510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K241313

B Applicant

Osang LLC

C Proprietary and Established Names

OHC COVID-19 Antigen Self Test

D Regulatory Information

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

II Submission/Device Overview:

A Purpose of Submission:

To obtain 510(k) clearance for the OHC COVID-19 Antigen Self Test.

B Measurand:

Nucleocapsid protein antigens from SARS-Coronavirus 2 (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 OHC COVID-19 Antigen Self Test is a visually read lateral flow immunoassay device intended for the rapid, qualitative detection of SARS-CoV-2 nucleocapsid protein antigens 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 and 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 infection with SARS-CoV-2 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 like symptoms, such as fever, cough and/or shortness of breath, should seek follow up care from their healthcare provider.

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

C Special Conditions for Use Statement(s):

OTC - Over The Counter

D Special Instrument Requirements:

Not applicable

IV Device/System Characteristics:

A Device Description:

The OHC COVID-19 Antigen Self Test is a visually read lateral flow immunoassay device intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 virus.
The test is for over-the-counter use and is packaged with the following components:

- Test Cassettes
- Extraction Buffer Tubes
- Extraction Buffer Filter Cap
- Sterile Swab for Anterior Nasal Swab collection
- Package Insert

The test cassette is assembled with a test strip that contains a membrane with two test lines: a test line (T line) and a control line (C line).

B Principle of Operation:

To perform the test, anterior nasal swabs collected by lay users from both their nostrils are processed in the extraction buffer provided with the kit. This step elutes the sample material from the swab and lyses cells and microbial organisms, including SARS-CoV-2 virus if present in the sample. This sample mixture is then added to the sample well of the test cassette from where the test sample migrates by capillary action across the test strip.

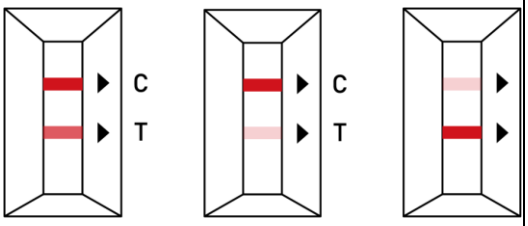
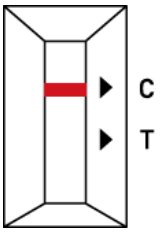
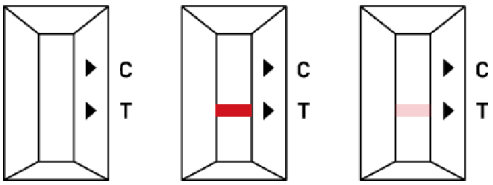
The test strip is composed of the following parts: sample pad, reagent pad, reaction membrane, and absorbing pad. The reagent pad contains the colloidal-gold conjugated with the monoclonal antibodies against the nucleocapsid protein of SARS-CoV-2; the reaction membrane contains the secondary antibodies for nucleocapsid protein of SARS-CoV-2. The whole strip is fixed inside a plastic device.

When the sample is added into the sample well, conjugates dried in the reagent pad are dissolved and migrate along with the sample. If SARS-CoV-2 nucleocapsid antigen is present in the sample, it forms a complex with the anti-SARS-CoV-2 conjugate that will be captured by the specific anti-SARS-CoV-2 monoclonal antibodies coated on the test line region (T). This binding results in a visible pink/purple colored test line in the T-marked (T) position in the result window.

To serve as an internal procedural control, a second conjugate dried in the reagent pad moves across the test strip with the sample. This control conjugate is a color-labeled rabbit antibody that will bind to an anti-rabbit antibody on the test strip, forming a colored line in the control line region (C) of the result window. Formation of the control line serves as an internal control indicating that membrane wicking has occurred adequately, and the test reagents were functional. The control line needs to be visible on every test independent of the result for the T-Line. A test without a colored line at the C-marked location of the cassette is not a valid result and cannot be interpreted.

C Interpretation of Results:

After dispensing the test specimen into the sample well, the result should be read at 15 minutes.

Result	Interpretation	Example Image
Positive	If a Control (C) line and the Test (T) line are visible, the test is positive. Any faint visible pink/purple Test (T) line with the Control line (C) should be read as positive.	
Negative	If the Control (C) line is visible, but the Test (T) line is not visible, the test is negative. Repeat testing is needed for all samples that are negative for COVID-19 on the first day of testing.	
Invalid	If the Control line is not visible, the test is not valid. Re-test with a new swab and a new test cassette.	

V Substantial Equivalence Information:

A Predicate Device Name:

Flowflex COVID-19 Antigen Home Test

B Predicate 510(k) Number(s):

K230828

C Comparison with Predicate(s):

Device & Predicate Device(s):	K241313 (Candidate Test)	K230828 (Predicate)
Device Trade Name	OHC COVID-19 Antigen Self Test	Flowflex COVID-19 Antigen Home Test
General Device Characteristic Similarities		
Intended Use/ Indications For Use	The OHC COVID-19 Antigen Self Test is a visually read lateral flow immunoassay device intended for the rapid, qualitative detection of SARS-CoV-2 nucleocapsid protein antigens directly in anterior nasal swab specimens	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

Device & Predicate Device(s):	K241313 (Candidate Test)	K230828 (Predicate)
	from individuals with signs and symptoms of COVID-19. This test is for non-prescription home use by individuals aged 14 years and 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 infection with SARS-CoV-2 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 like symptoms, such as fever, cough and/or shortness of breath, should seek follow up care from their healthcare provider. The performance characteristics for SARS-CoV-2 were established from June 2023 to July 2023 when SARS-CoV-2 Omicron was dominant. Test accuracy may change as new SARS-CoV-2 viruses emerge. Additional testing with a lab-based molecular test (e.g., PCR) should be considered in situations when a new virus or variant is suspected.	and symptoms of COVID19 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. This test is not a substitute for visits to a healthcare provider or appropriate follow-up and should not be used to determine any treatments without provider supervision. Individuals who test negative and experience continued or worsening COVID-19 like symptoms, such as fever, cough and/or shortness of breath, should seek follow up care from their healthcare provider. The performance characteristics for SARS-CoV-2 were established from December 2022 to March 2023 when SARS-CoV-2 Omicron was dominant. Test accuracy may change as new SARS-CoV-2 viruses emerge. Additional testing with a lab-based molecular test (e.g., PCR) should be considered in situations where a new virus or variant is suspected.
Regulation Number	21 CFR 866.3984	Same
Patient Population	Symptomatic individuals 14 years and older testing themselves and adults test-ing individuals aged 2 years and older.	Same
Patient Use	Over the counter use / self-testing	Same

Device & Predicate Device(s):	K241313 (Candidate Test)	K230828 (Predicate)
Usage	Single use test	Same
Specimen Type	Direct anterior nasal swab	Same
Format	Test cassette (cartridge)	Same
Analyte	SARS-CoV-2 nucleocapsid protein	Same
Test Technology	Lateral flow immunochromatography	Same
Test Result Type	Qualitative	Same
Controls	Internal Control	Same
General Device Characteristic Differences		
Time to Result	15 minutes	15-30 minutes

VI Standards/Guidance Documents Referenced:

Document	Title	Publisher	Applicable Study
21 CFR 866.3984 (Special controls)	Reclassification order for DEN220028 (Over-The-Counter Molecular Test To Detect Sars-Cov-2 From Clinical Specimens)	FDA/CDRH	All Studies
CLIA Waiver FDA Guidance	Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices: Guidance for Industry and Food and Drug Administration Staff	FDA/CDRH	Flex Studies
FDA Guidance	Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile | FDA.	FDA/CDRH	Sterility
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
ISO 10993-5	Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity	ISO	Biocompatibility
ISO 10993-10	Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization	ISO	Biocompatibility

VII Performance Characteristics:

A Analytical Performance

1. Precision/Reproducibility

The precision study for the OHC COVID-19 Antigen Self Test was evaluated in two different studies conducted at one site, each using three lots of test kits.

Study 1 was conducted to assess lot-to-lot variability of three lots of the OHC COVID-19 Antigen Self Test. Heat-inactivated SARS-CoV-2 (isolate USA/MD-HP20874/2021) were spiked in pooled nasal wash (PNW) to form the following test panel samples:

(1) Negative, Surrogate Negative Matrix
(2) Low positive (1x LoD)
(3) Positive (4x LoD)

Each operator applied 50 µL of each sample to a dry nasal swab and processed the sample per the IFU of the proposed device. The three-test panel sample were tested by two operators for 10 non-consecutive days. All three lots were tested by each operator on each testing day. Each sample level was tested in triplicate in each of two runs per operator per day (i.e., 3 lots × 2 operators × 3 replicates/run × 2 runs × 10 days). A total of 360 test were run per panel member.

The agreement of obtained results with expected results was 100% across all lots, operators, and days. Variability in results was not observed between the three manufactured lots. The results are summarized below in Table 1.

Table 1: Summary Results of Lot-to-Lot Precision Study

Analyte Concentration	Analyte	Lot 1		Lot 2		Lot 3		Total Lot-to-Lot Precision		
		n/N[1]	% Agmt[2]	n/N1	% Agmt[2]	n/N[1]	% Agmt[2]	n/N[1]	% Agmt[2]	95% CI
Negative	**SARS-CoV-2**	120/120	100%	120/120	100%	120/120	100%	360/360	100%	98.7-100%
1X LoD	**SARS-CoV-2**	120/120	100%	120/120	100%	120/120	100%	360/360	100%	98.7-100%
4xLoD	**SARS-CoV-2**	120/120	100%	120/120	100%	120/120	100%	360/360	100%	98.7-100%

[1] n/N = Obtained results per analyte / Expected results per analyte
[2] Agmt = Agreement

Study 2 was specifically conducted to further evaluate potential differences between distinct lots, because study 1 resulted in 100% agreement across all sources of variation and did not allow to conclusively assess lot-to-lot variability of the test. The study was performed using a negative sample without the SARS-CoV-2 and one low positive sample at 0.75x LoD (i.e., below the concentration tested in study 1 and near the analytes' C_{95} concentration) and one positive sample at 4x LoD.

Unlike Study 1, Study 2 was conducted using distinct 3 lots (i.e., lots with different antibody raw materials) of the device in a randomized and blinded manner. Two (2) runs were conducted each day by each of two operators and for each of the 3 lots. Testing was conducted over 3 days for a total of 72 results per sample (3 days × 3 lots × 2 operators × 2 runs per day × 2 replicates per run). For the negative and the 4x LoD samples the results were in 100% agreement with the expected result. Consistent with the analyte concentration of the low positive sample, the 0.75x LoD sample resulted in percent agreements less than 95%, with similar results for all lots. The results are summarized below in Table 2.

Table 2: Summary of Supplemental Precision Study

Analyte Concentration	Analyte	Lot 1		Lot 2		Lot 3		Total Lot-to-Lot Precision		
		n/N[1]	% Agmt[2]	n/N[1]	% Agmt[2]	n/N[1]	% Agmt[2]	n/N[1]	% Agmt[2]	95% CI
Negative	**SARS-CoV-2**	24/24	100%	24/24	100%	24/24	100%	72/72	100%	95.0-100%
0.75X LoD	**SARS-CoV-2**	16/24	66.7%	18/24	75%	17/24	70.8%	51/72	70.8%	58.5-81.0%
4xLoD	**SARS-CoV-2**	24/24	100%	24/24	100%	24/24	100%	72/72	100%	95.0-100%

[1] n/N = Obtained results per analyte / Expected results per analyte
[2] Agmt = Agreement

2. Linearity

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

3. Analytical Specificity/Interference

a. Cross-Reactivity/Microbial Interference:

The analytical specificity of the OHC COVID-19 Antigen Self Test was evaluated by testing various high priority pathogens (6) and microorganisms (28) likely present in respiratory samples and negative clinical matrix (pooled nasal wash) in the absence (cross-reactivity) and presence (microbial interference) of SARS-CoV-2 at 2x LoD.

To demonstrate that the OHC COVID-19 Antigen Self Test does not react with related viruses, high prevalence disease agents, and normal or pathogenic flora that are reasonably likely to be encountered in nasal swab specimens were tested.

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

Table 3: Cross-Reactivity/Microbial Interference Study Results

Virus/Microorganism	Concentration	Units	# of Positive Results / # of Replicates Tested	
			Cross-Reactivity	Interference
Human coronavirus 229E	1.43×10^5	$TCID_{50}$/mL	0/3	3/3

Virus/Microorganism	Concentration	Units	# of Positive Results / # of Replicates Tested	
			Cross-Reactivity	Interference
Human coronavirus OC43	1.43×10^5	$TCID_{50}$/mL	0/3	3/3
Human coronavirus NL63	7.05×10^4	$TCID_{50}$/mL	0/3	3/3
Human coronavirus HKU1 (rAg)	1	µg/mL	0/3	3/3
MERS-coronavirus	1.43×10^5	$TCID_{50}$/mL	0/3	3/3
SARS-coronavirus (rAg)	1	µg/mL	10/10	0/10
	0.1	µg/mL	10/10	0/10
	0.01	µg/mL	10/10	0/10
	0.001	µg/mL	0/10	10/10
Adenovirus type 1	1.29×10^5	$TCID_{50}$/mL	0/3	3/3
Adenovirus type 2	1.43×10^5	$TCID_{50}$/mL	0/3	3/3
Adenovirus type 3	1.43×10^5	$TCID_{50}$/mL	0/3	3/3
Adenovirus type 5	1.43×10^5	$TCID_{50}$/mL	0/3	3/3
Adenovirus type 7A	7.05×10^4	$TCID_{50}$/mL	0/3	3/3
Adenovirus Type 21	8.50×10^4	$TCID_{50}$/mL	0/3	3/3
hMPV 27 Type A2	1.43×10^5	$TCID_{50}$/mL	0/3	3/3
Parainfluenza virus 1	1.43×10^5	$TCID_{50}$/mL	0/3	3/3
Parainfluenza virus 2	1.43×10^5	$TCID_{50}$/mL	0/3	3/3
Parainfluenza virus 3	1.43×10^5	$TCID_{50}$/mL	0/3	3/3
Parainfluenza virus 4a	1.43×10^5	$TCID_{50}$/mL	0/3	3/3
Parainfluenza virus 4b	1.43×10^5	$TCID_{50}$/mL	0/3	3/3
Influenza type A	1.43×10^5	$TCID_{50}$/mL	0/3	3/3
Influenza type B	1.43×10^5	$TCID_{50}$/mL	0/3	3/3
Enterovirus type 68	1.43×10^5	$TCID_{50}$/mL	0/3	3/3
Enterovirus type 71	1.43×10^5	$TCID_{50}$/mL	0/3	3/3
Respiratory syncytial virus A	1.43×10^5	$TCID_{50}$/mL	0/3	3/3
Respiratory syncytial virus B	7.75×10^3	$TCID_{50}$/mL	0/3	3/3
Rhinovirus	1.43×10^5	$TCID_{50}$/mL	0/3	3/3
Haemophilus influenzae type b	1.00×10^6	CFU/mL	0/3	3/3
Streptococcus pneumoniae	1.00×10^6	CFU/mL	0/3	3/3
Streptococcus pyogenes	1.00×10^6	CFU/mL	0/3	3/3
Candida albicans	1.00×10^6	CFU/mL	0/3	3/3
Mycoplasma pneumoniae	1.00×10^6	CFU/mL	0/3	3/3
Chlamydia pneumoniae	2.90×10^7	IFU/mL	0/3	3/3
Legionella pneumophila	1.00×10^6	CFU/mL	0/3	3/3
Staphylococcus aureus	1.00×10^6	CFU/mL	0/3	3/3
Staphylococcus epidermidis	1.00×10^6	CFU/mL	0/3	3/3
Bordetella pertussis	1.00×10^6	CFU/mL	0/3	3/3
Pooled Nasal Wash (human)	N/A	N/A	0/3	3/3

No cross-reactivity or microbial interference was observed for any of the microorganisms tested, except for SARS-coronavirus(rAg) which was cross-reactive with the test and also interfered with the detection of inactivated SARS-CoV-2 when tested at 1 µg/mL as shown in the table above. A titration study of SARS-coronavirus (rAg) was performed to find the concentration at which interference was no longer observed. Cross-reactivity and microbial interference was no longer observed for SARS-coronavirus(rAg) at 0.001 µg/mL.

The OHC COVID-19 Antigen Self Test targets the nucleocapsid protein present in both SARS-CoV and SARS-CoV-2. Since wet testing for SARS-coronavirus and HKU1 was not conducted, cross reactivity cannot be ruled out.

b. Interfering Substances:

Twenty-five (25) potentially interfering substances were evaluated with the OHC COVID-19 Antigen Self Test. Each substance was tested in three (3) replicates in the absence or presence of heat-inactivated SARS-CoV-2 (Lineage B.1.1.529 USA/MD-HP20874/2021) at 2x LoD (5.01 x 10^3 $TCID_{50}$/mL). Based on the test results, the endogenous and exogenous interfering substances tested at a concentration listed in Table 5 below, no interference was observed for any of the interfering substance tested, except for mupirocin.

In the presence of mupirocin at 10mg/mL false negative results occurred. The titration study of mupirocin, performed to find concentrations where false negative results were no longer observed, demonstrated no interference at mupirocin concentration of 5 mg/mL or below.

Table 4: Interfering Substances Study Results

Interfering Substance	Concentration	Cross-Reactivity (without analyte) (# pos/ # total)	Interference (with analyte) (# pos/ # total)
Human whole blood (Anticoagulant: K2-EDTA)	2.5 % v/v	0/3	3/3
Leukocytes	5.0 x 10^6 cells/mL	0/3	3/3
Mucin	2.5 mg/mL	0/3	3/3
Throat Lozenges (Menthol/Benzocaine)	3 mg/mL	0/3	3/3
Nasal spray or drops (Sodium chloride with preservatives)	15 %v/v	0/3	3/3
Nasal spray or drops (Phenylephrine)	15 %v/v	0/3	3/3
Nasal spray or drops (Oxymetazoline)	15 %v/v	0/3	3/3
Nasal spray or drops (Cromolyn)	15 %v/v	0/3	3/3
Nasal gel (Luffa opperculata, Galphimia glauca, Histaminum hydrochloricum, Sulphur)	15 %v/v	0/3	3/3
Homeopathic Allergy relief, or nasal wash	15 %v/v	0/3	3/3
Sore Throat Spray (Phenol)	15 %v/v	0/3	3/3
Antibiotic (Tobramycin)	4 µg/mL	0/3	3/3
Antibiotic, nasal ointment (Mupirocin)	10 mg/mL	0/3	0/10
	5 mg/mL	NT*	10/10
Anti-viral drugs (Tamiflu)	5 mg/mL	0/3	3/3
Nasal corticosteroids (Beclomethasone)	15 %v/v	0/3	3/3
Nasal corticosteroids (Budesonide)	15 %v/v	0/3	3/3
Nasal corticosteroids (Dexamethasone)	15 %v/v	0/3	3/3

Interfering Substance	Concentration	Cross-Reactivity (without analyte) (# pos/ # total)	Interference (with analyte) (# pos/ # total)
Nasal corticosteroids (Flunisolide)	15 %v/v	0/3	3/3
Nasal corticosteroids (Fluticasone)	15 %v/v	0/3	3/3
Nasal corticosteroids (Mometasone)	15 %v/v	0/3	3/3
Nasal corticosteroids (Triamcinolone)	15 %v/v	0/3	3/3
Body lotion	10 %v/v	0/3	3/3
Hand soap	10 % v/v	0/3	3/3
Hand sanitizer	10 %v/v	0/3	3/3
Anti-viral drugs (Remdesivir)	10mg/mL	0/3	3/3

*NT= Not Tested

4. Assay Reportable Range

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

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

a. Controls

The OHC COVID-19 Antigen Self Test has a built-in internal procedural control. A built-in internal control is needed to indicate the test is working and is automatically run onboard within the development time of each test run. This procedural control consists of a non-specific rabbit antibody dried into the reagent pad and an anti-rabbit antibody immobilized in the control region of the test strip that captures the rabbit conjugate at the control line and generates a colored line at the "C" marked control region of the test window. The control line should always appear to demonstrate that the test procedure was performed properly, reagents are working as intended, and for a result to be valid.

b. Stability

i. Shelflife

In order to determine the stability of the OHC COVID-19 Antigen Self Test at the intended storage conditions, 2-30°C, throughout its shelf life of 24 months, three (3) test kits produced within one month of one another were stored at the following three conditions:

(1) 2°C/ ambient humidity
(2) 15°C/ 45% RH
(3) 30°C/ 45% RH

The study tested two (2) positive samples contrived in negative clinical matrix (PNW) at concentrations of 1x LoD and 4x LoD of heat inactivated SARS-CoV-2 (Wild-type, Hong Kong/VM20001061/2020). The study also tested un-spiked PNW as a negative sample. Testing panels were evaluated at time 0 (as soon as practical after a product lot was

manufactured) and after 6, 12, 18, 20, 24, and 27-months of storage under the above listed conditions.

All replicates for the two positive samples consistently yielded positive results, and all replicates of the negative sample consistently yielded negative results for all device lots and at all time points, including the last timepoint tested (i.e., 27 months). Data from this shelflife study support the intended storage of the device between 2°C and 30°C for 24 months.

ii. Shipping Stability:

Transport stability under simulated summer and winter shipping conditions was tested to evaluate worst-case shipping and handling conditions. Performance of unopened test kits was assessed by comparing pre- (T0) and post-distribution (Td) results, using a test panel comprised of negative samples (pooled negative nasal wash) and low positive samples (3x LoD) tested in replicates of five (5) each. Candidate test kits were stored at room temperature and the designated temperature profiles described below and then tested with the test panel to evaluate performance. The following summer and winter temperature profiles were assessed as shown in Table 5 and Table 6:

Table 5: Summer Profile

Cycle No.	Temperature Setpoint	Relative Humidity (RH) Setpoint	Cycle Period (hour)	Total Time (hour)
01	40 °C	90%	08	80
02	22 °C		04	
03	40 °C		06	
04	30 °C		56	
05	40 °C		06	

Table 6: Winter Profile

Cycle No.	Temperature Setpoint	Relative Humidity (RH) Setpoint	Cycle Period (hour)	Total Time (hour)
01	-10 °C	n/a	08	80
02	18 °C		04	
03	-10 °C		06	
04	10 °C		56	
05	-10 °C		06	

All results were as expected for all time points and support shipping under expected shipping conditions with temperature spikes up to 40 ºC.

iii. Sample Stability:

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

6. Detection Limit

a. Limit of Detection (LoD)

The Limit of Detection (LoD) of the OHC COVID-19 Antigen Self Test was determined by evaluating different dilutions of heat-inactivated SARS-CoV-2 (isolate USA/MD-HP20874/2021) in negative PNW. Equivalency of PNW with nasal swab matrix was demonstrated. The LoD was determined as the lowest virus concentration that was detected >95% of the time (e.g., concentration at which at least 19 out of 20 replicates tested positive). The limit of detection was established in two phases.

i. Preliminary LoD Study:

Five serial dilutions were made from heat-inactivated SARS-CoV-2 virus into negative PNW. Five replicates of each serial dilution were tested on 3 lots of the device to determine the preliminary LoD concentration of the device. The lowest concentration with 5/5 positive results from each lot was considered the preliminary LoD of the virus strain. For each replicate 50 µl of the virus dilution was applied to the swab and the swab was processed according to the Instructions for Use. The results are summarized below in Table 7 below with the preliminary LoD in bold.

Table 7: Preliminary LoD Study Summary of SARS-CoV- 2

Concentration of SARS-CoV- 2 ($TCID_{50}$/mL)	Lot 1	Lot 2	Lot 3
5.01×10^4	5/5	5/5	5/5
5.01×10^3	5/5	5/5	5/5
2.51×10^3	**5/5**	**5/5**	**5/5**
5.01×10^2	0/5	0/5	0/5
1.26×10^3	0/5	0/5	0/5
0.63×10^3	0/5	0/5	0/5

ii. Confirmatory LoD Study:

The preliminary LoD concentration and at concentrations above and below the LoD were tested with a total of twenty (20) replicates for each of 3 kit lots. The final data set from this testing included the confirmed LoD level with at least one additional level tested above and below to demonstrate that the levels above the LoD were 100% positive and the levels below the LoD were <95% positive. The results are summarized in Table 8 below.

Table 8: Confirmatory LoD Study Summary of SARS-CoV- 2

Concentration of SARS-CoV- 2 ($TCID_{50}$/mL)	Lot 1	Lot 2	Lot 3
1.00×10^4	20/20	20/20	20/20
5.01×10^3	20/20	20/20	20/20
2.51×10^3	**20/20**	**20/20**	**20/20**
1.26×10^3	0/20	0/20	0/20
0.63×10^3	0/20	0/20	0/20

The limit of detection for the OHC COVID-19 Antigen Self Test was determined to be 2.51 x

10^3 $TCID_{50}$/mL of sample and was achieved by all tested lots. This is equivalent to 125.5 $TCID_{50}$/swab.

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

The LoD of the OHC COVID-19 Antigen Self Test was determined by evaluating different dilutions of SARS-CoV-2 antigen (NIBSC code: 21/368) in pooled negative swab matrix (PNSM). Two vials of SARS-CoV-2 Antigen (NIBSC 21/368) were reconstituted in 250 µL ultra-pure water each and then combined for testing one (1) lot of the OHC COVID-19 Antigen Self Test. The LoD was determined as the lowest virus concentration that was detected ≥ 95% of the time (i.e., concentration at which at least 19 out of 20 replicates tested positive). The limit of detection was established in two (2) phases.

i. Preliminary LoD Study

The SARS-CoV-2 Antigen stock solution (concentration $2x10^4$ IU/mL) was diluted 1:5, 1:10, and 1:20 into PNSM. Three (3) replicates were tested for each of three dilutions. For each replicate 50 µL of virus dilution was applied to a swab and the swab was processed according to the IFU. The lowest concentration with 3/3 positive results was considered the preliminary LoD (i.e., 1000 IU/mL). The results are summarized below in Table 9.

Table 9: Preliminary LoD for SARS-CoV-2 Antigen (NIBSC code: 21/368)

Concentration SARS-CoV-2 antigen (NIBSC code: 21/368)		Positive/Tested
IU/mL applied sample	**IU/Swab**	
4000 IU/mL	200	3/3
2000 IU/mL	100	3/3
1000 IU/mL	**50**	**3/3**
400 IU/mL	20	0/3
40 IU/mL	2	0/3

ii. Confirmatory LoD Study

The preliminary LoD concentration of the NIBSC 21/368 material, one concentration above (2x LoD) and one concentration below (0.5 X LoD) were then tested with a total of twenty replicates. To confirm the preliminary concentration as LoD, at least 19 of the 20 replicates should be positive. The results of the confirmatory testing are summarized below in Table 10.

Table 10: Confirmatory LoD for SARS-CoV-2 Antigen (NIBSC code: 21/368)

Concentration of SARS-CoV-2 antigen		Positive/Tested
IU/mL	**IU/swab**	
2000	100	20/20
1000	**50**	**20/20**
500	25	14/20

The LoD for the OHC COVID-19 Antigen Self Test using International Standard for SARS-CoV-2 antigen (NIBSC code: 21/368) in nasal matrix was confirmed to be 1000 IU/mL (50 IU/swab).

7. High Dose Hook Effect

The purpose of this study was to evaluate the effect of a high concentration of SARS antigen on the performance of the OHC COVID-19 Antigen Self Test. 50µl of heat-inactivated SARS-CoV-2 (Lineage B.1.1.529 USA/MD-HP20874/2021) at 5.01 x 10^5 $TCID_{50}$/mL concentration was added on each swab and was tested in five (5) replicates on the OHC COVID-19 Antigen Self Test. The testing was conducted according to the Instructions for Use for the test.

No High-Dose hook effect was observed with a concentration of 5.01 x 10^5 $TCID_{50}$/mL of heat-inactivated SARS-CoV-2 virus with OHC COVID-19 Antigen Self Test. The results are summarized below in Table 11.

Table 11: Summary of High Dose Hook Effect Study

Concentration of SARS CoV-2	Positive/Tested
5.01 x 10^5 $TCID_{50}$/mL	5/5

8. Inclusivity (Analytical Reactivity):

Analytical reactivity for OHC COVID-19 Antigen Self Test was demonstrated using 9 additional strains/isolates of SARS-CoV-2 virus. Heat-inactivated SARS-CoV-2 isolates were each diluted into PNW at different concentrations. Each concentration was tested with 5 replicates until two consecutive dilutions produced one or more negative replicates out of 5. The reactivity of the OHC COVID-19 Antigen Self Test with the variants is summarized below in Table 12 with the lowest concentration that returned 100% positive replicates (i.e., 5/5):

Table 12: Inclusivity Study Results

SARS-CoV-2 Variants	Lowest Variant Concentration with 5/5 positive replicates
USA-WA1/2020 (Wild-Type)	2.88 x 10^4 $TCID_{50}$/mL
Hong Kong/VM20001061/2020 (Wild-Type)	1.38 x 10^4 $TCID_{50}$/mL
Italy-INMI1 (Wild-Type)	1.28 x 10^5 $TCID_{50}$/mL
USA/CA CDC_5574/2020 (Alpha) (B.1.1.7)	5.25 x 10^3 $TCID_{50}$/mL
South Africa/KRISP-K005325/2020 (Beta) (B.1.351)	1.14 x 10^4 $TCID_{50}$/mL
Japan/TY7-503/2021 (Gamma) (P.1)	1.26 x 10^3 $TCID_{50}$/mL
USA/PHC658/2021 (Delta) (B.1.617.2)	1.25 x 10^3 $TCID_{50}$/mL
USA/CA-Stanford-15_S02/2021 (Kappa) (B.1.617.1)	6.15 x 10^5 $TCID_{50}$/mL
USA/MD-HP24556/2022 (Omicron) (BA.2.3)	5.85 x 10^2 $TCID_{50}$/mL
JN.1 Pooled Remnant Clinical Samples	2.1x 10^5 GE/mL

9. Assay Cut-Off:

Not applicable, the device is a binary qualitative assay.

B Comparison Studies:

1. Method Comparison with Predicate Device:

   Not applicable. See "C. Clinical Studies." for performance comparison with a clinical comparator.

2. Matrix Comparison:

   The OHC COVID-19 Antigen Self Test is only intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in direct anterior nasal swab specimens. As no other specimen or sample type is claimed for this device, a Matrix Comparison study is not applicable. However, in support of the analytical studies equivalency between nasal swab matrix (PNSM) and nasal wash matrix (PNW) was demonstrated.

C Clinical Studies:

1. Prospective Clinical Study

   The performance of the OHC COVID-19 Antigen Self Test was compared to a SARS-CoV-2 molecular assay in a prospective clinical study completed at four (4) sites in the United States. Samples were collected by lay users from themselves or collected for a household member. A total of 716 subjects who were currently experiencing symptoms associated with COVID-19 were enrolled into the study. Of those, 709 subjects (59.4% female and 40.6% male) were within 6 days of symptom onset and evaluable based upon the inclusion and exclusion criteria for analysis. The demographics of the enrolled clinical study subjects are summarized in Table 13.

Table 13: Demographics of the Enrolled Symptomatic Clinical Study Subjects

Demographic	Total # of Study Subjects n=709	Total Percentage n=709
Gender		
Male	288	40.6% (288/709)
Female	421	59.4% (421/709)
Age		
2-13 years old	81	11.4% (81/709)
14-24 years old	108	15.2% (108/709)
25-64 years old	443	62.5% (443/709)
≥65 years old	77	10.9% (77/709)
Education		
Less than high school diploma	101	14.2% (101/709)
High school diploma	274	38.3% (274/709)
Some college, but no degree	103	14.4% (103/709)
Associate degree	46	6.4% (46/709)
Bachelor's Degree	138	19.4% (138/709)
Master's Degree	29	4.1% (29/709)
Doctorate	5	0.7% (5/709)
Professional Degree	9	1.3% (9/709)
Other	11	1.5% (11/709)

Demographic	Total # of Study Subjects n=709	Total Percentage n=709
Sample Collector		
Self-collected sample	622	87.7% (622/709)
Sample collected by other	87	12.2% (87/709)

An analysis based upon the comparator's Ct values estimates that the study cohort included 38.8% low positive samples. The OHC COVID-19 Antigen Self Test detected SARS-CoV-2 with a Positive Percent Agreement (PPA) of 85.3% and a Negative Percent Agreement (NPA) of 99.3% in symptomatic individuals as compared to highly sensitive FDA 510(k) cleared molecular SARS-CoV-2 assay. Results are provided in Table 14 and Table 15.

Table 14: SARS-CoV-2 Results: Candidate Test vs. Comparator

	Comparator Positives	Comparator Negatives	Total
Candidate Positives	110	4	114
Candidate Negatives	19	576	595
Total	129	580	709
Positive Percent Agreement (PPA): 85.3% (110/129)		95% CI: 78.1%-90.4%	
Negative Percent Agreement (NPA): 99.3% (576/580)		95% CI: 98.2%-99.7%	

Table 15: OHC COVID-19 Antigen Self Test DPSO Stratified Clinical Performance

DPSO	Total Number of Specimens Tested	Investigational Positives	Comparator Positives	PPA (95% CI)
0	20	5	6	83.3% (43.6% - 99.1%)
1	58	4	5	80.0% (37.6% - 99.0%)
2	165	15	22	68.2% (47.3% - 83.6%)
3	173	17	20	85.0% (64.0% - 94.8%)
4	133	18	20	90.0% (69.9% - 97.2%)
5	115	34	37	91.9% (78.7% - 97.2%)
6	45	17	19	89.5% (68.6% - 97.1%)
Total	**709**	**110**	**129**	**85.3% (78.1% - 90.4%)**

2. Usability Study

A usability study was conducted to assess the lay user's ability to understand the instructions for use and to adequately execute the OHC COVID-19 Antigen Self Test workflow accordingly.

A total of 100 subjects were enrolled in the human factors assessment studies concurrently with the clinical evaluation at three sites. Out of these subjects, fifty (50) of the participants self-collected and tested their samples and fifty (50) of the participants had their collection performed by another lay user.

Table 16: Human Factors and Usability Study - Demographics of Testers

Factor	Testers self-collecting and self-testing (N=50)	Testers collecting and testing someone else (N=50)	Overall (N=100)
Age			
Mean (SD)	48.4 (20.9)	7.4 (3.6)	27.9 (25.4)
Median [Min, Max]	53.5 (14, 79)	6.5 [2, 13]	13.5 [2, 79]
Age Group			
≥2 – <14 years of age	0 (0.0%)	50 (100.0%)	50 (50.0%)
14 – 24 years of age	11 (22.0%)	0 (0.0%)	11 (11.0%)
>24 – 64 years of age	24 (48.0%)	0 (0.0%)	24 (24.0%)
≥65 years of age	15 (30.0%)	0 (0.0%)	15 (15.0%)
Sex at Birth			
Male	22 (44.0%)	18 (36.0%)	40 (40.0%)
Female	28 (56.0%)	32 (64.0%)	60 (60.0%)
Education Level			
Less than high school diploma	9 (18.0%)	4 (8.0%)	13 (13.0%)
High school diploma	18 (36.0%)	23 (46.0%)	41 (41.0%)
Some college (no degree)	7 (14.0%)	7 (14.0%)	14 (14.0%)
Associate degree (e.g., AA, AS)	3 (6.0%)	7 (14.0%)	10 (10.0%)
Bachelor's degree (e.g., BA, BBA, BS)	10 (20.0%)	6 (12.0%)	16 (16.0%)
Master's degree (e.g., MA, MS, MEng)	2 (4.0%)	2 (4.0%)	4 (4.0%)
Professional Degree/ Doctorate (e.g., MD, DDS, JD, PhD, EdD)	1 (2.0%)	1 (2.0%)	2 (2.0%)

Users were assessed for their ability to perform critical and non-critical tasks during the testing process as shown below in table format. Overall, 83.5% of all critical and 90.2% of non-critical tasks associated with the OHC COVID-19 Antigen Self Test were performed correctly.

Table 17: Critical vs Non-Critical Tasks Correctly Performed

Steps	Total number of steps	Steps performed correctly	Percentage of steps performed correctly
Critical	800	668	83.5%
Non- Critical	500	451	90.2%
Sum	1300	1119	86.1%

Overall, 99 out of 100 subjects who participated in the human factors assessment found the instructions clear and easy to follow and none of the subjects had difficulty collecting the sample or running the investigational test.

Following the usability study, all subjects were issued a questionnaire to assess their comprehension of the test. The questionnaire was completed by 100 subjects enrolled in the clinical study The questionnaire assessed users 'understanding of concepts such as the test

purpose and interpretation of results. In the labeling and comprehension assessment of the investigational test QRI, all subjects understood that the investigational test is for the detection of SARS-CoV-2 and they understood that they should self-isolate if they test positive with the investigational test. Most of the subjects understood that they should collect a new sample and run a new test if they had an invalid result, skipped a step or performed a step incorrectly.

3. Readability Study

The purpose of this study is to evaluate whether lay home-users (patients or their caregivers) can interpret test results correctly with low positive samples from the OHC COVID-19 Antigen Self Test.

The Readability Study was conducted according to an IRB approved protocol in a simulated home environment. A total of 500 lay users with diverse gender, ages and educational background who met the study inclusion criteria, were enrolled for the Readability Study and provided with a panel of device representations with results for interpretation. interpret. Each panel of investigational tests with mock results will consist of at least one each of the following: a negative result, a low positive result at no more than 1.5 - 2x LoD, a positive result at 3 - 5x LoD, and an invalid result. Each. Each investigational test with the mock result were blinded and coded with a sample ID.

60% of the study participants were female and 40% of the study participants were female. 29% of individuals were either still at high school or had a high school degree as their highest level of education. The Readability Study results are shown in Table 18 and Table 19.

Table 18: Interpretation of Mock Results

Interpreted Result	**Confirmed Result**			
	Low Positive	**Negative**	**Invalid**	**Sum**
Low Positive/Positive	245	1	1	247
Negative	1	152	0	153
Invalid	1	0	99	100
Sum	247	153	100	500
Accuracy in interpreting positive results: 245/247 = 99.2% (95% CI:97.1%-99.8%)				
Accuracy in interpreting negative results: 152/153 = 99.3% (95% CI: 96.4%-100.0%)				
Accuracy in interpreting invalid results: 99/100 = 99.0% (95% CI:94.6%-99.9%)				

Table 19: Readability Study Result Summary by Age Group

Age Group	**Total #**	**Correct Reads**	**Incorrect Reads**	**Percentage of Correct Reads**
14 -24 years of age	65	65	0	100.0
>24 – 64 years of age	345	344	1	99.7
≥65 years of age	90	87	3	96.7
Total	**500**	**496**	**4**	**99.2**

D Clinical Cut-Off:

Not Applicable. The candidate device is a qualitative assay with a visually read binary result without numeric raw data.

E Expected Values/Reference Range:

A patient sample is expected to be negative for SARS-CoV-2. This section is therefore not applicable.

F Other Supportive Study/Device Information

a. Variant Monitoring Plan

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

b. Flex Studies

To assess the robustness of the OHC COVID-19 Antigen Self Test, flex studies were conducted that assessed all major aspects of the test procedure (sample volume, reading time, extraction buffer volume, swab elution time and procedure) and variability of environmental test conditions that the test may be subjected to when in use (device orientation, lighting, various temperature, and humidity stress conditions). Testing was performed with contrived positive nasal swabs generated by diluting heat inactivated SARS-CoV-2 virus into PNW at 2xLoD. The studies support that the test is robust in the intended use condition with an insignificant risk of erroneous result.

VIII Proposed Labeling

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

IX Conclusion

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