Instructions for Use

CareSuperb™ COVID-19 Antigen Home Test

AccessBio

REF RCTM-00171 RCTM-00271 RCTM-00571 RCTM-02071

English

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

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

A rapid test for the detection of SARS-CoV-2 nucleocapsid antigens in anterior nasal swab specimens.

Intended Use

The CareSuperb™ COVID-19 Antigen Home Test is a visually read lateral flow immunoassay device intended for the rapid, qualitative detection of SARS-CoV-2 virus nucleocapsid protein antigen directly in anterior nasal swab specimens from individuals with signs and symptoms of COVID-19.

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. Symptomatic individuals with an initial negative test result must be re-tested once between 48 and 72 hours after the first test using either an antigen test or a molecular test for SARS-CoV-2. Negative results do not rule out SARS-CoV-2 infections or other pathogens and should not be used as the sole basis for treatment.

Positive results do not rule out co-infection with other respiratory pathogens.

This test is not a substitute for visits to a healthcare provider or appropriate follow-up and should not be used to determine any treatments without provider supervision. Individuals who test negative and experience continued or worsening COVID-19 symptoms, such as fever, cough and/or shortness of breath, should seek follow up care from their healthcare provider.

Performance characteristics for SARS-CoV-2 were established from October 2023 to April 2024 when SARS-CoV-2 Omicron variant was dominant. Test accuracy may change as new SARS-CoV-2 viruses emerge. Additional testing with a lab-based molecular test (e.g., PCR) should be considered in situations where a new virus or variant is suspected.

Kit Components

Component Name	Quantity (in a kit)				Description
	Product Reference No. (REF)				
	RCTM-00171	RCTM-00271	RCTM-00571	RCTM-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 Antigen Home Test is an *in vitro* diagnostic immunochromatographic assay that utilizes lateral flow technology designed to detect the SARS-CoV-2 nucleocapsid protein antigen in human anterior nasal swab specimens.

To initiate the CareSuperb™ COVID-19 Antigen 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 nucleoprotein antigens. SARS-CoV-2 antigens present in the sample bind with anti-SARS-CoV-2 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 test line region, causing a colored line to appear on the membrane. The complexes are interpreted visually between 15 to 30 minutes based on the presence or absence of the test line.

Warnings, Precautions, and Safety Information

- Read all the instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.
- **Do not use this test when you have symptoms greater for 4 days or more, or if you have no symptoms.**
- **This test is for use in individuals with symptoms of respiratory infection that started within the last 4 days and serial testing should be performed for initial negative results (see Serial Testing Information and Limitations section). You may need to purchase additional tests to perform this serial (repeat) testing.**
- This test is read visually. Individuals with impaired vision or color-impaired vision should ensure help in interpretation of their test results.
- Do not use on anyone under 2 years of age.
- 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.
- Use the test cassette immediately once opened.
- Keep the test cassette on a flat surface during the testing.
- When collecting a nasal swab sample, use ONLY the nasal swab provided in the kit.

- Do not touch the swab tip.
- 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 an incorrect test result.
- Operate your test in an ambient temperature of 59°F to 86°F (15-30 °C).
- Do not use if any of the test kit contents or packaging is damaged.
- Test components are single use. Do not re-use.
- Do not use kit past its expiration date.
- 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.

Hazard Category (mixture)	GHS Hazard Statement for Mixture	Labeling of Harm(s)	Hazardous Ingredients (%)
2	Skin irritation	Causes skin irritation (H315)	• Triton x-100 / 1% • Trizma base / 1.21% • Sodium chloride / 2.9%
2	Eye irritation	Causes eye irritation (H320)	• Triton x-100 / 1% • Trizma base / 1.21% • Sodium chloride / 2.9%

Serial Testing Information and Limitations

- If your first test result is negative, you should test again in 48 hours.
- 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 as compared to a molecular test.
- All negative results with this test are presumptive and confirmation with a molecular assay may be necessary. If you continue to have symptoms of COVID-19, however you should follow-up with a healthcare provider.
- If the test is positive, then proteins from the virus that causes COVID-19 have been found in the sample, and you likely have COVID-19.

Storage and Handling

- Store kit at 35.6 - 86°F (2-30°C).
- The test cassette must remain in the sealed foil pouch until use. Once the pouch has been opened, it should be used immediately.
- Do not freeze any contents of the kit.

Quality Control

The CareSuperb™ COVID-19 Antigen 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 “C” 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 15 minutes, the test result

is considered invalid and retesting with a new device is recommended.

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.

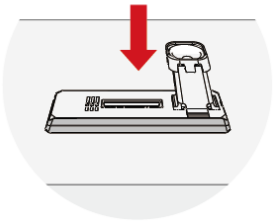
Test Device (Test Cassette in pouch)

Anterior Nasal Swab

Dropper Vial

3. Open the pouch and remove the test cassette from the foil pouch.

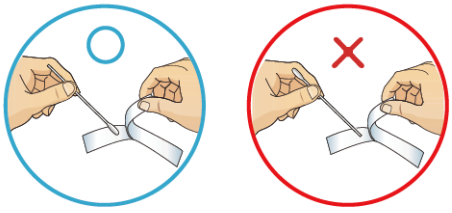
4. Place the test cassette on a flat surface.



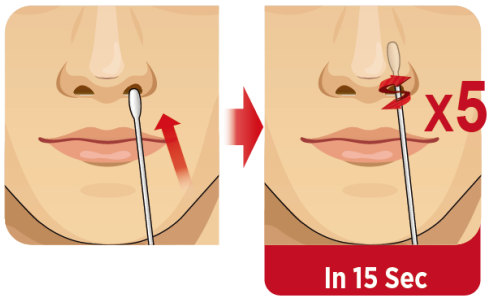
Part B. Collect Nasal Sample

5. Remove a swab from the wrapper.

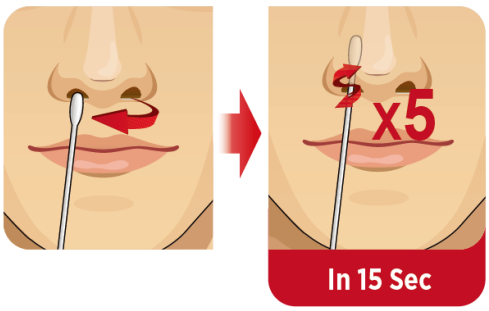
⚠ IMPORTANT Be careful not to touch the swab tip.



6. 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.



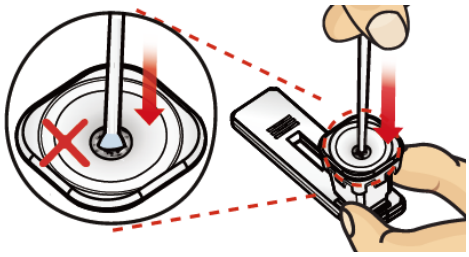
7. Gently remove the swab from the **LEFT** nostril and place it directly into RIGHT nostril, repeating the process of rotating at least 5 times in a circular path for a total of 15 seconds. Remove the swab from the **RIGHT** nostril.



Part C. Perform the Test

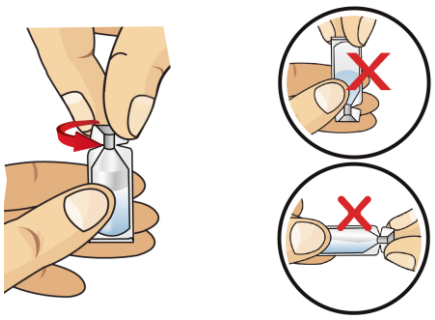
8. Insert the collected swab into the sample port and gently push the swab through the sealed silver foil sheet. Continue to gently push until the swab tip is **FULLY NOT VISIBLE**, ensuring it is completely below the sample port.

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



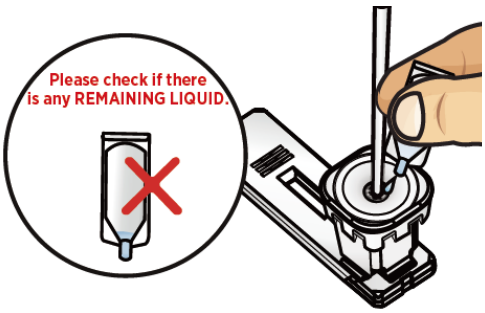
9. Remove the dropper vial cap by twisting it off while it's facing upward.

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



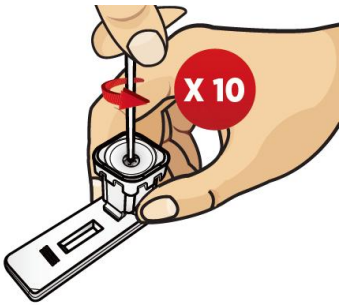
10. Add the ENTIRE VOLUME of the liquid into the sample port.

IMPORTANT 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.



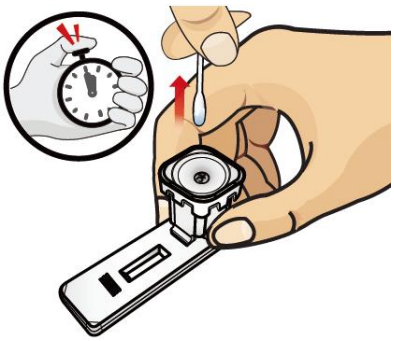
11. Rotate the swab **10 times.**

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



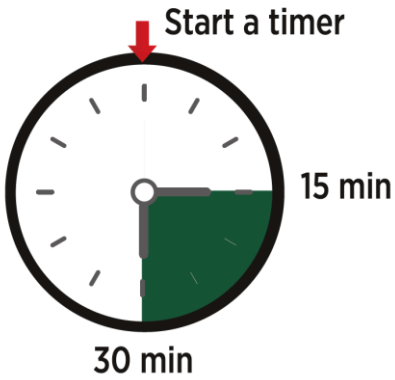
12. Remove the swab immediately from the sample port after rotating the swab.

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



13. Start a timer and read the result at **15 minutes**. The test result should not be read after **30 minutes.**

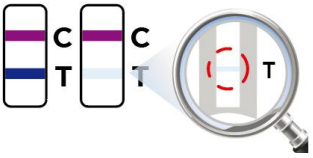
IMPORTANT Do not move or lift the test cassette. Results should not be read before 15 minutes or after 30 minutes.



Part D. Interpretation of Results

Positive Result

If the purple-colored line next to “C” and blue-colored line next to “T” line are visible, the test result should be read as positive. A positive test result means that the virus that causes COVID-19 was detected in the sample, and it is highly likely the individual has COVID-19.

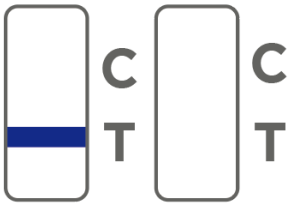


Negative Result

One purple-colored line ONLY next to “C” indicates a negative result. This means the virus that causes COVID-19 was not detected in the sample.

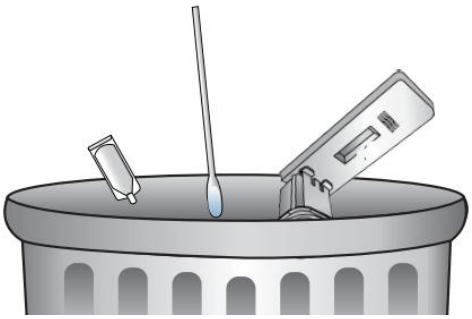
Invalid Result

No purple-colored line next to “C” indicates an invalid result. An invalid test result indicates that the test assay has experienced an error and is unable to interpret the test result. A new test is required.



Part E. Disposal

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



Limitations

- The performance characteristics for SARS-CoV-2 were established during October 2023 and April 2024 when COVID-19 variant Omicron was dominant. Test accuracy may change as new SARS-CoV-2 viruses emerge. Additional testing with a lab-based molecular test (e.g., PCR) should be considered in situations where a new virus or variant is suspected.
- 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 as compared to a molecular test.
- All negative results with this test are presumptive and confirmation with a molecular assay may be necessary. If you continue to have symptoms of COVID-19, and both your first and second tests are negative, you may not have COVID-19, however you should follow-up with a healthcare provider.
- 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.
- False-negative results may occur if the target antigen concentration in the clinical specimen is below the test's detection limits.
- If the test is positive, then proteins from the virus that causes COVID-19 have been found in the sample and the individual is likely to have COVID-19.
- 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 sever disease from respiratory pathogens (e.g., chronic lung or heart disease, compromised immune system, diabetes, and other conditions listed by the CDC) should consult and follow-up with a healthcare provider, who will advise if additional testing or treatment are necessary.

Performance Characteristics

1. Limit of Detection

The Limit of Detection (LoD) of CareSuperb™ COVID-19 Antigen Home Test was determined by evaluating different dilutions of gamma-irradiated SARS-CoV-2 isolates USA-WA1/2020 and Omicron B.1.1.529 in natural negative swab matrix (NSM).

To determine the preliminary LoD, a 10-fold dilution series was established. 50 µL of each dilution was added to swabs and tested in 5 replicates per the test's instructions for use. The lowest concentration that yielded a positive result in all 5 tests from each of 3 product lots tested was the preliminary LoD. The LoD was confirmed by testing the preliminary LoD concentration and additional higher and lower concentrations in 20 replicates using kits from 3 product lots. The lowest concentration that gave positive results in 95% or more of the replicates (at least 19 out of 20 replicates for each lot) was determined the LoD for the strain.

The 1st WHO International Standard for SARS-CoV-2 Antigen (NIBSC 21/368) was also tested to determine the LoD of the CareSuperb™ COVID-19 Antigen Home Test. The preliminary LoD was determined by testing a series of 5-fold dilutions starting from 4000 IU/mL. 50 µL of each dilution was added to swabs and tested in 5 replicates using a test kit from 1 lot. The LoD was confirmed by testing the preliminary LoD concentration and additional concentrations above and below the preliminary LoD in 20 replicates.

Virus Strain	LoD Concentration	LoD Concentration per Swab
WA1/2020	2.63 x 10^2 $TCID_{50}$/mL	1.32 x 10^1 $TCID_{50}$/Swab
Omicron B.1.1.529	1.5 x 10^2 $TCID_{50}$/mL	7.5 x 10^1 $TCID_{50}$/Swab
WHO Standard (NIBSC 21/368)	32 IU/mL	1.6 IU/swab

2. High-dose Hook Effect

No hook effect was observed when SARS-CoV-2 WA1/2020 and Omicron B.1.1.529 were tested at concentrations up to 4.0 x 10^5 and 7.5 x 10^5 $TCID_{50}$/mL, respectively.

3. Precision

The precision study was conducted with gamma-irradiated SARS-CoV-2 Omicron B.1.1.529 (hCoV-19/USA/GA-EHC-2811C/2021) diluted into NSM and involved testing across multiple operators, sample types, and product lots. Samples were blinded and randomized for testing. The results yielded 100% agreement with the expected results when tested with contrived negative and positive samples at 1.5X, 2X and 4X LoD, 99.8% positivity agreements at 1X LoD, and 92.6% positivity agreement when tested with 0.75X LoD. The results demonstrated that the precision of the device across the operators, runs and days and no significant variability was observed between three independently manufactured lots. The results are summarized in the table below.

Lot	True Negative	High Negative (0.75X LoD)	Low Positive (1X LoD)	Low Positive (1.5X LoD)	Low Positive (2X LoD)	Moderative Positive (4X LoD)
Lot 1 (3 operators)	540/540	167/180	180/180	180/180	180/180	180/180
Lot 2 (3 operators)	540/540	164/180	180/180	180/180	180/180	180/180
Lot 3 (3 operators)	540/540	169/180	179/180	180/180	180/180	180/180
Total	1620/1620	500/540	539/540	540/540	540/540	540/540
% Agreement	100%	92.6%	99.8%	100%	100%	100%
95% CI	99.8-100.0%	90.1-94.5%	99.0-100.0%	99.5-100.0%	99.5-100.0%	99.5-100.0%

4. Inclusivity (Analytical Reactivity)

To evaluate the analytical reactivity of the CareSuperb™ COVID-19 Antigen Home Test, additional 7 strains of SARS-CoV-2 variants were tested in a dilution series using contrived samples and the lowest concentration that yielded 100% positive results for each strain is summarized in table below.

SARS-CoV-2 Variants	Lowest Concentration
USA/CA_CDC_5574/2020 (Alpha)	4.0×10^2 $TCID_{50}$/mL
B.1.617.2 (Delta)	1.41×10^3 $TCID_{50}$/mL
BA.2.12.1 (Omicron)	2.02×10^3 $TCID_{50}$/mL
BA.2.3 (Omicron)	1.87×10^2 $TCID_{50}$/mL
BA.2.75.5 (Omicron)	2.72×10^2 $TCID_{50}$/mL
BA.4.6 (Omicron)	1.84×10^3 $TCID_{50}$/mL
Lineage JN.1.4 (Omicron)	6.74×10^2 $TCID_{50}$/mL

5. Cross-Reactivity/Microbial Interference (Analytical Specificity)

To evaluate the potential cross-reactivity and microbial interference of the CareSuperb™ COVID-19 Antigen Home Test, 18 non-SARS-CoV-2 viruses and 10 other microorganisms were diluted into negative NSM at high concentrations. Nasal wash was tested as representative of normal respiratory microbial flora. Organisms and viruses were each tested in 3 replicates in the absence or presence of gamma-irradiated SARS-CoV-2. Both, WA1/2020 and Omicron B.1.1.529 were tested, each at their respective 2x LoD concentration (5.2×10^2 and 3.0×10^2 $TCID_{50}$/mL). Based on the test results summarized in table below, none of the organisms and viruses tested showed cross-reactivity or interference with the device at the concentrations tested.

Microorganisms	Testing Concentration	Results (# of Positive / # of Replicate)		
		Interference		Cross-Reactivity
		WA1/2020	Omicron B.1.1.529	
Adenovirus 1	1.58 x 10^5 $TCID_{50}$/mL	3/3	3/3	0/3
Adenovirus 7	1.6 x 10^5 $TCID_{50}$/mL	3/3	3/3	0/3
Enterovirus	1.6 x 10^6 $TCID_{50}$/mL	3/3	3/3	0/3
Human coronavirus (OC43)	1.4 x 10^5 $TCID_{50}$/mL	3/3	3/3	0/3
Human coronavirus (229E)	1.4 x 10^4 $TCID_{50}$/mL	3/3	3/3	0/3
Human coronavirus (NL63)	8.0 x 10^4 $TCID_{50}$/mL	3/3	3/3	0/3
Human metapneumovirus (hMPV)	2.8x 10^5 $TCID_{50}$/mL	3/3	3/3	0/3
Influenza A/California/55/2020 (H3N2)	3.5 x 10^5 FFU/mL	3/3	3/3	0/3
Influenza B (Yamagata Lineage)	7.6 x 10^5 $TCID_{50}$/mL	3/3	3/3	0/3
MERS-Coronavirus, Irradiated Lysate	1.78 x 10^5 $TCID_{50}$/mL	3/3	3/3	0/3
Parainfluenza virus type 1	7.4 x 10^5 $TCID_{50}$/mL	3/3	3/3	0/3
Parainfluenza virus type 2	1.58 x 10^5 $TCID_{50}$/mL	3/3	3/3	0/3
Parainfluenza virus type 3	1.58 x 10^5 $TCID_{50}$/mL	3/3	3/3	0/3
Parainfluenza virus type 4	5.0 x 10^5 $TCID_{50}$/mL	3/3	3/3	0/3
Respiratory syncytial virus Type B	1.58 x 10^5 $TCID_{50}$/mL	3/3	3/3	0/3
Rhinovirus	1.58 x 10^5 $TCID_{50}$/mL	3/3	3/3	0/3
SARS-Coronavirus	1.0 x 10^5 $TCID_{50}$/mL	3/3	3/3	0/3
Human coronavirus HKU1	Clinical Sample [a]	3/3	3/3	0/3
Bordetella pertussis	1.0 x 10^7 CFU/mL	3/3	3/3	0/3
Chlamydophila pneumoniae	1.4 x 10^6 IFU/mL	3/3	3/3	0/3
Haemophilus influenzae	1.6x 10^6 CFU/mL	3/3	3/3	0/3
Legionella pneumophila	1.35 x 10^6 CFU/mL	3/3	3/3	0/3
Mycoplasma pneumoniae	6.5x 10^5 CFU/mL	3/3	3/3	0/3
Streptococcus pneumoniae	1.0 x 10^7 CFU/mL	3/3	3/3	0/3
Streptococcus pyogenes,	1.0 x 10^7 CFU/mL	3/3	3/3	0/3

Microorganisms	Testing Concentration	Results (# of Positive / # of Replicate)		
		Interference		Cross-Reactivity
		WA1/2020	Omicron B.1.1.529	
Group A				
Staphylococcus aureus	1.0 x 10^7 CFU/mL	3/3	3/3	0/3
Staphylococcus epidermidis	1.0 x 10^7 CFU/mL	3/3	3/3	0/3
Candida albicans	1.0 x 10^7 CFU/mL	3/3	3/3	0/3
Pooled human nasal wash	N/A	3/3	3/3	0/3

[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.

6. Endogenous/Exogenous Interference Substances

To evaluate the potential interfering effect of natural or artificial substances to the CareSuperb™ COVID-19 Antigen Home Test, 42 interfering substances were diluted into negative NSM. Each substance was tested in three replicates in the absence or presence of two gamma-irradiated SARS-CoV-2 strains, WA1/2020 and Omicron B.1.1.529, each at their 2x LoD concentration (5.2 x 10^2 and 3.0 x 10^2 $TCID_{50}$/mL). Based on the test results summarized in table below, none of the endogenous or exogenous substances tested showed cross-reactivity or interference with the assay at the concentrations tested.

Substances	Testing Concentration	Results (# of Positive / # of Replicate)		
		Positive		Negative
		WA1/2020	Omicron B.1.1.529	
Acetaminophen	10 mg/mL	3/3	3/3	0/3
Acetyl salicylic acid	15 mg/mL	3/3	3/3	0/3
Beconase AQ Nasal Spray (Beclomethasone)	5 mg/mL	3/3	3/3	0/3
Benzocaine	5 mg/mL	3/3	3/3	0/3
Budesonide	2 mg/mL	3/3	3/3	0/3
Chlorpheniramine maleate	5 mg/mL	3/3	3/3	0/3
Dexamethasone	1 mg/mL	3/3	3/3	0/3
Dextromethorphan HBr	2 mg/mL	3/3	3/3	0/3
Diphenhydramine HCl	5 mg/mL	3/3	3/3	0/3
Nasarel Nasal Spray (Flunisolide)	5 mg/mL	3/3	3/3	0/3

Substances	Testing Concentration	Results (# of Positive / # of Replicate)		
		Positive		Negative
		WA1/2020	Omicron B.1.1.529	
Fluticasone	1 mg/mL	3/3	3/3	0/3
Guaiacol Glyceryl Ether	20 mg/mL	3/3	3/3	0/3
Histamine Dihydrochloride	10 mg/mL	3/3	3/3	0/3
Menthol	10 mg/mL	3/3	3/3	0/3
Mometasone	1 mg/mL	3/3	3/3	0/3
Molnupiravir	1 mg/mL	3/3	3/3	0/3
Mucin (Bovine submaxillary glands -Type I-S)	2.5 mg/mL	3/3	3/3	0/3
Mupirocin	1 mg/mL	3/3	3/3	0/3
Phenylpropanolamine	5 mg/mL	3/3	3/3	0/3
Remdesivir	1 mg/mL	3/3	3/3	0/3
Tamiflu (Oseltamivir Phosphate)	5 mg/mL	3/3	3/3	0/3
Tobramycin	1 mg/mL	3/3	3/3	0/3
Triamcinolone	1 mg/mL	3/3	3/3	0/3
Zanamivir	1 mg/mL	3/3	3/3	0/3
Sore Throat Spray (Phenol)	15 % v/v	3/3	3/3	0/3
Zicam Oral Mist (Zincum aceticum, Zincum gluconicum)	15 % v/v	3/3	3/3	0/3
Nasal Spray (Phenylephrine HCl)	15 % v/v	3/3	3/3	0/3
NasalCrom Nasal Spray (Cromolyn sodium)	15 % v/v	3/3	3/3	0/3
Vicks Sinex Nasal spray (Oxymetazoline HCl)	15 % v/v	3/3	3/3	0/3
Alkalol Allergy Relief	15 % v/v	3/3	3/3	0/3
Zicam Allergy Relief	15 % v/v	3/3	3/3	0/3
Hand Sanitizer	15 % v/v	3/3	3/3	0/3
Hand Soap	15 % v/v	3/3	3/3	0/3
Whole blood	2.5 % v/v	3/3	3/3	0/3
Buffy Coat	2.5 % v/v	3/3	3/3	0/3

Substances	Testing Concentration	Results (# of Positive / # of Replicate)		
		Positive		Negative
		WA1/2020	Omicron B.1.1.529	
Allergy Spray (Mometasone Furoate)	15 % v/v	3/3	3/3	0/3
Budesonide Nasal Spray	15 % v/v	3/3	3/3	0/3
Nasacort Allergy 24HR	15 % v/v	3/3	3/3	0/3
Allergy Relief Nasal Spray	15 % v/v	3/3	3/3	0/3
Saline Nasal Spray	15 % v/v	3/3	3/3	0/3
Alkalol Saline Nasal Spray	15 % v/v	3/3	3/3	0/3
Leukocytes	5.0 x 10^6 cells/mL	3/3	3/3	0/3

7. Biotin Supplement Interfering Effect

The interfering effect of biotin was evaluated by testing different concentrations of biotin ranging between 312.5 ng/mL and 5.000 ng/mL. Each concentration in the absence and presence of Gamma-Irradiated SARS-CoV-2 strain (isolate USA-WA1/2020) and SARS-CoV-2 Omicron variant (Lineage B.1.1.529) at the 2x LoD concentration was tested. Biotin concentrations up to 2,500 ng/mL did not lead to any false negative results; however, false negative results consistently appeared in the samples with biotin concentration exceeding 2,500 ng/mL. The results are summarized in the table below.

Biotin Concentration	Results (# of Positive / # of Replicate)		
	Positive		Negative
	WA1/2020	Omicron B.1.1.529	
5000 ng/mL	0/10	0/10	0/5
3750 ng/mL	0/5	0/5	0/5
2500 ng/mL	10/10	10/10	0/5
1250 ng/mL	5/5	5/5	0/5
625 ng/mL	5/5	5/5	0/5
312.5 ng/mL	5/5	5/5	0/5
0 ng/mL	5/5	5/5	0/5

8. Clinical Performance

The clinical performance characteristics of the CareSuperb™ COVID-19 Antigen Home Test using anterior nasal swab specimen were evaluated at ten clinical sites across the U.S. between October 2023 and April 2024 and compared against an FDA-cleared molecular assay as a comparator method. Subjects self-sampled and self-tested using the CareSuperb™ COVID-19 Antigen Home Test in a simulated home setting utilizing only the labeling provided with the test. A total of 646 symptomatic subjects within 4 days post symptom onset were

evaluated in this study. The CareSuperb™ COVID-19 Antigen Home Test when conducted by a lay user correctly identified 97.2% of positive samples and 98.8% of negative samples. All discrepant results were investigated by testing using an alternative FDA-cleared molecular assay at the central laboratory. The overall clinical performance is shown in the following tables.

CareSuperb™ COVID-19 Antigen Home Test clinical performance against the comparator method

CareSuperb™ COVID-19 Antigen Home Test	FDA-cleared Molecular Assay		
	Positive	Negative	Total
Positive	140	6[a]	146
Negative	4[b]	496	500
Total	144	502	646[c]
Positive Percent Agreement	97.2% (140/144) (95% CI: 93.1% - 98.9%)		
Negative Percent Agreement	98.8% (496/502) (95% CI: 97.4% - 99.5%)		

[a]COVID-19 was detected in 6 / 6 False Positive specimens using the alternative FDA cleared RT-PCR assay
[b]COVID-19 was not detected in 0 / 4 False Negative specimens using the alternative FDA cleared RT-PCR assay
[c] One test was invalid and upon repeat testing a valid result was obtained

Patient Demographics

Age Group	CareSuperb™ COVID-19 Antigen Home Test		
	Female	Male	Positivity Rate %
2 - 13 Years of Age	34	31	7.7% (5/65)
14 - 21 Years of Age	22	18	25.0% (10/40)
22 - 64 Years of Age	282	199	23.7% (114/481)
≥65 Years of Age	37	23	28.3% (17/60)
Total	375	271	22.6% (146/646)

Results are broken down by days post symptom onset (DPSO)

DPSO	Positive Percent Agreement	Negative Percent Agreement
0	100.0% (1/1) (95% CI:20.7% - 100.0%)	88.9% (8/9) (95% CI:56.5% - 98.0%)
1	100.0% (21/21) (95% CI:84.5% - 100.0%)	99.1% (110/111) (95% CI:95.1% - 99.8%)
2	98.0% (49/50) (95% CI:89.5% - 99.6%)	100.0% (196/196) (95% CI:98.1% - 100.0%)
3	100.0% (48/48) (95% CI:92.6% - 100.0%)	99.2% (131/132) (95% CI:95.8% - 99.9%)
4	87.5% (21/24) (95% CI:69.0% - 95.7%)	94.4% (51/54) (95% CI:84.9% - 98.1%)

9. Serial Testing

A prospective clinical study was conducted between January 2021 and May 2022 as a component of the Rapid Acceleration of Diagnostics (RADx) initiative of the National Institutes of Health (NIH). A total of 7,361 individuals were enrolled via a decentralized clinical study design, covering a broad geographical representation of the United States. Per inclusion criteria, all individuals were asymptomatic for at least 14 days prior to enrollment in the study and did not have a history of SARS-CoV-2 infection within three months prior to enrollment. Participants were assigned to one of three different Emergency Use Authorized SARS-CoV-2

over-the-counter rapid antigen tests to conduct serial testing (every 48 hours) for 15 days. If an antigen test was positive, the serial-antigen testing result was considered positive.

At each rapid antigen testing time point, study subjects also collected a nasal swab for comparator testing using a home collection kit (using a 15-minute normalization window between swabs). SARS-CoV-2 infection status was determined by a composite comparator method on the day of the first antigen test, using at least two highly sensitive EUA RT-PCR test methods. If results of the first two molecular tests were discordant, a third highly sensitive EUA RT-PCR test was performed, and the final test result was based upon the majority rule.

Study participants reported status of symptoms throughout the study using the MyDataHelps mobile application. Two-day serial antigen testing is defined as performing two antigen tests 36 to 48 hours apart. Three-day serial antigen testing is defined as performing three antigen tests over five days with at least 48 hours between each test.

Out of the 7,361 participants enrolled in the study, 5,609 were eligible for analysis. Among eligible participants, 154 tested positive for SARS-CoV-2 infection based on RT-PCR, of which 97 (62%) were asymptomatic on the first day of their infection, whereas 57 (39%) reported symptoms on the first day of infection. Performance of the antigen test utilizing serial testing is described in the table below.

PPA of COVID-19 Antigen Serial Testing Compared to Molecular Comparator Single Day Testing

DAYS AFTER FIRST PCR POSITIVE TEST RESULT	**Ag Positive/PCR Positive (Antigen Test Performance % PPA) SYMPTOMATIC ON FIRST DAY OF TESTING**		
	1 Test	2 Tests	3 Tests
0	34/57 (59.6%)	47/51 (92.2%)	44/47 (93.6%)
2	58/62 (93.5%)	59/60 (98.3%)	43/43 (100%)
4	55/58 (94.8%)	53/54 (98.1%)	39/40 (97.5%)
6	27/34 (79.4%)	26/33 (78.8%)	22/27 (81.5%)
8	12/17 (70.6%)	12/17 (70.6%)	7/11 (63.6%)
10	4/9 (44.4%)	3/7 (42.9%)	-

10. Usability Study

A usability study was conducted to assess the lay user's ability to understand the IFU of the CareSuperb™ COVID-19 Antigen Home Test and to perform testing using the components provided in the test kit in simulated setting of the intended use. Fifty users participated in the study and the overall success rate for all critical tasks was ≥ 80% demonstrating that the users sufficiently comprehended the test procedure described in the IFU and were able to use the device safely and effectively.

Explanation of Symbols

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

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