510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K251604

B Applicant

Access Bio, Inc.

C Proprietary and Established Names

CareSuperb COVID-19/Flu A&B Antigen Combo Home Test

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
SCA	Class II	21 CFR 866.3987 - Multi-Analyte Respiratory Virus Antigen Detection Test	MI - Microbiology

II Submission/Device Overview:

A Purpose for Submission:

To obtain 510(k) clearance for the CareSuperb COVID-19/Flu A&B Antigen Combo Home Test

B Measurand:

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

All negative results are presumptive and should be confirmed with an FDA-cleared molecular assay when determined to be appropriate by a healthcare provider. Negative results do not rule out infection with influenza, SARS-CoV-2, or other pathogens.

Individuals who test negative and experience continued or worsening respiratory symptoms, such as fever, cough, and/or shortness of breath, should seek follow up care from their healthcare provider.

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

C Special Conditions for Use Statement(s):

OTC - Over The Counter

D Special Instrument Requirements:

Not applicable. There is no associated instrumentation as the test is visually.

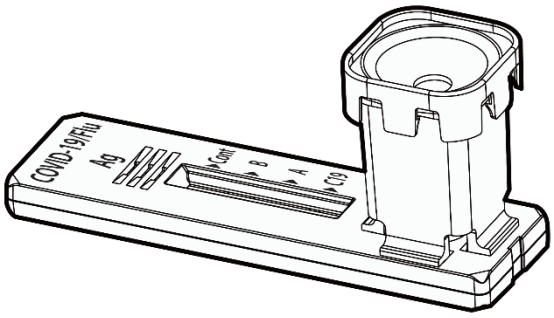
IV Device/System Characteristics:

A Device Description:

The CareSuperb COVID-19/Flu A&B Antigen Combo Home Test is a rapid lateral flow immunochromatographic assay for the qualitative detection and differentiation of SARS-CoV-2, influenza A, and influenza B antigens from anterior nasal swab specimens.
Each kit includes:

- Single-use test cassette in a foil pouch with desiccant
- Assay buffer dropper vial (250 μL)
- Sterile anterior nasal swab
- Quick Reference Instructions (QRI)

The test device is packaged in a sealed aluminum foil pouch containing a single-use test cassette and a desiccant pack. Each cassette is labeled with "COVID-19/Flu" above the result window for identification. The plastic cassette housing contains an integrated adaptor that includes a silver-foiled cap and sample port. The conjugate wick filter within the adaptor is dispensed with labeled detecting antibodies. See Figure below.



B Principle of Operation:

The CareSuperb COVID-19/Flu A&B Antigen Combo Home Test is a lateral flow immunochromatographic assay intended for the qualitative detection and differentiation of SARS-CoV-2 nucleocapsid antigen and influenza A and B nucleoprotein antigens in anterior nasal swab specimens.

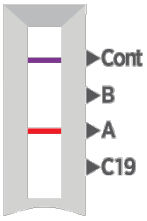
To initiate testing, the user collects an anterior nasal specimen using the sterile nasal swab provided in the test kit. For individuals aged 14 years or older, the specimen samples are self-collected; for individuals younger than 14 years, an adult collects the sample. The swab is then inserted into the sample port of the test cassette and the extraction reagent in the dropper vial is added to the sample port for the sample extraction to occur exposing the viral antigens. The viral antigens present in the sample bind to their respective labeled antibodies dispensed in the conjugate wick filter. These antigen-antibody complexes migrate to the test strip encased in a plastic cassette and across the membrane through capillary action and are captured by either anti-SARS-CoV, anti-influenza A, or anti-influenza B antibodies causing color at the defined lines, respectively: “C19” (blue line), "A" (red line), and "B" (blue line). The control line incorporates anti-chicken IgY antibody and is designated as "Cont", causing a purple-colored line to appear on the membrane. The complexes are interpreted visually between 10 to 15 minutes based on the presence or absence of the test line.

C Interpretation of Results:

Positive Result

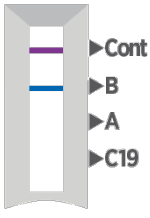
Influenza A Positive

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



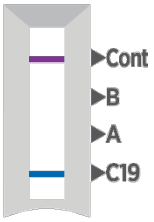
Influenza B Positive

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



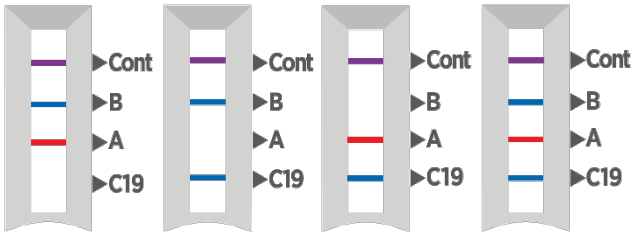
COVID-19 Positive

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



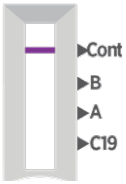
Coinfection Positive Result

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



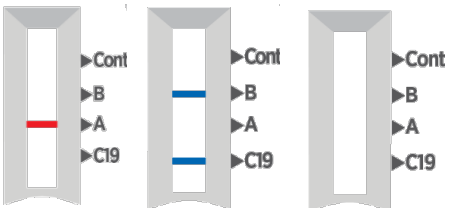
Negative Result

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



Invalid Result

No purple-colored line next to "Cont" indicates an invalid result. A new test is needed to get a valid result.



V Substantial Equivalence Information:

A Predicate Device Name(s):

WELLlife COVID-19 / Influenza A&B Home Test; WELLlife COVID-19 / Influenza A&B AntigenTest

B Predicate 510(k) Number(s):

K243256

C Comparison with Predicate(s):

Device & Predicate Device(s):	K251604	K243256
Device Trade Name	CareSuperb COVID-19/Flu A&B Antigen Combo Home Test	WELLlife COVID-19/Influenza A&B Home Test / WELLlife COVID-19/Influenza A&B

		Antigen Test
General Device Characteristic Similarities		
Intended Use/Indications For Use	The CareSuperb COVID-19/Flu A&B Antigen Combo Home Test is a lateral flow immunochromatographic assay intended for the qualitative detection and differentiation of influenza A and influenza B nucleoprotein antigens and SARS-CoV-2 nucleocapsid antigen directly in anterior nasal swab samples from individuals with signs and symptoms of respiratory tract infection. Symptoms of respiratory infections due to SARS-CoV-2 and influenza can be similar. This test is for non-prescription home use by individuals aged 14 years or older testing themselves, or adults testing individuals aged 2 years or older. All negative results are presumptive and should be confirmed with an FDA-cleared molecular assay when determined to be appropriate by a healthcare provider. Negative results do not rule out infection with influenza, SARS-CoV-2, or other pathogens. Individuals who test negative and experience continued or worsening respiratory symptoms, such as fever, cough, and/or shortness of breath, should seek follow up care from their healthcare provider. Positive results do not rule out co-infection with other respiratory pathogens and therefore do not substitute for a visit to a healthcare provider for appropriate follow-up.	WELLlife COVID-19 / Influenza A&B Home Test: The WELLlife COVID-19 / Influenza A&B Home Test is a lateral flow immunochromatographic assay intended for the qualitative detection and differentiation of influenza A, and influenza B nucleoprotein antigens and SARS-CoV2 nucleocapsid antigen directly in anterior nasal swab samples from individuals with signs and symptoms of respiratory tract infection. Symptoms of respiratory infections due to SARS-CoV-2 and influenza can be similar. This test is for non-prescription home use by individuals aged 14 years or older testing themselves, or adults testing individuals aged 2 years or older. All negative results are presumptive and should be confirmed with an FDA-cleared molecular assay when determined to be appropriate by a healthcare provider. Negative results do not rule out infection with influenza, SARS-CoV-2 or other pathogens. Individuals who test negative and experience continued or worsening respiratory symptoms, such as fever, cough and/or shortness of breath, should seek follow-up care from their healthcare provider. Positive results do not rule out co-infection with other respiratory pathogens, and therefore do not substitute for a visit to a healthcare provider or appropriate follow-up. WELLlife COVID-19 / Influenza A&B Antigen Test: The WELLlife COVID-19 / Influenza A&B Antigen Test is a lateral flow immunochromatographic assay intended for the qualitative detection and differentiation of influenza A, and influenza B nucleoprotein antigens and SARS-CoV2 nucleocapsid antigen directly in anterior nasal swab samples from individuals with signs and symptoms of respiratory tract infection. Symptoms of respiratory infections due to SARS-CoV-2 and influenza can be similar. This test is for use by individuals aged 14

		years or older testing themselves, or adults testing aged 2 years or older. All negative results are presumptive and should be confirmed with an FDA-cleared molecular assay when determined to be appropriate by a healthcare provider. Negative results do not rule out infection with influenza, SARS-CoV-2, or other pathogens. Individuals who test negative and experience continued or worsening respiratory symptoms, such as fever, cough and/or shortness of breath, should seek follow-up care from their healthcare providers. Positive results do not rule out co-infection with other respiratory pathogens. Test results should not be used as the sole basis for treatment or other patient management decisions.
Test Principle	Lateral flow immunoassay	Same
Assay Type	Qualitative	Same
Intended Use Population	Self-testing for symptomatic individuals aged 14 years or older and adults testing individuals aged 2 years and older within 4 days post symptom onset.	Same
Assay Target	Influenza A nucleoprotein antigen, Influenza B nucleoprotein antigen and/or SARS-CoV-2 nucleocapsid antigen	Same
Specimen Type	Direct anterior nasal swab specimen	Same
Result Interpretation	Visually read	Same
Control	Internal control	Same
Storage Condition	2-30°C	Same
General Device Characteristic Differences		
Development Time	10-15 minutes	10-20 minutes
Intended Users	Over-the-counter lay users	Over-the-counter lay users or professional use

VI Standards/Guidance Documents Referenced:

Document	Title	Publisher	Applicable Study
Special Controls under 21 CFR 866.3987 (multi-analyte respiratory virus antigen detection test)	Special controls under 21 CFR 866.3987	FDA/CDRH	All Studies

Document	Title	Publisher	Applicable Study
ISO11135:2014	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
10993-10: Third Edition 2009-06-01	Biological Evaluation of Medical Devices – Part 5: Tests for in vitro cytotoxicity	ISO	Biocompatibility
10993-10: Third Edition 2010-08-01	Biological Evaluation of Medical Devices – Part 10: Tests for irritation and skin sensitization	ISO	Biocompatibility
10993-23: First Edition 2021-01	Biological Evaluation of Medical Devices – Part 23: Tests for irritation	ISO	Biocompatibility

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

The precision study for the CareSuperb COVID-19/Flu A&B Antigen Combo Home Test was evaluated in two different studies conducted at single internal site each using three (3) lots of test kits and two (2) operators. Both studies are described below separately, and results are presented in the Table 1 together.

Study 1 was conducted using test samples prepared at three (3) different concentrations of heat inactivated SARS-CoV-2 B.1.1.529, live influenza A (Flu A): H1N1pdm09/A/Indiana/02/2020, and live influenza B (Flu B): Victoria/New Hampshire /01/2021 spiked into pooled negative swab matrix (PNSM) to prepare the following test sample panel members:

- Negative sample of each analyte
- Co-spike of each analyte (1xLoD)
- Co-spike of each analyte (3xLoD)

Samples were blinded and randomized before allotting them to the operators. 50µL of each sample was applied to dry nasal swabs and processed per the IFU of the candidate device. All panel members were tested in triplicate with 3 device lots, each in 2 runs per day for each of 2 operators, and the study was conducted for 10 days (i.e., 1 site x 3 lots x 2 operators x 2 runs per day with 3 replicates each x 10 days). 360 results were obtained for each panel member. All replicates prepared at 1xLoD demonstrated above 95% detection across the operators, lots, days and runs test. All replicates prepared at 3xLoD demonstrated 100% agreement with the expected results.

Study 2 was specifically conducted to further evaluate potential variability between lots and was performed using a negative sample without any of the analytes, and low positive samples

prepared at the 0.75x LoD for each analyte (i.e., below the concentration tested in study 1 and near the analytes' C95 concentration):

- Negative sample for each analyte
- Co-spike of each analyte as described in study 1 (0.75xLoD)

Two operators tested the samples above in a randomized and blinded manner each using three different lots of the CareSuperb COVID-19/Flu A&B Antigen Combo Home Test in a total of 2 runs/operators and across 3 non-consecutive days (i.e., 3 replicates × 2 runs/day × 3 days × 2 operators = 36 sample replicates/lot).

The results for Study 2 demonstrated 100% agreement for negative results and results for 0.75 LoD detection did not indicate significant variability between lots for each analytes tested.. The results from study 1 and study 2 are summarized below.

Table 1. Summary of precision study 1 and study 2

Analyte concentration	Analyte	# of positive replicates/# of total replicates			Percent Positive	95% CI
		Lot 1	Lot 2	Lot 3		
Negative	**SARS-CoV-2**	0/156	0/156	0/156	0%	97.6-100%
	Flu A	0/156	0/156	0/156	0%	97.6-100%
	Flu B	0/156	0/156	0/156	0%	97.6100%
0.75x LoD	**SARS-CoV-2**	32/36	29/36	31/36	85.2%	77.2-90.1%
	Flu A	32/36	31/36	33/36	88.9%	81.6-93.5%
	Flu B	32/36	32/36	34/36	90.7%	83.8-94.9%
1x LoD	**SARS-CoV-2**	120/120	120/120	117/120	99.2%	97.6-99.7%
	Flu A	120/120	120/120	117/120	99.2%	97.6-99.7%
	Flu B	120/120	120/120	119/120	99.7%	98.4-100%
3x LoD	**SARS-CoV-2**	120/120	120/120	120/120	100%	98.9-100%
	Flu A	120/120	120/120	120/120	100%	98.9-100%
	Flu B	120/120	120/120	120/120	100%	98.9-100%

2. Linearity:

Not Applicable - the device is a qualitative assay with binary visually-read results.

3. Analytical Specificity/Interference:

Cross Reactivity and Microbial Interference:

Cross reactivity and microbial interference studies were conducted to determine if other respiratory pathogens/microbial flora that may be present in nasal swab samples could cause a false positive test result or interfere with the detection of a true positive result and cause a false negative result. A panel of viruses, bacteria, fungi, and pooled nasal wash were used for these studies.

For the cross-reactivity study, dilutions of the organisms were prepared in pooled nasal swab matrix (PNSM) and tested in triplicates in the absence of SARS-CoV-2, influenza A, and

influenza B. No cross-reactivity was observed with the organisms tested for any of the 3 analytes (Table 2).

For the microbial interference study, dilutions of the panel organisms were prepared in PNSM, in the presence of low levels (3x LoD) of heat inactive SARS-CoV-2 (SARS-CoV-2 B.1.1.529, omicron), live influenza A (H1N1; A/Indiana/02/2020), and live influenza B (Victoria; B/New Hampshire/01/2021) and tested in triplicate. No microbial interference was observed for any of the 3 analytes tested (Table 2).

Table 2. Cross-reactivity and microbial interference study results

Microorganism	Conc.	Analyte	Test Results			
			Cross reactivity		Microbial interference	
			n/N[1]	Result Agreement (%)[2]	n/N[1]	Result Agreement (%)[2]
Adenovirus 1	1.58 X 10^5 CID_{50}/mL	SARS-CoV-2	0/3	100%	3/3	100%
		Flu A	0/3	100%	3/3	100%
		Flu B	0/3	100%	3/3	100%
Adenovirus 7	1.6 X 10^5 $TCID_{50}$/ml	SARS-CoV-2	0/3	100%	3/3	100%
		Flu A	0/3	100%	3/3	100%
		Flu B	0/3	100%	3/3	100%
Enterovirus71	1.6 X 10^6 $TCID_{50}$/mL	SARS-CoV-2	0/3	100%	3/3	100%
		Flu A	0/3	100%	3/3	100%
		Flu B	0/3	100%	3/3	100%
Human coronavirus (OC43)	1.4 X 10^5 $TCID_{50}$/mL	SARS-CoV-2	0/3	100%	3/3	100%
		Flu A	0/3	100%	3/3	100%
		Flu B	0/3	100%	3/3	100%
Human coronavirus (229E)	1.4 X 10^4 $TCID_{50}$/mL	SARS-CoV-2	0/3	100%	3/3	100%
		Flu A	0/3	100%	3/3	100%
		Flu B	0/3	100%	3/3	100%
Human coronavirus (NL63)	8 X 10^4 $TCID_{50}$/mL	SARS-CoV-2	0/3	100%	3/3	100%
		Flu A	0/3	100%	3/3	100%
		Flu B	0/3	100%	3/3	100%
Human metapneumovirus (hMPV)	2.8 X 10^5 $TCID_{50}$/mL	SARS-CoV-2	0/3	100%	3/3	100%
		Flu A	0/3	100%	3/3	100%
		Flu B	0/3	100%	3/3	100%
MERS-Coronavirus, Irradiated Lysate	1.78 X 10^5 CID_{50}/mL	SARS-CoV-2	0/3	100%	3/3	100%
		Flu A	0/3	100%	3/3	100%
		Flu B	0/3	100%	3/3	100%
Parainfluenza virus type 1	7.4 X 10^5 $TCID_{50}$/mL	SARS-CoV-2	0/3	100%	3/3	100%
		Flu A	0/3	100%	3/3	100%
		Flu B	0/3	100%	3/3	100%
Parainfluenza virus type 2	1.58 X 10^5 CID_{50}/mL	SARS-CoV-2	0/3	100%	3/3	100%
		Flu A	0/3	100%	3/3	100%
		Flu B	0/3	100%	3/3	100%
	1.58 X 10^5	SARS-CoV-2	0/3	100%	3/3	100%

Parainfluenza virus type 3	CID_{50}/mL	Flu A	0/3	100%	3/3	100%
		Flu B	0/3	100%	3/3	100%
Parainfluenza virus type 4	5.0 X 10^5 $TCID_{50}$/mL	SARS-CoV-2	0/3	100%	3/3	100%
		Flu A	0/3	100%	3/3	100%
		Flu B	0/3	100%	3/3	100%
Respiratory Syncytial virus	1.58 X 10^5 CID_{50}/mL	SARS-CoV-2	0/3	100%	3/3	100%
		Flu A	0/3	100%	3/3	100%
		Flu B	0/3	100%	3/3	100%
Rhinovirus	1.58 X 10^5 CID_{50}/mL	SARS-CoV-2	0/3	100%	3/3	100%
		Flu A	0/3	100%	3/3	100%
		Flu B	0/3	100%	3/3	100%
SARS-Coronavirus	1.0 X 10^5 PFU/ml	SARS-CoV-2	0/3	100%	3/3	100%
		Flu A	0/3	100%	3/3	100%
		Flu B	0/3	100%	3/3	100%
Human coronavirus HKU1* **(clinical specimen)**	0.1X Stock	SARS-CoV-2	0/3	100%	3/3	100%
		Flu A	0/3	100%	3/3	100%
		Flu B	0/3	100%	3/3	100%
Bordetella pertussis	1.0 X 10^7 CFU/ml	SARS-CoV-2	0/3	100%	3/3	100%
		Flu A	0/3	100%	3/3	100%
		Flu B	0/3	100%	3/3	100%
Chlamydophila pneumoniae	1.4 X 10^6 IFU/ml	SARS-CoV-2	0/3	100%	3/3	100%
		Flu A	0/3	100%	3/3	100%
		Flu B	0/3	100%	3/3	100%
Haemophilus influenzae	1.6 X 10^6 CFU/ml	SARS-CoV-2	0/3	100%	3/3	100%
		Flu A	0/3	100%	3/3	100%
		Flu B	0/3	100%	3/3	100%
Legionella pneumophila	1.35 X 10^6 CFU/ml	SARS-CoV-2	0/3	100%	3/3	100%
		Flu A	0/3	100%	3/3	100%
		Flu B	0/3	100%	3/3	100%
Mycoplasma pneumoniae	6.5 X 10^5 CFU/ml	SARS-CoV-2	0/3	100%	3/3	100%
		Flu A	0/3	100%	3/3	100%
		Flu B	0/3	100%	3/3	100%
Streptococcus pneumoniae	1.0 X 10^7 CFU/ml	SARS-CoV-2	0/3	100%	3/3	100%
		Flu A	0/3	100%	3/3	100%
		Flu B	0/3	100%	3/3	100%
Streptococcus pyogenes	1.0 X 10^7 CFU/ml	SARS-CoV-2	0/3	100%	3/3	100%
		Flu A	0/3	100%	3/3	100%
		Flu B	0/3	100%	3/3	100%
Staphylococcus aureus	1.0 X 10^7 CFU/ml	SARS-CoV-2	0/3	100%	3/3	100%
		Flu A	0/3	100%	3/3	100%
		Flu B	0/3	100%	3/3	100%
Staphylococcus epidermidis	1.0 X 10^7 CFU/ml	SARS-CoV-2	0/3	100%	3/3	100%
		Flu A	0/3	100%	3/3	100%
		Flu B	0/3	100%	3/3	100%
Candida albicans	1.0 X 10^7	SARS-CoV-2	0/3	100%	3/3	100%

	CFU/ml	Flu A	0/3	100%	3/3	100%
		Flu B	0/3	100%	3/3	100%
Pooled human nasal wash	N/A	SARS-CoV-2	0/3	100%	3/3	100%
		Flu A	0/3	100%	3/3	100%
		Flu B	0/3	100%	3/3	100%

[1] # of positive results/# of replicates.
[2] Agreement with the expected result.
[*] 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.

Competitive Interference:

A competitive inhibition study was conducted to evaluate the potential for a high concentration of one target analyte to interfere with the detection of another target analyte at low concentration. Testing was performed in triplicate with different combinations of low (3x LoD) and high concentrations ($\geq 10^5$ $CEID_{50}$/mL or $TCID_{50}$/mL) of SARS-CoV-2, influenza A, and influenza B. The study used inactivated SARS-CoV-2 but live influenza A and B virus strains. There was no competitive interference observed.

Table 3: Competitive inhibition study results

Testing Panel	Viral targets in sample			Results (# pos / total reps)		
	Influenza A	Influenza B	SARS-CoV-2	Influenza A	Influenza B	SARS-CoV-2
1	High	Low	Negative	3/3	3/3	0/3
2	High	Negative	Low	3/3	0/3	3/3
3	High	Low	Low	3/3	3/3	3/3
4	Low	High	Negative	3/3	3/3	0/3
5	Negative	High	Low	0/3	3/3	3/3
6	Low	High	Low	3/3	3/3	3/3
7	Low	Negative	High	3/3	0/3	3/3
8	Negative	Low	High	0/3	3/3	3/3
9	Low	Low	High	3/3	3/3	3/3
10	High	High	Low	3/3	3/3	3/3
11	High	Low	High	3/3	3/3	3/3
12	Low	High	High	3/3	3/3	3/3
13	High	High	Negative	3/3	3/3	0/3
14	High	Negative	High	3/3	0/3	3/3
15	Negative	High	High	0/3	3/3	3/3
16	High	High	High	3/3	3/3	3/3
17	High	Negative	Negative	3/3	0/3	0/3
18	Negative	High	Negative	0/3	3/3	0/3
19	Negative	Negative	High	0/3	0/3	3/3

Endogenous/Exogenous Substances Interference:

The CareSuperb COVID-19/Flu A&B Antigen Combo Home Test was evaluated for performance in the presence of potentially interfering substances that might be present in respiratory specimens. Potentially interfering substances were prepared and diluted in PNSM to the recommended concentration. Virus negative PNSM specimens were evaluated in triplicate to confirm that the potentially interfering substances were not cross-reactive with the test. Positive samples were prepared in PNSM at 3x LoD using each analyte individually and in combination together (co-spiked) to confirm that these substances do not interfere

with detection of SARS-CoV-2, influenza A, and influenza B. No cross-reactivity or interference was observed among the substances tested.

Table 4. Interfering substances study results

Microorganism	Conc.	Analyte	Test Results			
			No analyte		With Analyte	
			n/N[1]	Result Agreement (%)[2]	n/N[1]	Result Agreement (%)[2]
Acetaminophen	10 mg/mL	SARS-CoV-2	0/3	100%	3/3	100%
		Flu A	0/3	100%	3/3	100%
		Flu B	0/3	100%	3/3	100%
Acetyl salicylic acid	15 mg/mL	SARS-CoV-2	0/3	100%	3/3	100%
		Flu A	0/3	100%	3/3	100%
		Flu B	0/3	100%	3/3	100%
Beclomethasone	5 mg/mL	SARS-CoV-2	0/3	100%	3/3	100%
		Flu A	0/3	100%	3/3	100%
		Flu B	0/3	100%	3/3	100%
Benzocaine	5 mg/mL	SARS-CoV-2	0/3	100%	3/3	100%
		Flu A	0/3	100%	3/3	100%
		Flu B	0/3	100%	3/3	100%
Budesonide	2 mg/mL	SARS-CoV-2	0/3	100%	3/3	100%
		Flu A	0/3	100%	3/3	100%
		Flu B	0/3	100%	3/3	100%
Chlorpheniramine maleate	5 mg/mL	SARS-CoV-2	0/3	100%	3/3	100%
		Flu A	0/3	100%	3/3	100%
		Flu B	0/3	100%	3/3	100%
Dexamethasone	1 mg/mL	SARS-CoV-2	0/3	100%	3/3	100%
		Flu A	0/3	100%	3/3	100%
		Flu B	0/3	100%	3/3	100%
Dextromethorphan HBr	2 mg/mL	SARS-CoV-2	0/3	100%	3/3	100%
		Flu A	0/3	100%	3/3	100%
		Flu B	0/3	100%	3/3	100%
Diphenhydramine HCl	5 mg/mL	SARS-CoV-2	0/3	100%	3/3	100%
		Flu A	0/3	100%	3/3	100%
		Flu B	0/3	100%	3/3	100%
Flunisolide	5 mg/mL	SARS-CoV-2	0/3	100%	3/3	100%
		Flu A	0/3	100%	3/3	100%
		Flu B	0/3	100%	3/3	100%
Fluticasone	1 mg/mL	SARS-CoV-2	0/3	100%	3/3	100%
		Flu A	0/3	100%	3/3	100%
		Flu B	0/3	100%	3/3	100%
Guaiacol Glyceryl Ether	20 mg/ml	SARS-CoV-2	0/3	100%	3/3	100%
		Flu A	0/3	100%	3/3	100%
		Flu B	0/3	100%	3/3	100%
Histamine Dihydrochloride	10 mg/ml	SARS-CoV-2	0/3	100%	3/3	100%
		Flu A	0/3	100%	3/3	100%
		Flu B	0/3	100%	3/3	100%

Menthol	10 mg/ml	SARS-CoV-2	0/3	100%	3/3	100%
		Flu A	0/3	100%	3/3	100%
		Flu B	0/3	100%	3/3	100%
Mometasone	1 mg/ml	SARS-CoV-2	0/3	100%	3/3	100%
		Flu A	0/3	100%	3/3	100%
		Flu B	0/3	100%	3/3	100%
Molnupiravir	1mg/ml	SARS-CoV-2	0/3	100%	3/3	100%
		Flu A	0/3	100%	3/3	100%
		Flu B	0/3	100%	3/3	100%
Mucin (Bovine submaxillary glands)	2.5 mg/ml	SARS-CoV-2	0/3	100%	3/3	100%
		Flu A	0/3	100%	3/3	100%
		Flu B	0/3	100%	3/3	100%
Mupirocin	1 mg/ml	SARS-CoV-2	0/3	100%	3/3	100%
		Flu A	0/3	100%	3/3	100%
		Flu B	0/3	100%	3/3	100%
	10 mg/ml	SARS-CoV-2	0/3	100%	3/3	100%
		Flu A	0/3	100%	3/3	100%
		Flu B	0/3	100%	3/3	100%
Phenylpropanol-amine	5 mg/ml	SARS-CoV-2	0/3	100%	3/3	100%
		Flu A	0/3	100%	3/3	100%
		Flu B	0/3	100%	3/3	100%
Remdesivir	1 mg/ml	SARS-CoV-2	0/3	100%	3/3	100%
		Flu A	0/3	100%	3/3	100%
		Flu B	0/3	100%	3/3	100%
Tamiflu	5 mg/ml	SARS-CoV-2	0/3	100%	3/3	100%
		Flu A	0/3	100%	3/3	100%
		Flu B	0/3	100%	3/3	100%
Tobramycin	1 mg/ml	SARS-CoV-2	0/3	100%	3/3	100%
		Flu A	0/3	100%	3/3	100%
		Flu B	0/3	100%	3/3	100%
Trimcinolone	1 mg/ml	SARS-CoV-2	0/3	100%	3/3	100%
		Flu A	0/3	100%	3/3	100%
		Flu B	0/3	100%	3/3	100%
Zanamivir	1 mg/ml	SARS-CoV-2	0/3	100%	3/3	100%
		Flu A	0/3	100%	3/3	100%
		Flu B	0/3	100%	3/3	100%
Sore throat spray (Phenol)	15% v/v	SARS-CoV-2	0/3	100%	3/3	100%
		Flu A	0/3	100%	3/3	100%
		Flu B	0/3	100%	3/3	100%
Zicam Oral Mist (Zincum aceticum, Zincum gluconicum)	15% v/v	SARS-CoV-2	0/3	100%	3/3	100%
		Flu A	0/3	100%	3/3	100%
		Flu B	0/3	100%	3/3	100%
Nasal Spray (Phenylephrine HCl)	15% v/v	SARS-CoV-2	0/3	100%	3/3	100%
		Flu A	0/3	100%	3/3	100%
		Flu B	0/3	100%	3/3	100%
	15% v/v	SARS-CoV-2	0/3	100%	3/3	100%
		Flu A	0/3	100%	3/3	100%

NasalCrom Nasal Spray (Cromoly sodium)		Flu B	0/3	100%	3/3	100%
Vicks Sinex Nasal (Oxymspertaayzoline HCl)	15% v/v	SARS-CoV-2	0/3	100%	3/3	100%
		Flu A	0/3	100%	3/3	100%
		Flu B	0/3	100%	3/3	100%
Alkalol AllergyRelief (Galphimiaglauca, Luffa operculate, Sabadilla)	15% v/v	SARS-CoV-2	0/3	100%	3/3	100%
		Flu A	0/3	100%	3/3	100%
		Flu B	0/3	100%	3/3	100%
Zicam Allergy Relief (Galphimia glauca, Histaminum hydrochloricum, Luffa operculate, Sulphur)	15% v/v	SARS-CoV-2	0/3	100%	3/3	100%
		Flu A	0/3	100%	3/3	100%
		Flu B	0/3	100%	3/3	100%
Hand sanitizer	15% v/v	SARS-CoV-2	0/3	100%	3/3	100%
		Flu A	0/3	100%	3/3	100%
		Flu B	0/3	100%	3/3	100%
Hand soap	15% v/v	SARS-CoV-2	0/3	100%	3/3	100%
		Flu A	0/3	100%	3/3	100%
		Flu B	0/3	100%	3/3	100%
Whole blood	2.5% v/v	SARS-CoV-2	0/3	100%	3/3	100%
		Flu A	0/3	100%	3/3	100%
		Flu B	0/3	100%	3/3	100%
Buffy coat	2.5% v/v	SARS-CoV-2	0/3	100%	3/3	100%
		Flu A	0/3	100%	3/3	100%
		Flu B	0/3	100%	3/3	100%
Allergy spray (Mometasone Furoate)	15% v/v	SARS-CoV-2	0/3	100%	3/3	100%
		Flu A	0/3	100%	3/3	100%
		Flu B	0/3	100%	3/3	100%
Budesonide Nasal Spray (Budesonide/Gluco corticoid)	15% v/v	SARS-CoV-2	0/3	100%	3/3	100%
		Flu A	0/3	100%	3/3	100%
		Flu B	0/3	100%	3/3	100%
Nasacort Allergy 24HR (Triamcinolone acetonide)	15% v/v	SARS-CoV-2	0/3	100%	3/3	100%
		Flu A	0/3	100%	3/3	100%
		Flu B	0/3	100%	3/3	100%
Allergy Relief Nasal Spray (Fluticasone Propionate)	15% v/v	SARS-CoV-2	0/3	100%	3/3	100%
		Flu A	0/3	100%	3/3	100%
		Flu B	0/3	100%	3/3	100%
Saline Nasal Spray (Sodium chloride and preservatives)	15% v/v	SARS-CoV-2	0/3	100%	3/3	100%
		Flu A	0/3	100%	3/3	100%
		Flu B	0/3	100%	3/3	100%
Alkalol Saline Nasal Spray	15% v/v	SARS-CoV-2	0/3	100%	3/3	100%

(Sodium chloride, Menthol, Thymol, Camphor, Benzoin, Resin Extract, Oils of Eucalyptus, Wintergreen, Spearmint, fir needle, Cinnamon & preservatives)		Flu A	0/3	100%	3/3	100%
		Flu B	0/3	100%	3/3	100%
Leukocytes	5.0×10^6 cells/mL	SARS-CoV-2	0/3	100%	3/3	100%
		Flu A	0/3	100%	3/3	100%
		Flu B	0/3	100%	3/3	100%
Zinc Throat Spray (Thera Zinc Throat spray)	15% v/v	SARS-CoV-2	0/3	100%	3/3	100%
		Flu A	0/3	100%	3/3	100%
		Flu B	0/3	100%	3/3	100%

[1] # of positive results/# of replicates.
[2] Agreement with the expected result.

Biotin Interference:

The CareSuperb COVID-19/Flu A&B Antigen Combo Home Test uses streptavidin/biotin technology for antibody immobilization for the detection of influenza A. A study on biotin interference was performed to evaluate the effect of high biotin (vitamin B7) levels on test results. Biotin serial dilutions (5,000 to 0 ng/mL) were assessed in triplicate with both analyte-negative and analyte-positive samples (3x LoD co-spiked SARS-CoV-2, Influenza A, and Influenza B). There were no false positives detected at any concentration for any of the three (3) analytes. However, false negative results were detected for influenza A at concentrations of 3,750 ng/mL and 5,000 ng/mL.

Table 5. Biotin interference study results

Biotin Concentration (ng/mL)	# of Positive / # of Replicates			Negative (Analyte-absent)
	SARS-CoV-2	Influenza A	Influenza B	
5,000	3/3	0/3	3/3	0/3
3,750	3/3	0/3	3/3	0/3
2,500	3/3	3/3	3/3	0/3
1,250	3/3	3/3	3/3	0/3
625	3/3	3/3	3/3	0/3
312.5	3/3	3/3	3/3	0/3
0	3/3	3/3	3/3	0/3

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):

Controls

a. Internal Controls:

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

b. External Controls:

Not applicable. This test is intended for non-prescription over the counter use.

Stability

a. Real Time Stability:

A real-time stability study was conducted to evaluate stability and determine the shelf-life of the unopened kit. To validate shelf life for 2-30°C storage, three unopened CareSuperb COVID-19/Flu A&B Antigen Combo Home Test kit lots were stored at 2°C and 30 °C. At defined intervals, an assessment of each lot was conducted with the following panel of test samples: negative clinical matrix, and co-spiked positive samples with inactivated SARS-CoV-2, live Flu A and/or Flu B viruses, each at 4x LoD.

Fifty (50) µL of each sample were applied to the swab and tested according to the Instructions for Use. Five replicates of each sample were tested at each time point.

Baseline testing was performed within one month of each manufactured lot. Subsequent testing was performed each month after baseline and up to 15 months. At the time of clearance, all study data have met the protocol defined acceptance criteria, and support storage of the test kits at 2-30°C for up to 13 months.

b. Shipping Stability:

Transport stability under simulated summer and winter shipping conditions was tested to evaluate worst-case shipping and handling conditions. Unopened test kits were stored for each condition for 10 days. Performance of unopened test kits was assessed by testing at baseline (T0) and every day post-distribution for up to 10 days, using the same sample panel described for the real-time stability study (above). Samples were tested in replicates of five for each of three device lots. Candidate test kits were stored at the designated temperature profiles described below and then tested with the test panel to evaluate performance. The following temperature profiles were assessed:

- To mimic summer shipping conditions, test kits were incubated in a chamber set to 60ºC/85% RH for 10 days.
- To mimic winter shipping conditions, test kits were incubated at -20ºC for 10 days.

All results were as expected for all time points and support shipping at high and low temperatures experienced around the USA during summer and winter months, respectively.

6. Detection Limit:

Single Analyte Limit of Detection (LoD):

A limit of detection (LoD) study was conducted to determine the lowest detectable concentration of two strains of SARS-CoV-2 (USA-WA1/2020, and B.1.1.529 omicron; both heat-inactivated), five strains of live influenza A (3 strains of H1N1 and 2 strains of H3N2), and four strains of live influenza B (2 strains of Victoria and 2 strains of Yamagata) at which at least 95% of all true positive replicates return a positive result. Testing was conducted on three lots of test devices.

A preliminary LoD was first determined by testing serial 10-fold dilutions of virus stocks diluted in PNSM in five replicates per device lot for a total of 15 replicates per dilution. A 50-µL sample of each virus diluted in PNSM was pipetted onto the dry swab. The swab was then tested per the instructions for use. The preliminary LoD of each virus was confirmed by testing an additional twenty samples/lot for each viral stock at the preliminary LoD concentration as well as 10-fold above and below. The last concentrations that produced 20-positive test results/lot from a 1:10 dilution was further evaluated using a 3-fold dilution series, in 20 replicates/lot for each level, to refine the LoD.

As per the acceptance criteria for confirmation of the LoD, at least 95% of the replicates (≥ 19/20) should be positive to be considered as the confirmed LoD. The confirmed LoDs observed were identical for the three lots tested for each virus strain. The results of the last two 10-fold dilution of preliminary LoD and all confirmatory LoD at 10-fold and 3- fold dilutions for each strain are included below. Final stated LoD for each virus is presented in the bold in the tables 5, 6 and 7.

Table 6. SARS-CoV-2 single analyte LoD results

Virus Strain	Virus conc.		Positive results/total replicates	
	$TCID_{50}$/mL	$TCID_{50}$/Swab	Preliminary LoD	Confirmatory LoD
USA-WA1/2020	7.9×10^3	3.9×10^2	15/15	60/60
	7.9×10^2	3.9×10^1	15/15	60/60
	2.6×10^2	**1.3×10^1**	**-**	**60/60**
	8.8×10^1	4.4×10^0	-	20/60
B.1.1.529, Omicron	1.5×10^3	7.5×10^1	15/15	60/60
	1.5×10^2	**7.5×10^0**	15/15	**60/60**
	5×10^1	2.5×10^0	-	8/60

Table 7. Influenza A single analyte LoD results

Virus strain	Virus concentration		Positive results/total replicates	
	$CEID_{50}$/mL	$CEID_{50}$/Swab	Preliminary LoD	Confirmatory LoD
A/Indiana/02/2020 (H1N1) pdm09	1.6×10^8	8.0×10^6	15/15	60/60
	1.6×10^7	**8.0×10^5**	**15/15**	**60/60**
	5.3×10^6	2.6×10^5	-	0/60
A/Hawaii/66.2019 (H1N1) pdm09	7.4×10^7	3.7×10^6	15/15	60/60
	7.4×10^6	**3.7×10^5**	**15/15**	**60/60**
	2.4×10^6	1.2×10^5	-	0/60
A/Brisbane/59/2007 (H1N1)	9.7×10^6	4.8×10^5	15/15	60/60
	9.7×10^5	**4.8×10^4**	**15/15**	**60/60**
	3.2×10^5	1.6×10^4	-	0/60
Virus strain	**Virus concentration**		**Positive results/total replicates**	
	FFU/mL	**FFU/Swab**	**$CEIDD_{50}$/mL**	**$CEID_{50}$/Swab**

Virus strain	Virus concentration		Positive results/total replicates	
	$CEID_{50}$/mL	$CEID_{50}$/Swab	Preliminary LoD	Confirmatory LoD
A/California/55/2020 (H3N2)	3.5×10^6	1.7×10^5	15/15	60/60
	3.5×10^5	1.7×10^4	15/15	60/60
	1.1×10^5	**5.8×10^3**	-	**60/60**
	3.8×10^4	1.9×10^3	-	3/60
A/Delaware/01/2021 (H3N2)	3.1×10^5	1.5×10^4	15/15	60/60
	3.1×10^4	**1.5×10^3**	**15/15**	**60/60**
	1.0×10^4	5.1×10^2	-	0/60

Table 8. Influenza B single analyte LoD results

Virus strain	Virus concentration		Positive results/total replicates	
	$TCID_{50}$/mL	$TCID_{50}$/Swab	Preliminary LoD	Confirmatory LoD
B/New Hampshire/01/2021 (Victoria)	1.3×10^4	6.5×10^2	15/15	60/60
	1.3×10^3	6.5×10^1	15/15	60/60
	4.3×10^2	**2.1×10^1**	**-**	**60/60**
	1.4×10^2	7.2 x 10	-	3/60
B/Michigan/01/2021 (Victoria)	5.7×10^4	2.8×10^3	15/15	60/60
	5.7×10^3	2.8×10^2	15/15	60/60
	1.9×10^3	**9.5×10^1**	**-**	**60/60**
	6.3×10^2	3.1×10^1	-	3/60
Virus strain	**Virus concentration**		**Positive results/total replicates**	
	$TCID_{50}$/mL	**$TCID_{50}$/Swab**	**$CEIDD_{50}$/mL**	**$CEID_{50}$/Swab**
B/Oklohoma/10/2018 (Yamagata)	7.6×10^5	3.8×10^4	15/15	60/60
	7.6×10^4	**3.8×10^3**	**15/15**	**60/60**
	2.5×10^4	1.2×10^3	-	60/60
B/Indiana/17/2017 (Yamagata)	1.0×10^6	5×10^4	15/15	60/60
	1.01×10^5	5×10^3	15/15	60/60
	3.3×10^4	**1.6×10^2**	**-**	**60/60**
	1.1×10^4	5.5×10^2	-	60/60

Co-spiked multi-analyte LoD:

After single analyte LoDs were determined, co-spiked equivalency testing was conducted to characterize the performance of samples that contained all analytes at their respective 1x LoD concentrations. Based on individual analyte LoDs, 3-fold above and below and at 1x LoD of the single analyte was evaluated in co-spiked samples prepared by mixing viruses (one each of SARS-CoV-2, Flu A, and Flu B) in PNSM. Two panels were tested for the co-spike study as shown in the table below.

Overall, 20 replicates per lot were evaluated at each concentration for both panels by pipetting 50 µL of co-spiked sample at defined LoD concentration onto the dry swab and testing swabs with the device according to the instructions for use. Equivalency is confirmed separately for each analyte if ≥95% replicates are positive within 2x LoD of the individually tested analyte.

The CareSuperb COVID-19/Flu A&B Antigen Combo Home Test demonstrated co-spike equivalency for SARS- CoV-2, Influenza A and Influenza B at 1x single analyte LoD. This study supports the use of co-spiked samples in subsequent analytical studies.

Table 9. Summary of Co-spike equivalency LoD study results

Fold LoD	Analytes	Conc. (Titer Unit/mL)	Conc. (Titer Unit/swab)	Test Results # of positives/# of replicates	Positive result agreement (%)
Panel 1					
3x	SARS-CoV-2 (B.1.1.529, omicron)	4.5×10^2	2.2×10^1	60/60	100%
	Flu A (Indiana/02/2020 (H1N1) pdm09)	2.9×10^6	1.4×10^5	60/60	100%
	Flu B Victoria (New Hampshire/01/2021)	1.3×10^3	6.5×10^1	60/60	100%
1x	SARS-CoV-2 (B.1.1.529, omicron)	**1.5×10^2**	**7.5×10^0**	**59/60**	**98.3%**
	Flu A (Indiana/02/2020 (H1N1) pdm09)	**9.7×10^5**	**4.8×10^4**	**58/60**	**96.6%**
	Flu B Victoria (New Hampshire/01/2021)	**4.3×10^2**	**2.1×10^1**	**59/60**	**98.3%**
1/3x	SARS-CoV-2 (B.1.1.529, omicron)	5×10^0	2.5×10^0	0/60	0%
	Flu A (Indiana/02/2020 (H1N1) pdm09)	3.2×10^5	1.6×10^4	0/60	0%
	Flu B Victoria (New Hampshire/01/2021)	1.5×10^2	7.2×10^0	0/60	0%
Panel 2					
3x	SARS-CoV-2 (B.1.1.529, omicron	4.5×10^2	2.2×10^1	60/60	100%
	Flu A (Hawaii/66.2019 (H1N1) pdm09)	2.2×10^7	1.1×10^6	60/60	100%
	Flu B Victoria (Michigan/01/2021)	5.7×10^3	2.8×10^2	60/60	100%
1x	SARS-CoV-2 (B.1.1.529, omicron	**1.5×10^2**	**7.5×10^0**	**59/60**	**98.3%**
	Flu A (Hawaii/66.2019 (H1N1) pdm09)	**7.4×10^6**	**3.7×10^5**	**58/60**	**96.6%**
	Flu B Victoria (Michigan/01/2021)	**1.9×10^3**	**9.5×10^1**	**59/60**	**98.3%**
1/3x	SARS-CoV-2 (B.1.1.529, omicron	5×10^0	2.5×10^0	0/60	0%

	Flu A (Hawaii/66.2019 (H1N1) pdm09)	2.4 x 10^6	1.2 x10^5	0/60	0%
	Flu B Victoria (Michigan/01/2021)	6.3 x 10^2	3.1 x10^0	0/60	0%

7. ***International Standard Material NIBSC code: 21/368 – Limit of Detection:***

The LoD of the CareSuperb COVID-19/Flu A&B Antigen Combo Home Test was also determined by evaluating different dilutions of the International Standard for SARS-CoV-2 antigen (NIBSC code: 32/368) in negative pooled nasal swab matrix. The International Standard for SARS-CoV-2 containing lyophilized SARS-CoV-2 antigen was reconstituted in ultra-pure water (for a final concentration of 20,000 IU/mL). The LoD was determined as the lowest virus concentration that was detected ≥95% of the time (i.e., concentration at which at least 19/20 replicates tested positive).

Five-fold serial dilutions were made from the International Standard for SARS-CoV-2 antigen into negative clinical matrix (pooled nasal swab matrix). Three (3) replicates were tested on one (1) lot of the test device for each dilution to determine the preliminary LoD concentration of the device. The lowest concentration with all concordant 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.

The preliminary LoD concentration was tested with an additional 20 replicates to confirm the LoD. Concentrations above and below the preliminary LoD were also tested with 20 replicates to further refine the LoD. Samples were prepared as for the preliminary LoD study above. To confirm the LoD, at least 19 of 20 replicates should be positive per lot. The results are summarized in Table below.

Table 10. Summary of LoD study for the international standard

Conc. (IU/mL)	Conc. on dry swab (IU/swab)	# Positive replicates	
		Preliminary LoD	Confirmatory LoD
4000	200	3/3	-
800	40	3/3	20/20
160	**8**	**3/3**	**19/20**
32	1.6	0/3	0/20
6.4	0.32	0/3	-
1.28	0.064	0/3	-

The LoD for the CareSuperb COVID-19/Flu A&B Antigen Combo Home Test using the 1st International Standard for SARS-CoV-2 antigen (NIBSC code: 21/368) in nasal matrix was determined to be 160 IU/mL (8 IU/swab).

8. ***High Dose Hook Effect:***

A high-dose hook effect study was conducted to evaluate whether high levels of any of the target analytes in a sample could result in a false-negative test result. Individually spiked samples were prepared; where each sample was prepared at a high, or "stock," viral concentration with the following analytes: SARS-CoV-2 (heat-inactivated), influenza A

(live), and influenza B (live) viruses. Each sample was tested across a series of two-fold dilutions up to 3 dilutions. Fifty (50) µL sample was spiked onto swabs and swabs were processed in accordance with the instructions for use. Analytes were tested co-spiked, and all samples were tested in 5-replicates. No evidence of a high-dose hook effect was observed with the virus stocks and concentrations tested.

Table 11. High-dose hook effect study results

Virus Strain	Testing concentration	Test results (# of positives/ # total replicates)		
		SARS-CoV-2	Influenza A	Influenza B
SARS-CoV-2				
USA-WA1/2020	3.9×10^5 $TCID_{50}$/mL	5/5	0/5	0/5
	1.9×10^5 $TCID_{50}$/mL	5/5	0/5	0/5
	9.8×10^4 $TCID_{50}$/mL	5/5	0/5	0/5
B.1.1.529, Omicron	7.5×10^5 $TCID_{50}$/mL	5/5	0/5	0/5
	3.7×10^5 $TCID_{50}$/mL	5/5	0/5	0/5
	1.8×10^5 $TCID_{50}$/mL	5/5	0/5	0/5
Influenza A				
A/Indiana/02/2020 (H1N1) pdm09	4.8×10^8 $CEID_{50}$/mL	0/5	5/5	0/5
	2.4×10^8 $CEID_{50}$/mL	0/5	5/5	0/5
	1.2×10^8 $CEID_{50}$/mL	0/5	5/5	0/5
A/Delaware/01/2021 (H3N2)	1.5×10^7 FFU/mL	0/5	5/5	0/5
	7.7×10^6 FFU/mL	0/5	5/5	0/5
	3.8×10^6 FFU/mL	0/5	5/5	0/5
Influenza B				
B/New Hampshire/01/2021 (Victoria)	6.5×10^5 $TCID_{50}$/mL	0/5	0/5	5/5
	3.2×10^5 $TCID_{50}$/mL	0/5	0/5	5/5
	1.6×10^5 $TCID_{50}$/mL	0/5	0/5	5/5
B/Indiana/17/2017 (Yamagata)	5.0×10^7 $TCID_{50}$/mL	0/5	0/5	5/5
	2.5×10^7 $TCID_{50}$/mL	0/5	0/5	5/5
	1.2×10^7 $TCID_{50}$/mL	0/5	0/5	5/5

9. ***Inclusivity:***

Analytical reactivity testing for the CareSuperb COVID-19/Flu A&B Antigen Combo Home Test was performed to ensure that the device can adequately detect a variety of strains for the SARS-CoV-2, influenza A, and influenza B viruses. A selection of temporally, geographically, and genetically diverse SARS-CoV-2 and influenza strains were tested for inclusivity, including 21 Influenza A strains (10 H1N1 and 10 H3N2, and 1 H5N1), 10 Influenza B strains (5 Yamagata and 5 Victoria lineages), and 5 SARS-CoV-2 strains. A series of ten-fold dilutions of each virus strain was spiked into PNSM and tested to determine an approximate LoD of the test for each virus. The lowest concentration with 100% positive replicates was identified and additional 2-fold dilutions above and below that approximate LoD were tested to demonstrate inclusivity. Based on the dilution series, the minimum detectable concentration was defined as the lowest concentration for which all five (5) replicates were detected. Results are summarized below and demonstrate that the test tests can detect the analytes across a range of viral strains.

Table 12. Inclusivity results

Strain name	Titer Unit/mL	Titer unit/Swab

SARS-CoV-2		
BA2.12.1, Omicron	6.3×10^2 $TCID_{50}$/mL	3.1×10^1 $TCID_{50}$/swab
BA. 2.3, Omicron	1.1×10^2 $TCID_{50}$/mL	5.8×10^0 $TCID_{50}$/swab
BA.2.75.5, Omicron	8.5×10^1 $TCID_{50}$/mL	4.2×10^0 $TCID_{50}$/swab
BA.4.6, Omicron	5.7×10^2 $TCID_{50}$/mL	2.8×10^1 $TCID_{50}$/swab
JN.1.4 Omicron	2.1×10^2 $TCID_{50}$/mL	1.0×10^1 $TCID_{50}$/swab
Influenza A		
Wisconsin/588/2019 (H1N1)pdm09	1.4×10^3 FFU/ml	7.0×10^1 FFU/Swab
Dominican Republic/7293/2013 (H1N1)pdm09	1.2×10^3 $TCID_{50}$/mL	6.2×10^1 $TCID_{50}$/Swab
Massachusetts/15/2013 (H1N1)pdm09	8.0×10^5 $CEID_{50}$/mL	4.0×10^4 $CEID_{50}$/Swab
Bangladesh/3002/2015 (H1N1)pdm09	1.3×10^4 $CEID_{50}$/mL	6.5×10^2 $CEID_{50}$/Swab
Michigan/45/2015 (H1N1)pdm09	7.8×10^2 $CEID_{50}$/mL	3.9×10^1 TCID50/Swab
lowa/53/2015 (H1N1)pdm09	1.4×10^6 $CEID_{50}$/mL	7.2×10^4 $CEID_{50}$/Swab
St. Petersburg/61/2015 (H1N1pdm09)	4.6×10^5 $CEID_{50}$/mL	2.3×10^4 $CEID_{50}$/Swab
Hong Kong/H090-761-V1(0)/2009 (H1N1)pdm09	4.0×10^2 $TCID_{50}$/mL	2.0×10^1 $TCID_{50}$/Swab
Victoria/4897/2022 (H1N1)pdm09	$1.0 \times 10^{6.5}$ EID_{50}/mL	$5.0 \times 10^{4.5}$ EID_{50}/ Swab
Victoria/2570/2019 (H1N1)pdm09	$1.0 \times 10^{5.3}$ EID_{50}/mL	$5.0 \times 10^{3.3}$ EID_{50}/ Swab
New York/21/2020 (H3N2)	1.30×10^5 FFU/ml	6.5×10^3 FFU/Swab
Michigan/173/2020 (H3N2)	1.9×10^5 FFU/ml	9.7×10^3 FFU/Swab
Tasmania/503/2020 (H3N2)	6.5×10^4 FFU/ml	3.2×10^3 FFU/Swab
Texas/50/2012 (H3N2)	8.7×10^3 $TCID_{50}$/mL	4.3×10^2 $TCID_{50}$/Swab
Switzerland/9715293/2013 (H3N2)	6.0×10^5 $CEID_{50}$/mL	3.0×10^4 $CEID_{50}$/Swab
Hong Kong/4801/2014 (H3N2)	9.6×10^5 $CEID_{50}$/mL	4.8×10^4 $CEID_{50}$/Swab
Singapore/lNFIMH-16-0019/2016 (H3N2)	5.5×10^4 $CEID_{50}$/mL	2.7×10^3 $CEID_{50}$/Swab
Perth/16/2009 (H3N2)	1.1×10^5 $CEID_{50}$/mL	5.5×10^3 $CEID_{50}$/Swab
Darwin/9/2021 (H3N2)	$1.0 \times 10^{4.3}$ EID_{50}/ml	$5.0 \times 10^{2.3}$ EID_{50}/Swab
Georgia/02/2022 (H3N2)	$5.0 \times 10^{5.5}$ EID_{50}/mL	$2.5 \times 10^{4.5}$ EID_{50}/Swab
bovine/Ohio/824OSU-439/2024 (H5N1)	3.1×10^2 $TCID_{50}$/mL	1.5×10^1 $TCID_{50}$/Swab
Influenza B		
Texas/43/2019 (Victoria Lineage)	5.0×10^2 $TCID_{50}$/mL	2.5×10^1 $TCID_{50}$/Swab
Washington/02/2019 (Victoria Lineage)	2.1×10^6 $CEID_{50}$/ml	1.0×10^5 $CEID_{50}$/Swab
Brisbane/60/2008 (Victoria Lineage)	5×10^3 $CEID_{50}$/mL	2.5×10^2 $CEID_{50}$/Swab
Austria/1359417/2021 (Victoria Lineage)	$5.0 \times 10^{4.5 EID50}$/mL	$2.5 \times 10^{3.5}$ EID_{50}/Swab
Netherlands/10894/2022 (Victoria Lineage)	$1.0 \times 10^{4.7}$ EID_{50}/mL	$5.0 \times 10^{2.7}$ EID_{50}/Swab
Phuket/3073/2013 (Yamagata Lineage)	2.7×10^4 $CEID_{50}$/mL	$5.5x\ 10^2$ $CEID_{50}$/Swab
Wisconsin/10/2016 (NA 1221V) (Yamagata Lineage)	3.2×10^5 $TCID_{50}$/mL	1.6×10^4 $TCID_{50}$/Swab
Texas/06/2011 (Yamagata Lineage)	1.6×10^5 $CEID_{50}$/mL	8.0×10^3 $CEID_{50}$/Swab
Phuket/3073/2013 (Yamagata Lineage)	$1.0 \times 10^{3.8}$ EID_{50}/mL	$5.0 \times 10^{1.8}$ EID_{50}/Swab
Norway/2134/2019 (Yamagata Lineage)	$2.5 \times 10^{4.5}$ EID_{50}/mL	$1.2 \times 10^{3.5}$ EID_{50}/Swab

10. Assay Cut-Off:

N/A as this is a qualitative visually read assay without numeric raw data.

B Comparison Studies:

1. Method Comparison with Predicate Device:

   See Section C (Clinical Studies) below.

2. Matrix Comparison:

   The CareSuperb COVID-19/Flu A&B Antigen Combo Home Test is only intended for use with direct anterior nasal swab specimens. As no other sample types are claimed for use with the CareSuperb COVID-19/Flu A&B Antigen Combo Home Test, a matrix comparison study is not applicable.

C Clinical Studies:

1. A prospective lay person clinical study was conducted from November 2023 to March 2025 to assess the performance of the CareSuperb COVID-19/Flu A&B Antigen Combo Home Test when compared to a 510(k)-cleared SARS-CoV-2 RT-PCR assay with an extraction step. The study prospectively enrolled symptomatic subjects at 13 CLIA-waived clinical study sites (representative of lay-user environment) located in the United States. Enrolled subjects were aged 2 years or older who exhibited symptoms of respiratory infection consistent with COVID-19 or influenza at the time of collection.

   Testing was performed in a simulated home environment. Two swabs were collected in random order: a nasopharyngeal (NP) swab for comparator, and an anterior nasal (AN) swab for candidate test. NP swabs for comparator testing were collected by an operator and placed into transport tubes containing universal transport media, refrigerated, and shipped to a central lab for testing with a highly sensitive RT-PCR comprator assay. AN swabs were either self-collected by a lay user aged ≥14 years, or collected by an adult (parent/ guardian) from individuals aged 2 to <14 years. Samples were then immediately tested with the CareSuperb COVID-19/Flu A&B Antigen Combo Home Test according to the instructions.

   A total of 1799 participants were enrolled, with 155 samples deemed unevaluable and removed from the final performance analysis: 85 participants were excluded due to being over 4 days post symptom onset, and 68 participants were excluded for protocol deviation, invalid results on either the candidate test or comparator test, resulting in 1644 evaluable study participants. Of these 1644 subjects, 27 samples were excluded from both influenza A/B analysis due to transit delays of comparator samples. Therefore, the total of 182 samples were excluded from both influenza A/B analysis. In addition, one more sample was excluded from influenza B analysis as one subject did not record an influenza B result but had valid results for COVID-19 and influenza A, therefore, total 183 samples were excluded from influenza B analysis.

   Table 13. Demographics of evaluable subjects

Characteristic	Self-Collecting (N=1447)	Lay-user/ Tester Collection (N=197)	Overall (N=1644)
Age			
Mean (SD)	42.0 (17.2)	7.6 (3.7)	37.8 (19.8)
Median [Min, Max]	41 [13, 90]	7.5 [2, 17]	37 [2, 90]
Age Group			

2-13	1	192	193
14-24	267	5	272
25-64	1025	0	1025
>64	154	0	154
Sex at Birth			
Female	842	104	946
Male	605	93	698
Ethnicity			
Hispanic or Latino (of any race)	635	74	709
Not Hispanic or Latino	806	116	922
Unknown	6	7	13
Race			
American Indian or Alaskan Native	6	1	7
Asian	91	13	104
Black or African American	208	16	224
Native Hawaiian or Other Pacific Islander	14	2	16
More Than One Race	31	11	42
Prefer Not to Answer	1	0	1
Unknown	16	12	28
White	1080	142	1222

Results obtained with the CareSuperb COVID-19/Flu A&B Antigen Combo Home Test were compared to the results obtained with highly sensitive RT-PCR comparator tests giving rise to the following performance estimates:

SARS-CoV-2 Performance:

Table 14. Clinical Performance Compared to SARS-CoV-2 Molecular Assay

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

Table 15. SARS-CoV-2 performance by DPSO

DPSO	**Candidate positive**	**Comparator positive**	**PPA**
Day 0	-	0	Not tested
Day 1	16	18	88.2%
Day 2	44	47	93.5%
Day 3	35	36	97.2%
Day 4	16	19	84.2%

Influenza A Performance:

Table 16. Clinical Performance Compared to influenza A Molecular Assay

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

Influenza B Performance:

Table 17. Clinical Performance Compared to influenza B Molecular Assay

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

Clinical Sensitivity:

Please refer to Section VII.C (Clinical Studies) above for the clinical validation.

Clinical Specificity:

Please refer to Section VII.C (Clinical Studies) above for the clinical validation.

2. ***Usability Study:***

Concurrent with the clinical study, the sponsor evaluated usability of the CareSuperb COVID-19/Flu A&B Antigen Combo Home Test and user comprehension of the test's Quick Reference Instructions (QRI). Of the 1799 enrolled subjects, 1795 individuals were included in the usability and user comprehension study, irrespective of their evaluability for analysis in the clinical study, while four subjects were excluded due to not meeting the inclusion criteria. Each subject filled out a usability questionnaire as part of their visit and interpreted mock test results in the user comprehension (readability) study. Demographics of the enrolled subjects are summarized in table below.

a. Human Factor Assessment

All subjects in the study received the QRI prior to performing the test. For the human factors assessment, the study personnel or a healthcare provider observed and evaluated the subject/tester's ability to correctly perform the test and interpret the results by evaluating test tasks during the testing process as shown below in table format. The study personnel did not provide any training, or assistance to the subjects/testers. Overall, 98.4% critical task and 90.8% non-critical tasks associated with sample collection and

running the CareSuperb COVID-19/Flu A&B Antigen Combo Home Test were performed correctly.

Table 18. Critical and non-critical task performed correctly.

Steps		Tasks Performed Correctly	Total Number of Tasks	Percentage of Tasks Performed Correctly
Critical	▪ Swabbed one nostril 5 rotations and for 15 seconds, then second nostril for 5 rotations and 15 seconds. ▪ Placed the swab into the sample port before the vial contents added. ▪ Added the entire contents of the vial into the sample port. ▪ Rotate swab approximately 10x in the sample port before discarding swab. ▪ Removed the swab from the sample port and discarded. ▪ Read the test between 10-15 minutes.	10,582	10,754	98.40%
Non-critical	▪ Washed or sanitized hands. ▪ Used a timer.	3,257	3,586	90.83%
Sum		13,839	14,340	96.51%

Table 19. Evaluation of user test tasks performance.

Task	Yes	No
Washed or sanitized hands?	84.29% (1513/1795)	15.71% (282/1795)
Swabbed one nostril 5 rotations and for 15 seconds, then second nostril for 5 rotations and 15 seconds?	96.88% (1739/1795)	3.12% (56/1795)
Placed the swab into the sample port before the vial contents added?*	98.55% (1767/1793)	1.45% (26/1793)
Added the entire contents of the vial into the sample port?*	99.22% (1778/1792)	0.78% (14/1792)
Rotate swab approximately 10x in the sample port before discarding swab	98.21% (1760/1792)	1.79% (32/1792)
Removed the swab from the sample port and discarded?*	98.66% (1768/1792)	1.34% (24/1792)
Read the test between 10-15 minutes?*	98.88% (1770/1790)	1.12% (20/1790)
Did the subject use a timer?*	97.38% (1744/1791)	2.62% (47/1791)
Does the observer agree with Subject/Tester results?*	98.71% (1763/1786)	1.29% (23/1786)

*9 subjects did not complete all steps. These subjects were re-tested and completed all steps successfully, however that data is not included in the table above.

The results of the usability/user comprehension questionnaire demonstrated that the instructions were clear and easy to follow, samples could be collected and processed easily. The overall evaluation of the lay user experience did not raise any concerns regarding the usability of the investigational device.

b. *Readability Assessment*

A readability study was conducted with a total of 50 lay users. Out of 50 subjects, 21 subjects had some vision impairment (7 near-sighted, 10 far-sighted, and 7 astigmatism). Subjects interpreted two mock panels of investigational test results and thereafter, completed a labeling and comprehension questionnaire. The mock panel contained results for various analyte combinations and analyte concentrations. Mock samples were prepared at concentrations of negative, 1-2x LoD, and 3-5x LoD. All 50 lay users interpreted the mock results in a blinded and randomized fashion. Each lay user interpreted ten random mock samples to avoid a training effect. Overall, the study demonstrated that lay user participants can accurately read and interpret the test as 94.8% of the samples were interpreted correctly across all analyte concentration.

D Clinical Cut-Off:

The test is a qualitative test with a binary positive/negative signal and there is no clinical cut-off for the test.

E Expected Values/Reference Range:

When the test is valid, it produces binary values, positive or negative for SARS-CoV-2, influenza A and influenza B antigens.

F 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], delay in sample 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).

Flex study design incorporated 3 operators who tested a test panel comprised of negative samples (PNSM only), low positive samples (2x co-spike LoD with all analytes in PNSM), in replicates of five (5)/operator, upon varying the conditions during testing with the candidate device. The strains used for testing were SARS-CoV-2 B.1.1.529, omicron, Influenza A H1N1, and Influenza B Victoria. Samples were blinded and randomized for testing.

The flex study that assessed the timing of reading results from test initiation noted that reading the device at 4 minutes or 30 minutes after test initiation leads to false positive or false negative results. The package insert instructs users to not interpret the test result before 10 minutes or after 15 minutes.

Overall, the studies support that the test is robust when used as instructed with an insignificant risk of erroneous result.

VIII Proposed Labeling:

The labeling supports finding of substantial equivalence for this device.

IX Conclusion:

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