Abbott

BinaxNOW™

COVID-19/FLU A&B COMBO SELF TEST

INSTRUCTIONS FOR USE (IFU)

For *in vitro* diagnostic use
For over-the-counter use
For use with anterior nasal swabs specimens only

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INSTRUCTIONS FOR USE (IFU)

1. INTENDED USE

The BinaxNOW™ COVID-19/Flu A&B Combo Self Test is a lateral flow immunochromatographic assay intended for the qualitative detection and differentiation of influenza A, and influenza B nucleoprotein antigens and SARS-CoV-2 nucleocapsid protein directly in anterior nasal swab samples from individuals with signs and symptoms of respiratory tract infection. Symptoms of respiratory infections due to SARS-CoV-2 and influenza can be similar. This test is for non-prescription home use by individuals aged 14 years or older testing themselves, or adults testing individuals aged 2 years or older.

All negative results are presumptive and should be confirmed with an FDA-cleared molecular assay when determined to be appropriate by a healthcare provider. Negative results do not rule out infection with influenza, SARS-CoV-2, or other pathogens. Individuals who test negative and experience continued or worsening respiratory symptoms, such as fever, cough and/or shortness of breath, should seek follow-up care from their healthcare provider.

Positive results do not rule out co-infection with other respiratory pathogens, and therefore do not substitute for a visit to a healthcare provider or appropriate follow-up.

2. SUMMARY and EXPLANATION of the TEST

The ongoing COVID-19 pandemic, along with other seasonally prevalent illnesses such as influenza (Flu), continue to be among the world's most pressing healthcare issues. While contagious respiratory illnesses such as COVID-19 and influenza share similar symptoms and means of transmission, they are caused by different viruses. The Centers for Disease Control and Prevention (CDC) has also raised concerns about the potential co-infection with two or more of the respiratory viruses. There is an urgent need for rapid COVID-19 and Influenza A/B diagnostic over-the-counter tests so that patients can seek appropriate treatment with their healthcare provider before their symptoms worsen.

The BinaxNOW COVID-19/Flu A&B Combo Self Test is a rapid lateral flow test for the qualitative detection of the SARS-CoV-2, Influenza A and Influenza B using anterior nares nasal swab samples from those who are suspected of COVID-19, Influenza A and Influenza B. The BinaxNOW COVID-19/Flu A&B Combo Self Test is validated for testing direct samples without transport media.

The cassette contains membranes which are pre-coated with anti-SARS-CoV-2 nucleocapsid protein monoclonal antibodies, anti-influenza A nucleoprotein monoclonal antibodies and anti-influenza B nucleoprotein monoclonal antibodies on the test lines. Another anti-SARS-CoV-2 nucleocapsid protein monoclonal antibodies, anti-influenza A nucleoprotein monoclonal antibodies and anti-influenza B nucleoprotein monoclonal antibodies are each bound to the beads. When the sample is put into the sample well, the antibodies bound to the beads and the antigen in the sample bind to form complexes and migrate to the membrane. The complexes will be captured by coated antibodies on the membrane, and then the line will form a visible line. The presence of SARS-CoV-2, influenza A and influenza B antigens are indicated by lines visible in the S-marked position, A-marked position, and B-marked position in the results window, respectively.

The results of the test are interpreted at 15 minutes. Refer to the Interpretation of Results section.

3. MATERIALS and REAGENTS PROVIDED

The BinaxNOW COVID-19/Flu A&B Combo Self Test is offered in a 2, 4 and 10 test/kit sizes. The kit configurations are provided below:

Component	Qty	Qty	Qty
Test Cassette	2	4	10
Sterile Swab	2	4	10
Extraction Buffer Tube & Filter Cap	2	4	10
Quick Reference Instructions (QRI)	1	1	1

4. MATERIALS REQUIRED but not INCLUDED

- Materials required but not provided: A clock or timer
- Recommended materials: Disposable gloves and mask, if swabbing others.

5. WARNINGS, PRECAUTIONS, and SAFETY INFORMATION

- **Do not use the test if you have had symptoms for more than 4 days or no symptoms at all.**
- Do not use the test if the test kit components or packaging is damaged or opened.
- When collecting a sample, only use the swab provided in the kit.
- Test components are for single-use. Do not re-use.
- Testing should be performed in an area with good lighting.
- Once opened, the test cassette should be used immediately.
- When the tests are stored at hot or humid conditions, faint lines may appear on the unused test strip prior to the addition of the sample. Do not read or interpret test results until after the sample has been added to the test cassette and the test has been allowed to run for 15 minutes.
- Faint blue lines can occur near the "A" position of the test strip with some Flu B samples at high viral loads. Only test lines that appear at both the correct position and in the correct color should be read and interpreted.
- Do not use any nasal sprays, gels or creams at least 30 minutes before you collect a nasal sample.
- Do not use this test if you have been vaccinated with the FluMist/FluMist quadrivalent live intranasal influenza virus vaccine within the last two weeks.
- Please ensure that hands are dry after washing prior to performing the test.
- Remove any piercings from nose before starting the test.
- **Keep testing kit and kit components away from children and pets before and after use.**
- **Avoid contact with your skin, eyes, nose, or mouth. Do not ingest any kit components. The reagent solution contains harmful chemicals (see table in the next column). If the solution contacts your skin, eyes, nose, or mouth, flush with large amounts of water. If irritation persists, seek medical advice: https://www.poisonhelp.org or 1-800- 222-1222.**

Hazard Category (Mixture)	GHS Hazard Statement for Mixture	Labeling of Harm(s)	Hazardous Ingredients (%)
3	Mild skin irritation	Causes mild skin irritation (H316)	• Triton X-100 / 1% • Proclin 300 / 0.05%
2	Serious eye irritation	Causes serious eye irritation (H319)	• Triton X-100 / 1% • Proclin 300 / 0.05%

- For the most up to date information on COVID-19, please visit: www.cdc.gov/COVID19

6. STORAGE and STABILITY

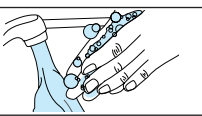
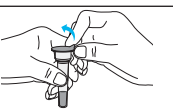
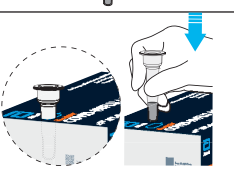
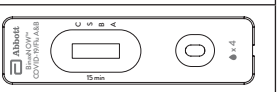
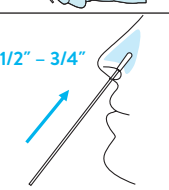
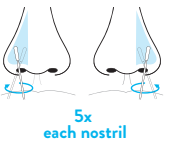
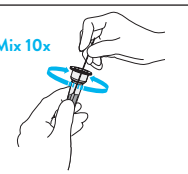
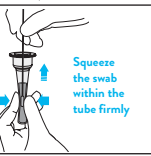
- BinaxNOW COVID-19/Flu A&B Combo Self Test should be stored between 36 °F (2°C) to 86°F (30 °C) in a place out of direct sunlight.

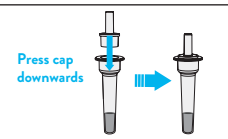
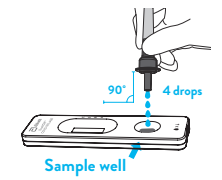
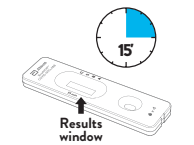
7. QUALITY CONTROL

Internal Quality Control

Each BinaxNOW COVID-19/Flu A&B Combo Self Test has a built-in internal procedural control. The red line appearing at the "C" position is an internal procedural control. This procedural control line indicates that sufficient flow has occurred, and the functional integrity of the test cassette has been maintained. A distinct red Control line should always appear if the test has been performed correctly. If the Control line does not appear, the test result is invalid, and a new test should be performed.

8. TEST PROCEDURE

BEFORE GETTING STARTED	
1. Check expiration date on the outside of the box. Do not use beyond the expiration date.	
2. Wash hands thoroughly for at least 20 seconds before and after handling nasal swab samples.	
3. Before testing, read the Quick Reference Instructions carefully. Bring the test kit to room temperature (59-86°F) when you are ready to begin the test.	
PREPARE THE MATERIALS	
4. Arrange the materials on a clean, dry, flat surface. Your box may contain one or more test kits. Use only one of each individually packaged kit and its components for each test. DO NOT open the individual pouches until you are ready to begin the test.	
5. Open the foil pouch that contains the extraction buffer tube and filter cap.	
6. Pick up the extraction buffer tube and remove the sealing foil of the tube without spilling the buffer solution inside the tube.	
7. Push the extraction buffer tube into the perforated tube holder located at the front of the box, labeled "Insert Tube Here."	
8. Remove the test cassette from its foil pouch. DO NOT remove the test cassette until you are ready to begin the test.	
PERFORMING THE TEST	
9. Open swab package from the stick end and remove the swab by the stick side. DO NOT touch the swab head. Accidental contamination of the swab head with liquid gel soap can lead to false results.	
10. Gently insert the swab head ½ to ¾ inch into individual's nostril. For young children, swab should not be inserted more than 1/2 inch. DO NOT insert the swab any farther if you feel any resistance. Using medium pressure, rub and rotate the swab against the inside of the individual's nostril, making at least 5 circles. ***NOTE:*** *When swabbing others, wear a face mask. With children, you may not need to insert the swab as far into the nostril. For young children, you may need another person to steady the child's head while swabbing. Do not use on children below age 2.*	
11. **REPEAT IN THE OTHER NOSTRIL USING THE SAME SWAB.** **STOP: Did you swab BOTH nostrils? Inaccurate test results may occur if the nasal sample is not properly collected.**	
12. Place the swab into the extraction buffer tube and completely immerse the swab head in the solution. Vigorously mix the solution by rotating the swab forcefully against the side of the tube **at least 10 times**, keeping the swab tip submerged in the buffer solution the entire time.	
13. Remove the swab while squeezing the tube with your fingers to ensure that the sample on the swab is fully mixed into the buffer solution.	

14. Attach the filter cap onto the test tube.	
15. Squeeze only 4 DROPS of the buffer solution into the sample well. *DO NOT squeeze more than 4 drops from the tube into the sample well.*	
16. SET A TIMER AND READ THE TEST RESULT AFTER 15 MINUTES. **DO NOT disturb the cassette during this time. Inaccurate results can occur if the cassette is disturbed.** **DO NOT interpret test result before 15 minutes or after 30 minutes as this may result in false or invalid results.**	

9. INTERPRETATION of RESULTS

Test results are read and interpreted visually. Read result at 15-30 minutes with good lighting. Test results should not be read until after the sample has been added and the test has been allowed to run for 15 minutes, and only test lines that appear at the correct position and in the correct color should be read and interpreted.

Look at the result window and locate the letters 'C' (Control), 'S' (COVID-19), 'B' (Flu B), and 'A' (Flu A) on the side of the window.

A red line should always appear at the C position; this is a control line and signal that the test is working properly. The information for each line is as follows:

C = Control (red line)

S = COVID-19 (SARS-CoV-2) (red line)

B = Influenza B (blue line)

A = Influenza A (red line)

IMPORTANT: Do not use the test as the only guide to manage your illness. Consult your healthcare provider if your symptoms persist or become more severe. Individuals should provide all results obtained with this product to their healthcare provider.

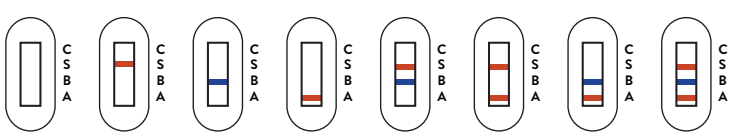
INVALID

If a control line is not visible at "C" after 15 minutes, even if any other line is visible in the results window, **THE TEST HAS FAILED** and is considered invalid.

DO NOT CONTINUE reading the results. Repeat the test with a new sample and new test kit materials.

STOP: If the test is invalid, repeat the test procedure using a new test kit and sample.

If the test cassette looks like the examples below then the test **result is invalid** and you must **repeat the test with a new swab sample, a new tube, and a new test cassette**.



WHAT DOES AN INVALID TEST MEAN?

If the control line (C) is not visible, the test is invalid, even if any other test line is visible. An invalid test result means that the test is unable to determine if you are infected with influenza or SARS-CoV-2 (COVID-19) or not. The test needs to be repeated with a new kit and sample.

NEGATIVE (-)

If the control line at "C" is visible and you do not see a line at 'S', 'B', or 'A', the test is negative. It means you may not have COVID-19, Flu B, or Flu A virus. If you still have COVID-19, Flu B, or Flu A symptoms, you should seek follow-up care with your healthcare provider.

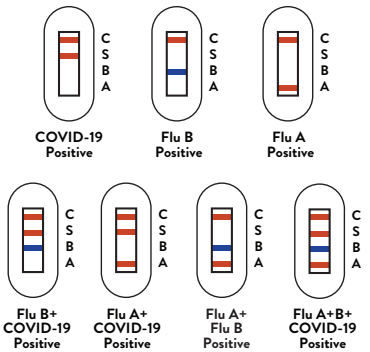
Negative

WHAT DOES A NEGATIVE TEST MEAN?

A negative test result means that COVID-19, Flu A, and/or Flu B viruses were not detected in the sample. A negative result is presumptive because despite a negative result you may still have COVID-19, Flu A and/or Flu B infection. This is because the amount of virus in your sample may be too low for the test to detect it, which is called a "false negative result". False negative results can occur if you read the test before the 15 minutes have passed or when your sample has low amount of virus in it. Low amount of virus can occur if you take your sample at a time when your symptoms just started appearing, or when you already started to feel better at the end of your infection. There is a higher chance of false negative results with antigen tests compared to laboratory-based molecular tests. If you tested negative and continue to experience COVID-19, Flu A, and/or Flu B-like symptoms, you should therefore seek follow-up care with your healthcare provider who will determine the best course of action. Your healthcare provider can also determine if confirmation of your test result with a molecular assay is necessary.

POSITIVE (+)

If the control line at **C** is visible, and any other line or multiple lines on **S**, **B** and/or **A** appear, the test is **positive**. **The virus next to the positive line was detected in your sample**. Consult your healthcare provider to discuss your results. Self-isolate at home per CDC recommendations to stop spreading the virus to others.



Note: *The Test line may vary in shade and intensity (light or dark, weak, or strong). The intensity of the Control line should not be compared to that of the Test line for the interpretation of the test result.*

WHAT DOES A POSITIVE TEST MEAN?

A positive test result means that one, or multiple, of the viruses detected by this test were also detected in your sample. It is very likely that you have the respective COVID-19 and/or influenza infection(s) and are contagious. You should self-isolate following local guidelines. Please contact your physician or healthcare provider to discuss your test results and follow-up care. In rare instances, individuals may also have coinfections with other bacteria or viruses that this test is not designed to detect. This means that the virus detected by this test may not be the definitive or the only cause of your disease. There is a small chance that this test can give you a positive result that is incorrect (a false positive).

Report your test result(s) at MakeMyTestCount.Org – this voluntary and anonymous reporting helps public health teams understand COVID-19 spread in your area and across the country and informs public health decisions. https://report.makemytestcount.org/

10. LIMITATIONS

- The clinical performance of this test was established based on the evaluation of a limited number of clinical specimens collected between October, 2023 to June, 2024. There is a risk of false negative results due to the presence of novel, emerging respiratory virus variants. Test accuracy may change as new virus variants of COVID-19 and influenza emerge. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of COVID-19 and influenza and their prevalence, which change over time. Additional testing with a laboratory-based molecular test (e.g., PCR) should be considered in situations where a new virus or variant is suspected.
- A negative test result may occur if the level of antigen in the sample is below the detection limit of the test or if the sample is collected, handled, or transported improperly.
- There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests due to the sensitivity of the test technology. This means that there is a higher chance this test will give a false negative result in an individual with COVID-19 and influenza as compared to a molecular test, especially in samples with low viral load.
- False positive test results are more likely when the prevalence of SARS-CoV-2, Flu A/B is low in the community.
- Persons with risk factors for severe disease from respiratory pathogens (e.g., young children, elderly individuals, chronic lung disease, heart disease, compromised immune systems, diabetes, and other conditions) should contact a healthcare provider.
- All users should contact a healthcare provider if symptoms worsen.
- This test is read visually. Because test lines can be very faint, users with conditions affecting their vision- such as far-sightedness, glaucoma, or color blindness-are encouraged to seek assistance to interpret results accurately (e.g., reading glasses, additional light source, or another person). This test has not been validated for use by those with color-impaired vision.
- This device is qualitative test and cannot provide information on the amount of virus present in the specimen.
- This test detects both viable (live) and non-viable influenza A, influenza B, and SARS-CoV-2. Test performance depends on the amount of virus (antigens) in the sample.
- Liquid gel hand soap may cause false negative results with this test.
- FluMist/FluMist quadrivalent live intranasal influenza virus vaccine may cause false positive influenza A and B results with this test.

11. PERFORMANCE CHARACTERISTICS

A. Analytical Performance

• **Limit of Detection (LoD) (Analytical Sensitivity)**

The Limit of Detection (LoD) of the BinaxNOW COVID-19/Flu A&B Combo Self Test was determined using serial dilutions of one strain of UV inactivated SARS-CoV-2 (USA-WA1/2020) and two live strains of Influenza A and Influenza B. Contrived samples were prepared by spiking the strain into pooled human negative swab matrix (PNSM) obtained from healthy volunteers confirmed negative by RT-PCR. The preliminary LoD initially determined by testing ten-fold serial dilution series of three (3) replicates was confirmed by testing twenty (20) replicates. The confirmed LoD for the BinaxNOW COVID-19/Flu A&B Combo Self Test is shown in the table below.

Virus Strains	Stock Concentration ($TCID_{50}$/mL)	LoD Concentration ($TCID_{50}$/mL)	$TCID_{50}$/Swab	# Positive/ #Total Tested	Percent Detected (%)
SARS-CoV-2 (USA-WA1/2020)	3.16×10^6	1.58×10^3	7.90×10^1	20/20	100%
Influenza A H1N1pdm09: A/ Victoria/4897/2022	2.02×10^5	2.02×10^2	1.01×10^1	20/20	100%
Influenza A H3N2: A/ Darwin/6/2021	4.17×10^5	2.09×10^2	1.04×10^1	20/20	100%
Influenza B Victoria: B/ Washington/02/2019	3.16×10^6	3.16×10^3	1.58×10^2	20/20	100%
Influenza B Yamagata: B/ Florida/4/2006	1.17×10^5	2.93×10^1	1.46	20/20	100%

• **NIBSC - WHO Standard Testing**

The sensitivity of BinaxNOW COVID-19/Flu A&B Combo Self Test was evaluated with the 1st WHO International Standard for SARS-CoV-2 antigen (NIBSC code: 21/368) spiked into pooled negative swab matrix (PNSM). The unitage of this material has an assigned value of 5,000 International Units of SARS-CoV-2 antigen per ampule when reconstituted per instructions. A 2-fold dilution series was made to determine the preliminary LoD, which was measured using one device lot and triplicate measurements (n=3). The measurements were done by adding 50µl of each dilution directly to the test swab and processing the sample per the test's QRI. The preliminary LoD was determined to be 1000 IU/ml (or 50 IU/swab). The LoD confirmatory study was performed using 20 replicates (n=20) per dilution. The lowest concentration at which a minimum of 95% of results were positive was confirmed to be 1000 IU/ml or 50 IU/Swab as shown below.

Description	Source	NIBSC No.	Concentration(IU/mL)	Concentration (IU/swab)	# Positive Results
WHO International Standard for SARS-CoV-2	National Institute for Biological Standards and Controls	NIBSC 21/368	1,000 IU/mL	50 IU/swab	20/20

• **Analytical Reactivity**

The BinaxNOW COVID-19/Flu A&B Combo Self Test had wet testing (analytical reactivity) performed by establishing the LoD for Influenza A strains, Influenza B strains and SARS-CoV-2 strains on the BinaxNOW COVID-19/Flu A&B Combo Self Test to determine if the device can detect target analytes across a variety of strains. A selection of temporal, geographic and genetically diverse Influenza strains were tested on the BinaxNOW COVID-19/Flu A&B Combo Self Test for inclusivity. Individual virus strains were diluted in pooled negative swab matrix (PNSM) at 10-fold dilutions and tested in triplicate. PNSM, un-spiked, was tested in triplicate. After a 10-fold break point was established testing two-fold dilution points of the lowest positive ten-fold dilution was completed. The lowest 10-fold or 2-fold dilution that demonstrated three (3) positives replicates for each was identified.

Analyte	Virus Strain	Concentration	Units
SARS-CoV-2	XBB 1.5 (Omicron) Heat Inactivated	$4.0x10^2$	$TCID_{50}$/mL
Flu A H1N1	A/California/04/2009	2.8×10^3	$TCID_{50}$/mL
	A/Brisbane/02/2018	1.9×10^2	$TCID_{50}$/mL
	A/Michigan/45/2015	1.9×10^1	$TCID_{50}$/mL
	A/Guangdong-Maonan/SWL1536/2019	1.0×10^3	$TCID_{50}$/mL
	A/NY/03/2009	4.6×10^4	$TCID_{50}$/mL
	A/Indiana/02/2020	9.7×10^6	$CEID_{50}$/mL
	A/Wisconsin/588/2019	2.8×10^4	FFU/mL
	A/Sydney/5/2021	6.0×10^3	$TCID_{50}$/mL
	A/Hawaii/66/2019	7.4×10^7	$CEID_{50}$/mL
	A/Wisconsin/67/2022	4.2×10^2	$TCID_{50}$/mL
	A/Ohio/09/2015	1.4×10^6	$CEID_{50}$/mL
Flu A H1N2	A/Minnesota/19/2011	8.0×10^6	$CEID_{50}$/mL
Flu A H3N2	A/Tasmania/503/2020	1.3×10^5	FFU/mL
	A/New York/21/2020	3.3×10^5	FFU/mL
	A/Alaska/01/2021	3.8×10^4	FFU/mL
	A/Hong Kong/45/2019	3.8×10^4	FFU/mL
	A/Hong Kong/2671/2019	1.1×10^3	$TCID_{50}$/mL
	A/Indiana/08/2011	8.1×10^2	$TCID_{50}$/mL
Flu A H5N1	A/mallard/Wisconsin/2576/2009	4.0×10^6	$CEID_{50}$/mL
	A/bovine/Ohio/B24OSU-439/2024	$7.8x10^3$	$TCID_{50}$/mL
	A/duck/Guangxi/S11002/2024	$1.7x10^6$	EID_{50}/mL
Flu A H5N6	A/duck/Guangxi/S10888/2024	$1.7x10^6$	EID_{50}/mL
Flu A H5N8	A/goose/Liaoning/S1266/2021	$1.7x10^6$	EID_{50}/mL
Flu A H7N3	A/northern pintail/Illinois/10OS3959/2010	2.8×10^6	$CEID_{50}$/mL
Flu B non-Victoria, non-Yamagata	B/Maryland/1/1959	3.4×10^3	$CEID_{50}$/mL
Flu B Victoria lineage	B/Brisbane/60/2008	1.6×10^0	$TCID_{50}$/mL
	B/Colorado/06/2017	2.9×10^1	$TCID_{50}$/mL
	B/Texas/02/2013	2.5×10^1	$TCID_{50}$/mL
	B/Michigan/01/2021	1.4×10^4	$TCID_{50}$/mL
Flu B Yamagata lineage	B/Texas/06/2011	1.5×10^3	$TCID_{50}$/mL
	B/Utah/09/2014	1.3×10^3	$TCID_{50}$/mL
	B/Wisconsin/01/2010	1.8×10^2	$TCID_{50}$/mL

* The lowest concentration that returned 100% positive replicates (i.e., 5/5)

• **Competitive Interference**

Competitive interference testing (i.e., evaluation of potential for a high concentration of one target virus to interfere with detection of a low concentration of another target virus) for the BinaxNOW COVID-19/Flu A&B Combo Self Test was completed and no competitive interference across analytes was observed. The testing was performed with different combinations of low (3x LoD) and high concentrations (either 1000x LoD or the highest concentration achievable exceeding 10^5 PFU/mL, $CEID_{50}$/mL or $TCID_{50}$/mL) of live Influenza A, live Influenza B and UV inactivated SARS-CoV-2 on the BinaxNOW COVID-19/Flu A&B Combo Self Test device to determine if the candidate device can detect target analytes across a variety of analyte concentrations.

Combination	Viral Target in Sample			
	Influenza A (H1N1pdm09/A/ Victoria/4897/2022)	Influenza B (Yamagata/B/ Florida/4/2006)	SARS-CoV-2 (USA-WA1/2020)	Results
1	High	3X LoD	Negative	No interference
2	High	Negative	3X LoD	No interference
3	High	3X LoD	3X LoD	No interference
4	3X LoD	High	Negative	No interference
5	Negative	High	3X LoD	No interference
6	3X LoD	High	3X LoD	No interference
7	3X LoD	Negative	High	No interference
8	Negative	3X LoD	High	No interference
9	3X LoD	3X LoD	High	No interference

• **High-dose hook effect**

No high dose hook effect was observed when tested with up to a concentration below with the BinaxNOW COVID-19/Flu A&B Combo Self Test.

Analyte	Strain	Lineage	Concentration ($TCID_{50}$/mL)	Virus Concentration ($TCID_{50}$/swab)
SARS-CoV-2	USA-WA1/2020	SARS-CoV-2	3.16×10^6	$1.58x10^5$
Influenza A (H1N1)	A/Victoria/4897/2022	H1N1pdm09	2.02×10^5	$1.01x10^4$
Influenza A (H3N2)	A/Darwin/6/21	H3N2	4.17×10^5	$2.09x10^4$
Influenza B (Victoria)	B/Washington/02/2019	Victoria	3.16×10^6	$1.58x10^5$
Influenza B (Yamagata)	B/Florida/04/2006	Yamagata	1.17×10^5	$5.85x10^3$

B. Analytical Performance:

• Cross-reactivity and microbial interference

Cross-reactivity and microbial interference studies were performed with related pathogens, high prevalence disease agents, and normal or pathogenic flora that are reasonably likely to be encountered in the clinical specimens of the nasal cavity. Each organism was tested with and without the presence of UV inactivated SARS-CoV-2, live Influenza A, and Influenza B viruses at 3X co-spike equivalency LoD.

Cross reactivity:

For cross reactivity, each organism was tested in replicate of three (3) at the concentrations listed in the following table of results. All testing samples were prepared in the pooled nasal wash (PNW). No cross reactivity or interference was observed for any of the organisms tested.

IDI	Organism	Concentration	Influenza A Test Results (positive/total)	Influenza B Test Results (positive/total)	SARS-CoV-2 Test Results (positive/total)
229E	Human coronavirus 229E	1.58E+05 $TCID_{50}$/mL	0/3	0/3	0/3
OC43	Human coronavirus OC43	7.00E+05 $TCID_{50}$/mL	0/3	0/3	0/3
NL63	Human coronavirus NL63	7.05E+04 $TCID_{50}$/mL	0/3	0/3	0/3
HKU1	Human Coronavirus HKU1	1.74E +07 GE/mL	0/3	0/3	0/3
SARS	SARS-coronavirus	1.25E+05 PFU/mL	0/3	0/3	0/3
MERS	MERS-coronavirus	1.47E+05 $TCID_{50}$/mL	0/3	0/3	0/3
AV1	Adenovirus Type 1	2.23E+05 $TCID_{50}$/mL	0/3	0/3	0/3
AV7	Adenovirus Type 7	1.58E+05 $TCID_{50}$/mL	0/3	0/3	0/3
hMPV	Human metapneumovirus	3.50E+05 $TCID_{50}$/mL	0/3	0/3	0/3
P1	Parainfluenza virus 1	2.00E+05 $TCID_{50}$/mL	0/3	0/3	0/3
P2	Parainfluenza virus 2	1.75E+05 $TCID_{50}$/mL	0/3	0/3	0/3
P3	Parainfluenza virus 3	7.00E+05 $TCID_{50}$/mL	0/3	0/3	0/3
P4	Parainfluenza virus 4b	2.39E+05 $TCID_{50}$/mL	0/3	0/3	0/3
EV68	Enterovirus 68	2.23E+05 $TCID_{50}$/mL	0/3	0/3	0/3
RSVA	Respiratory syncytial virus A	3.50E+05 $TCID_{50}$/mL	0/3	0/3	0/3
RSVB	Respiratory syncytial virus B	2.29E+05 $TCID_{50}$/mL	0/3	0/3	0/3
RV	Rhinovirus	7.05E+04 $TCID_{50}$/mL	0/3	0/3	0/3
HI	*Haemophilus influenzae*	9.68E+06 CFU/mL	0/3	0/3	0/3
SPN	*Streptococcus pneumonia*	1.81E+07 CFU/mL	0/3	0/3	0/3
SPY	*Streptococcus pyogenes*	7.50E+07 CFU/mL	0/3	0/3	0/3
CA	*Candida albicans*	1.21E+07 CFU/mL	0/3	0/3	0/3
BP	*Bordetella pertussis*	2.90E+08 CFU/mL	0/3	0/3	0/3
MP	*Mycoplasma pneumonia*	2.50E+07 CFU/mL	0/3	0/3	0/3
CP	*Chlamydia pneumoniae*	4.33E+06 IFU/mL	0/3	0/3	0/3
LP	*Legionella pneumophila*	6.50E+06 CFU/mL	0/3	0/3	0/3
MT	*Mycobacterium tuberculosis*	3.03E+06 CFU/mL	0/3	0/3	0/3
PJ	*P. jiroveci-S. cerevisiae*	1.30E+07 CFU/mL	0/3	0/3	0/3
SA	*Staphylococcus aureus* subsp. *aureus*	2.60E+08 CFU/mL	0/3	0/3	0/3
SE	*Staphylococcus epidermidis*	9.00E+07 CFU/mL	0/3	0/3	0/3
CX	*Corynebacterium xerosis*	2.30E+07 CFU/mL	0/3	0/3	0/3
EC	*Escherichia coli*	1.79E+08 CFU/mL	0/3	0/3	0/3
LA	*Lactobacillus acidophilus*	1.21E+07 CFU/mL	0/3	0/3	0/3
MC	*Moraxella catarrhalis*	2.50E+08 CFU/mL	0/3	0/3	0/3
NM	*Neisseria meningitidis*	3.43E+06 CFU/mL	0/3	0/3	0/3
NE	*Neisseria elongata*	2.68E+08 CFU/mL	0/3	0/3	0/3
PA	*Pseudomonas aeruginosa*	3.45E+08 CFU/mL	0/3	0/3	0/3
SS	*Streptococcus salivarius*	1.01E+06 CFU/mL	0/3	0/3	0/3
ME	Measles	8.48E+05 $TCID_{50}$/mL	0/3	0/3	0/3
MU	Mumps	8.48E+05 $TCID_{50}$/mL	0/3	0/3	0/3
EBV	Epstein Barr Virus	1.83E+06 CP/mL	0/3	0/3	0/3
CMV	Cytomegalovirus	7.05E+04 $TCID_{50}$/mL	0/3	0/3	0/3
PNW	Pooled Negative Nasal Wash	N/A	0/3	0/3	0/3

Microbial interference:

For evaluating microbial interference against the SARS-CoV-2, Influenza A (H1N1pdm09), Influenza B (Yamagata) test lines, the organisms were tested with SARS-CoV-2 UV-inactivated SARS-CoV-2: USA-WA1/2020 (ZeptoMetrix # 0810587UV), Live Flu A: H1N1pdm09/A/Victoria/4897/2022 (ZeptoMetrix # 0810684CF), Live Flu B: Yamagata/B/Florida/4/2006 (ZeptoMetrix # 0810255CF) diluted to 3x LoD concentration in negative pooled nasal wash (PNW). No microbial interference was seen with the organisms tested at the concentrations shown below.

IDI	Organism	Concentration	Influenza A Test Results (positive/total)	Influenza B Test Results (positive/total)	SARS-CoV-2 Test Results (positive/total)
229E	Human coronavirus 229E	1.58E+05 $TCID_{50}$/mL	3/3	3/3	3/3
OC43	Human coronavirus OC43	7.00E+05 $TCID_{50}$/mL	3/3	3/3	3/3
NL63	Human coronavirus NL63	7.05E+04 $TCID_{50}$/mL	3/3	3/3	3/3
HKU1	Human coronavirus HKU1	1.74E+07 GE/mL	3/3	3/3	3/3
SARS	SARS-coronavirus	1.25E+05 PFU/mL	3/3	3/3	3/3
MERS	MERS-coronavirus	1.47E+05 $TCID_{50}$/mL	3/3	3/3	3/3
AV1	Adenovirus Type 1	2.23E+05 $TCID_{50}$/mL	3/3	3/3	3/3
AV7	Adenovirus Type 7	1.58E+05 $TCID_{50}$/mL	3/3	3/3	3/3
hMPV	Human metapneumovirus 4 Type B2	3.50E+05 $TCID_{50}$/mL	3/3	3/3	3/3
P1	Parainfluenza virus 1	2.00E+05 $TCID_{50}$/mL	3/3	3/3	3/3
P2	Parainfluenza virus 2	1.75E+05 $TCID_{50}$/mL	3/3	3/3	3/3
P3	Parainfluenza virus 3	7.00E+05 $TCID_{50}$/mL	3/3	3/3	3/3
P4	Parainfluenza virus 4b	2.39E+05 $TCID_{50}$/mL	3/3	3/3	3/3
EV68	Enterovirus 68	2.23E+05 $TCID_{50}$/mL	3/3	3/3	3/3
RSVA	Respiratory syncytial virus A	3.50E+05 $TCID_{50}$/mL	3/3	3/3	3/3
RSVB	Respiratory syncytial virus B	2.29E+05 $TCID_{50}$/mL	3/3	3/3	3/3
RV	Rhinovirus 1A	7.05E+04 $TCID_{50}$/mL	3/3	3/3	3/3
HI	*Haemophilus influenzae*	9.68E+06 CFU/mL	3/3	3/3	3/3
SPN	*Streptococcus pneumonia*	1.81E+07 CFU/mL	3/3	3/3	3/3
SPY	*Streptococcus pyogenes*	7.50E+07 CFU/mL	3/3	3/3	3/3
CA	*Candida albicans*	1.21E+07 CFU/mL	3/3	3/3	3/3
BP	*Bordetella pertussis*	2.90E+08 CFU/mL	3/3	3/3	3/3

IDI	Organism	Concentration	Influenza A Test Results (positive/total)	Influenza B Test Results (positive/total)	SARS-CoV-2 Test Results (positive/total)
MP	*Mycoplasma pneumonia*	2.50E+07 CFU/mL	3/3	3/3	3/3
CP	*Chlamydia pneumoniae*	4.33E+06 IFU/mL	3/3	3/3	3/3
LP	*Legionella pneumophila*	6.50E+06 CFU/mL	3/3	3/3	3/3
MT	*Mycobacterium tuberculosis*	3.03E+06 CFU/mL	3/3	3/3	3/3
PJ	*P. jiroveci-S. cerevisiae*	1.30E+07 CFU/mL	3/3	3/3	3/3
SA	*Staphylococcus aureus* subsp. *aureus*	2.60E+08 CFU/mL	3/3	3/3	3/3
SE	*Staphylococcus epidermidis*	9.00E+07 CFU/mL	3/3	3/3	3/3
CX	*Corynebacterium xerosis*	2.30E+07 CFU/mL	3/3	3/3	3/3
EC	*Escherichia coli*	1.79E+08 CFU/mL	3/3	3/3	3/3
LA	*Lactobacillus acidophilus*	1.21E+07 CFU/mL	3/3	3/3	3/3
MC	*Moraxella catarrhalis*	2.50E+08 CFU/mL	3/3	3/3	3/3
NM	*Neisseria meningitidis*	3.43E+06 CFU/mL	3/3	3/3	3/3
NE	*Neisseria elongata*	2.68E+08 CFU/mL	3/3	3/3	3/3
PA	*Pseudomonas aeruginosa*	3.45E+08 CFU/mL	3/3	3/3	3/3
SS	*Streptococcus salivarius*	1.01E+06 CFU/mL	3/3	3/3	3/3
ME	Measles	8.48E+05 $TCID_{50}$/mL	3/3	3/3	3/3
MU	Mumps	8.48E+05 $TCID_{50}$/mL	3/3	3/3	3/3
EBV	Epstein Barr Virus	1.83E+06 CP/mL	3/3	3/3	3/3
CMV	Cytomegalovirus	7.05E+04 $TCID_{50}$/mL	3/3	3/3	3/3
PNW	Pooled Negative Nasal Wash	N/A	3/3	3/3	3/3

• **Endogenous/Exogenous Interfering Substances**

The BinaxNOW COVID-19/Flu A&B Combo Self Test was evaluated for performance in the presence of potentially interfering substances that might be present in a respiratory specimen. The positive (3x LoD co-spike PNW with UV inactivated SARS-CoV-2, and live Influenza A and B) and negative specimens were tested with the addition of the potentially interfering substances. Each substance was tested in replicates of three (3). The performance of the BinaxNOW COVID-19/Flu A&B Combo Self Test was not affected by any of the potentially interfering substances listed in the table below at the concentrations noted.

With the exception of FluMist Quadrivalent Live intranasal influenza virus vaccine, none of the substances caused a false-positive test result in unspiked samples. While the presence of FluMist Quadrivalent Live intranasal influenza virus vaccine at 15%, 6%, and 3% v/v concentration did not interfere with the detection of true positive results of the 3x LoD co-spiked samples, the vaccine resulted in false positive results for Flu A and Flu B (as expected based on the composition of the vaccine). Hand soap liquid gel at 10%, 1%, and 0.1% w/v showed false negative results for Flu B, but detected all analytes at 0.05% w/v.

Interfering Substance	Concentration	Cross-Reactivity (no analyte) (#pos/ #total)			Interference (3x co-spiked analyte LoD) (#pos/ #total)		
		SARS-CoV-2	Flu A	Flu B	SARS-CoV-2	Flu A	Flu B
Human Whole Blood (EDTA tube)	4% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Leukocytes	2.85 x 10^6 cells/mL	0/3	0/3	0/3	3/3	3/3	3/3
Throat lozenges (Menthol/Benzocaine)	3.0 mg/mL	0/3	0/3	0/3	3/3	3/3	3/3
Mucin (bovine submaxillary glands Type I-S)	2.5 mg/mL	0/3	0/3	0/3	3/3	3/3	3/3
Naso GEL (NeilMed)	5% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Nasal gel (Zicam (Galphimia glauca, Histanium hydrocloricum, Luffa operculate, Sulfur))	1.25% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Nasal Drops (Phenylephrine)	15% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Nasal Spray (Oxymetazoline)	15% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Nasal Spray (Cromolyn)	15% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Nasal spray (Saline)	15% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Zicam Nasal spray (Galphimia glauca, luffa operculate)	15% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Nasal spray (Alkalol)	15% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Homeopathic allergy relief (Histaminum hydrochloricum)	15% v/v	0/3	0/3	0/3	3/3	3/3	3/3
TheraZinc Throat Spray (Zinc)	15% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Sore Throat Spray (Phenol)	15% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Antibiotic (Tobramycin)	4 µg/mL	0/3	0/3	0/3	3/3	3/3	3/3
Antibiotic, nasal ointment (Mupirocin)	10 mg/mL	0/3	0/3	0/3	3/3	3/3	3/3
Nasal corticosteroid (Fluticasone)	15% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Nasal corticosteroid (Triamcinolone)	15% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Nasal corticosteroid (Dexamethasone)	1mg/mL	0/3	0/3	0/3	3/3	3/3	3/3
Tamiflu (Oseltamivir Phosphate)	5 mg/mL	0/3	0/3	0/3	3/3	3/3	3/3
FluMist/FluMist Quadrivalent Live intranasal influenza virus vaccine	15% v/v	0/3	3/3	3/3	3/3	3/3	3/3
	6% v/v	0/3	3/3	3/3	3/3	3/3	3/3
	3% v/v	0/3	3/3	3/3	3/3	3/3	3/3
	1.5% v/v	0/3	0/3	0/3	NA	NA	NA
Zanamivir	282 ng/mL	0/3	0/3	0/3	3/3	3/3	3/3
Remdesivir	10 mg/mL	0/3	0/3	0/3	3/3	3/3	3/3
Biotin	3,500 ng/mL	0/3	0/3	0/3	3/3	3/3	3/3
Body and Hand Lotion	0.5% w/v	0/3	0/3	0/3	3/3	3/3	3/3
Body Lotion with 1.2% dimethicone	0.5% w/v	0/3	0/3	0/3	3/3	3/3	3/3
Hand Lotion	5% w/v	0/3	0/3	0/3	3/3	3/3	3/3
Hand Sanitizer with Aloe, 62% ethyl alcohol	5% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Hand Sanitizer with cream lotion	15% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Hand Sanitizer, 80% ethanol, fast drying	15% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Hand soap liquid gel	10% w/v	0/3	0/3	0/3	3/3	3/3	0/3
	1% w/v	NA	NA	NA	3/3	3/3	0/3
	0.1% w/v	NA	NA	NA	3/3	3/3	0/3
	0.05% w/v	NA	NA	NA	3/3	3/3	3/3

• **Precision Studies:**

The lot-to-lot precision of the BinaxNOW COVID-19/Flu A&B Combo Self Test was evaluated by using three (3) production lots.

For Study 1, a series of contrived samples were prepared as negative, low positive SARS-CoV-2 (2x LoD), low positive of Influenza A (2x LoD), low positive of Influenza B (2x LoD), SARS-CoV-2 and Influenza A (2x co-spike LoD), SARS-CoV-2 and Influenza B (2x co-spike LoD), Influenza A and B (2x co-spike LoD) and SARS-CoV-2, Influenza A and Influenza B (2x co-spike LoD) using UV inactivated SARS-CoV-2, live influenza A and live influenza B isolates. Each blinded and randomized sample was tested on each device lot (total 3 lots) for each operator (two (2) operators) in in two (2) runs per day over ten (10) days. The precision testing demonstrated there was no difference in results lot-to-lot and between operators.

Study 1 Summary Results for Lot-to-Lot Precision Study (Operators Combined)

Sample	N	Lot 1		Lot 2		Lot 3		Total % Agreement	95% CI
		Count*	% Agreement	Count*	% Agreement	Count*	% Agreement		
Negative	240	80/80	100%	80/80	100%	80/80	100%	100%	96.9-100%
2x LoD SARS-CoV-2	240	80/80	100%	80/80	100%	80/80	100%	100%	96.9-100%
2x LoD Flu A	240	80/80	100%	80/80	100%	80/80	100%	100%	96.9-100%
2x LoD Flu B	240	80/80	100%	80/80	100%	80/80	100%	100%	96.9-100%
2x LoD SARS-CoV-2 & Flu A	240	80/80	100%	80/80	100%	80/80	100%	100%	96.9-100%
2x LoD SARS-CoV-2 & Flu B	240	80/80	100%	80/80	100%	80/80	100%	100%	96.9-100%
2x LoD Flu A & Flu B	240	80/80	100%	80/80	100%	80/80	100%	100%	96.9-100%
2x LoD SARS-CoV-2 & Flu A & Flu B	240	80/80	100%	80/80	100%	80/80	100%	100%	96.9-100%

Study 2 was specifically conducted to further evaluate potential differences between lots. The study used negative samples (without the virus analyte) and very low positive samples at 0.75x LoD, commonly referred to as a high negative sample. Samples were prepared near the C95 concentration for all three analytes and were randomized and blinded. This supplemental precision testing was carried out over 3 days only, but otherwise followed the same study design as above. This resulted in 72 total tests per analyte and sample level (24 replicates for each analyte with each lot). Data from this testing are integrated into Table below. The random errors of the testing procedure across different days and runs, paired with an operator's ability to read the line intensity for samples with very low analyte concentration (commonly referred to as 'high negative samples') is expected to confound lot-specific variability and to have a significant impact on the precision estimates for high negative samples such as the 0.75x LoD sample tested in this second part of the precision assessment. Taken together, the results of both precision assessments demonstrate a test precision and a lot-to-lot precision that are consistent with the expectations for the analyte concentration in the samples, the test's technology, and the test's LoD. The between-lot variability does not impact low concentrated samples equal to or above 2 x LoD of the test.

Study 2 Summary Results for Lot-to-Lot Precision Study (Operators Combined)

Sample	N	Lot 1		Lot 2		Lot 3		Total % Agreement	95% CI
		Count*	% Agreement	Count*	% Agreement	Count*	% Agreement		
Negative	72	24/24	100%	24/24	100%	24/24	100%	100%	94.39-100%
0.75x LoD SARS-CoV-2 & Flu B	72**	18/24	75%	14/24	58.3%	17/24	70.8%	68.1%	56.6-77.7%
	72***	19/24	79.2%	13/24	54.2%	18/24	75.2%	69.4%	58.0-78.9%
0.75x LoD Flu A	72	15/24	62.5%	23/24	95.8%	17/24	70.8%	76.4%	65.4-84.7%

** SARS-CoV-2 Result

*** Flu B Result

12. CLINICAL EVALUATION

A prospective clinical study was completed at six (6) sites in the United States for clinical validation of the BinaxNOW COVID-19/Flu A&B Combo Self Test for the detection of SARS-CoV-2, Influenza A and/or Influenza B in subject-collected anterior nasal swab (ANS) samples. The study evaluated the BinaxNOW COVID-19/Flu A&B Combo Self Test performance in symptomatic individuals (those suspected of COVID-19, Influenza A and/or Influenza B) with symptoms up to four (4) days after symptom onset. A total of 890 symptomatic subjects were enrolled who were currently experiencing symptoms associated with COVID-19, Influenza A and/or Influenza B. Each enrolled subject either self-collected one sample from their anterior nasal passages (from both nostrils), or had one sample collected from him/her by another individual. Each of the subjects also had an ANS sample (from both nostrils) collected from him/her by one of the study personnel. Test results from the BinaxNOW COVID-19/Flu A&B Combo Self Test were compared to highly sensitive molecular FDA cleared SARS-CoV-2, Influenza A, and Influenza B RT-PCR assays. Out of 794 enrolled subjects, there were 788 evaluable subjects. Of the 788 evaluable subjects for SARS-CoV-2, the analysis resulted in a positive percent agreement (PPA) of 90.6% (95% CI: 84.3%-94.6%) and negative percent agreement (NPA) of 99.4% (95% CI: 98.5%-99.8%). There were 788 evaluable subjects for Influenza A, the analysis resulted in a PPA of 89.7 % (95% CI: 79.2%-95.2%) and a NPA of 98.8% (95% CI:97.7%-99.4%). There were 788 evaluable subjects for Influenza B, the analysis resulted in a PPA of 86.0% (95% CI: 72.7%-93.4%) and a NPA of 99.7% (95% CI: 99.0%-99.9%).

SARS-CoV-2 Primary Analysis

SARS-CoV-2	Comparator Positives	Comparator Negatives	Total
BinaxNOW COVID-19/Flu A&B Combo Self Test Positives	116	4	**120**
BinaxNOW COVID-19/Flu A&B Combo Self Test Negatives	12	656	**668**
Total	**128**	**660**	**788**
Positive Percent Agreement = (116/128) = 90.6% (95% CI: 84.3% - 94.6%)			
Negative Percent Agreement = (656/660) = 99.4% (95% CI: 98.5% - 99.8%)			

Positive Results Broken Down by Days Since Symptom Onset for SARS-CoV-2

Days post Symptoms Onset	Number of Subject samples tested	BinaxNOW™ COVID-19/Flu A&B Positives	Comparator Positives	% Positive Rate (by Comparator)	PPA
0	19	0	0	0.0%	NA
1	180	27	31	17.2%	87.1%
2	274	39	45	16.4%	86.7%
3	185	32	33	17.8%	97.0%
4	130	18	19	14.6%	94.7%
Total	**788**	**116***	**128**	**16.2%**	**90.6% (81.4%-92.3%)**

**NOTE:* *Four false positive subjects were excluded from the BinaxNOW COVID-19/Flu A&B Combo Self Test Positives count for the purposes of this table.*

Influenza A Primary Analysis

Influenza A	Comparator Positives	Comparator Negatives	Total
BinaxNOW COVID-19/Flu A&B Combo Self Test Positives	52	9	61
BinaxNOW COVID-19/Flu A&B Combo Self Test Negatives	6	721	727
Total	**58**	**730**	**788**
Positive Percent Agreement = (52/58) = 89.7% (95% CI: 79.2% - 95.2%)			
Negative Percent Agreement = (721/730) = 98.8% (95% CI: 97.7% - 99.4%)			

Influenza B Primary Analysis

Influenza B	Comparator Positives	Comparator Negatives	Total
BinaxNOW COVID-19/Flu A&B Combo Self Test Positives	37	2	39
BinaxNOW COVID-19/Flu A&B Combo Self Test Negatives	6	743	749
Total	**43**	**745**	**788**
Positive Percent Agreement = (37/43) = 86.0% (95% CI: 72.7% - 93.4%)			
Negative Percent Agreement = (743/745) = 99.7% (95% CI: 99.0% - 99.9%)			

Subjects Demographics

	Subjects (by lay-user collection and testing) (N=111)	Self-collecting and testing (N=677)	Overall (N=788)
Mean (SD)	11.1 (12.1)	38.4 (16.3)	34.4 (18.4)
Median [Min, Max]	9 [2, 74]	36 [14, 80]	32 [2, 80]
Age Group			
≥2-<14 years of age	104 (93.7%)	0 (0.0%)	104 (13.2%)
14-24 years of age	2 (1.8%)	176 (26.0%)	178 (22.6%)
>24-64 years of age	1 (0.9%)	445 (65.7%)	446 (56.6%)
≥65 years of age	4 (3.6%)	56 (8.3%)	60 (7.6%)
Sex at Birth			
Female	48 (43.2%)	414 (61.2%)	462 (58.6%)
Male	63 (56.8%)	263 (38.8%)	326 (41.4%)
Ethnicity			
Hispanic/Latino	5 (4.5%)	109 (16.1%)	114 (14.5%)
Not Hispanic/Latino	106 (95.5%)	568 (83.9%)	674 (85.5%)
Race			
American Indian or Alaskan Native	0 (0.0%)	0 (0.0%)	0 (0.0%)
Asian	0 (0.0%)	11 (1.6%)	11 (1.4%)
Black or African American	4 (3.6%)	54 (8.0%)	58 (7.4%)
Native Hawaiian/Pacific Islander	0 (0.0%)	5 (0.7%)	5 (0.6%)
White	100 (90.1%)	596 (88.0%)	696 (88.3%)
Unknown/Prefer not to answer	0 (0.0%)	2 (0.3%)	2 (0.3%)
Other (Mixed race/biracial)	7 (6.3%)	9 (1.3%)	16 (2.0%)

13. CUSTOMER SUPPORT

For questions, or to report a problem, please call Technical Support at 1-855-513-8348 (Mon. to Sun.: 8:00 am to 8:00 pm EST) or ts.scr@abbott.com.

Test system problems may also be reported to the FDA using the MedWatch reporting system (phone: 1-800 FDA-1088; fax: 1-800 FDA-1078: or http://www.fda.gov/medwatch).

14. SYMBOLS USED on the PRODUCT LABELS

The table below describes the symbols on the BinaxNOW COVID-19/Flu A&B Combo Self Test package.

	Use-by date		Storage temperature range
REF	Catalogue number		Do not use if seal or packaging is broken or damaged
Σ N	Contains sufficient for <n> test	IVD	*In vitro* Diagnostic
	Caution		Distributor
LOT	Batch code		Do not reuse
	Consult Instructions For Use		Date of manufacture

Abbott

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Product of South Korea
www.globalpointofcare.abbott

ISC03409 Rev. 02 2025/01

Abbott
BinaxNOW
COVID-19/Flu A&B Combo
Self Test

HCP IFU - EN

Size:
8.5 in x 11 in

Printed Colors

CMYK

Incoming Inspection Colors

PMS 2995 U
Primary Blue

PMS 1505 U
Orange

PMS 303 U
Dark Blue

Black

PN: ISC03409
Rev: 02
Designer: Cary Morgan

Date of Last Revision:
02.2 2025/01/23