BinaxNOW™
COVID-19 Ag CARD

Abbott

Technical Support Advice Line
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PROCEDURE CARD

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

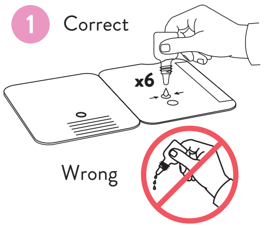
The BinaxNOW COVID-19 Ag Card is a lateral flow immunoassay for the qualitative detection of the nucleocapsid protein antigen to SARS-CoV-2 directly from anterior nasal (nares) swab specimens collected from individuals who are suspected of COVID-19 by their healthcare provider within seven days of the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

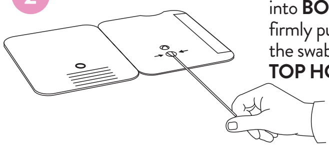
Patient Samples require 6 drops of Extraction Reagent.

1



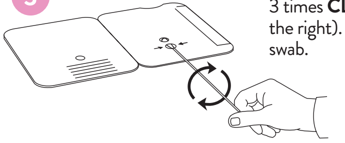
Hold Extraction Reagent bottle vertically. Hovering 1/2 inch above the **TOP HOLE,** slowly add **6 DROPS** to the **TOP HOLE** of the swab well. **DO NOT** touch the card with the dropper tip while dispensing.

2



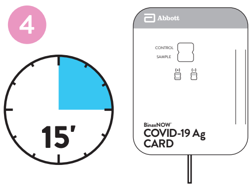
Insert sample or control swab into **BOTTOM HOLE** and firmly push upwards so that the swab tip is visible in the **TOP HOLE**.

3



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

4



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.

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

Part 2 - Result Interpretation

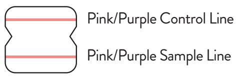
A negative specimen will give a single pink/purple colored Control Line in the top half of the window, indicating a negative result. This Control Line means that the detection part of the test was done correctly, but no COVID-19 antigen was detected.

Negative results should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management, may be performed.

Negative Result

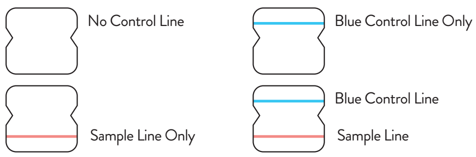
A positive specimen will give two pink/purple colored lines. This means that COVID-19 antigen was detected. Specimens with low levels of antigen may give a faint Sample Line. Any visible pink/purple colored line is positive.

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.

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℞ Only
IVD

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Abbott BinaxNOW COVID-19 Ag ProCard **Size:** 5.5" x 8.0"	**Printed Colors** CMYK **Incoming Inspection Colors** **(For Reference Only)** **Colors below are not used for printing** PMS 2995 U Primary Blue PMS 2995 U Primary Blue 70% PMS 224 U Magenta Pink PMS 303 U Dark Blue PMS 185 U Red PMS 185 U Red 70%	**PN:** IN195001 **Rev:** 2 **Date of Last Revision:** 2.4 2020/12/16