



**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION  
DECISION SUMMARY  
ASSAY ONLY**

**I Background Information:**

**A 510(k) Number**

K241915

**B Applicant**

Access Bio, Inc.

**C Proprietary and Established Names**

CareSuperb COVID-19 Antigen Home Test

**D Regulatory Information**

Product Code(s)	Classification	Regulation Section	Panel
QYT	Class II	21 CFR 866.3984 - Over-The-Counter Test To Detect SARS-Cov-2 From Clinical Specimens	MI - Microbiology

**II Submission/Device Overview:**

**A Purpose for Submission:**

To obtain 510(k) clearance for the CareSuperb COVID-19 Antigen Home Test

**B Measurand:**

Nucleocapsid protein antigen from SARS-Coronavirus (SARS-CoV-2)

**C Type of Test:**

Qualitative lateral flow immunoassay

### **III Intended Use/Indications for Use:**

#### **A Intended Use(s):**

See Indications for Use below.

#### **B Indication(s) for 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 lab-based molecular test (e.g., PCR) should be considered in situations where a new virus or variant is suspected.

#### **C Special Conditions for Use Statements(s):**

OTC - Over The Counter

#### **D Special Instrument Requirements:**

Not applicable (N/A)

### **IV Device/System Characteristics:**

#### **A Device Description:**

The CareSuperb COVID-19 Antigen Home Test is a lateral flow immunoassay device intended for the qualitative detection of nucleocapsid protein antigen from the SARS-CoV-2 virus in anterior nasal swab (ANS) samples.

The test package is composed of the following components:

- Test Cassette with attached adaptor (individually packaged in an aluminum foil pouch)

- Assay Buffer Dropper Vial (250 µL per vial)
- Disposable Sterile Anterior Nasal Swab
- Quick Reference Instructions (QRI)

The CareSuperb COVID-19 Antigen Home Test comes in three different kit configurations:

Catalog Number	Package Size (Test/kit)	Contents
RCTM-00171	1	1 Test Cassette, 1 Assay Buffer Dropper Vial, 1 Disposable Anterior Nasal Swab, and 1 QRI
RCTM-00271	2	2 Test Cassettes, 2 Assay Buffer Dropper Vials, 2 Disposable Anterior Nasal Swabs, and 1 QRI
RCTM-02071	20	20 Test Cassettes, 20 Assay Buffer Dropper Vials, 20 Disposable Anterior Nasal Swabs, and 1 QRI

The test device (i.e., cassette) utilizes an adaptor composed of a silver foiled cap and sample port which is assembled and attached to the plastic cassette housing made of High Impact Polystyrene (HIPS). Encased inside the plastic test cassette is a nitrocellulose membrane, filter pad and an absorbent pad attached on a plastic backing card. The top of the cassette is printed with the letters “C” and “T” next to the result window marking where the control line and SARS-CoV-2 test line should appear and “COVID-19 Ag” on the top of the cassette identifying the test kit.

## B Principle of Operation:

The CareSuperb COVID-19 Antigen Home Test employs typical lateral flow technology in a sandwich design to detect nucleocapsid protein from SARS-CoV-2 in ANS samples enhanced with the application of a sample port adaptor. The sample port contains a dedicated flow tunnel, enabling the entire volume of sample to be loaded to the assay system. In addition, the sample port contains a cylindrical conjugate wick filter which contains a mixed solution of the test reagents, including gold and biotin labeled virus specific detection antibodies. The wick filter complements the shortcoming of the traditional lateral flow assay (relatively low sensitivity compared to molecular assays) by increasing the concentrations of the sample material and prolonging its incubation time with the analyte specific reagents for the formation of the immunocomplexes. This results in an increased amount of the antigen-capture antibody complexes from a given sample volume.

To begin the test, an anterior nares swab (ANS) sample is inserted into the small round opening of the sample port of the test cassette adaptor sealed with a silver foil sheet. The swab is pushed down until the swab tip is invisible, ensuring it is completely inserted below the sample port. This step prevents the immediate draining of the test sample into the test cassette during the next step. Next, extraction/lysis buffer is added to the sample port. The swab remains inserted in the sample port and rotated ten (10) times as the assay buffer lyses and disrupts the SARS-CoV-2 virus particles to expose the viral nucleocapsid antigens and elutes the sample material from the swab. The swab is then removed allowing the sample to vertically descend through the conjugate wick filter and be flushed to the test strip. The test strip encased in the plastic cassette is composed of a filter pad, a nitrocellulose membrane with control and SARS-CoV-2 specific antibodies immobilized at the test’s C Line and T Line, respectively, streptavidin, and an absorbent pad attached on a plastic backing card. The test results can be interpreted after 15 minutes but no later than 30 minutes.

If the extracted specimen contains SARS-CoV-2 antigens, a blue colored T Line from the formation of SARS CoV-2 antigen immune complexes, along with a purple C Line will appear

on the cassette indicating a positive result. If SARS-CoV-2 antigens are not present, or present at levels below the limit of detection, only a purple C Line will appear. The C Line must appear for a sample result to be valid and interpretable.

## V Substantial Equivalence Information:

### A Predicate Device Name(s):

Flowflex COVID-19 Antigen Home Test

### B Predicate 510(k) Numbers(s):

K230828

### C Comparison with Predicate(s):

Device & Predicate Device(s):	<u>K230828</u> (Predicate Device)	<u>K241915</u> (Candidate Device)
Device Trade Name	Flowflex COVID-19 Antigen Home Test	CareSuperb COVID-19 Antigen Home Test
<b>Similarities</b>		
Intended Use/ Indications For Use	<p>The Flowflex 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 within the first 6 days of symptom onset.</p> <p>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.</p> <p>The Flowflex COVID-19 Antigen Home Test does not differentiate between SARS-CoV and SARS-CoV-2.</p> <p>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 an antigen test or a molecular test for SARS-CoV-2. Negative results do not preclude SARS-CoV-2 infections or other pathogens and should not be used as</p>	<p>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.</p> <p>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.</p> <p>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.</p> <p>Positive results do not rule out co-infection with other respiratory pathogens.</p>

	<p>the sole basis for treatment.</p> <p>Positive results do not rule out co-infection with other respiratory pathogens.</p> <p>Performance characteristics for SARS-CoV-2 were established from December 2022 to March 2023 of the SARS-CoV-2 pandemic when SARS-CoV-2 Omicron was the predominant SARS-CoV-2 variant in circulation. When other SARS-CoV-2 virus variant are emerging, performance characteristics may vary.</p> <p>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 like symptoms, such as fever, cough and/or shortness of breath, should seek follow up care from their healthcare provider.</p>	<p>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 like symptoms, such as fever, cough and/or shortness of breath, should seek follow up care from their healthcare provider.</p> <p>Performance characteristics for SARS-CoV-2 were established from October 2023 to April 2024 of the SARS-CoV-2 pandemic 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.</p>
Regulation Number	21 CFR 866.3984	Same
Test Principle	Lateral flow immunoassay	Same
Test Result Type	Qualitative	Same
Analyte	SARS-CoV-2 nucleocapsid protein antigen	Same
Intended Use Settings	Over-the-counter	Same
Intended Use Population	Symptomatic	Same
Specimen Type	Direct anterior nasal swab specimen	Same
Time to Result	15-30 Minutes	Same
Detection Format	Visually Read	Same
Storage Temperature	2-30°C	Same
<b>Differences</b>		
Device Type	Test Cartridge (cassette)	Test cartridge (cassette) with a sample port
Extraction Buffer Volume Used	4 drops	Entire sample volume (~250 µL)

The differences in the CareSuperb COVID-19 Antigen Home Test (candidate device) and the Flowflex COVID-19 Antigen Home Test (predicate device, K230828) would include the utilization of the device cassette sample port attached to the test device cassette of the candidate device which the predicate device does not have. As a result of the device cassette sample port, the processing of the anterior nasal swab (ANS) sample between the candidate device and predicate device is different. While these differences necessitate slightly different handling steps and instructions, they do not raise new questions of safety and effectiveness and do not affect the

overall substantial equivalence of the proposed device to the predicate device in terms of the technological similarity, intended use.

## VI Standards/Guidance Documents Referenced:

Document	Title	Publisher	Applicable Study
Special Controls under 21 CFR 866.3984 (Over-the-counter test to detect SARS-CoV-2)	<a href="#">Reclassification order for DEN220028 and special controls under 21 CFR 866.3984</a>	FDA/CDRH	All Studies
ISO 14971:2019	Medical Devices-Application of risk management to medical devices	ISO	All Studies
ISO 15223-1:2021	Medical Devices-Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements	ISO	Labeling
FDA Guidance	<a href="#">Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile   FDA</a>	FDA/CDRH	Sterility
ISO 11135:2014	Sterilization of health care products - Ethylene oxide - Requirements for development, validation and routine control of a sterilization process for medical devices	ISO	Sterility
ISO 10993-7	Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals	ISO	Sterility
ISO 10993-5	Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity	ISO	Biocompatibility
ISO 10993-10	Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization	ISO	Biocompatibility
ISO 10993-23	Biological evaluation of medical devices Part 23: Tests for irritation	ISO	Biocompatibility
CLSI EP05-A3:2019	Evaluation of Precision of Quantitative Measurement Procedures	CLSI	Precision Study
CLSI EP25-A	Evaluation of Stability of In Vitro Diagnostic Reagents	CLSI	Shelf-life

## VII Performance Characteristics (if/when applicable):

### A Analytical Performance:

#### 1. Multi-lot Precision:

A precision study was conducted in three (3) separate studies to assess variability between reagent lots, days, runs and operators. Two (2) levels of gamma-irradiated SARS-CoV-2 (Omicron Variant: hCoV-19/USA/GA-EHC-2811C/2021, Lineage B.1.1.529) were spiked into pooled negative natural clinical matrix (NSM) to prepare the following test sample panel members:

- Negative: NSM
- Positive (4X LoD Omicron:  $6.00 \times 10^2$  TCID<sub>50</sub>/mL)
- Low Positive (2X LoD: Omicron:  $3.00 \times 10^2$  TCID<sub>50</sub>/mL)
- Low Positive (1.5X LoD: Omicron:  $2.25 \times 10^2$  TCID<sub>50</sub>/mL)
- Low Positive (1.0X LoD: Omicron:  $1.50 \times 10^2$  TCID<sub>50</sub>/mL)
- Low Positive (0.75X LoD: Omicron:  $1.12 \times 10^2$  TCID<sub>50</sub>/mL)

Samples were blinded and randomized before allotting them to the operators. 50 µL of each sample was applied to dry nasal swabs and processed per the IFU of the candidate device. All panel members were tested with three (3) device lots, by three (3) operators, two (2) times a day, for ten (10) non-consecutive days (i.e., 3 lots x 3 operators x 3 replicates/run x 2 runs x 10 days). A total of 540 measurements per panel member. An agreement of 100% was obtained for all negative, 4X LoD, and 2X LoD positive samples and replicates, across all lots, operators, and days when compared to the expected result for the panel member. Lot variability between three independently manufactured kits lots would therefore not be assessed.

To assess between lot-to-lot variability, supplemental precision study #2 was conducted with negative and low positive samples at 1.5X LoD and 1.0X LoD. The same sample preparation materials and testing procedure as described above, except two (2) of the three (3) kit lots were not identical to the previous precision study lot numbers. A total of 540 measurements per panel member. An agreement of 100% was obtained for all negative and 1.5X LoD positive samples and replicates, across all lots, operators, and days when compared to the expected result for the panel member. As a result, of 1X LoD obtaining an overall 99.8% PPA, supplemental precision study #3 was performed to further evaluate the lot-to-lot variability utilizing the same study procedure as described above.

Supplemental precision study #3 was conducted with negative and low positive samples at 0.75X LoD. A total of 540 measurements per panel member. An agreement of 100% was obtained for the negative samples. As expected, sample analyte concentrations at 0.75X LoD achieved an overall 92.6% PPA.

Together these three (3) precision studies verified acceptable lot-to-lot variability for samples at or above the LoD of the test. There results of the precision study are summarized in Table 2 below:

**Table 2.** Summarized Multi-Lot Precision Study Results.

Analyte	Concentration	Agreement with Expected Results (# with expected results/# total tested)			Percent Agreement (n/N)
Initial Precision Study		CT23H02	CT23J01	CT23J02	(95% CI)
Negative		100% (180/180)	100% (180/180)	100% (180/180)	100% (540/540) (99.3% -100%)
SARS-CoV-2 (Omicron)	4X LoD	100% (180/180)	100% (180/180)	100% (180/180)	100% (540/540) (99.3% -100%)
	2X LoD	100% (180/180)	100% (180/180)	100% (180/180)	100% (540/540) (99.3% -100%)
Supplemental Precision Studies		CT24J01	CT24J02	CT23J03	
Negative		100% (180/180)	100% (180/180)	100% (180/180)	100% (540/540) (99.3% -100%)
SARS-CoV-2 (Omicron)	1.5X LoD	100% (180/180)	100% (180/180)	100% (180/180)	100% (540/540) (99.3% -100%)
	1.0X LoD	100% (180/180)	100% (180/180)	99.4% (179/180)	99.8% (539/540) (99.0% - 100%)
Negative		100% (180/180)	100% (180/180)	100% (180/180)	100% (540/540) (99.3% -100%)
SARS-CoV-2 (Omicron)	0.75X LoD	92.7% (167/180)	91.1% (164/180)	93.9% (169/180)	92.6% (500/540) (90.0% - 94.5%)

2. Linearity:

Not applicable, the device is a binary qualitative assay that is visually read.

3. Analytical Specificity/Interference:a. Cross Reactivity/Microbial Interference:

The analytical specificity of the CareSuperb COVID-19 Antigen Home Test was evaluated by testing various microorganisms (10), viruses (18), and NSM (1) in the absence (cross-reactivity) and presence (microbial interference) of two gamma-inactivated SARS-CoV-2 at 2X LoD (Wild Type (WT): USA-WA1/2020 ( $5.26 \times 10^2$  TCID<sub>50</sub>/mL) and Omicron Variant (Omicron): B.1.1.529 ( $3.00 \times 10^2$  TCID<sub>50</sub>/mL) in triplicate. To demonstrate that the CareSuperb Antigen Home Test does not react with related viruses, high prevalence disease agents, and normal or pathogenic flora that are reasonably likely to be encountered in nasal swab specimens were tested. Replicate samples were generated by spiking 50µL of virus diluted in NSM with or without the microorganisms listed in the Table below onto dry swabs. Swabs were then processed per the test's IFU.

The microbial interference and the cross-reactivity study were conducted simultaneously with samples tested in a randomized and blinded manner. The results are summarized in Table 3 below:



**Table 3.** Summary of Cross-Reactivity and Microbial Interference Study Results.

Microorganism	Testing Concentration	With SARS-CoV-2 Microbial Interference		Without SARS-CoV-2 Cross Reactivity
		WT	Omicron	
Adenovirus 1	1.58 x 10 <sup>5</sup> TCID <sub>50</sub> /mL	100% (3/3)	100% (3/3)	0% (0/3)
Adenovirus 7	1.6 x 10 <sup>5</sup> TCID <sub>50</sub> /mL	100% (3/3)	100% (3/3)	0% (0/3)
Enterovirus	1.6 x 10 <sup>6</sup> TCID <sub>50</sub> /mL	100% (3/3)	100% (3/3)	0% (0/3)
Human coronavirus (OC43)	1.4 x 10 <sup>5</sup> TCID <sub>50</sub> /mL	100% (3/3)	100% (3/3)	0% (0/3)
Human coronavirus (229E)*	1.4 x 10 <sup>4</sup> TCID <sub>50</sub> /mL	100% (3/3)	100% (3/3)	0% (0/3)
Human Coronavirus (NL63)*	8.0 x 10 <sup>4</sup> TCID <sub>50</sub> /mL	100% (3/3)	100% (3/3)	0% (0/3)
Human metapneumovirus (hMPV)	2.8 x 10 <sup>5</sup> TCID <sub>50</sub> /mL	100% (3/3)	100% (3/3)	0% (0/3)
Influenza A Virus, California/55/2020 (H3N2)	3.5 x 10 <sup>5</sup> TCID <sub>50</sub> /mL	100% (3/3)	100% (3/3)	0% (0/3)
Influenza B Virus, B/Oklahoma/10/2018 (NA D197N) (Yamagata Lineage)	7.6 x 10 <sup>5</sup> TCID <sub>50</sub> /mL	100% (3/3)	100% (3/3)	0% (0/3)
MERS-Coronavirus, Irradiated Lysate	1.78 x 10 <sup>5</sup> TCID <sub>50</sub> /mL	100% (3/3)	100% (3/3)	0% (0/3)
Parainfluenza virus type 1	7.4 x 10 <sup>5</sup> TCID <sub>50</sub> /mL	100% (3/3)	100% (3/3)	0% (0/3)
Parainfluenza virus type 2	1.58 x 10 <sup>5</sup> TCID <sub>50</sub> /mL	100% (3/3)	100% (3/3)	0% (0/3)
Parainfluenza virus type 3	1.58 x 10 <sup>5</sup> TCID <sub>50</sub> /mL	100% (3/3)	100% (3/3)	0% (0/3)
Parainfluenza virus type 4	5.0 x 10 <sup>5</sup> TCID <sub>50</sub> /mL	100% (3/3)	100% (3/3)	0% (0/3)
Respiratory syncytial virus Type B	1.58 x 10 <sup>5</sup> TCID <sub>50</sub> /mL	100% (3/3)	100% (3/3)	0% (3/3)
Rhinovirus	1.58 x 10 <sup>5</sup> TCID <sub>50</sub> /mL	100% (3/3)	100% (3/3)	0% (0/3)
SARS-Coronavirus	1.0 x 10 <sup>5</sup> TCID <sub>50</sub> /mL	100% (3/3)	100% (3/3)	0% (0/3)
Human coronavirus HKU1**	0.1X Stock	100% (3/3)	100% (3/3)	0% (0/3)
<i>Bordetella pertussis</i>	1.0 x 10 <sup>7</sup> CFU/mL	100% (3/3)	100% (3/3)	0% (3/3)
<i>Chlamydophila pneumoniae</i>	1.4 x 10 <sup>6</sup> CFU/mL	100% (3/3)	100% (3/3)	0% (0/3)
<i>Haemophilus influenzae</i>	1.6 x 10 <sup>6</sup> CFU/mL	100% (3/3)	100% (3/3)	0% (0/3)
<i>Legionella pneumophila</i>	1.35 x 10 <sup>6</sup> CFU/mL	100% (3/3)	100% (3/3)	0% (0/3)

Microorganism	Testing Concentration	With SARS-CoV-2 Microbial Interference		Without SARS-CoV-2 Cross Reactivity
		WT	Omicron	
<i>Mycoplasma pneumoniae</i>	6.5 x 10 <sup>5</sup> CFU/mL	100% (3/3)	100% (3/3)	0% (0/3)
<i>Streptococcus pneumoniae</i>	1.0 x 10 <sup>7</sup> CFU/mL	100% (3/3)	100% (3/3)	0% (0/3)
<i>Streptococcus pyogenes, Group A</i>	1.0 x 10 <sup>7</sup> CFU/mL	100% (3/3)	100% (3/3)	0% (0/3)
<i>Staphylococcus aureus</i>	1.0 x 10 <sup>7</sup> CFU/mL	100% (3/3)	100% (3/3)	0% (0/3)
<i>Staphylococcus epidermidis</i>	1.0 x 10 <sup>7</sup> CFU/mL	100% (3/3)	100% (3/3)	0% (0/3)
<i>Candida albicans</i>	1.0 x 10 <sup>7</sup> CFU/mL	100% (3/3)	100% (3/3)	0% (0/3)
Pooled human nasal wash	N/A	100% (3/3)	100% (3/3)	0% (0/3)
*The stock concentration is insufficiently high for a testing concentration				
**Obtained from a clinical sample purchased from Vector Bio Source.				

None of the organisms and viruses above showed cross-reactivity and interference when tested with the candidate device at the concentrations listed.

**b. Endogenous and Exogenous Interfering Substances:**

Forty-two (42) potential interference substances were evaluated with the CareSuperb COVID-19 Antigen Home Test. Each substance was tested in triplicate in the absence or presence of two gamma-inactivated SARS-CoV-2 strains at 2X LoD (Wild Type (WT): USA-WA1/2020 (5.26x10<sup>2</sup> TCID<sub>50</sub>/mL) and Omicron Variant (Omicron): B.1.1.529 (3.00x10<sup>2</sup> TCID<sub>50</sub>/mL) and the negative sample was NSM. Replicate samples were generated by spiking 50µL of virus diluted in NSM with or without the potentially interfering substance on a dry swab. Swabs were then processed per the test's IFU. Based on the test results, the endogenous and exogenous interfering substances tested at the concentrations listed in Table 4 below do not cross-react or interfere with the performance of the CareSuperb COVID-19 Antigen Home Test.

**Table 4.** Summary of Interfering Substances Study Results

Microorganism	Testing Concentration	With SARS-CoV-2 Interfering Substances		Without SARS-CoV-2 Interfering Substances
		WT	Omicron	NSM
Acetaminophen	10 mg/mL	100% (3/3)	100% (3/3)	0% (0/3)
Acetyl salicylic acid	15 mg/mL	100% (3/3)	100% (3/3)	0% (0/3)
Beconase AQ Nasal Spray (Beclomethasone)	5 mg/mL	100% (3/3)	100% (3/3)	0% (0/3)
Benzocaine	5 mg/mL	100% (3/3)	100% (3/3)	0% (0/3)
Budesonide	2 mg/mL	100%	100%	0%

Microorganism	Testing Concentration	With SARS-CoV-2 Interfering Substances		Without SARS-CoV-2 Interfering Substances
		WT	Omicron	NSM
		(3/3)	(3/3)	(0/3)
Chlorpheniramine maleate	5 mg/mL	100% (3/3)	100% (3/3)	0% (0/3)
Dexamethasone	1 mg/mL	100% (3/3)	100% (3/3)	0% (0/3)
Dextromethorphan HBr	2 mg/mL	100% (3/3)	100% (3/3)	0% (0/3)
Diphenhydramine HCl	5 mg/mL	100% (3/3)	100% (3/3)	0% (0/3)
Nasarel Nasal Spray (Flunisolide)	5 mg/mL	100% (3/3)	100% (3/3)	0% (0/3)
Fluticasone	1 mg/mL	100% (3/3)	100% (3/3)	0% (0/3)
Guaiacol Glyceryl Ether	20 mg/mL	100% (3/3)	100% (3/3)	0% (0/3)
Histamine Dihydrochloride	10 mg/mL	100% (3/3)	100% (3/3)	0% (0/3)
Menthol	10 mg/mL	100% (3/3)	100% (3/3)	0% (0/3)
Mometasone	1 mg/mL	100% (3/3)	100% (3/3)	0% (3/3)
Molnupiravir	1 mg/mL	100% (3/3)	100% (3/3)	0% (0/3)
Mucin (Bovine submaxillary glands - Type 1-S)	2.5 mg/mL	100% (3/3)	100% (3/3)	0% (0/3)
Mupirocin	1 mg/mL	100% (3/3)	100% (3/3)	0% (0/3)
Phenylpropanolamine	5 mg/mL	100% (3/3)	100% (3/3)	0% (3/3)
Remdesivir	1 mg/mL	100% (3/3)	100% (3/3)	0% (0/3)
Tamiflu (Oseltamivir Phosphate)	5 mg/mL	100% (3/3)	100% (3/3)	0% (0/3)
Tobramycin	1 mg/mL	100% (3/3)	100% (3/3)	0% (0/3)
Triamcinolone	1 mg/mL	100% (3/3)	100% (3/3)	0% (0/3)
Zanamivir	1 mg/mL	100% (3/3)	100% (3/3)	0% (0/3)
Sore Throat Spray (Phenol)	15 % v/v	100% (3/3)	100% (3/3)	0% (0/3)
Zicam Oral Mist (Zincum aceticum, Zincum gluconicum)	15 % v/v	100% (3/3)	100% (3/3)	0% (0/3)
Nasal Spray (Phenylephrine HCl)	15 % v/v	100% (3/3)	100% (3/3)	0% (0/3)

Microorganism	Testing Concentration	With SARS-CoV-2 Interfering Substances		Without SARS-CoV-2 Interfering Substances
		WT	Omicron	NSM
NasalCrom Nasal Spray (Cromolyn sodium)	15 % v/v	100% (3/3)	100% (3/3)	0% (0/3)
Vicks Sinex Nasal spray (Oxymetazoline HCl)	15 % v/v	100% (3/3)	100% (3/3)	0% (0/3)
Alkalol Allergy Relief (Galphimia glauca, Luffa operculata, Sabadilla)	15 % v/v	100% (3/3)	100% (3/3)	0% (0/3)
Zicam Allergy Relief (Galphimia glauca, Histaminum hydrochloricum, Luffa operculata, Sulphur)	15 % v/v	100% (3/3)	100% (3/3)	0% (0/3)
Hand Sanitizer	15 % v/v	100% (3/3)	100% (3/3)	0% (0/3)
Hand Soap	15 % v/v	100% (3/3)	100% (3/3)	0% (0/3)
Whole blood	2.5% v/v	100% (3/3)	100% (3/3)	0% (0/3)
Buffy coat	2.5% v/v	100% (3/3)	100% (3/3)	0% (0/3)
Allergy Spray (Mometasone Furoate)	15% v/v	100% (3/3)	100% (3/3)	0% (0/3)
Budesonide Nasal Spray (Budesonide/ Glucocorticoid)	15% v/v	100% (3/3)	100% (3/3)	0% (0/3)
Nasacort Allergy 24HR (Triamcinolone acetonide)	15% v/v	100% (3/3)	100% (3/3)	0% (0/3)
Allergy Relief Nasal Spray (Fluticasone Propionate)	15% v/v	100% (3/3)	100% (3/3)	0% (0/3)
Saline Nasal Spray (Sodium Chloride & Preservatives)	15% v/v	100% (3/3)	100% (3/3)	0% (0/3)
Alkalol Saline Nasal Spray*	15% v/v	100% (3/3)	100% (3/3)	0% (0/3)
Leukocytes	5.0 x 10 <sup>6</sup> cells/mL	100% (3/3)	100% (3/3)	0% (0/3)
*Sodium Chloride, Menthol, Thymol, Camphor, Benzoin Resin Extract, Oils of Eucalyptus, Wintergreen, Spearmint, Fir Needle, Cinnamon & Preservatives				

*c. Biotin Interference:*

The CareSuperb COVID-19 Antigen Home Test uses streptavidin/biotin technology for antibody immobilization. As a result, a biotin interference study was conducted by evaluating the performance of the candidate device with contrived positive and negative samples containing various concentrations of biotin up to 5000 ng/mL. Contrived positive samples were formulated at 2x LoD using gamma-inactivated SARS-CoV-2 WT (USA-WA1/2020) and Omicron strains (B.1.1.529), and the negative sample was NSM. Five (5) replicate swabs for each contrived sample containing various biotin concentrations were generated by spiking

50µL of sample on a dry swab. Swabs were randomized and coded and processed per the Instructions for Use (IFU) of the candidate device. Results are summarized in Table 5 below.

**Table 5.** Summary of Biotin Interference Testing.

Strain	SARS-CoV-2 Concentration (2X LoD)	Biotin Concentration (ng/mL)	Positive Percent Agreement (PPA)
WT (USA-WA1/2020)	5.26 x 10 <sup>2</sup> TCID <sub>50</sub> /mL	5000	0% (0/10)
		3750	0% (0/5)
		2500	100% (10/10)
		<=1250	100% (10/10)
Omicron (B.1.1.529)	3.00 x 10 <sup>2</sup> TCID <sub>50</sub> /mL	5000	0% (5/5)
		3750	0% (0/5)
		2500	100% (5/5)
		<=1250	100% (10/10)
NSM without Virus	NA	5000	0% (0/5)
		3750	0% (0/5)
		2500	0% (0/10)
		<=2500	0% (0/10)

No false-negative (FN) results were observed for SARS-CoV-2 positive samples with biotin concentrations up to 2,500 ng/mL. However, both SARS-CoV-2 strains consistently produced FN results for all five replicates for all tested biotin concentrations exceeding to 2,500 ng/mL.

The negative sample of NSM obtained no false-positive (FP) results at any tested biotin concentrations.

No invalid results were observed with positive and negative samples.

This study confirmed that biotin concentrations above 2,500 ng/mL showed interference with the performance of the CareSuperb COVID-19 Antigen Home, leading to FN results.

4. Assay Reportable Range:

Not applicable, the device is a binary qualitative assay that is visually read.

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

a. Internal Controls:

The CareSuperb COVID-19 Antigen Home Test contains an internal control, denoted directly on the test device as “C”. The test strip specific control line is needed to indicate that each test strip is working adequately in each performed test. The control line contains immobilized antibodies that capture the labeled control antibodies preloaded in the conjugated wick filter (i.e., reagent pad). The control line must be positive for a valid test result to demonstrate that the test reagents are functional, and the test was correctly performed. If the control line is not detected, the sample result is invalid and needs to be retested with a new sample and a new device.

b. Sample Stability:

Samples in the OTC environment will not undergo storage as the IFU instructs the users to immediately proceed from sample collection to the testing steps.

c. Real-Time Stability:

Shelf-life of the CareSuperb COVID-19 Antigen Rapid Test under the intended storage condition (2-30°C) was assessed in a real-time stability study using three (3) lots of test kits stored at 2°C and 30°C/80% Relative Humidity (RH). The test kits were assessed with negative samples (NSM) and contrived positives samples at 4X LoD prepared using gamma-irradiated SARS-CoV-2 Omicron (B.1.1.529 at  $6.00 \times 10^2$  TCID<sub>50</sub>/mL). Replicate samples were generated by spiking 50µL of virus diluted in NSM onto dry swabs. Five (5) replicates per time point per storage condition were tested.

Data collected to date in this study (1, 2, 3, 4, 5, 6, 7, 8 and 9 months) support a test kit shelf-life of 8 months when stored at the intended storage temperature of 2° to 30°C.

d. Shipping Stability:

i. *Summer Condition:*

To understand the stability of the test kit under summer shipping conditions, the CareSuperb COVID-19 Antigen Home Test kits from three (3) lots were stored at 60°C with 85% ±5% relative humidity for ten (10) days. The stored kits were taken out daily and tested with five (5) replicates of contrived positive (SARS-CoV-2 Omicron B.1.1.529 at 4X LoD) and negative samples. Replicate samples were generated by spiking 50µL of positive and negative samples in NSM onto dry swabs and process the swabs per the IFU of the test. All negative samples (NSM) tested negative, all contrived SARS CoV-2 Omicron positive samples (tested positive over the 10 days demonstrating shipping stability of the test under summer conditions.

ii. *Winter Condition:*

To determine the effect of winter shipping conditions on the performance of CareSuperb COVID-19 Antigen Home Test kits from three (3) different lots were exposed to the following two winter conditions:

- Study 1: Storage at -20°C for ten (10) days. For each day testing was conducted after a 4-hour equilibrium at RT.
- Study 2: Storage with fluctuating temperatures at -20°C with three (3) freeze/thaw cycles. Each cycle was 24 hours at -20°C and followed by 24 hours at RT. Next the kits were stored at 55°C for 35 days (testing every three days). After 35 days the kits underwent an additional three (3) freeze/thaw cycles.

Kits were tested as described for the summer conditions above. All negative samples (NSM) tested negative, all positive contrived samples (Omicron B.1.1.529 at 4X LoD tested positive in all storage conditions.

## 6. Detection Limit:

### a. Limit of Detection

The limit of detection (LoD) of the CareSuperb COVID-19 Antigen Home Test was determined by evaluating different dilutions of gamma-irradiated SARS-CoV-2 virus diluted with natural negative clinical anterior nasal swab matrix (NSM). Two SARS-CoV-2 strains were utilized USA-WA1/2020 and Omicron Lineage B.1.1.529. The LoD was assessed in two parts, a preliminary LoD, and a confirmatory LoD. Virus dilution (50 µL/swab) were each spiked onto dry sterile swabs and tested per IFU.

#### i. *Preliminary LoD:*

A preliminary LoD was determined by first testing ten-fold dilutions of each inactivated SARS-CoV-2 virus strains (Wild Type [WT]: USA-WA1/2020 and Omicron: B.1.1.529) in five (5) replicates using three (3) different lots of the candidate device. The lowest concentration with 5 out of 5 positive replicates) was defined as preliminary LoD. The preliminary LoD was determined to be  $7.9 \times 10^2$  TCID<sub>50</sub>/mL (WT) and  $1.5 \times 10^2$  TCID<sub>50</sub>/mL (Omicron), respectively. Results are shown in Table 6 below:

**Table 6.** Preliminary LoD with SARS-CoV-2 USA-WA1/2020 and Omicron: B.1.1.529

Strain	Lot Number	Concentration (TCID <sub>50</sub> /mL)	Detection Rate (Detected/Total Tested)
WT (USA-WA1/2020)	CT23H02	$7.9 \times 10^4$	100% (5/5)
		$7.9 \times 10^3$	
		<b><math>7.9 \times 10^2^*</math></b>	
		$7.9 \times 10^1$	0% (0/5)
		$7.9 \times 10^0$	
	CT23J01	$7.9 \times 10^4$	100% (5/5)
		$7.9 \times 10^3$	
		<b><math>7.9 \times 10^2^*</math></b>	
		$7.9 \times 10^1$	0% (0/5)
		$7.9 \times 10^0$	
	CT23J02	$7.9 \times 10^4$	100% (5/5)
		$7.9 \times 10^3$	
		<b><math>7.9 \times 10^2^*</math></b>	
		$7.9 \times 10^1$	0% (0/5)
		$7.9 \times 10^0$	
Omicron (B.1.1.529)	CT23H02	$1.5 \times 10^5$	100% (5/5)
		$1.5 \times 10^4$	
		$1.5 \times 10^3$	
		<b><math>1.5 \times 10^2^*</math></b>	0% (0/5)
		$1.5 \times 10^1$	
	CT23J01	$1.5 \times 10^5$	100% (5/5)
		$1.5 \times 10^4$	
		$1.5 \times 10^3$	
		<b><math>1.5 \times 10^2^*</math></b>	0% (0/5)
		$1.5 \times 10^1$	
	CT23J02	$1.5 \times 10^5$	100% (5/5)
		$1.5 \times 10^4$	
		$1.5 \times 10^3$	

Strain	Lot Number	Concentration (TCID <sub>50</sub> /mL)	Detection Rate (Detected/Total Tested)
		<b>1.5 x 10<sup>2</sup>*</b>	
		1.5 x 10 <sup>1</sup>	0% (0/5)
<b>*Preliminary LoD for WT and Omicron</b>			

ii. Confirmatory LoD:

A confirmatory LoD was performed for each SARS-CoV-2 virus strain using 3-fold dilutions in NSM at concentrations at, below and above the preliminary (1X) LoD. Additional concentrations were tested as needed based upon the results of the 3-fold dilutions. Each dilution was tested with twenty (20) replicates with three (3) candidate device kit lots. For the LoD to be confirmed, at least 95% of the replicates (19/20) at the preliminary LoD needed to obtain positive results. The confirmatory LoD was determined to be 2.63x10<sup>2</sup> TCID<sub>50</sub>/mL for the SARS-CoV-2 USA-WA1/2020 (WT) and 1.5x10<sup>2</sup> TCID<sub>50</sub>/mL for the Omicron variant B.1.1.529. Results of the confirmatory LoD study are shown in Table 7 below:

**Table 7.** Confirmatory LoD Study for WT and Omicron SARS-CoV-2

Strain	Lot Number	Concentration (TCID <sub>50</sub> /mL)	Detection Rate (Detected/Total Tested)
WT (USA-WA1/2020)	CT23H02	7.9 x 10 <sup>3</sup>	100% (20/20)
		7.9 x 10 <sup>2</sup>	
		2.63 x 10 <sup>2</sup> *	
		8.78 x 10 <sup>1</sup>	10 % (2/20)
		7.9 x 10 <sup>1</sup>	0% (0/20)
	CT23J01	7.9 x 10 <sup>3</sup>	100% (20/20)
		7.9 x 10 <sup>2</sup>	
		2.63 x 10 <sup>2</sup> *	
		8.78 x 10 <sup>1</sup>	15 % (3/20)
		7.9 x 10 <sup>1</sup>	0% (0/20)
	CT23J02	7.9 x 10 <sup>3</sup>	100% (20/20)
		7.9 x 10 <sup>2</sup>	
		2.63 x 10 <sup>2</sup> *	
		8.78 x 10 <sup>1</sup>	15 % (3/20)
		7.9 x 10 <sup>1</sup>	0% (0/20)
Omicron (B.1.1.529)	CT23H02	1.5 x 10 <sup>3</sup>	100% (20/20)
		1.5 x 10 <sup>2</sup> *	
		5.0 x 10 <sup>1</sup>	0% (0/20)
		1.5 x 10 <sup>1</sup>	
	CT23J01	1.5 x 10 <sup>3</sup>	100% (20/20)
		1.5 x 10 <sup>2</sup> *	
		5.0 x 10 <sup>1</sup>	10% (2/20)
		1.5 x 10 <sup>1</sup>	0% (0/20)
	CT23J02	1.5 x 10 <sup>3</sup>	100% (20/20)
		1.5 x 10 <sup>2</sup> *	
		5.0 x 10 <sup>1</sup>	5% (1/20)
		1.5 x 10 <sup>1</sup>	0% (0/20)
*Confirmed LoD			



b. International Standard for SARS-CoV-2 antigen (NIBSC code: 21/368) - LoD Testing

The LoD of the CareSuperb COVID-19 Antigen Home Test with an international standard material for SARS-CoV-2 antigen, NIBSC code: 21/368, was determined by testing different dilutions of the standard with one (1) lot of the CareSuperb COVID-19 Antigen Home Test. Ampoules of the lyophilized SARS-CoV-2 antigen standard were reconstituted in 250 µL ultra-pure water per the package insert of the standard and were then pooled together to obtain a final concentration of 20,000 IU/mL. Dilutions were made in NSM. The LoD was determined as the lowest virus concentration that was detected  $\geq 95\%$  of the time (i.e., concentration at which at least 19 out of 20 replicates tested positive). The limit of detection was established in two phases.

i. Preliminary LoD Study:

Five-fold serial dilutions were made from the heat inactivated SARS-CoV-2 antigen standard material into NSM. Three replicates were tested for each 5-fold dilution to determine the preliminary LoD concentration. The lowest concentration with 100% (3/3) positive results was considered the preliminary LoD. For each replicate 50 µL of virus dilution was applied to a swab and the swab was processed according to the IFU.

ii. Confirmatory LoD Study:

A total of twenty (20) replicates per concentration were tested to confirm the LoD. The LoD is confirmed at the lowest concentration that yields at least 19 positive results of the 20 replicates tested (95%). For the device lot tested, the final confirmation data set included the confirmed LoD level with at least one additional level tested above and below. Results of the preliminary and final confirmatory LoD are shown in Table 8 below:

**Table 8.** Preliminary and Confirmatory LoD Study Results with NIBSC code: 21/368

Concentration of SARS-CoV-2 NIBSC code: 21/368		Detection Rate (Detected/Total Tested)
Preliminary LoD Results		
4000 IU/mL	200 IU/Swab	100% (3/3)
800 IU/mL	40 IU/Swab	
160 IU/mL	8 IU/Swab	
32 IU/mL*	1.6 IU/Swab*	
6.4 IU/mL	0.32 IU/Swab	0%
1.25 IU/mL	0.064 IU/Swab	(0/3)
Confirmatory LoD Results		
160 IU/mL	8 IU/Swab	100% (20/20)
32 IU/mL**	1.6 IU/Swab**	100% (20/20)
6.4 IU/mL	0.32 IU/Swab	0% (0/20)
*Preliminary LoD, **Confirmed LoD		

The LoD for the CareSuperb COVID-19 Antigen Home Test using the SARS-CoV-2 antigen standard material NIBSC code: 21/368 in nasal matrix was confirmed to be 32 IU/mL (1.6 IU/swab).

7. Hook Effect:

The purpose of this study was to evaluate the effect of a high concentration of SARS antigen on the performance of the CareSuperb COVID-19 Antigen Home Test. Contrived positive samples were generated using gamma-irradiated SARS-CoV-2 virus strains (WT: USA-WA1/2020; Stock Concentration:  $7.9 \times 10^5$  TCID<sub>50</sub>/mL and Omicron: B.1.1.529; Stock Concentration:  $1.5 \times 10^6$  TCID<sub>50</sub>/mL) prepared by a series of two-fold dilutions with NSM. For each replicate 50 µL of SARS-CoV-2 dilution, was added to a dry sterile swab. Each concentration was tested in five replicates. The testing was conducted according to the IFU for the test. Results of the high dose hook effect are shown in Table 9 below:

**Table 9.** Results of High Does Hook Effect Study

Strain	Lot Number	Concentration (TCID <sub>50</sub> /mL)	Detection Rate (Detected/Total Tested)
WT (USA-WA1/2020)	CT23E01	4.0 x 10 <sup>5</sup>	100% (5/5)
		2.0 x 10 <sup>5</sup>	
		9.9 x 10 <sup>4</sup>	
Omicron (B.1.1.529)		7.5 x 10 <sup>5</sup>	
		3.8 x 10 <sup>5</sup>	
		1.9 x 10 <sup>5</sup>	

All concentrations for both strains obtained 100% agreement for the five replicates. A High-dose hook effect (i.e., false negative results) was not observed with the CareSuperb COVID-19 Antigen Home Test when tested with concentrations up to  $4.0 \times 10^5$  TCID<sub>50</sub>/mL for WT and  $7.5 \times 10^5$  TCID<sub>50</sub>/mL for Omicron of gamma-inactivated SARS-CoV-2 virus strains.

8. Inclusivity (Analytical Reactivity)

Analytical reactivity for the CareSuperb COVID-19 Antigen Home Test was demonstrated using seven additional strains/isolates of SARS-CoV-2 virus. Heat-inactivated SARS-CoV-2 isolates were diluted in NSM at different concentrations. Each concentration was tested with five replicates until two consecutive dilutions produced one or more negative replicates. The reactivity of the CareSuperb COVID-19 Antigen Home Test with the variants is summarized in Table 10 below with the lowest concentration that returned 100% positive replicates (i.e., 5/5):

**Table 10.** Variant Inclusivity of the CareSuperb COVID-19 Antigen Home Test.

SARS-CoV-2 Variants	Lowest Variant Concentration With 5/5 Positive Replicates [TCID <sub>50</sub> /mL]
hCoV-19/USA/CA CDC 5574/2020 (Alpha)	$4.00 \times 10^2$
B.1.617.2 (Delta)	$1.41 \times 10^3$
BA.2.12.1 (Omicron)	$2.02 \times 10^3$
BA.2.3 (Omicron)	$1.87 \times 10^2$
BA.2.75.5 (Omicron)	$2.72 \times 10^2$
BA.4.6 (Omicron)	$1.84 \times 10^3$
JN.1.4 (Omicron)	$6.74 \times 10^2$

A plan has been established by the sponsor to closely monitor the emergence of any circulating variants of concern. The plan includes the monitoring of publicly available databases and information from public health authorities, and a multi-tier approach that determines reactivity of the test with emerging variants (including silico analysis, use of antibody escape mutational profile, and wet testing).

9. Assay Cut-Off

Not applicable, the device is a binary qualitative assay.

**B Comparison Studies:**

1. Method Comparison with Predicate Device:

Not applicable, See “C. Clinical Studies.” for performance comparison with a clinical comparator.

2. Matrix Comparison:

The CareSuperb COVID-19 Antigen Home Test is only intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in direct anterior nasal swab specimens. As no other specimen or sample type is claimed for this device. A Matrix Comparison study is not applicable.

**C Clinical Studies:**

1. Clinical Sensitivity and Specificity:

The performance of the CareSuperb COVID-19 Antigen Home Test was compared to the sample results as generated by a highly sensitive 510(k) cleared molecular SARS-CoV-2 RT-PCR assay. For discordant results, another highly sensitive 510(k) cleared molecular assay was utilized. Ten (10) clinical sites across the U.S. conducted a prospective clinical study from October 2023 through April 2024. 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.

Both the comparator and the candidate test used anterior nasal swab (ANS) samples and the collection order was randomized by study subject. Collection time between swab collections was 15 minutes. Comparator test samples were collected by the clinical study staff at the clinical study sites and inserted individually into 3 mL of viral transport media (UVT) per the IFU of the comparator test. Samples were then sent to a reference laboratory for RT-PCR comparator testing. Samples for the candidate device were either self-collected by a lay user aged  $\geq 14$  years old or collected by an adult (parent/guardian) from individuals 2-13 years old. Each ANS sample was collected and processed by the lay user per the IFU of the candidate device.

A total 646 symptomatic subjects of various ages were enrolled in this study within 4 DPSO were collected. The demographics of the enrolled clinical study subjects are summarized in Table 11 below:

**Table 11.** Enrolled Symptomatic Clinical Study Subject Demographics.

Study Subject Demographic (Symptomatic)	Symptomatic Study Subjects n=646	Total Percentage n=646
<b>Gender</b>		
Male	271	42% (271/646)
Female	375	58% (375/646)
<b>Age</b>		
2-13 years old*	65	10.1% (65/646)
14-21 years old	40	6.2% (40/646)
22-64 years old	481	74.4% (481/646)
≥65 years old	60	9.3% (60/646)
<b>Education</b>		
Not School Age	19	2.9% (19/646)
Some Elementary School	50	7.7% (50/646)
Some Middle School	26	4.0% (26/646)
Some High School	76	11.8% (76/646)
Graduated High School	171	26.5% (171/646)
Some College	102	15.8% (102/646)
Graduated College	153	23.7% (153/646)
Postgraduate/Profession Degree	49	7.6% (49/646)
*Were tested by adults >14 years old per the intended use.		

Across the entire study population, the CareSuperb COVID-19 Antigen Home Test detected SARS-CoV-2 with a Positive Percent Agreement (PPA) of 97.2% when compared to the result of the SARS-CoV-2 RT-PCR comparator assay and Negative Percent Agreement (NPA) of 98.8%. Results are listed in Table 12 and 13 (stratified data by Day Post Symptom Onset; DPSO) below:

**Table 12.** Clinical Performance of CareSuperb COVID-19 Antigen Home Test.

	High Sensitivity SARS-CoV-2 RT-PCR Comparator Assay		
	Positive	Negative	Total
Positive	140	6 <sup>a</sup>	146
Negative	4 <sup>b</sup>	496	500
Total	144	502	646 <sup>c</sup>
Positive Percent Agreement (PPA)	97.2% (140/144) (95% CI:93.1%-98.9%)		
Negative Percent Agreement (NPA)	98.8% (496/502) (95% CI:97.4%-99.5%)		

<sup>a</sup> COVID-19 was detected in 6/6 false positives specimens using a second SARS-CoV-2 RT-PCR test for discrepant analysis.

<sup>b</sup> COVID-19 was not detected in 0/4 false negative specimens using second SARS-CoV-2 RT-PCR test for discrepant analysis

<sup>c</sup> One test was invalid and upon repeat testing a valid result was obtained.

**Table 13.** CareSuperb COVID-19 PPA and NPA Results stratified by DPSO.

DPSO	PPA with 95% Confidence Interval	NPA with 95% Confidence Interval
0	100% (1/1) (95% CI:20.7%-100%)	88.9% (8/9) (95% CI:56.5%-98%)
1	100% (21/21) (95% CI:84.5%-100%)	99.1% (110/111) (95% CI:95.1%-99.8%)
2	98% (49/50) (95% CI:89.5%-99.6%)	100% (196/196) (95% CI:98.1%-100%)
3	100% (48/48) (95% CI:92.6%-100%)	99.2% (131/132) (95% CI:95.8%-99.9%)

DPSO	PPA with 95% Confidence Interval	NPA with 95% Confidence Interval
4	87.5% (21/24) (95% CI:69%-95.7%)	94.4% (51/54) (95% CI:84.9%-98.1%)

## 2. Usability:

A usability study was conducted to assess the lay user's ability to understand the instructions for use to adequately execute the CareSuperb COVID-19 Antigen Home Test workflow accordingly. A total of fifty (50) subjects were enrolled and divided into two (2) separate groups of twenty-five (25) subjects each consisting of the following:

- **Group 1 (n=25):** Home users (testers) age fourteen (14) years old and older, with no medical/laboratory training or background, testing themselves.
- **Group 2 (n=25):** Home users (testers) age eighteen (18) years old or older, with no medical/laboratory training or background, testing another adult or their child aged 2-13 years (donor).

Each study subject enrolled in the study was observed during testing. A total of fourteen (14) predefined tasks were rated by the observer for each study subject participating in the usability study. The usability study obtained an overall success rate of 91.8% (643/700 tasks) with most critical tasks obtaining a success rate of 100%. Two tasks related to washing hands and discarding the test materials were considered artefacts of the simulated home environment.

## 3. Readability:

The purpose of this study was to evaluate whether lay home-users (patients or their care givers) can interpret test results correctly with negative, low positive (1.5X LoD) and positive (5X LoD) samples from the CareSuperb COVID-19 Antigen Home Test.

The readability study was conducted according to an IRB approved protocol in a simulated home environment with the same fifty (50) study subjects which were divided into Group 1 (n=25) and Group 2 (n=25) as described above under the usability study. The study subjects were lay users with diverse gender, ages and educational background who meet the study inclusion criteria, were enrolled for the readability study. Each lay user was asked to interpret four (4) mock test devices with three different concentrations that were arranged in blinded test panels with the following sample results; the order of the results within the panel were randomized:

- Odd Number Study Subjects: Panel 1: Negative, 1.5X LoD, 1.5X LoD, 5X LoD
- Even Number Study Subjects: Panel 2: Negative, Negative, 1.5X LoD, 5X LoD

Fifty percent (50%) of the study participants were male and 50% of the study participants were female. Forty-eight percent (48%) of the individuals were vision impaired, and about thirty-four percent (34%) were still in high school or had a high school degree as their highest level of education.

The readability study obtained an overall success rate of 95% (190/200 mock devices). Incorrect results occurred at random across all age groups and across study participants with and without impaired vision.

**Table 14.** Readability Study Summary Stratified by Age and Overall PPA/NPA

Age group		Correctly Read Results for Usability Samples			
		Negative	Low Positive (1.5xLoD)	Positive (5xLoD)	Total
14-17 years		15/15	13/15	9/10	37/40
18-30 years		16/16	12/14	9/10	37/40
31-55 years		33/33	33/36	23/23	89/92
> 55 years		11/11	9/10	7/7	27/28
<b>Total</b>		<b>75/75</b>	<b>67/75</b>	<b>48/50</b>	<b>190/200</b>
<b>Negative Agreement</b>		<b>100% (75/75)</b>	<b>n/a</b>	<b>n/a</b>	<b>100% (75/75)</b> (95%CI: 95.1%-100%)
<b>Positive Agreement</b>	<b>1.5xLoD</b>	<b>n/a</b>	<b>89.3% (67/75)</b>	<b>n/a</b>	<b>89.3% (67/75)</b> (95%CI: 80.3%-94.5%)
	<b>5xLoD</b>	<b>n/a</b>	<b>n/a</b>	<b>96.0% (48/50)</b>	<b>96.0% (48/50)</b> (95% CI: 86.5%-98.9%)

#### D Clinical Cut-Off:

There is no clinical cut-off for this device. This section is therefore not applicable.

#### E Expected Values/Reference Range:

A patient sample is expected to be negative for SARS-CoV-2

#### F Other Supportive Information:

##### 1. Flex Studies:

To assess the robustness and risk for false results of the test when deviating from the IFU/QRI test steps, flex studies were conducted that assessed all major aspects of the test procedure (extraction buffer volume, reading time, procedure involving sample port [swab insertion, rotation, and removal], sample hold time before and during processing) and variability of environmental test conditions that the test may be subjected to when in use (non-level surface, lighting, disturbance during use, temperature and humidity stress conditions). Testing was performed with contrived positive nasal swabs generated by diluting SARS-CoV-2 virus (USA-WA1/2020 and Omicron B.1.1529) into negative NSM at 2X LoD. False results were observed with too little extraction buffer volume and delayed reading time, specifically with less than 110 µL (5-6 drops) of extraction buffer added onto the swab inserted into the sample port and read times of five and fifty minutes. The studies support that the test is robust in the intended use condition with an insignificant risk of erroneous result.

## 2. Variant Monitoring Plan:

To determine whether the CareSuperb COVID-19 Antigen Home Test can detect newly emerging variants, and/or to assess whether new mutations are impacting analytical sensitivity of the test performance, the sponsor provided the variant monitoring plan as described below:

- a) *In silico* analysis will be conducted using the amino acid sequences of the nucleocapsid protein from various SARS-CoV-2 variants deposited in the GISAID/NCBI database every three months to assist identifying any mutations which could impact the test performance.
- b) Escape mutation profiling (Escape-Map) analysis of antibodies used in the CareSuperb COVID-19 Antigen Home test.
- c) Wet testing of inactivated new variants if they can be obtained will be conducted utilizing the sample protocol as the inclusivity study.
- d) Wet testing using nucleocapsid recombinant proteins by using serial dilution of each recombinant protein to compare the results using the same concentration of each recombinant protein. Results will be reported in the variant monitoring report. However, when inactivated virus can be obtained, wet testing using inactivated virus will be conducted.

## **VIII Proposed Labeling:**

The labeling supports the finding of substantial equivalence for this device.

## **IX Conclusion:**

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.