

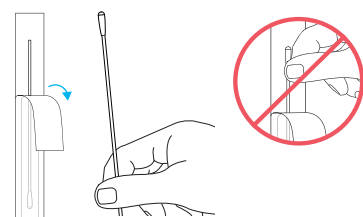
Individuals using assistive technology may not be able to fully access the information contained in this document. For assistance, please call 1(800) 638-2041 or (301) 796-7100 or send an email to CDRH's [Division of Industry and Consumer Education \(DICE\)](#). Please include “**508 Accommodation**” and the **title of the document** in the subject line of your e-mail.



## B. COLLECT NASAL SAMPLE

**!** Keep fingers away from the swab end.

4. Open swab package at stick end. Take swab out.

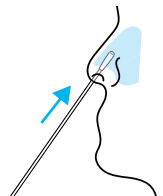


5. Swab both nostrils carefully as shown.

Insert the entire soft tip of the swab into a nostril (usually 1/2 to 3/4 of an inch).

You do not need to go deeper.

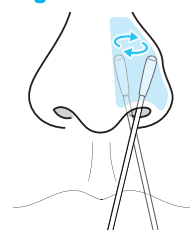
**a** Up to 3/4 of an inch



Using medium pressure, rub the swab against all of the inside walls of your nostril.

Make at least **5 big circles**. Do not just spin the swab.

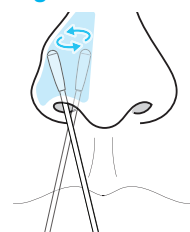
**b** At least 5 big circles



Each nostril must be swabbed for about **15 seconds**.

Using the same swab, repeat step 5 in your other nostril.

**c** At least 5 big circles



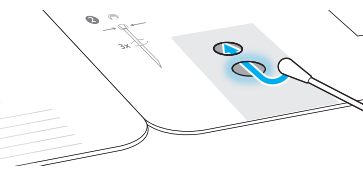
**STOP** Check: Did you swab BOTH nostrils?

**Note:** False negative result may occur if the nasal swab is not properly collected.

## C. PERFORM THE TEST

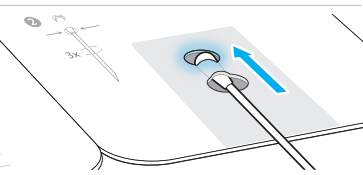
**!** Keep card FLAT on table.

6. Insert swab tip into lower hole.



Firmly push the swab tip from the lower hole until it is visible in the top hole.

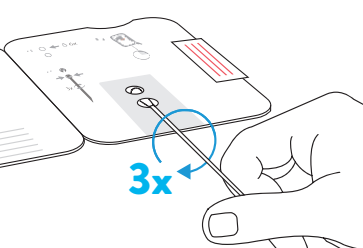
Do not remove the swab from the card.



7. Turn swab to right 3 times to mix the swab with the drops.

Do not skip this step.

Leave the swab in the card for the remainder of the test.

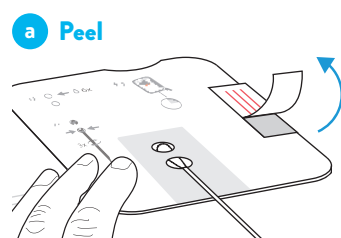


**Note:** False negative result can occur if swab is not turned.

## C. PERFORM THE TEST continued

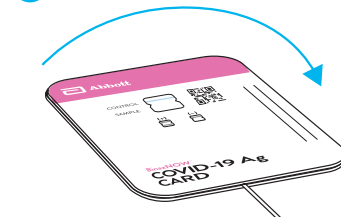
**!** DO NOT remove swab.

8. Peel adhesive liner off. Be careful not to touch other parts of card.



Close left side of the card over swab. Press firmly on the two lines on right edge of the card to seal.

**b** Seal



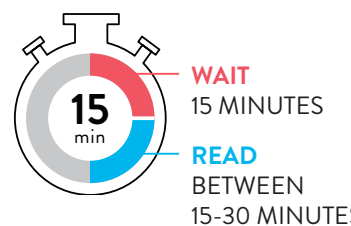
Keep card face up on table.

**!** DO NOT move or touch the card during this time.

9. Wait 15 minutes.

Read the result at 15 minutes.

Do not read the result before 15 minutes or after 30 minutes.



**Note:** A control line may appear in the result window in a few minutes but a sample line may take as long as 15 minutes to appear.

**Note:** Results should not be read after 30 minutes.

## D. INTERPRET RESULTS

Repeat testing is needed to improve test accuracy. Please follow the table below when interpreting test results for COVID-19.

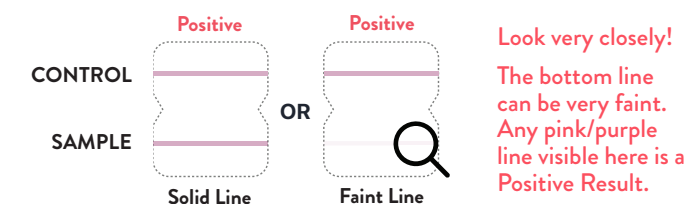
Status on First Day of Testing	First Result Day 1	Second Result Day 3	Third Result Day 5	Interpretation
With Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	N/A	Negative for COVID-19
Without Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	Positive	Positive for COVID-19
	Negative	Negative	Negative	Negative for COVID-19

Results should be considered in the context of an individual's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

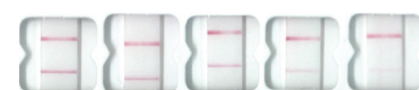
### Check for Positive COVID-19 Result

Find result window and look carefully for two pink/purple lines.

**Positive Result:** If you see two pink/purple lines (one on the top half and one on the bottom half), this means **COVID-19 was detected**.



Actual photos of positive tests. On the right, note how faint the bottom line can get.



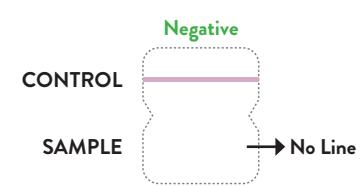
**You do not need to perform repeat testing if you have a positive result at any time.**

## D. INTERPRET RESULTS continued

### Check for Negative COVID-19 Result

Find result window and look for a single pink/purple line in window.

**Negative Result:** If you see **only** one pink/purple line on the top half, where it says "Control" this means **COVID-19 was not detected**.



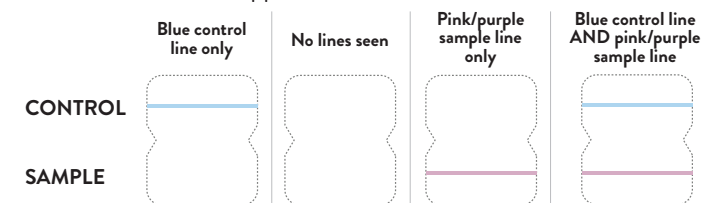
To increase the chance that the negative result for COVID-19 is accurate, you should:

- Test again in 48 hours if you have symptoms on the first day of testing.
- Test 2 more times at least 48 hours apart if you do not have symptoms on the first day of testing.

### Check for Invalid Result

If you see any of these, the test is invalid. An invalid result means this test was unable to determine whether you have COVID-19 or not. A new test is needed to get a valid result.

Please contact Technical Support at +1-833-637-1594.



**Note:** See other side to read about what your results mean.

## E. DISPOSE THE TEST KIT

Throw away all used test kit components in the trash.



## F. REPORT YOUR RESULTS



Visit [www.globalpointofcare.abbott/us/en/support/binaxnow-covid-19-antigen-self-test-us.html](http://www.globalpointofcare.abbott/us/en/support/binaxnow-covid-19-antigen-self-test-us.html) to report your results.

**Abbott**  
BinaxNOW  
COVID-19 Antigen Self Test

OTC PI - EN

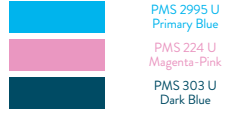
**Size:**  
Flat size: 17 in x 11 in  
Folded size: 4.25 in x 5.50 in

**Note:**  
Fold lines are not printed.

**Printed Colors**



**Incoming Inspection Colors**



**PN:** IN195150  
**Rev:** 7  
**SAP:** 40003868

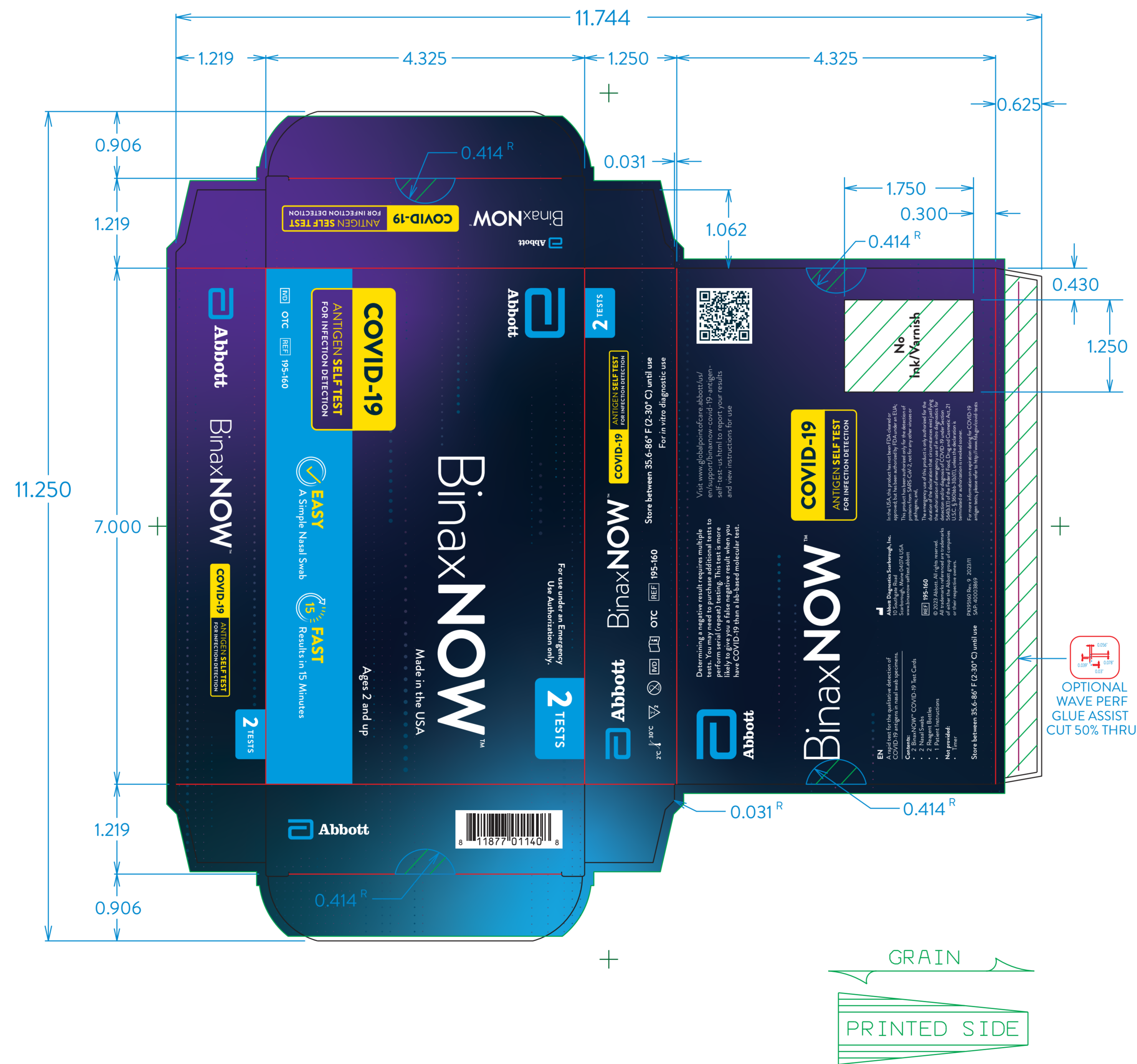
**Date of Last Revision:**  
7.5 2023/11/15



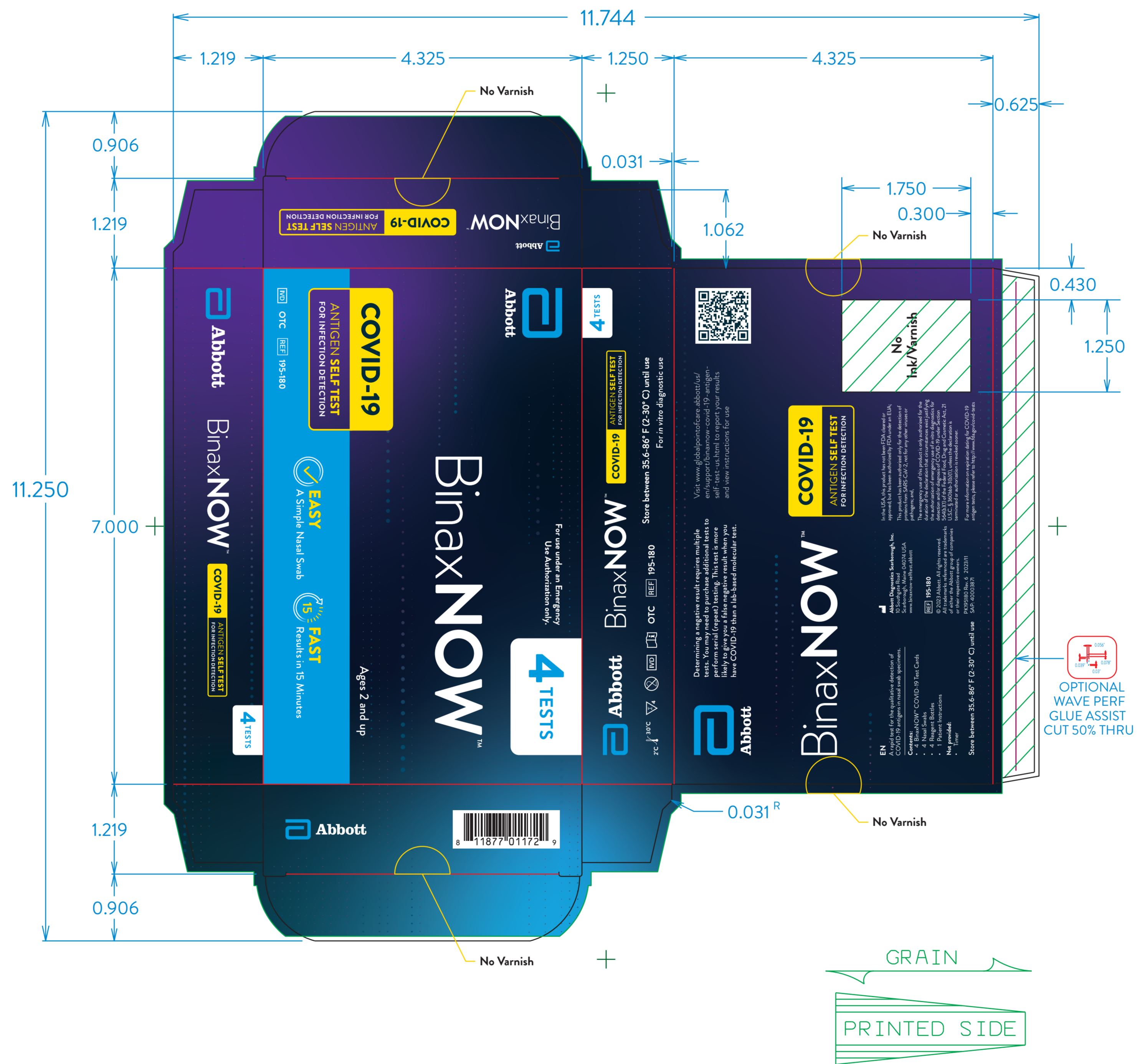
Abbott BinaxNOW COVID-19 Antigen Self Test 5 Pack	<p>CMYK PMS 3025 C Primary Blue PMS 303 C Dark Blue C10, M19, Y100, K10 Abbott Yellow</p>	PN: PK1951XX-5T Rev: 2 SAP: XXXX
5 Tests	<p>Create Line Do Not Print Cut Line Do Not Print</p>	Date of Revision: 2.2 2023/11/16
Dieline: 2T6		
Dimensions: 9 3/32 in x 5 1/16 in x 1 1/8 in		



<b>Abbott</b> BinaxNOW COVID-19 Antigen Self Test 1 Pack 1 Test <b>Dieline:</b> 2T7 <b>Dimensions:</b> 4.5 in x 7 in x 0.7 in	CMYK	<b>PN:</b> PK195140 <b>Rev:</b> 3 <b>SAP:</b> 40003867  <b>Date of Revision:</b> 3.3 2023/11/16
	PMS 2925 C Primary Blue PMS 303 C Dark Blue C=0, M=9, Y=100, K=0 Abbott Yellow	
	Crease Line Do Not Print Cut Line Do Not Print	



Abbott BinaxNOW COVID-19 Antigen Self Test 2 Pack 2 Tests DieLine: 2T8 Dimensions: 4.325 in x 7 in x 1.25 in	<p>CMYK PMS 2925 C Primary Blue PMS 383 C Dark Blue C10, M19, Y100, K10 Abbott Yellow</p>	PN: PK195160 Rev: 9 SAP: 40003869  Date of Revision: 9.7.2023/11/16
---	---	--



Abbott BinaxNOW COVID-19 Antigen Self Test 4 Pack 4 Tests DieLine: 2T8 Dimensions: 4.325 in x 7 in x 1.25 in	<p>CMYK PMS 2925 C Primary Blue PMS 383 C Dark Blue C10, M19, Y100, K10 Abbott Yellow</p>	PN: PK195180 Rev: 6 SAP: 40003871  Date of Revision: 6.3 2023/11/16
	<p>Create Line Do Not Print Cut Line Do Not Print</p>	

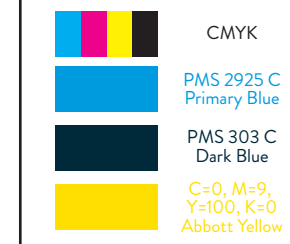


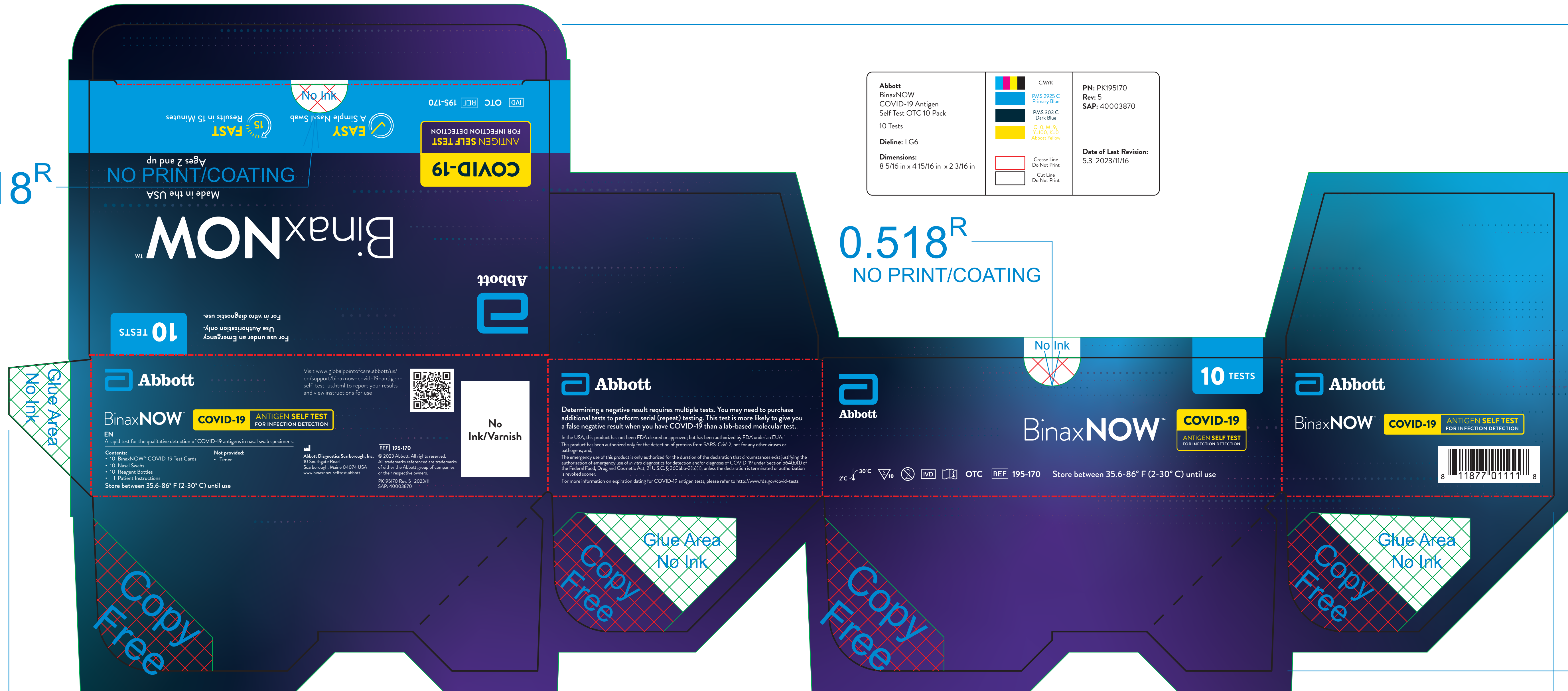
0.518<sup>R</sup>

0.518<sup>R</sup>  
NO PRINT/COATING

11<sup>13</sup>/<sub>16</sub>

28<sup>1</sup>/<sub>4</sub>

<b>Abbott</b> BinaxNOW COVID-19 Antigen Self Test OTC 10 Pack 10 Tests Dieline: LG6 Dimensions: 8 5/16 in x 4 15/16 in x 2 3/16 in		<b>PN:</b> PK195170 <b>Rev:</b> 5 <b>SAP:</b> 40003870  <b>Date of Last Revision:</b> 5.3 2023/11/16
---	---	---



ANTIGEN SELF TEST FOR INFECTION DETECTION  
**COVID-19**  
 EASY A Simple Nasal Swab  
 FAST Results in 15 Minutes  
 OTC REF 195-170

NO PRINT/COATING  
 Ages 2 and up  
 Made in the USA  
**BinaxNOW**  
 Abbott  
 For use under an Emergency Use Authorization only.  
 10 TESTS

Abbott  
 BinaxNOW COVID-19 ANTIGEN SELF TEST FOR INFECTION DETECTION  
 EN  
 A rapid test for the qualitative detection of COVID-19 antigens in nasal swab specimens.  
 Contents:  
 • 10 BinaxNOW COVID-19 Test Cards  
 • 10 Nasal Swabs  
 • 10 Reagent Bottles  
 • 1 Patient Instructions  
 Store between 35.6-86° F (2-30° C) until use  
 Not provided:  
 • Timer  
 Visit [www.globalpointofcare.abbott/us/en/support/binaxnow-covid-19-antigen-self-test-us.html](http://www.globalpointofcare.abbott/us/en/support/binaxnow-covid-19-antigen-self-test-us.html) to report your results and view instructions for use.  
 QR Code  
 No Ink/Varnish  
 © 2023 Abbott. All rights reserved. All trademarks referenced are trademarks of either the Abbott group of companies or their respective owners.  
 PK195170 Rev. 5 2023/11 SAP: 40003870

Abbott  
 Determining a negative result requires multiple tests. You may need to purchase additional tests to perform serial (repeat) testing. This test is more likely to give you a false negative result when you have COVID-19 than a lab-based molecular test.  
 In the USA, this product has not been FDA cleared or approved; but has been authorized by FDA under an EUA. This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens and:  
 The emergency use of 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 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 declaration is terminated or authorization is revoked sooner.  
 For more information on expiration dating for COVID-19 antigen tests, please refer to <http://www.fda.gov/covid-tests>

Abbott  
 BinaxNOW COVID-19 ANTIGEN SELF TEST FOR INFECTION DETECTION  
 10 TESTS  
 No Ink  
 Store between 35.6-86° F (2-30° C) until use  
 OTC REF 195-170

Abbott  
 BinaxNOW COVID-19 ANTIGEN SELF TEST FOR INFECTION DETECTION  
 Barcode: 8 11877 01111 8

Glue Area No Ink

Glue Area No Ink  
Copy Free

Copy Free

Glue Area No Ink  
Copy Free