

ABBOTT BINAXNOW OVERVIEW

Presented by

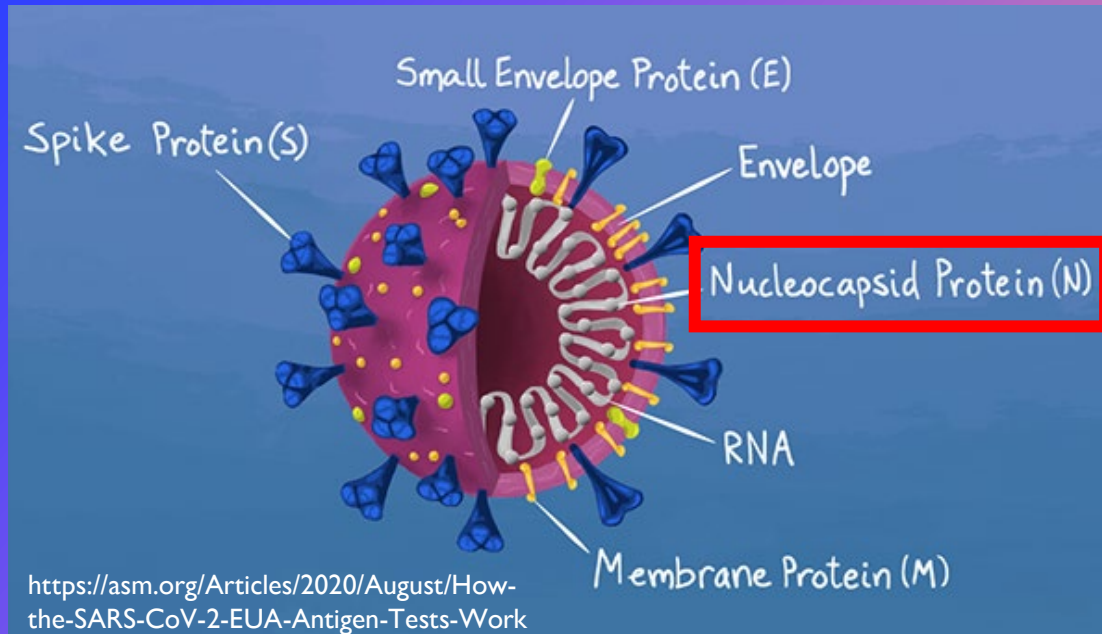
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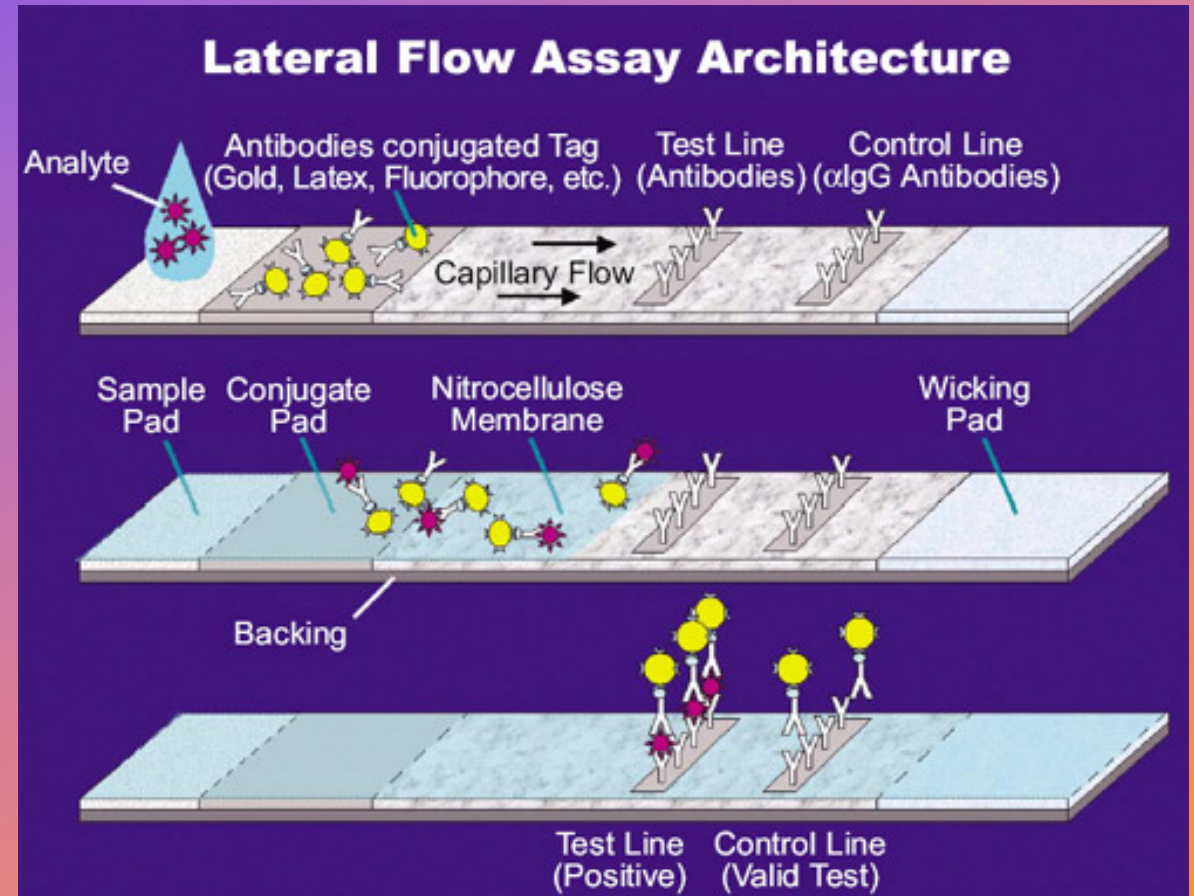
Overview

- The Binax NOW COVID-19 Ag Card is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein (**red box**) antigen from SARS-CoV-2 in nasal swabs without viral transport media.
- Nucleocapsid antigen is generally detectable in nasal swabs during the **acute phase of infection**.



PRINCIPLES OF THE PROCEDURE

- Detects the presence of nucleocapsid protein (antigen) in the nasal swab specimens.
- The specimen moves up the test membrane via capillary flow.
- Nucleocapsid antigen (if present) will bind to conjugated antibodies (gold, latex, Fluorophore, etc.).
- Binds to SARS-CoV-2 monoclonal antibodies and will present as pink if nucleocapsid present.
- Control line should ALWAYS turn pink.

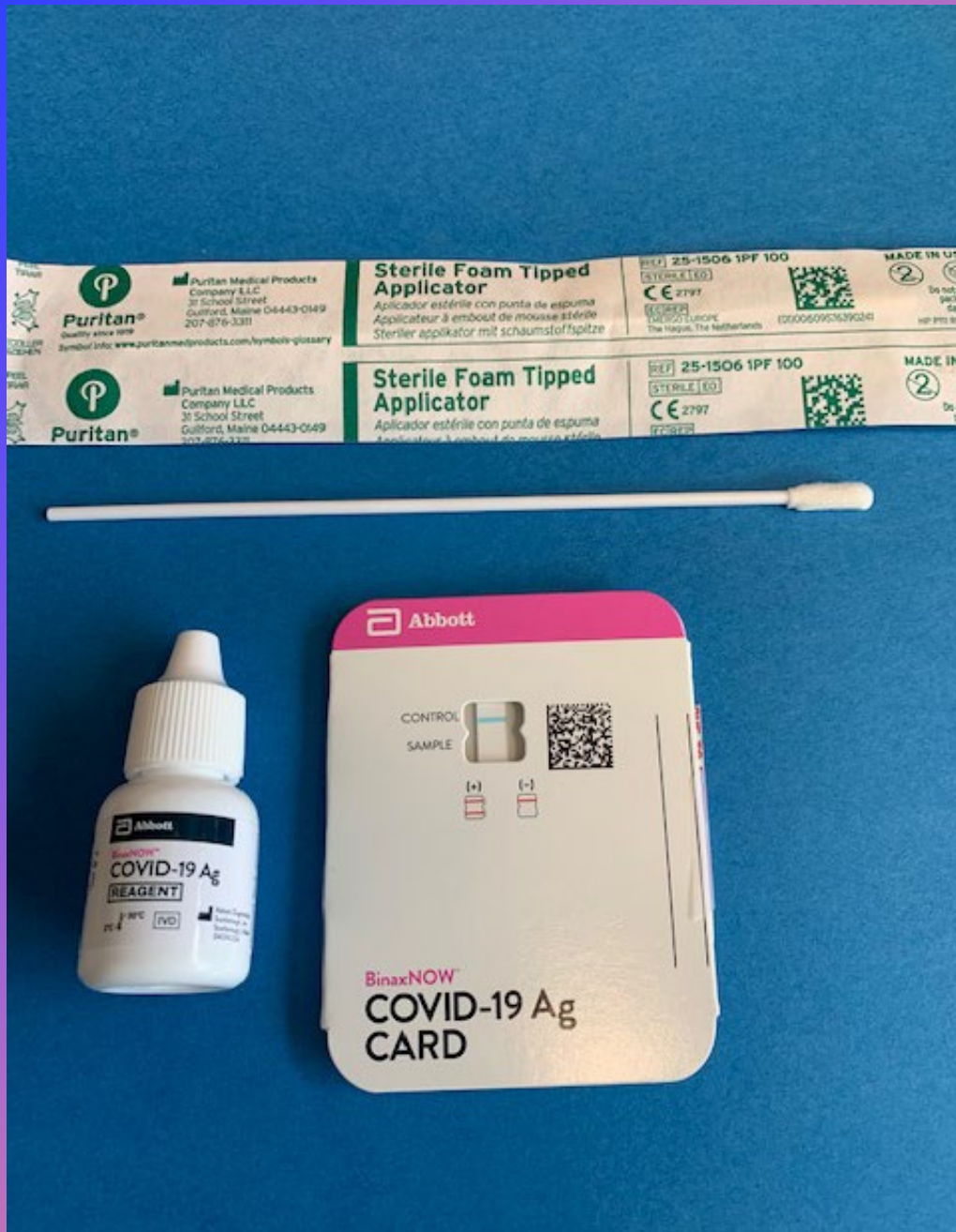


Reagents and Materials Provided

- Test Cards
- Extraction Reagent
- Nasal Swabs
- Positive Control Swabs
- Negative Control Swabs (sterile nasal swabs)

Not provided but helpful:

- **Clock, timer or stopwatch**
- **Swab Transport Tube Accessories**
- **PPE**





Storage

- Kits may be stored at 2–30 °C.
- DO NOT FREEZE.
- **Reagents and devices must be at room temperature (15–30 °C) when used for testing.**

Test Outline

Preparing Test
Card

Collecting Nasal
Swab

Testing

Interpreting Results



PERFORMING THE TEST





Recommended PPE

- N-95 or disposable mask
- Face shield or safety glasses
- Gloves
- Clothing protection
 - Disposable lab coat
 - Disposable gown

PREPARING WORKSPACE

- Procure an Abbott BinaxNOW kit
- Verify kit to be used is not expired
- Don appropriate PPE
- Prepare a clean workspace
- Lay out
 - COVID-19 Ag reagent
 - BinaxNOW COVID-19 Ag card
 - Sterile foam-tipped applicator in packaging

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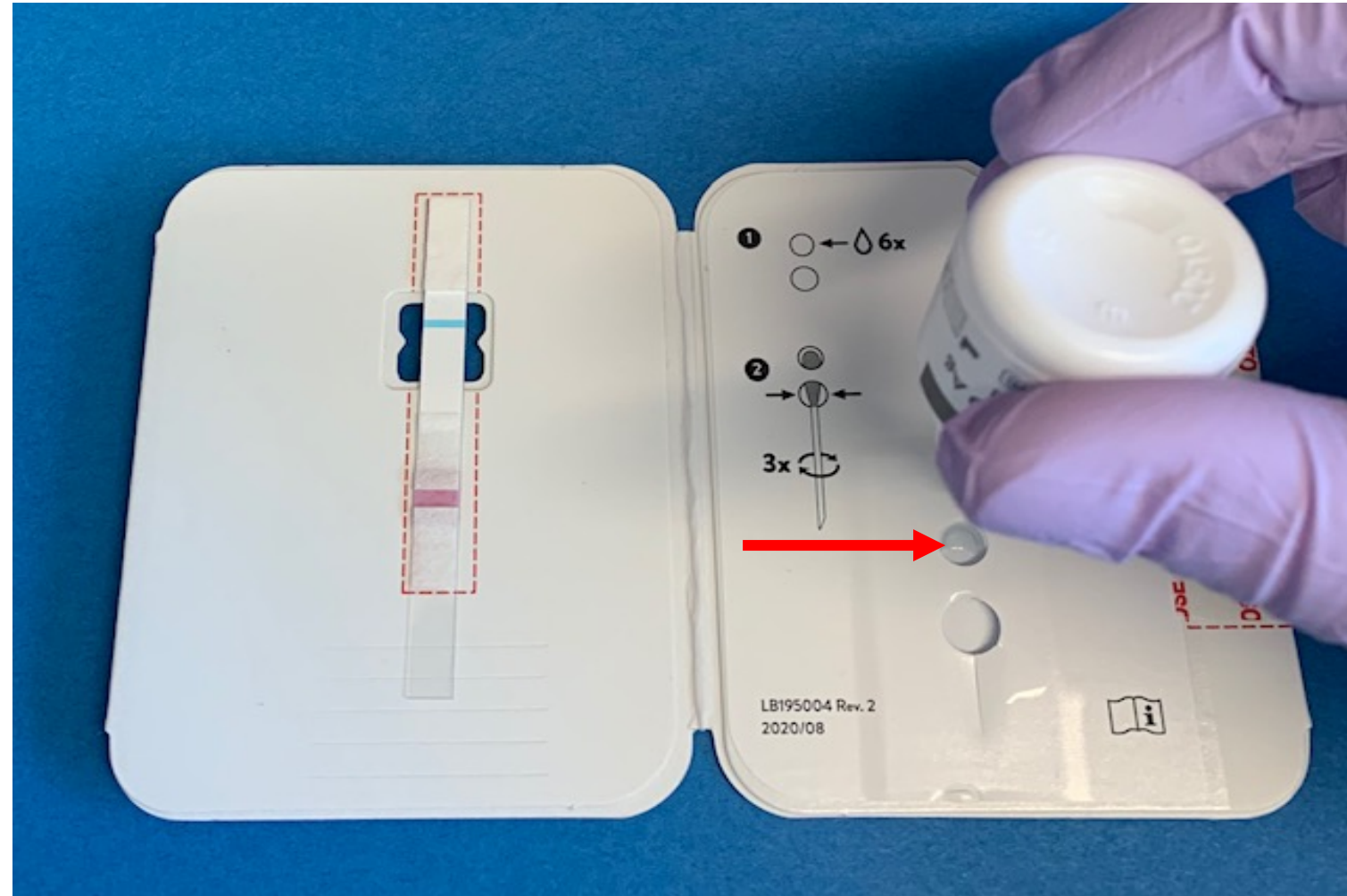
OPENING TEST CARD

- Open the BinaxNOW COVID-19 Ag card
- Bend the card back slightly beyond its crease and then forward slightly
- The card should now be open and laying flat on the intended workspace



Prepare Test Card and Reagent

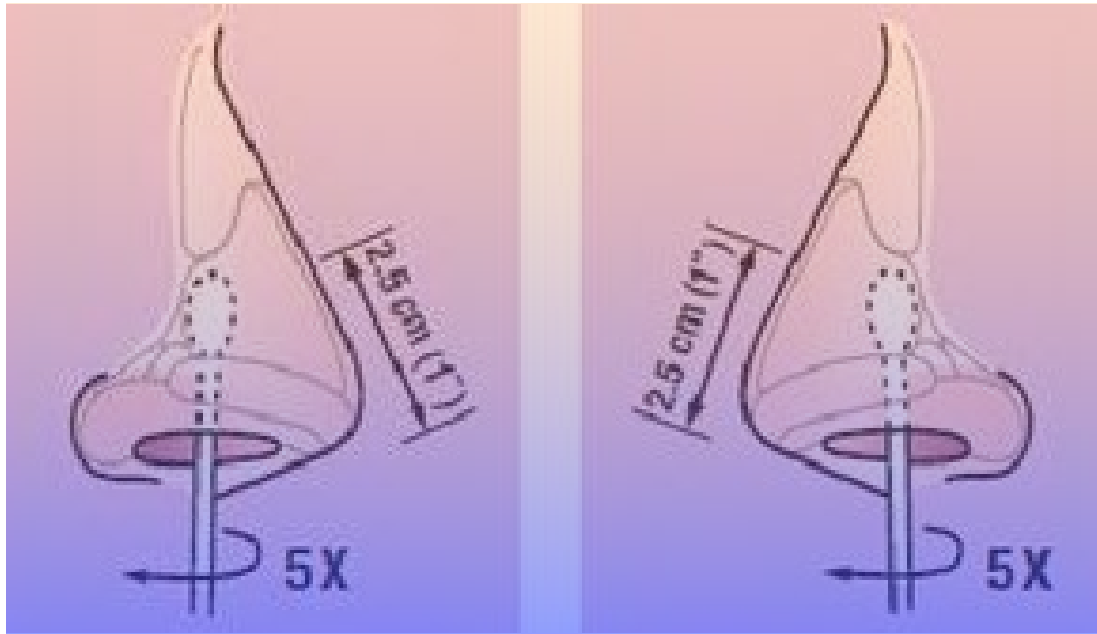
- Hovering $\frac{1}{2}$ inch from top hole (**red arrow**).
- Add 6 drops of COVID-19 reagent.
- **Prepare within 3 minutes** before collecting nasal swab.



Adding Reagent

- Prepare the BinaxNOW Ag card within 3 minutes of use.
- Hold the BinaxNOW COVID-19 Ag reagent vertically ½ inch above the top hole of the card
 - Do not touch the tip of the reagent bottle to the card. This may contaminate the bottle.
- For kit controls, add 8 drops.
- For patient samples, add 6 drops.

Collecting Nasal Swab



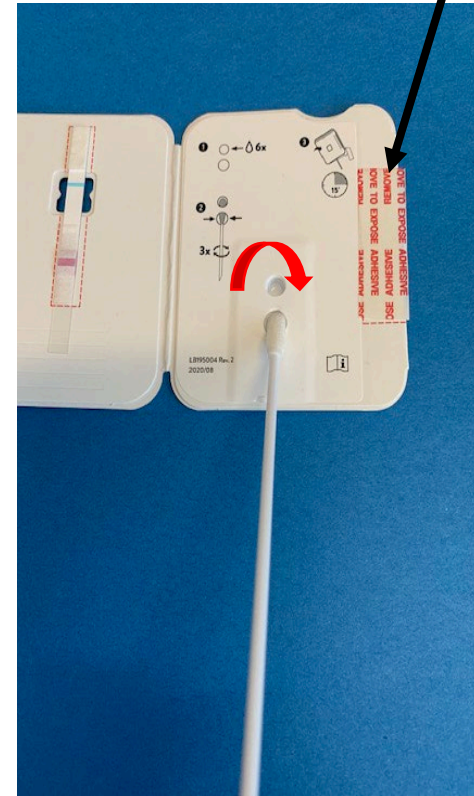
1. Insert the nasal swab about 1-inch into the nostril with the most visible drainage.
2. Gently rotate the swab until resistance is met.
3. ROTATE the nasal swab **5 TIMES** against the nasal wall.
4. Remove the swab.
5. Using the same swab, **REPEAT** the sample collection into the other nostril.
6. DO NOT return swab to its original package. Test **within 3 minutes preparing test card**.
7. Place swab in a clean, unused plastic tube with patient label. **DO NOT** store longer than 1-hour

Testing

1. Insert nasal swab into the bottom hole and push upward so that the swab tip is visible in top hole (**picture A**).
2. ROTATE the swab 3 TIMES CLOCKWISE (to the right, follow **red arrow**) (**picture B**).
3. Peel off adhesive liner (black arrow) on the right side of the card. Close card (**picture C**).
4. Wait 15 MINUTES



A



B

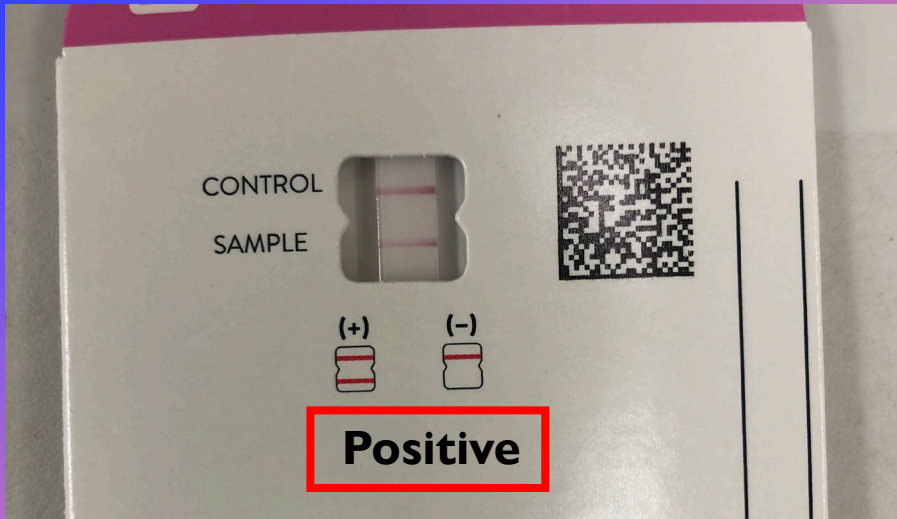
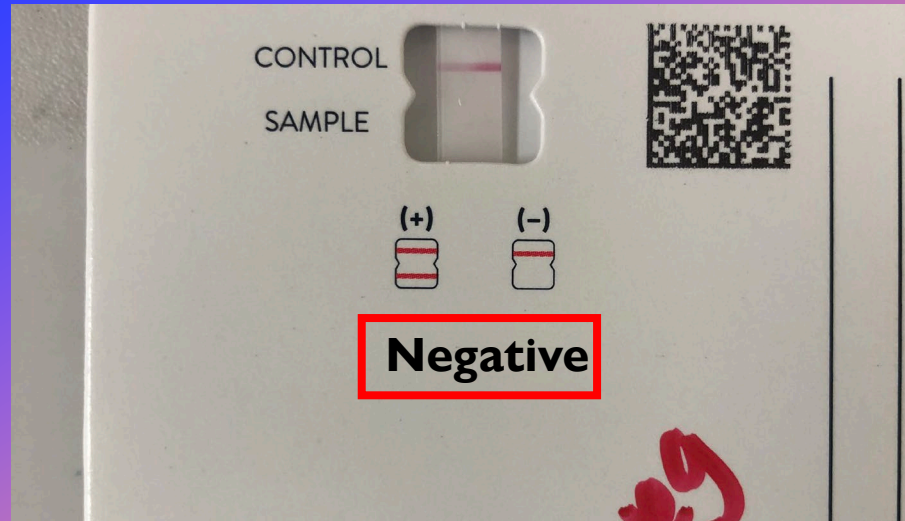


C

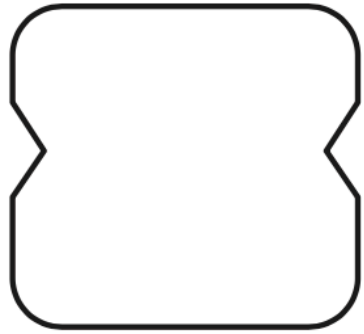
DO NOT interpret results after 30 minutes!!

Interpreting Results

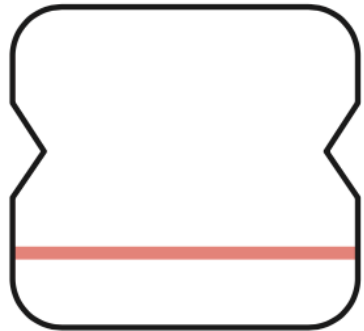
- Control line should be Pink.
- If control line pink and sample line empty, result is **NEGATIVE**.
- If control line pink and sample line is pink, result is **POSITIVE**.



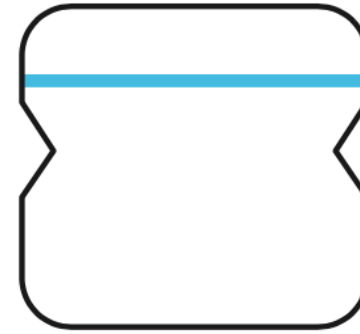
INVALID RESULTS



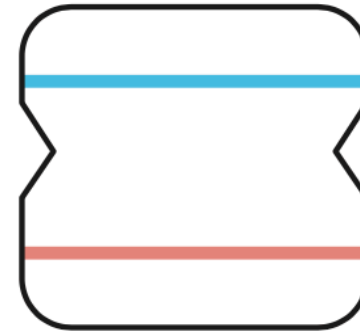
No Control Line



Sample Line Only



Blue Control Line Only



Blue Control Line

Sample Line

Invalid results NEED to be repeated.

DISPOSAL

Test cards and PPE are considered biohazard waste.

Use appropriate disinfectant to clean up test areas.

Check List N on FDA to see if it is appropriate to kill SARS-CoV-2

[List N How-To - YouTube](#)



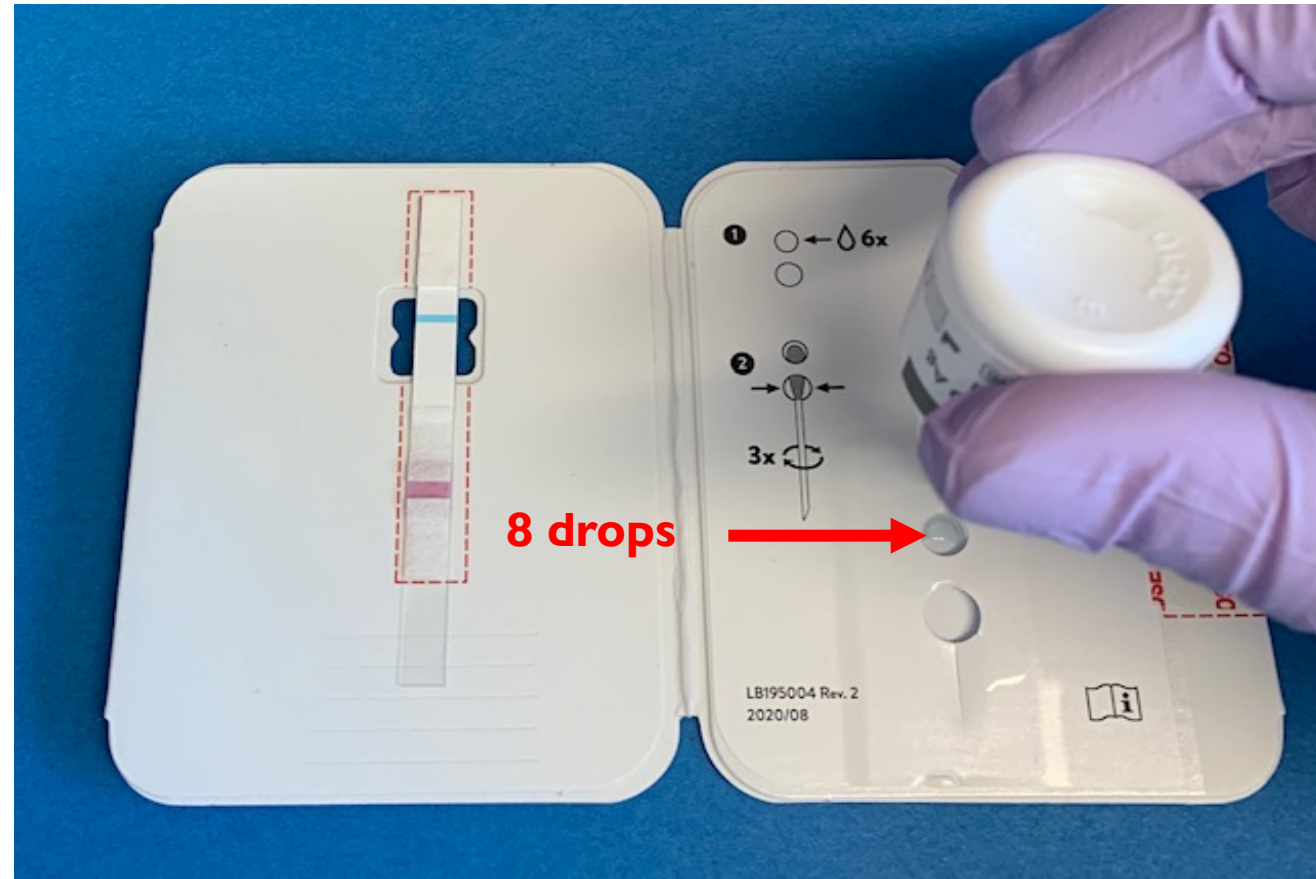
External Positive and Negative Controls

- Good laboratory practice suggests the use of positive and negative controls to ensure that test reagents are working and that the test is correctly performed.
- Binax NOW COVID-19 Ag Card kits contain a Positive Control Swab and Sterile Swabs that can be used as a Negative Control Swab.
- These swabs will monitor the entire assay.
- Test these swabs once with each new shipment received and once for each untrained operator.

Procedure for External Controls

Open the test card just prior to use, lay it flat, and perform assay as follows.

1. Hold Extraction Reagent bottle vertically
2. Hovering 1/2 inch above the TOP HOLE, slowly **add 8 DROPS** to the TOP HOLE (**red arrow**) of the swab well.
3. DO NOT touch the card with the dropper tip while dispensing

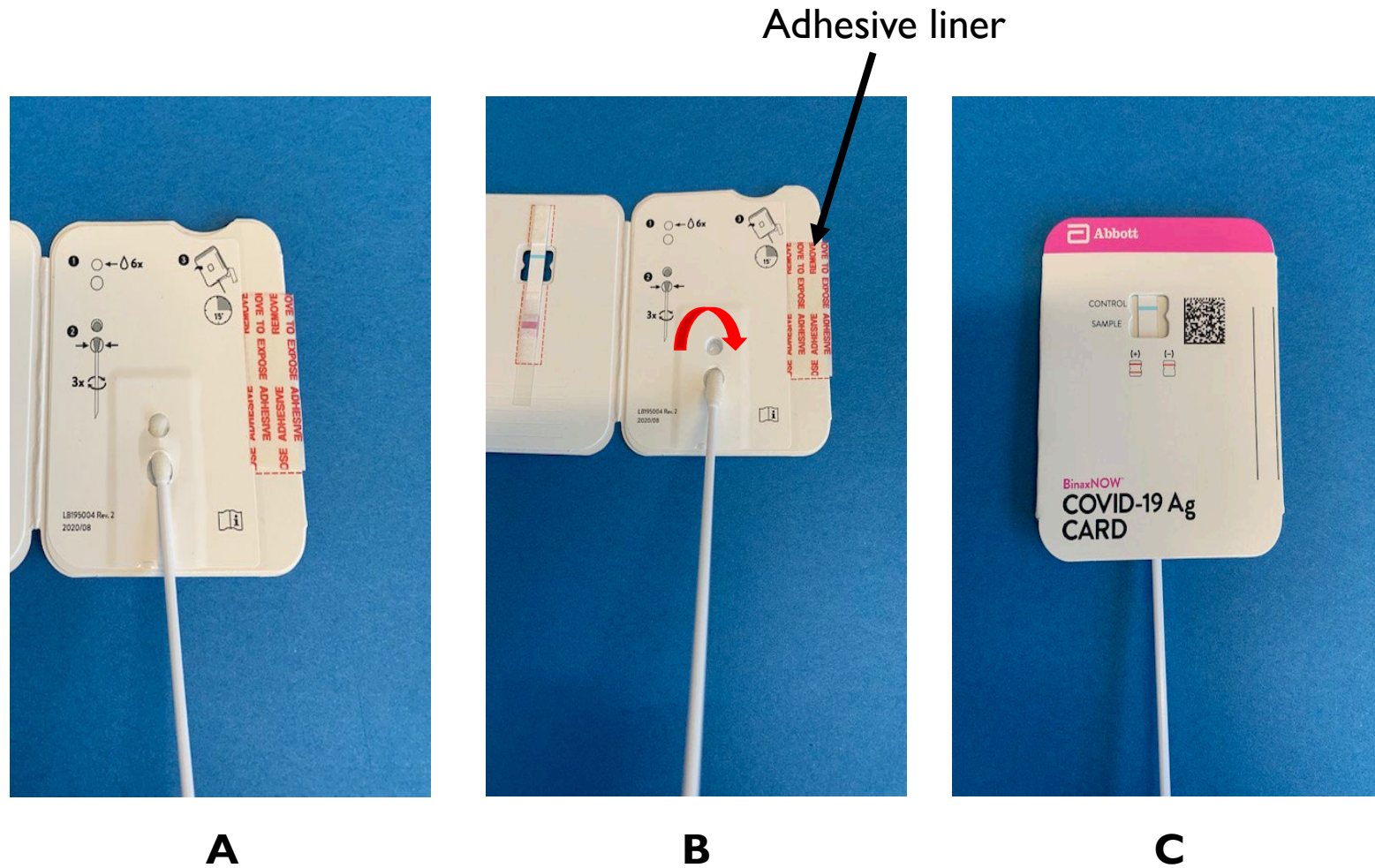


Testing Controls

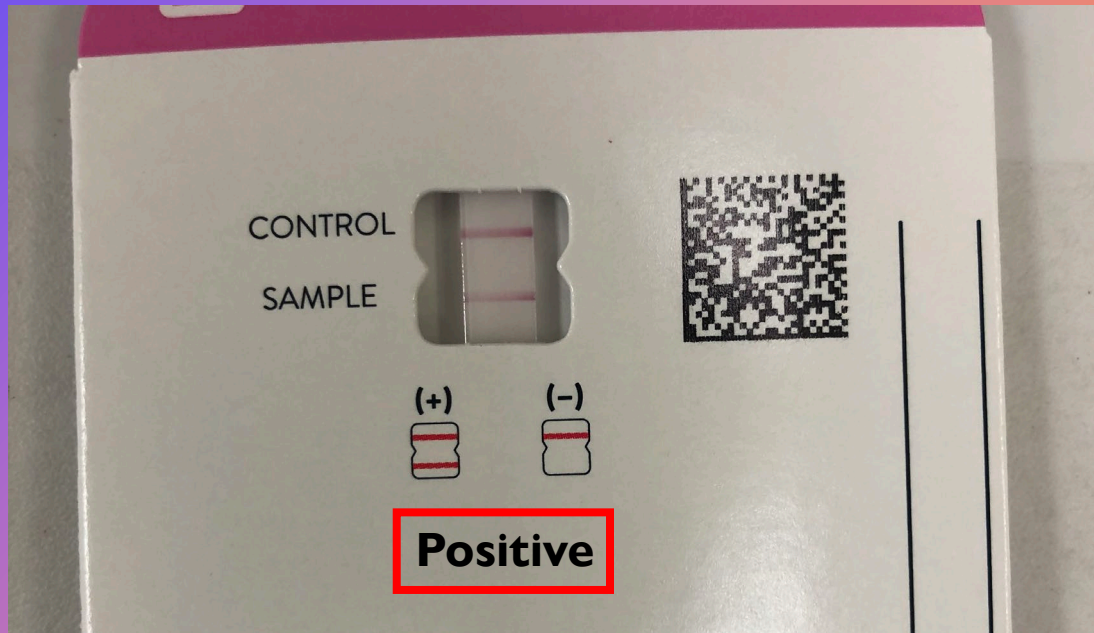
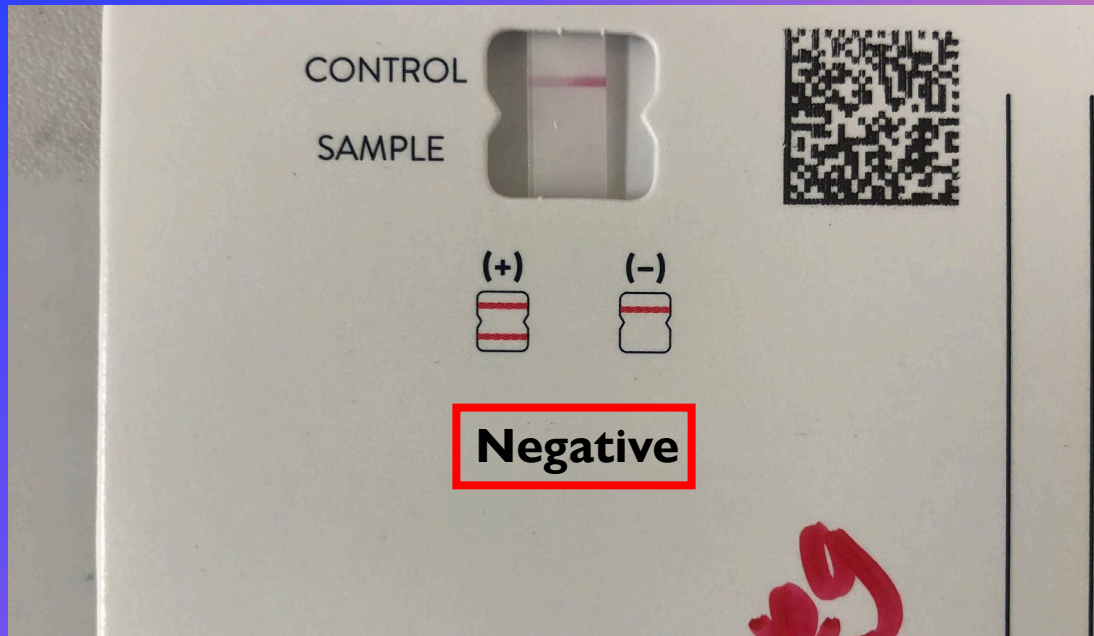
3. Insert sterile nasal swab (Negative control) or positive control swab into the bottom hole and push upward so that the swab tip is visible in top hole (**picture A**).

4. ROTATE the swab 3 TIMES CLOCKWISE (to the right, follow **red arrow**) (**picture B**).

5. Peel off adhesive liner (black arrow) on the right side of the card. Close card (**picture C**).



DO NOT interpret results after 30 minutes!!



Interpreting Results of Controls

- Control line should be Pink.
- If control line pink and sample line empty, result is **NEGATIVE**.
- If control line pink and sample line is pink, result is **POSITIVE**.

Controls Failing?

- If controls fail, **DO NOT USE** for sample testing.
- Report to Kelie Augustine (Abbott Technical consultant)
 - kelie.augustine@abbott.com

Abbott BinaxNOW Additional Video Links

[https://www.globalpointofcare.abbott/en/product-
details/navica-binaxnow-covid-19-us.html](https://www.globalpointofcare.abbott/en/product-details/navica-binaxnow-covid-19-us.html)

Additional Resource and Contact Information



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