit disease.
  - Observe established procedures for handling and disposal of microbial hazards and laboratory waste
- **Follow standard precautions when handling the kit and unused contents.**
- **Follow transmission based precautions when collecting patient specimens and when handling used patient testing materials.**
- **Wear appropriate person protective equipment (PPE) when collecting patient specimens, when handling patient samples when running tests:**
  - During sample collection procedure, wear a **RESPIRATOR** (in the form of a fit tested N95 or elastomeric half-facepiece respirator, or a PAPR) and **EYE PROTECTION** and **GLOVES. GOWNS** should be worn when spraying or splashing of blood or body fluids in anticipated.
  - During the processing of specimens and controls, the use of gloves is mandatory and wearing eye protection is recommended. Change gloves between collection procedures on individual patients and between testing individual specimens.
- **All used testing components must discarded as Biomedical Waste.**
- For additional information refer to:
  - IDD# 20.130 Exposure Control Plan/Management of Bloodborne Pathogens and Other Potentially Infectious Material
  - IDD# 14.004 Hazard Communication Standard – Code Orange
  - IDD# 14.005 Biomedical Waste Disposal

REFERENCES

- BinaxNOW COVID-19 Ag Product Insert; Abbott Diagnostics Scarborough, Inc., Scarborough, Maine; www.globalpointofcare.abbott; IN195000, Rev.3, 04/2021
- BinaxNOw COVID-19 Ag Card Procedure Card, available on-line; PN: IN195001, Rev. 2, 12/2020
- Abbott Swab Transport Tube Accessory Pack; Abbott Diagnostics Scarborough, Inc., Scarborough, Maine; www.globalpointofcare.abbott; IN190010 Rev.2 09/2020
- BinaxNOW COVID-19 Ag Card On-line Training, Modules 1-4 www.globalpointofcare.abbott/en/support/product-installation-training/navica-brand/navica-binaxnow-ag-training.html
- Abbott BinaxNOW Ag Test Card Guidance memo from the Maine Department of Health and Human Service Commissioner's Office, updated 8/30/2021.
- Redcap Maine CDC Point of Care Reporting system: https://redcap.link/MECDC_POC_Registration

BinaxNOW Covid-19 Ag Test - Training Checklist Testing Location: _____

Name: _____ Date: _____ Instructor: _____
Certification/Licensure Status *(check one)* ❒CNA ❒LPN ❒RN ❒Med.Assist ❒Unit Secretary/ Nursing Tech ❒Other *(specify)* _____

- ○ **Documentation:** Test Procedure, Training Checklist & exam
- ○ **Certification Process:** Initial Training, annual training (per facility process)
- ○ **Principle:** Refer to procedure
- ○ **Specimen Requirements**
  Type: Nasal swab
  Collection: Must use swab provided in kit. **Swab must be at room temperature before using**. Swab both nostrils (see Procedure)
  Transport and Handling: Test immediately. **DO NOT place swab back into its paper wrapper.**
  Rejection Criteria: DO NOT test swab specimens that are over 60 minutes old.
- ○ **Instrumentation, Reagents, Materials and Storage:**
  - BinaxNOW COVID-19 Card
  - Extraction Reagent
  - Timer or watch – Timing of the test is critical
  - Store test Cards, extraction reagent @ 2-30°C (35.6-86°F). **Must be at room temp before use.**
- ○ **Procedure:** Follow steps in procedure. Highlighted points:
  - Check that QC has been done before performing patient testing and the kit is acceptable for use.
  - Confirm **Blue line** is present at the Control line position. If not present – DO NOT use card.
  - Test card must be flat during testing process.
  - Must hold extraction dropper vertical for adequate dispensing of extraction reagent. DO NOT touch card w/ dropper.
  - **Insert swab in bottom hole of card and rotate 3 times.** Failure to rotate swab before card is closed can cause false negative result.
  - Set timer for 15 minutes immediately after closing and sealing card.
  - **Read results promptly at 15 minutes**. **DO NOT read after 30 minutes.** To reduce glare on the result window, try tilting the card while reading.
- ○ **Interpretation of Results**
  - **Must read 2 areas in the Result window to correctly interpret test results**:
    - Control Line result are (upper)
    - Patient Test result area (lower)
  - Positive Result = Two Pink/Purple Control Lines (any line, even if faint, is a line)
  - Negative Result = One Pink/Purple Control ONLY
  - Invalid Result = Sample Line Only, Blue Control Line Only, No Control Line, or Blue Control with Pink/Purple Patient Line
- ○ **Quality Control**
  - **Internal Controls (3 procedural controls)**
    - **Untested Card** = Has Blue Control Line
    - **Tested Card =** Blue Control Line turns Pink/Purple AND Test Window background color clears to light pink or white
  - **External Controls** (one positive swab included in kit; use sterile swab from kit for negative control)
    - Perform when opening new kit and when training new operator.
    - Use **8 drops** of extraction reagent when test control swabs
    - Both control levels must be acceptable; if NOT acceptable, DO NOT use the kit for patient testing.
    - Record QC results on *BinaxNOW Covid-19 Patient and QC Log*; document problems and corrective action; refer to procedure troubleshooting instruction
- ○ **Reporting Results-** Record test and Internal QC results on Patient log and in Patient EMR; **Required to report positive test results to Maine CDC within 24 hours, using Maine DHHS REDCAP reporting tool to state DHHS**
- ○ **Safety:**
  - Treat all patients as potentially infectious.
  - Use of gloves, respirators and eye protection are mandatory during the specimen collection and testing processes.

❒ **I have read the BinaxNOW COVID-19 Ag Card procedure** **Initials: _____**

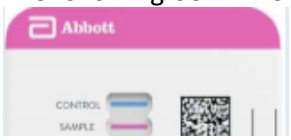
❒ **Direct Observation Successfully Completed by _____**

Qualified Trainer Signature

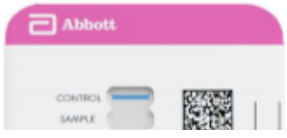
BinaxNOW Covid-19 Ag Test - Training Exam

1. The kit contents (including the swabs) must be at room temperature before using for testing. T F
2. A timer is required to perform testing. T F
3. Both nostrils are swabbed but the one with the most congestion/discharge should be swabbed first. T F
4. For best performance, patient swab samples should be tested immediately after collection. T F
5. If the Blue Control Line is not present on an untested card, do not use for testing and discard. T F
6. Extraction reagent dropper must be held vertically when dispensing drops on the card. T F
7. When performing a patient test, 8 drops of extraction reagent are used. T F
8. The extraction reagent is applied to the card just prior to collecting the patient sample. T F
9. False negative results can occur if swab shaft is NOT rotated at least 3 times prior to closing the card. T F
10. Read the test results promptly at 15 minutes and no more than 30 minutes after closing the card. T F
11. Invalid test result be repeated using the original nasal swab sample. T F
12. A sterile swab from the test kit is used as the Negative Control sample. T F
13. Quality Control testing is performed when newly opening every BinaxNOW COVID-19 Ag Kit. T F
14. The following COVID-19 Ag test result is _____.

15. The following COVID-19 Ag test result is _____.



16. The following COVID-19 Ag test result is _____ .



BinaxNOW Covid-19 Ag Card Training Exam
Answer Key

1. True
2. True — Timer should be set for 15 minutes immediately after closing the card. The correct timing of reading the result is critical for accurate test results.
3. True
4. True
5. True
6. True
7. False — 6 drops are used for patient testing; 8 drops are used for control swab testing.
8. True
9. True
10. True — Results should not be read before 15 minutes. If unable to read results w/in 30 minutes, test must be repeated.
11. False — Must collect a new swab sample and use a new card for repeat testing
12. True
13. True
14. Positive
15. Invalid — Control Line should be pink/purple NOT Blue
16. Invalid — Control Line should be pink/purple NOT Blue