Instructions for Use
CareSuperb™ COVID-19/Flu A&B Antigen Combo Home Test

AccessBio

REF RCUM-00171 RCUM-00271 RCUM-00571 RCUM-02071

English

Scan the QR code for video instructions to access a step-by-step guide on how to use this product.

<QR CODE>

For *in vitro* diagnostic use
Over-the-Counter (OTC)

A rapid test for the detection and differentiation of SARS-CoV-2 nucleocapsid antigens and Influenza A and B nucleoprotein antigens in anterior nasal swab specimens.

Intended Use

The CareSuperb™ COVID-19/Flu A&B Antigen Combo Home 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 antigens 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 for appropriate follow-up.

Summary and Explanation

COVID-19, Flu A, and Flu B are contagious respiratory infections that can present similar symptoms such as fever, cough, sore throat, and tiredness. Because these illnesses can feel alike, rapid identification of the specific infection can support timely decisions about isolation, supportive care, and, where appropriate, antiviral treatment.

The CareSuperb™ COVID-19/Flu A&B Antigen Combo Home Test is a rapid immunochromatographic assay that qualitatively detects nucleocapsid protein antigens from SARS-CoV-2, influenza A, and influenza B viruses in self-collected nasal swab specimens. The test is designed for home use by individuals 14 years or older, or with adult assistance for children ages 2 years and older.

Results are available within 15 minutes. Negative results do not rule out infection and should be considered in the context of clinical signs, symptoms, and recent exposures. Confirmatory testing with molecular methods may be necessary, especially in cases of ongoing symptoms or when clinical management requires it.

Kit Components

Component Name	Quantity (in a kit)				Description
	Product Reference No. (REF)				
	RCUM-00171	RCUM-00271	RCUM-00571	RCUM-02071	
Test Device	1	2	5	20	Individually foil pouched test cassette
Dropper Vial	1	2	5	20	The vial containing extraction reagent
Nasal Swab	1	2	5	20	Sterile swab for anterior nasal specimen collection
Quick Reference Instructions (QRI)	1				Paper-printed instruction

Materials required but not provided: Timer or watch

Principles of the Test

The CareSuperb™ COVID-19/Flu A&B Antigen Combo Home Test is an *in vitro* diagnostic immunochromatographic assay that utilizes lateral flow technology designed to detect and differentiate SARS-CoV-2 nucleocapsid antigen and Influenza A and B nucleoprotein antigens in anterior nasal swab specimens.

To initiate the CareSuperb™ COVID-19/Flu A&B Antigen Combo Home Test, a nasal swab provided in the test kit is used to collect a sample specimen from a patient's anterior nostril. The swab is then inserted into the sample port of the test cassette and the extraction reagent in the dropper vial is added to the sample port for the sample extraction to occur exposing the viral antigens. The viral antigens present in the sample bind to their respective labeled antibodies dispensed in the conjugate wick filter. These antigen-antibody complexes migrate to the test strip encased in a plastic cassette and across the membrane through capillary action. The complex is captured at the defined lines (SARS-CoV-2 test line, "C19"), streptavidin (Influenza A test line, "A"), anti-Influenza B antibody (Influenza B test line, "B"), and anti-chicken IgY antibody (control line, " Cont"), causing a colored line to appear on the membrane. The complexes are interpreted visually between 10 to 15 minutes based on the presence or absence of the test line.

Warnings and Precautions

- **Do not use this test when you have symptoms greater for 4 days or more, or if you have no symptoms.**
- Read all the instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.
- This test is read visually. Individuals with impaired vision or color-impaired vision should ensure help in interpretation of their test results.
- Testing should be performed in an area with good lighting.
- Taking biotin supplements may negatively affect the performance of this test. If you are taking biotin supplements and test negative, you should follow up with your physician.
- Keep the test cassette on a flat surface during the testing.
- Use the test components immediately once opened. Test components are single use. Do not re-use.
- Do not use if any of the test kit contents or packaging is damaged or open.
- When collecting a nasal swab sample, use ONLY the nasal swab provided in the kit.
- Keep foreign substances and household cleaning products away from the test during

the testing process. Contact with foreign substances and household cleaning products may result in incorrect test results.

- Do not use this test for individuals who recently received nasally administered influenza A or influenza B vaccine, as they may have false positive test results after vaccination.
- Do not conduct this test if prone to nose bleeds or have a nose injury.
- Remove any piercings from nose before starting the test.
- In case of spillage, ensure it is cleaned thoroughly with a suitable disinfectant.
- Keep testing kit and kit components away from children and pets before and after use.
- Avoid contact with your skin or eyes. Do not ingest any kit components. The reagent solution contains harmful chemicals (see table below). If the solution contacts your skin or eyes, flush with large amounts of water. If irritation persists, seek medical advice: https://www.poisonhelp.org or 1-800-222-1222.

Chemical Name / Concentration	GHS Code / Harm
Triton x-100 / 1.0% Trizma base / 1.2% Sodium chloride / 2.9%	H315/ Skin irritation
	H320/ Eye irritation

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

Storage and Handling

- Store kit at 35.6 - 86°F (2-30°C).
- The expiration date is on the package. Do not use kit past its expiration date.
- The test cassette must remain in the sealed foil pouch until use. Once the pouch has been opened, it should be used immediately.
- Operate your test in an ambient temperature of 59°F to 86°F (15-30°C).

Quality Control

The CareSuperb™ COVID-19/Flu A&B Antigen Combo Home Test contains a built-in internal procedural control that is included in the test cassette. A purple-colored line appearing in the control region “Cont” is designed as an internal procedural control. The appearance of the procedural control line indicates that sufficient flow has occurred, and functional integrity of the test cassette has been maintained. If the procedural control line does not develop in 10 minutes, the test result is considered invalid and retesting with a new device is recommended.

Test Procedure

Part A. Prepare for the Test

1. Wash your hands with soap and water for at least 20 seconds and dry them thoroughly or use hand sanitizer.

2. Open your test kit and locate the kit components from the box.

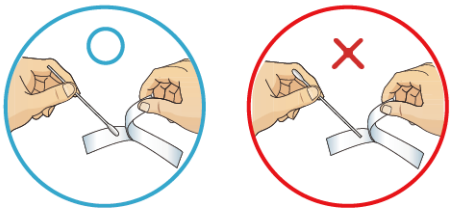
Test Device (Test Cassette in pouch) | Anterior Nasal Swab | Dropper Vial

3. Open the pouch and remove the test device from the foil pouch. Place the test device on a flat surface.

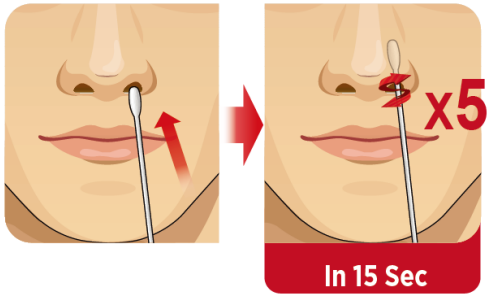
Part B. Collect Nasal Sample

4. Remove a swab from the wrapper.

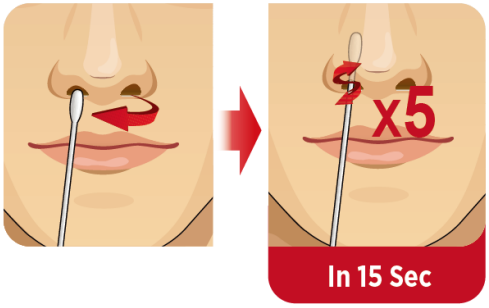
IMPORTANT Be careful not to touch the swab tip.



5. Gently insert the swab no more than ¾ inch into the **LEFT** nostril. Then, slowly rotate the swab at least 5 times in a circular path for a total of 15 seconds.



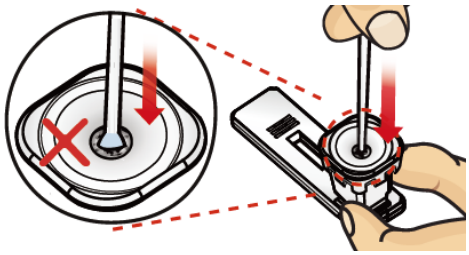
6. Gently remove the swab from the **LEFT** nostril and place it directly into **RIGHT** nostril, repeating the process of rotating at least 5 times in a circular path for a total of 15 seconds. Remove the swab from the **RIGHT** nostril.
Note: If you are swabbing others, please wear a face mask. With children, the maximum depth of insertion into the nostril may be less than ½ to ¾ of an inch, and you may require another adult to hold the child's head while swabbing.



Part C. Perform the Test

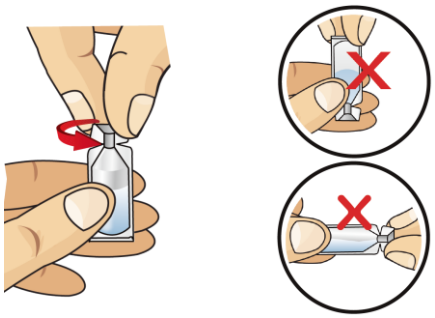
7. Insert the collected swab into the device port and gently push the swab through the sealed silver foil sheet. Continue to gently push until the swab tip is **FULLY NOT VISIBLE**, ensuring it is completely below the device port.

IMPORTANT Insert the swab into the device port before using the dropper bottle and keep the swab in the device port until further instructions.



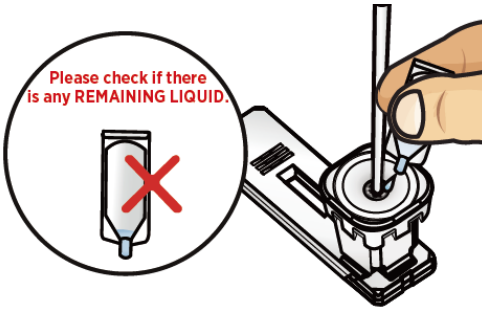
8. Remove the dropper bottle cap by twisting off.

IMPORTANT Do not use mouth or teeth to open the bottle.



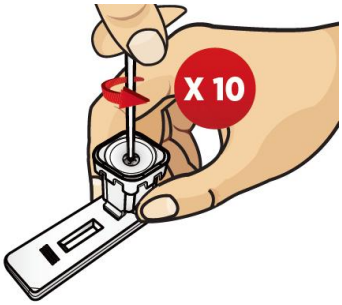
9. Add the ENTIRE VOLUME of the liquid into the sample port.

IMPORTANT Do not put the liquid in your eyes. Invalid or inaccurate results may occur if the entire volume is not added to the sample port. Make sure not to spill the liquid outside the sample port.



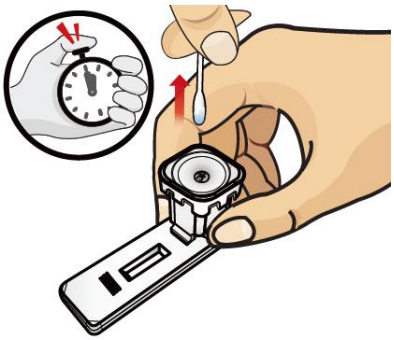
10. Rotate the swab **10 times.**

IMPORTANT Do not lift the swab until you fully complete 10 rotations.



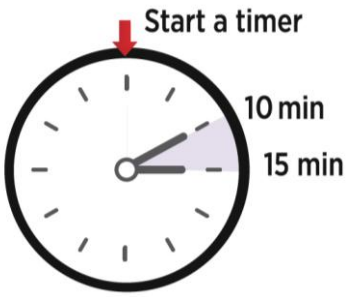
11. Remove the swab **immediately** from the sample port after rotating the swab.

IMPORTANT False negative results may occur if the order of testing procedures is not correctly followed.



12. Start a timer and read the result at **10 minutes**. The test result should not be read after **15 minutes.**

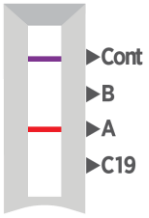
IMPORTANT Do not move or lift the test cassette. Results should not be read before 10 minutes or after 15 minutes.



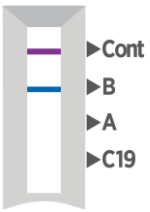
Part D. Interpretation of Results

⊕ Positive Result

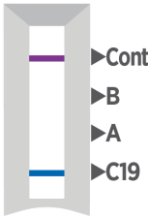
Influenza A Positive
One purple-colored line next to "Cont" and one red-colored line next to "A" indicates Influenza A positive result
(Influenza A antigen detected)



Influenza B Positive
One purple-colored line next to "Cont" and one blue-colored line next to "B" indicates Influenza B positive result
(Influenza B antigen detected)



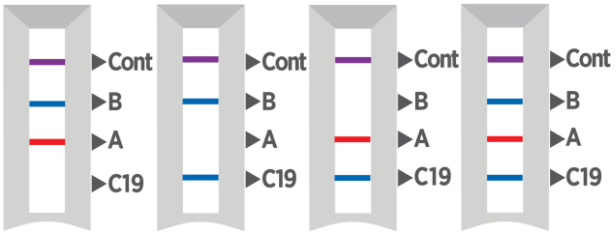
COVID-19 Positive
One purple-colored line next to "Cont" and one blue-colored line next to "C19" indicates COVID-19 positive result
(COVID-19 antigen detected)



Look very closely! The color intensity in the test region will vary. Any faint colored line in the test region should be considered as positive.

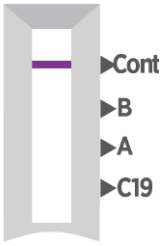
⊕ Coinfection Positive Result

Any lines next to "A", "B", and/or "C19" with a control line next to "Cont" indicate Influenza A, B, and/or COVID-19 positive results. (Influenza A, B, and/or COVID-19 antigen detected)



Negative Result

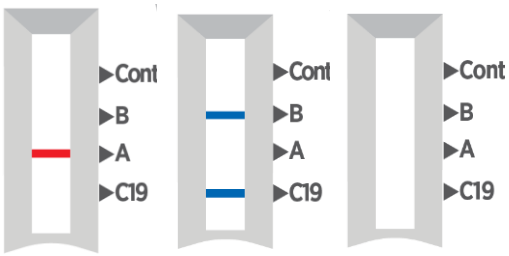
One purple-colored line ONLY next to “Cont” indicates a negative result, with no test line next to “A”, “B”, and “C19”. This means Influenza A, B, and COVID-19 antigen has not been detected.



Negative results are presumptive and may need to be confirmed with a molecular assay

Invalid Result

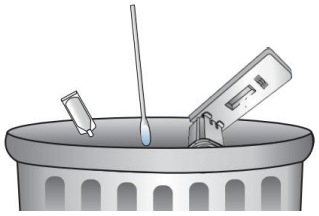
No purple-colored line next to “Cont” indicates an invalid result. A new test is needed to get a valid result. **Repeat the test with a new sample and new test kit materials.**



A control line next to “Cont” may appear in the result window in a few minutes but a test line may take as long as 10 minutes to appear. Incorrect results may occur if the test result is read before 10 minutes or after 15 minutes.

Part E. Disposal

Dispose of all used test kit components and sample swabs in household trash.



Understanding Your Results

Invalid Result: The test could not tell whether or not you have COVID-19, influenza A (Flu A), or influenza B (Flu B). The test needs to be repeated with a new kit and sample.

Negative Result: The virus from COVID-19, Flu A, and/or Flu B were not detected in the sample. A negative result does not mean it is certain that you do not have COVID-19, Flu A and/or Flu B 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 seek follow-up care with your healthcare provider.

All negative results should be treated as presumptive and confirmation with a molecular assay may be necessary. Negative results do not rule out SARS-CoV-2, Flu A, and/or Flu B infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions.

Positive Result: The SARS-CoV-2, Flu A and/or Flu B virus(es) were detected in your sample. It is very likely that you have the respective infection(s) and are contagious. Please contact your healthcare provider or your local health authorities and follow local guidelines for self-isolation. There is a small chance that this test can give you a positive result that is incorrect (a false positive).

Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.

Results Reporting

Report your test result(s) at https://learn.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.

Limitations

- The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between November 2023 and March 2025. The clinical performance has not been established for all circulating variants but is anticipated to be reflective of the prevalence variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.
- 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.
- No pharmacokinetic studies are available to demonstrate that biotin may be secreted in respiratory samples after ingestion of high-dose biotin supplements however, studies have shown that false negative results occur when this test is exposed to concentrations of biotin exceeding 2,500 ng/mL. Therefore, false negative results may occur in users who have indicated or whose clinical status or history would indicate they are currently taking high doses of biotin (>10 mg per day).
- False negative results are more likely after 4 days or more of symptoms.
- A negative test result may occur if the target antigen concentration in the sample is below the detection limit of the test or if the samples is collected or handled improperly.
- False positive test results are more likely when the prevalence of SARS-CoV-2, influenza A, and/or influenza B is low in the community.
- Viral Transport Media (VTM) should not be used with this test.
- This test does not distinguish between SARS-CoV and SARS-CoV-2.
- Persons with risk factors for severe disease from respiratory pathogens (e.g., chronic lung or heart disease, compromised immune system, diabetes, and other conditions) should contact a healthcare provider.
- 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 a 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 and may or may not correlate with viral culture results performed on the sample.
- This test was not evaluated for use with the FluMist ® vaccine. Individuals who recently received nasally administered influenza A or influenza B vaccine may have false positive test results after vaccination.

Performance Characteristics

1. Limit of Detection (LoD)

The sensitivity of the CareSuperb™ COVID-19/Flu A&B Antigen Combo Home Test was established by evaluating different concentrations of 2 strains of inactivated SARS-CoV-2 and multiple strains of live influenza A and influenza B. The viruses were diluted in pooled negative swab matrix (PNSM) to generate virus dilutions for testing. The lowest detectable concentration that generated ≥95% positive detection rate was determined as the LoD through serial dilution and confirmed with repeated testing.

Virus Strain	LoD	
	Titer Unit/mL	Titer Unit/Swab
SARS-Related Coronavirus 2, Isolate USA-WA1/2020	2.63×10^2 $TCID_{50}$/mL	1.32×10^1 $TCID_{50}$/Swab
SARS-Related Coronavirus 2, Isolate hCoV-19/USA/GA-EHC-2811C/2021 (Lineage B.1.1.529; Omicron Variant)	1.5×10^2 $TCID_{50}$/mL	7.50×10^0 $TCID_{50}$/Swab
A/Brisbane/59/2007 (H1N1)	1.6×10^7 $CEID_{50}$/mL	8.00×10^5 $CEID_{50}$/Swab
A/Hawaii/66/2019 (H1N1) pdm09	7.4×10^6 $CEID_{50}$/mL	3.70×10^5 $CEID_{50}$/Swab
A/Indiana/02/2020 (H1N1) pdm09	9.7×10^5 $CEID_{50}$/mL	4.85×10^4 $CEID_{50}$/Swab
A/California/55/2020 (H3N2)	1.17×10^5 FFU/mL	5.83×10^3 FFU/Swab
A/Delaware/01/2021 (H3N2)	3.1×10^4 FFU/mL	1.55×10^3 FFU/Swab
B/New Hampshire/01/2021 (Victoria Lineage)	4.33×10^2 $TCID_{50}$/mL	2.17×10^1 $TCID_{50}$/Swab
B/Michigan/01/2021 (Victoria Lineage)	1.90×10^3 $TCID_{50}$/mL	9.50×10^1 $TCID_{50}$/Swab
B/Oklahoma/10/2018 (NA D197N (Yamagata Lineage)	7.6×10^4 $TCID_{50}$/mL	3.80×10^3 $TCID_{50}$/Swab
B/Indiana/17/2017 (NA I221T) (Yamagata Lineage)	3.33×10^4 $TCID_{50}$/mL	1.67×10^3 $TCID_{50}$/Swab

2. WHO Standard Sensitivity

The detection limit was evaluated using the WHO International Standard for SARS-CoV-2 antigen. It was able to detect the virus at low international reference concentrations.

Analyte	LoD	
	Titer Unit/mL	Titer Unit/Swab
WHO Standard (NIBSC 21/368)	160	8

3. High-dose Hook Effect

High concentrations of each virus (SARS-CoV-2, Influenza A, and Influenza B) were tested to determine whether excess antigen would cause false negative results (hook effect). No high hook effect was observed.

Virus Strain	Testing Concentration (Titer Unit/mL)	Result Agreement
USA-WA1/2020	3.95×10^5 $TCID_{50}$/mL	100%
SARS-Related Coronavirus 2, Isolate hCoV-19/USA/GA-EHC-2811C/2021 (Lineage B.1.1.529; Omicron Variant)	7.50×10^5 $TCID_{50}$/mL	100%
A/Indiana/02/2020 (H1N1) pdm09	4.85×10^8 $CEID_{50}$/mL	100%
A/Delaware/01/2021 (H3N2)	1.55×10^7 FFU/mL	100%
B/New Hampshire/01/2021 (Victoria Lineage)	6.50×10^5 $TCID_{50}$/mL	100%
B/Indiana/17/2017 (NA I221T) (Yamagata lineage)	5.00×10^7 $TCID_{50}$/mL	100%

4. Competitive Interference

This study evaluated whether a high amount of one virus could interfere with the detection of the others. Various combinations of high and low virus concentrations were tested. The test consistently detected all low-level viruses, even when others were present in excess, showing no competitive interference between analytes.

5. Precision

A precision study was evaluated in two different studies conducted at single internal site each using three (3) lots of test kits and two (2) operators.

Study 1 was conducted using test samples prepared at three (3) different concentrations of heat inactivated SARS-CoV-2 B.1.1.529, live Flu A: H1N1pdm09/A/Indiana/02/2020, and live Flu B: Victoria/New Hampshire /01/2021 spiked into pooled negative swab matrix (PNSM) to prepare the following test sample panel members: a negative sample, low positive sample (1x co-spike LoD of each analyte), and moderate positive samples (3x co-spike LoD of each analyte). Samples were blinded and randomized before allotting them to the operators. 50µL of each sample was applied to dry nasal swabs and processed per the IFU of the candidate device. All panel members were tested in triplicate with 3 device lots, each in 2 runs per day for each of 2 operators, and the study was conducted for 10 days (i.e., 1 site x 3 lots x 2 operators x 2 runs per day with 3 replicates each x 10 days). 360 results were obtained for each panel member. All replicates prepared at 1xLoD and 3xLoD, demonstrated above 95% agreement across the operators, lots, days and runs test.

Study 2 was performed using a negative sample without any of the analytes, and low positive samples prepared at the 0.75x LoD for each analyte to demonstrate potential lot variability. Two operators tested the samples above in a randomized and blinded manner each using three different lots in a total of 2 runs/operators and across 3 non-consecutive days (i.e., 3 replicates × 2 runs/day × 3 days × 2 operators = 36 sample replicates/lot). The precision of the test was assessed by repeating tests over multiple days, by different users, and across three product lots.

Summary data are shown in the table below.

Sample	Analyte	# of Positive / # of Replicates (Result Agreement (%))			% Positive	95% CI
		Lot 1	Lot 2	Lot 3		
Negative	NSM	0/156	0/156	0/156	0	97.6-100%
0.75X LoD	SARS-CoV-2	32/36	29/36	31/36	85.2	77.2-90.1%
	Flu A	32/36	31/36	33/36	88.9	81.6-93.5%
	Flu B	32/36	32/36	34/36	90.7	83.8-94.9%
1X LoD	SARS-CoV-2	120/120	120/120	117/120	99.2	97.6-99.7%
	Flu A	120/120	120/120	117/120	99.2	97.6-99.7%
	Flu B	120/120	120/120	119/120	99.7	98.4-100%
3X LoD	SARS-CoV-2	120/120	120/120	120/120	100	98.9-100%
	Flu A	120/120	120/120	120/120	100	98.9-100%
	Flu B	120/120	120/120	120/120	100	98.9-100%

6. Inclusivity (Analytical Reactivity)

The analytical reactivity of the test was evaluated using a panel of temporally, geographically, and genetically diverse strains of SARS-CoV-2, Influenza A, and Influenza B. Each strain was spiked into pooled natural clinical anterior nasal swab matrix and tested using 10-fold and subsequent 2-fold serial dilutions. The lowest concentration yielding 5 out of 5 positive results was defined as the detection endpoint for each strain. Results are summarized in the table below.

Virus Strain	Lowest Reactive Concentration (Titer Unit/mL)
SARS-Related Coronavirus 2 (SARS-CoV-2) Lineage BA.2.12.1	6.30×10^2 $TCID_{50}$/mL
SARS-Related Coronavirus 2 (SARS-CoV-2) Lineage BA.2.3	1.17×10^2 $TCID_{50}$/mL
SARS-Related Coronavirus 2 (SARS-CoV-2) Lineage BA.2.75.5	8.50×10^1 $TCID_{50}$/mL
SARS-Related Coronavirus 2 (SARS-CoV-2) Lineage BA.4.6	5.75×10^2 $TCID_{50}$/mL
SARS-Related Coronavirus 2 (SARS-CoV-2) Lineage JN.1.4	2.11×10^2 $TCID_{50}$/mL
A/Wisconsin/588/2019 (H1N1)pdm09	1.40×10^3 FFU/mL
A/Dominican Republic/7293/2013 (H1N1)pdm09	1.25×10^3 $TCID_{50}$/mL
A/Massachusetts/15/2013 (H1N1)pdm09	8.00×10^5 $CEID_{50}$/mL
A/Bangladesh/3002/2015 (H1N1)pdm09	1.3×10^4 $CEID_{50}$/mL
A/Michigan/45/2015 (H1N1)pdm09	7.8×10^2 $TCID_{50}$/mL
A/Iowa/53/2015 (H1N1)pdm09	1.45×10^6 $CEID_{50}$/mL
A/St. Petersburg/61/2015 (H1N1pdm09)	4.65×10^5 $CEID_{50}$/mL
A/Hong Kong/H090-761-V1(0)/2009 (H1N1)pdm09	4.00×10^2 $TCID_{50}$/mL
A/Victoria/4897/2022 (H1N1)pdm09	$1.0 \times 10^{6.5}$ EID_{50}/mL
A/Victoria/2570/2019 (H1N1)pdm09	$1.0 \times 10^{5.3}$ EID_{50}/mL
A/New York/21/2020 (H3N2)	1.30×10^5 FFU/mL
A/Michigan/173/2020 (H3N2)	1.95×10^5 FFU/mL
A/Tasmania/503/2020 (H3N2)	6.50×10^4 FFU/mL
A/Texas/50/2012 (H3N2)	8.75×10^3 $TCID_{50}$/mL
A/Switzerland/9715293/2013 (H3N2)	6.00×10^5 $CEID_{50}$/mL
A/Hong Kong/4801/2014 (H3N2)	9.6×10^5 $CEID_{50}$/mL

Virus Strain	Lowest Reactive Concentration (Titer Unit/mL)
A/Singapore/INFIMH-16-0019/2016 (H3N2)	5.50×10^4 $CEID_{50}$/mL
A/Perth/16/2009 (H3N2)	1.1×10^5 $CEID_{50}$/mL
A/Darwin/9/2021 (H3N2)	$1.0 \times 10^{4.3}$ EID_{50}/mL
A/Georgia/02/2022 (H3N2)	$5.00 \times 10^{5.5}$ EID_{50}/mL
A/bovine/Ohio/B24OSU-439/2024 (H5N1)	3.1×10^2 $TCID_{50}$/mL
B/Texas/43/2019 (Victoria Lineage)	5.0×10^2 $TCID_{50}$/mL
B/Washington/02/2019 (Victoria Lineage)	2.1×10^6 $CEID_{50}$/mL
B/Brisbane/60/2008 (Victoria Lineage)	5×10^3 $CEID_{50}$/mL
B/Austria/1359417/2021 (Victoria Lineage)	$5.00 \times 10^{4.5}$ EID_{50}/mL
B/Netherlands/10894/2022 (Victoria Lineage)	$1.0 \times 10^{4.7}$ EID_{50}/mL
B/Phuket/3073/2013 (Yamagata Lineage)	2.75×10^4 $CEID_{50}$/mL
B/Wisconsin/10/2016 (NA I221V) (Yamagata Lineage)	3.2×10^5 $TCID_{50}$/mL
B/Texas/06/2011 (Yamagata Lineage)	1.6×10^5 $CEID_{50}$/mL
B/Phuket/3073/2013 (Yamagata Lineage)	$1.0 \times 10^{3.8}$ EID_{50}/mL
B/Norway/2134/2019 (Yamagata Lineage)	$2.5 \times 10^{4.5}$ EID_{50}/mL

7. Cross-Reactivity/Microbial Interference

To evaluate the potential for cross-reactivity and microbial interference, 27 microorganisms were tested. These included viruses, bacteria, yeast, and representative nasal flora commonly found in the anterior nasal specimens. Each was evaluated in triplicate both in the absence and presence of the target analytes: SARS-CoV-2 (Omicron, B.1.1.529), Influenza A (H1N1), and Influenza B (Victoria lineage). Analyte negative samples were prepared using pooled natural clinical anterior nasal swab matrix, and analyte positive samples were contrived by spiking all three targets at 3X LoD. No cross-reactivity or interference was observed. All negative samples produced negative results, and all positive samples showed 100% agreement with expected results.

Microorganism/Virus	Testing Concentration
Adenovirus 1	1.58×10^5 $TCID_{50}$/mL
Adenovirus 7	1.6×10^5 $TCID_{50}$/mL
Enterovirus 71, Tainan/4643/1998	1.6×10^6 $TCID_{50}$/mL
Human coronavirus (OC43)	1.4×10^5 $TCID_{50}$/mL
Human coronavirus (229E)	1.4×10^4 $TCID_{50}$/mL
Human coronavirus (NL63)	8.0×10^4 $TCID_{50}$/mL
Human metapneumovirus (hMPV)	2.8×10^5 $TCID_{50}$/mL
MERS-Coronavirus, Irradiated Lysate	1.78×10^5 $TCID_{50}$/mL
Parainfluenza virus type 1	7.4×10^5 $TCID_{50}$/mL
Parainfluenza virus type 2	1.58×10^5 $TCID_{50}$/mL
Parainfluenza virus type 3	1.58×10^5 $TCID_{50}$/mL
Parainfluenza virus type 4	5.0×10^5 $TCID_{50}$/mL
Respiratory syncytial virus Type B	1.58×10^5 $TCID_{50}$/mL
Rhinovirus	1.58×10^5 $TCID_{50}$/mL
SARS-Coronavirus	1.0×10^5 PFU/mL
Human coronavirus HKU1* (clinical specimen)	N/A
Bodetella pertussis	1.0×10^7 CFU/mL
Chlamydophila pneumoniae	1.4×10^6 IFU/mL
Haemophilus influenzae	1.6×10^6 CFU/mL

Microorganism/Virus	Testing Concentration
Legionella pneumophila	1.35 x 10^6 CFU/mL
Mycoplasma pneumoniae	6.5 x 10^5 CFU/mL
Streptococcus pneumoniae	1.0 x 10^7 CFU/mL
Streptococcus pyogenes, Group A	1.0 x 10^7 CFU/mL
Staphylococcus aureus	1.0 x 10^7 CFU/mL
Staphylococcus epidermidis	1.0 x 10^7 CFU/mL
Candida albicans	1.0 x 10^7 CFU/mL
Pooled human nasal wash – representative of normal respiratory microbial flora	N/A

* 10-fold dilution of the stock Human Coronavirus HKU1 (HCoV-HKU1) clinical sample was tested in triplicates in the presence and absence of SARS-CoV-2. The Ct value of the undiluted sample was 11.7.

8. Endogenous/Exogenous Interference Substances

The potential interference of endogenous and exogenous substances was evaluated using 43 compounds commonly found in respiratory specimens. These included over-the-counter nasal sprays, throat lozenges, prescription medications, homeopathic remedies, and biological components such as whole blood, buffy coat, mucin, and leukocytes. Each substance was tested in triplicate both without and with the target analytes present. The analytes tested were SARS-CoV-2 (Omicron, B.1.1.529), Influenza A (H1N1), and Influenza B (Victoria lineage), spiked at 3X LoD. Analyte-negative samples were prepared by mixing each substance with pooled negative nasal swab matrix (NSM), while analyte-positive samples were co-spiked with the analytes and then mixed with the substances. No cross-reactivity or interference was observed. All analytes were detected in the presence of potentially interfering substances, and no false-positive results occurred in their absence.

Substances	Testing Concentration
Acetaminophen	10 mg/mL
Acetyl salicylic acid	15 mg/mL
Beclomethasone	5 mg/mL
Benzocaine	5 mg/mL
Budesonide	2 mg/mL
Chlorpheniramine maleate	5 mg/mL
Dexamethasone	1 mg/mL
Dextromethorphan HBr	2 mg/mL
Diphenhydramine HCl	5 mg/mL
Flunisolide	5 mg/mL
Fluticasone	1 mg/mL
Guaiacol Glyceryl Ether	20 mg/mL
Histamine Dihydrochloride	10 mg/mL
Menthol	10 mg/mL
Mometasone	1 mg/mL
Molnupiravir	1 mg/mL
Mucin (Bovine submaxillary glands -Type I-S)	2.5 mg/mL
Mupirocin	1 mg/mL and 10 mg/mL
Phenylpropanolamine	5 mg/mL
Remdesivir	1 mg/mL
Tamiflu (Oseltamivir Phosphate)	5 mg/mL
Tobramycin	1 mg/mL

Substances	Testing Concentration
Triamcinolone	1 mg/mL
Zanamivir	1 mg/mL
Sore Throat Spray (Phenol)	15 % v/v
Zicam Oral Mist (Zincum aceticum, Zincum gluconicum)	15 % v/v
Nasal Spray (Phenylephrine HCl)	15 % v/v
NasalCrom Nasal Spray (Cromloyn sodium)	15 % v/v
Vicks Sinex Nasal spray (Oxymetazoline HCl)	15 % v/v
Alkalol Allergy Relief (Galphimia glauca, Luffa operculate, Sabadilla)	15 % v/v
Zicam Allergy Relief (Galphimia glauca, Histaminum hydrochloricum, Luffa operculate, Sulphur)	15 % v/v
Hand Sanitizer	15 % v/v
Hand Soap	15 % v/v
Whole blood	2.5 % v/v
Buffy coat	2.5 % v/v
Allergy Spray (Mometasone Furoate)	15 % v/v
Budesonide Nasal Spray (Budesonide/Glucocorticoid)	15 % v/v
Nasacort Allergy 24HR (Triamcinolone acetonide)	15 % v/v
Allergy Relief Nasal Spray (Fluticasone Propionate)	15 % v/v
Saline Nasal Spray (Sodium Chloride & Preservatives)	15 % v/v
Alkalol Saline Nasal Spray (Sodium Chloride, Menthol, Thymol, Camphor, Benzoin Resin Extract, Oils of Eucalyptus, Wintergreen, Spearmint, Fir Needle, Cinnamon & Preservatives)	15 % v/v
Leukocytes	5.0×10^6 cells/mL
Zinc Throat Spray (Thera Zinc Throat Spray)	15 % v/v

9. Biotin Supplement Interfering Effect

A study was performed to evaluate the potential interference of biotin (vitamin B7) on test performance. Biotin concentrations ranging from 0 to 5,000 ng/mL were tested in triplicate using both analyte-negative and analyte-positive samples containing SARS-CoV-2, Influenza A, and Influenza B at 3X LoD. No false-positive results were observed at any concentration. False-negative results for Influenza A occurred at 3,750 ng/mL and 5,000 ng/mL, indicating potential interference at high biotin levels.

10. Clinical Performance

The clinical performance characteristics of the CareSuperb™ COVID-19/Flu A&B Antigen Combo Home Test was evaluated in symptomatic subjects, suspected of respiratory infection at 13 clinical sites across the U.S. between November of 2023 and March of 2025. Two anterior nasal swab specimens were collected in randomized order from each participant: one swab was self-collected and immediately tested with the CareSuperb™ COVID-19/Flu A&B Antigen Combo Home Test in a simulated home-use setting by participants and the other swab sample was collected by healthcare professional for testing using FDA-cleared molecular RT-PCR comparator assays for SARS-CoV-2, and Influenza A and Influenza B. The CareSuperb™ COVID-19/Flu A&B Antigen Combo Home Test demonstrated the following clinical agreement with the molecular comparator methods.

Subject Demographics

Characteristic	Self-Collecting (N=1447)	Lay-user/ Tester Collection (N=197)	Overall (N=1644)
Age			
Mean (SD)	42.0 (17.2)	7.6 (3.7)	37.8 (19.8)
Median [Min, Max]	41 [13, 90]	7.5 [2, 17]	37 [2, 90]
Age Group			
2-13	1	192	193
14-24	267	5	272
25-64	1025	0	1025
>64	154	0	154
Sex at Birth			
Female	842	104	946
Male	605	93	698
Ethnicity			
Hispanic or Latino (of any race)	635	74	709
Not Hispanic or Latino	806	116	922
Unknown	6	7	13
Race			
American Indian or Alaskan Native	6	1	7
Asian	91	13	104
Black or African American	208	16	224
Native Hawaiian or Other Pacific Islander	14	2	16
More Than One Race	31	11	42
Prefer Not to Answer	1	0	1
Unknown	16	12	28
White	1080	142	1222

Clinical Performance Compared to SARS-CoV-2 Molecular Assay

CareSuperb™ COVID-19/Flu A&B Antigen Combo Home Test	FDA-cleared Molecular Assay		
	Positive	Negative	Total
Positive	111	6	117
Negative	9	1518	1527
Total	120	1524	1644
Positive Percent Agreement	92.5% (111/120) (95% CI:86.4%-96.0%)		
Negative Percent Agreement	99.6% (1518/1524) (95% CI:99.1%-99.8%)		

SARS-CoV-2 Performance Stratified by Days Post Symptoms Onset (DPSO)

DPSO	# of Subject Samples Tested	CareSuperb™ COVID-19/Flu A&B Antigen Combo Home Test Positives	Comparator Positives	PPA
Day 0	24	N/A	N/A	N/A
Day 1	226	16	18	88.9%
Day 2	567	44	47	93.6%
Day 3	553	35	36	97.2%
Day 4	274	16	19	84.2%
Total	1644	111	120	92.5%

Clinical Performance Compared to Influenza A Molecular Assay

CareSuperb™ COVID-19/Flu A&B Antigen Combo Home Test	Comparator		
	Positive	Negative	Total
Positive	95	15	110
Negative	16	1491	1507
Total	111	1506	1617
Positive Percent Agreement (PPA)	85.6% (95/111) (95% CI:77.9%-90.9%)		
Negative Percent Agreement (NPA)	99.0% (1491/1506) (95% CI:98.4%-99.4%)		

Clinical Performance Compared to Influenza B Molecular Assay

CareSuperb™ COVID-19/Flu A&B Antigen Combo Home Test	Comparator		
	Positive	Negative	Total
Positive	37	5	42
Negative	6	1568	1574
Total	43	1573	1616
Positive Percent Agreement (PPA)	86.0% (37/43) (95% CI:72.7%-93.4%)		
Negative Percent Agreement (NPA)	99.7% (1568/1573) (95% CI:99.3%-99.9%)		

11. Usability Study

A usability study was conducted to evaluate the performance of intended users in conducting the CareSuperb™ COVID-19/Flu A&B Antigen Combo Home Test by assessing the ability of individuals aged 14 and older, as well as adults testing children aged 2 and above, to correctly perform the test and interpret the results in a home setting. Among 1,795 participants representing the lay population, over 98% completed each critical test step correctly, including sample collection, buffer addition, swab handling, timing, and result interpretation. Observer agreement with user-interpreted results was 98.7%. Questionnaire responses indicated that more than 94% of users found the instructions easy to understand and the test simple to perform. The study demonstrated that individuals without training can safely and effectively use the CareSuperb™ COVID-19/Flu A&B Antigen Combo Home Test as intended and the product instruction was found to be clear and accessible across the intended population.

Explanation of Symbols

	Single use		Use by
	Manufacturer		Date of manufacture
LOT	Batch code	REF	Catalogue number
OTC	Over-the-Counter		Temperature limitation
	Contains sufficient for <n> tests		Do not use if package is damaged
	Consult instructions for use	IVD	*In vitro* diagnostic medical device

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