January 29, 2025

Access Bio, Inc.
Sung Jang
Senior Manager of Regulatory Affairs
65 Clyde Road
Suite A
Somerset, New Jersey 08873

Re: K241915

Trade/Device Name:	CareSuperb COVID-19 Antigen Home Test
Regulation Number:	21 CFR 866.3984
Regulation Name:	Over-The-Counter Test To Detect SARS-Cov-2 From Clinical Specimens
Regulatory Class:	Class II
Product Code:	QYT
Dated:	June 29, 2024
Received:	July 1, 2024

Dear Sung Jang:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Silke Schlottmann -S

Digitally signed by Silke Schlottmann -S
Date: 2025.01.29 14:12:50 -05'00'

Silke Schlottman, Ph.D.
Deputy Assistant Director
Bacteriology Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241915

Device Name
CareSuperb COVID-19 Antigen Home Test

Indications for Use *(Describe)*
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.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(k) Summary

Date Prepared: Jan. 27, 2025

1. Submitter Information

1.1. Name: Access Bio, Inc.
1.2. Address: 65 Clyde Road, Suite A, Somerset, NJ 08873
1.3. Telephone Number: +1-732-873-4040
1.4. Contact Person:
Sung Jang, Senior Manager of Regulatory Affairs
Email: sajang@accessbio.net

2. Device Information

2.1. Trade or Proprietary Name: *CareSuperb*™ COVID-19 Antigen Home Test
2.2. Common Name: COVID-19 Antigen Detection Test
2.3. Classification: Class II
2.4. Classification Name: Over-the-counter Covid-19 Antigen Test
2.5. Product Code: QYT
2.6. Regulation Number: 21 CFR 866.3984
2.7. Review Panel: Microbiology

3. Legally Marketed Predicate Device

3.1. Trade Name: Flowflex COVID-19 Antigen Home Test
3.2. Manufacturer: ACON Laboratories, Inc.
3.3. 510(k) Number: K230828
3.4. Product Code: QYT
3.5. Review Panel: Microbiology

4. Device Description

The *CareSuperb*™ COVID-19 Antigen Home Test is a lateral flow immunoassay device intended for the qualitative detection of SARS-CoV-2 nucleocapsid protein in anterior nasal samples.

To begin the test, a self-collected anterior nasal swab sample (in individuals aged 14 and older or individuals between the age of 2 to 14 a swab collected by a parent or guardian), or a healthcare-provider collected anterior nasal swab sample is inserted into the sample port and the extraction reagent in the dropper vial is added to the sample port for the extraction to occur exposing the viral nucleocapsid antigens. The 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 the plastic cassette and travel across the membrane through capillary action. The complexes are captured at the test line region, causing a colored line to appear on the membrane.

If the sample contains SARS-CoV-2 antigen, a visible line at the test line ("T") and a procedural control line at the control line ("C") will appear in the result window indicating a positive result. If SARS-CoV 2 viral nucleocapsid antigens are not present, or are present at very low levels, only the procedural control line will appear.

4.1. Kit Components:

The *CareSuperb*™ COVID-19 Antigen Home Test is available in three package sizes (Catalog/Reference Number: RCTM-

00171, RCTM-00271 and RCTM-02071).

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

5. Indications for Use / 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.

6. Comparison with Predicate Device

Contents	Predicate Device	Subject Device
Manufacturer	ACON Laboratories, Inc.	Access Bio, Inc.
Proprietary name	Flowflex COVID-19 Antigen Home Test	*CareSuperb*™ COVID-19 Antigen Home Test
K Number	K230828	K241915
Product Code	QYT	QYT
Regulation Number	21 CFR 866.3984	21 CFR 866.3984
Regulatory Class	Class II	Class II
Test Principle	Lateral flow immunoassay	Lateral flow immunoassay
Qualitative/Quantitative	Qualitative	Qualitative
Analyte/Assay Target	SARS-CoV-2 nucleocapsid protein antigen	SARS-CoV-2 nucleocapsid protein antigen

Contents	Predicate Device	Subject Device
Intended Use/ Indications for Use	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. 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. The Flowflex COVID-19 Antigen Home Test does not differentiate between SARS-CoV and SARS-CoV-2. 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 preclude 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. 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 variants are emerging, performance characteristics may vary. 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	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.,

Contents	Predicate Device	Subject Device
	or worsening COVID-19 like symptoms, such as fever, cough and/or shortness of breath, should seek follow up care from their healthcare provider.	PCR) should be considered in situations where a new virus or variant is suspected.
Intended Use Settings	Over-the-counter use/self-testing	Over-the-counter use/self-testing
Intended Use Population	Individuals with symptoms of COVID-19	Individuals with symptoms of COVID-19
Specimen Type	Direct anterior nasal swab specimen	Direct anterior nasal swab specimen
Development Time	15-30 min	15-30 min
Result Interpretation	Visually Read	Visually Read
Storage Condition	2-30°C	2-30°C
Device Type	Test cartridge (cassette)	Test cartridge (cassette with a sample port)
Extraction Buffer Volume Used	4 drops	~250 µL

7. Performance Data

7.1. Analytical Performance

1) Precision (Repeatability/Reproducibility) Study

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 negative nasal swab matrix 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 agreement 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.

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%

2) Limit of Detection (LoD)

The LoD of the *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 resulting in positive detection of ≥ 95% of the replicates (at least 19 out of 20 replicates for each lot) for each strain was confirmed as the LoD.

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.

The confirmed LoD concentration is summarized in the table below.

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

3) Hook Effect Study

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

4) Cross Reactivity/Microbial Interference Study

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 three 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.

Microorganism/Virus	Testing Concentration	Cross-Reactivity (Yes/No)	Interference (Yes/No)
Adenovirus 1	1.58×10^5 $TCID_{50}$/mL	No	No
Adenovirus 7	1.6×10^5 $TCID_{50}$/mL	No	No
Enterovirus	1.6×10^6 $TCID_{50}$/mL	No	No
Human coronavirus (OC43)	1.4×10^5 $TCID_{50}$/mL	No	No
Human coronavirus (229E)	2.8×10^4 $TCID_{50}$/mL	No	No
Human coronavirus (NL63)	8.0×10^4 $TCID_{50}$/mL	No	No
Human metapneumovirus (hMPV)	2.8×10^5 $TCID_{50}$/mL	No	No
Influenza A Virus (H3N2)	3.5×10^5 FFU/mL	No	No
Influenza B Virus (Yamagata)	7.6×10^5 $TCID_{50}$/mL	No	No
MERS-CoV	1.78×10^5 $TCID_{50}$/mL	No	No
Parainfluenza virus type 1	7.4×10^5 $TCID_{50}$/mL	No	No
Parainfluenza virus type 2	1.58×10^5 $TCID_{50}$/mL	No	No
Parainfluenza virus type 3	1.58×10^5 $TCID_{50}$/mL	No	No

Microorganism/Virus	Testing Concentration	Cross-Reactivity (Yes/No)	Interference (Yes/No)
Parainfluenza virus type 4	5.0 x 10^5 $TCID_{50}$/mL	No	No
Respiratory syncytial virus Type B	1.58 x 10^5 $TCID_{50}$/mL	No	No
Rhinovirus	1.58 x 10^5 $TCID_{50}$/mL	No	No
SARS-Coronavirus	1.0 x 10^5 PFU/mL	No	No
Human coronavirus HKU1	Clinical Sample[a]	No	No
Bordetella pertussis	1.0 x 10^7 CFU/mL	No	No
Chlamydophila pneumoniae	1.4 x 10^6 CFU/mL	No	No
Haemophilus influenzae	1.6 x 10^6 CFU/mL	No	No
Legionella pneumophila	1.4 x 10^6 CFU/mL	No	No
Mycoplasma pneumoniae	6.5 x 10^5 CFU/mL	No	No
Streptococcus pneumoniae	1.0 x 10^7 CFU/mL	No	No
Streptococcus pyogenes, Group A	1.0 x 10^7 CFU/mL	No	No
Staphylococcus aureus	1.0 x 10^7 CFU/mL	No	No
Staphylococcus epidermidis	1.0 x 10^7 CFU/mL	No	No
Candida albicans	1.0 x 10^7 CFU/mL	No	No
Pooled human nasal wash	N/A	No	No

[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.

5) Interfering Substances Effect Study

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	Cross-Reactivity (Yes/No)	Interference (Yes/No)
Acetaminophen	10 mg/mL	No	No
Acetyl salicylic acid	15 mg/mL	No	No
Beconase AQ Nasal Spray (Beclomethasone)	5 mg/mL	No	No
Benzocaine	5 mg/mL	No	No
Budesonide	2 mg/mL	No	No
Chlorpheniramine maleate	5 mg/mL	No	No
Dexamethasone	1 mg/mL	No	No
Dextromethorphan HBr	2 mg/mL	No	No
Diphenhydramine HCl	5 mg/mL	No	No
Nasarel Nasal Spray (Flunisolide)	5 mg/mL	No	No
Fluticasone	1 mg/mL	No	No
Guaiacol Glyceryl Ether	20 mg/mL	No	No
Histamine Dihydrochloride	10 mg/mL	No	No
Menthol	10 mg/mL	No	No

Substances	Testing Concentration	Cross-Reactivity (Yes/No)	Interference (Yes/No)
Mometasone	1 mg/mL	No	No
Molnupiravir	1 mg/mL	No	No
Mucin (Bovine submaxillary glands -Type I-S)	2.5 mg/mL	No	No
Mupirocin	1 mg/mL	No	No
Phenylpropanolamine	5 mg/mL	No	No
Remdesivir	1 mg/mL	No	No
Tamiflu (Oseltamivir Phosphate)	5 mg/mL	No	No
Tobramycin	1 mg/mL	No	No
Triamcinolone	1 mg/mL	No	No
Zanamivir	1 mg/mL	No	No
Sore Throat Spray (Phenol)	15 % v/v	No	No
Zicam Oral Mist (Zincum aceticum, Zincum gluconicum)	15 % v/v	No	No
Nasal Spray (Phenylephrine HCl)	15 % v/v	No	No
NasalCrom Nasal Spray (Cromolyn sodium)	15 % v/v	No	No
Vicks Sinex Nasal spray (Oxymetazoline HCl)	15 % v/v	No	No
Alkalol Allergy Relief (Galphimia glauca, Luffa operculate, Sabadilla)	15 % v/v	No	No
Zicam Allergy Relief (Galphimia glauca, Histaminum hydrochloricum, Luffa operculate, Sulphur)	15 % v/v	No	No
Hand Sanitizer	15 % v/v	No	No
Hand Soap	15 % v/v	No	No
Whole blood	2.5 % v/v	No	No
Buffy coat	2.5 % v/v	No	No
Allergy Spray (Mometasone Furoate)	15 % v/v	No	No
Budesonide Nasal Spray (Budesonide/Glucocorticoid)	15 % v/v	No	No
Nasacort Allergy 24HR (Triamcinolone acetonide)	15 % v/v	No	No
Allergy Relief Nasal Spray (Fluticasone Propionate)	15 % v/v	No	No
Saline Nasal Spray (Sodium Chloride & Preservatives)	15 % v/v	No	No
Alkalol Saline Nasal Spray (Sodium Chloride, Menthol, Thymol, Camphor, Benzoin Resin Extract, Oils of Eucalyptus, Wintergreen, Spearmint, Fir Needle, Cinnamon & Preservatives)	15 % v/v	No	No
Leukocytes	5.0 x 10^6 cells/mL	No	No

6) Biotin Interference Study

A potential interference effect of biotin to the *CareSuperb*™ COVID-19 Antigen Home Test was tested and false negative results were obtained when the biotin concentration in the positive samples exceeded 2,500 ng/mL.

7) Inclusivity (Analytical Reactivity) Study

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 with 5/5 positive replicates ($TCID_{50}$/mL)
SARS-Co V-2, hCoV-1 9/USA/CA; CDC_5574/2020; Alpha variant	4.00×10^2
SARS-Co V-2, Lineage B.1.617.2; Delta Variant	1.41×10^3
SARS-CoV-2, Lineage BA.2.12.1; Omicron Variant	2.02×10^3
SARS-CoV-2, Lineage BA.2.3; Omicron Variant	1.87×10^2
SARS-CoV-2, Lineage BA.2.75.5; Omicron Variant	2.72×10^2
SARS-Co V-2, Lineage BA.4.6; Omicron Variant	1.84×10^3
SARS-CoV-2 Lineage JN.1.4; Omicron Variant	6.74×10^2

8) Flex Studies

To assess the robustness of the *CareSuperb*™ COVID-19 Antigen Home Test, flex studies were conducted that assessed all major aspects of the test procedure for potential sources of error that may occur when (1) performing the test (e.g., different reading times, extraction buffer volume variability, delay in swab collection to insertion into sample port, delay in addition of extraction buffer after swab insertion into sample port, swab rotation variability after insertion into sample port, delay in removing swab after rotation, delay in initiating testing after opening pouch, variations of swab insertion into sample port) and (2) when environmental test conditions that the test may be subjected to when in use vary (e.g., various temperature and humidity stress, cassette on non-level surface, cassette disturbance, impact of different light sources). Testing was performed with contrived positive nasal swabs prepared by diluting gamma-irradiated SARS-CoV-2 virus (WA1/2020 and Omicron B.1.1.529) into NSM at 2X LoD and negative samples (NSM). The studies support that the test is robust in the intended use condition with an insignificant risk of erroneous results.

7.2. Clinical Performance

The clinical performance characteristics of the *CareSuperb*™ COVID-19 Antigen Home Test using anterior nasal swab specimen were evaluated at 10 clinical sites in the U.S. between October 2023 and April 2024 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%)

7.3. 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.

7.4. Readability Study

The purpose of this study was to assess users' comprehension of various levels of positive, negative, and invalid test results for the *CareSuperb*™ COVID-19 Antigen Home Test. Two panels of mock devices with results were prepared, the first panel comprising a negative, two low positives (1.5 to 2x LoD) and a positive (5x LoD) and the second one comprising two negatives, one low positive (1.5 to 2x LoD) and a positive (5x LoD). The panels were randomized, and each study participant was given one of the panels and asked to interpret the results per the IFU. Fifty users participated in the study and the overall success rate for both panels was 95.0% demonstrating that the users were able to competently interpret the results for the *CareSuperb*™ COVID-19 Antigen Home Test with the IFU.

7.5. Conclusion

These studies demonstrated equivalent performance of the *CareSuperb*™ COVID-19 Antigen Home Test to the predicate device, Flowflex COVID-19 Antigen Home Test (K230828).