May 30, 2025

Osang LLC
% Lisa Baumhardt
Senior Medical Device Regulatory Expert
Hyman, Phelps & McNamara P.C.
700 Thirteenth Street, N.W., Suite 1200
Washington, District of Columbia 20005-5929

Re: K241313
Trade/Device Name: OHC COVID-19 Antigen Self Test
Regulation Number: 21 CFR 866.3984
Regulation Name: Over-The-Counter Test To Detect SARS-Cov-2 From Clinical Specimens
Regulatory Class: Class II
Product Code: QYT
Dated: May 7, 2024
Received: May 9, 2024

Dear Lisa Baumhardt:

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

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

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

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

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

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

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

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Silke Schlottmann -S

Digitally signed by Silke Schlottmann -S
Date: 2025.05.30 17:50:27 -04'00'

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K241313

Device Name
OHC COVID-19 Antigen Self Test

Indications for Use *(Describe)*
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.

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

OHC COVID-19 Antigen Self Test

510(k) Summary

In accordance with 21 CFR 807.87(h) and 21 CFR 807.92, the following 510(k) Summary for OHC COVID-19 Antigen Self Test is provided:

Submitter Information

Applicant/Submitter:	OSANG Healthcare Co., Ltd. 132, Anyangcheondong-Ro Dongan-Gu Anyang-Si, Gyeonggi-Do, Republic of Korea 14040 Phone: 82-31-4600415
Date Prepared:	May 7, 2024
Contact Person:	Lisa Baumhardt, Sr. Medical Device Regulatory Consultant Hyman, Phelps, & McNamara, P.C. Phone: 202-424-9631 Email: lbaumhardt@hpm.com
Secondary Contact	Seungyeob Lee OSANG LLC 625 Fair Oaks Ave, Ste 360, South Pasadena, CA 91030 Phone: 213-800-1820 Email: dan@osangllc.com

Identification of the Device

Trade Name:	OHC COVID-19 Antigen Self Test
Common Name:	Over-the-Counter COVID-19 Antigen Test
Classification Name	Over-the-Counter COVID-19 Antigen Test 21 C.F.R. 866.3984
Product Code:	QYT
Device Class:	Class II

Predicate Device(s)

Predicate Device(s):	Flowflex COVID-19 Antigen Home Test (K230828)

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 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.

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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.

Device Description

The OHC COVID-19 Antigen Self Test is a lateral flow chromatographic immunoassay intended to detect the nucleocapsid protein antigen from SARS-CoV-2 in non-prescription home use from:

- Self-collected anterior nasal (nares) swab specimens from individuals aged 14 years and older with symptoms of COVID-19 within the first 6 days of symptom onset.
- Adult-collected anterior nasal (nares) swab specimens from individuals aged 2 years and older with symptoms of COVID-19 within the first 6 days of symptom onset.

The OHC COVID-19 Antigen Self Test is based on a lateral flow immunoassay and detects the N-Protein (nucleocapsid protein) of SARS-CoV-2. The cassette contains membranes which are pre-coated with anti-SARS-CoV-2 nucleocapsid protein monoclonal antibodies on test line. Another anti-SARS-CoV-2 nucleocapsid protein monoclonal antibodies are bound to colloidal gold. When the sample is loaded to the sample inlet, SARS-CoV-2 antibodies, that were conjugated with the small colloidal gold articles, and SARS-CoV-2 antigen complexes are formed and travel up the strip. If the sample contains SARS-CoV-2 antigens (“analyte”), the complexes will be captured by coated antibodies on membrane to form an analyte-labeled antibody complex. When these complexes reach the test line of the cassette they are retained by another set of SARS-CoV-2 antibodies. This so-called sandwich complex appears as a visible pink/purple line on the test line (T). The presence of SARS- CoV-2 antigen will be indicated by a visible red test line in T-marked (T) position on side of result window. If the sample does not contain SARS-CoV-2 antigens, no sandwich complexes are formed and thus no colored line appears on the test line (T). Regardless of the presence or absence of SARS-CoV-2 antigens in the sample, a colored line will appear on the control line (C). The control (C) line appears in each result window when sample has

flowed through the strip. The control line is used as an internal procedural control. The control line should always appear if the test procedure is performed properly and the reagents are working as intended. If no colored line appears on the control line (C), it implies that the test has not worked as intended.

Substantial Equivalence

The proposed OHC COVID-19 Antigen Self Test has similar indications for use, and uses the same fundamental technology as, the legally marketed predicate device to which substantial equivalence is claimed, the Flowflex COVID-19 Antigen Home Test (K230828).

Table 1. Comparison of the Proposed Device, Predicate Device and Reference Devices

Specification	Proposed Device: OHC COVID-19 Antigen Self Test	Predicate Device: Flowflex COVID-19 Antigen Home Test K230828
Intended Use	Over-the-counter test to detect SARS-CoV-2 from clinical specimens.	Over-the-counter test to detect SARS-CoV-2 from clinical specimens.
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 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 for SARS-CoV-2 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	The Flowflex COVID-19 Antigen Home Test is a visually read lateral flow immunoassay device intended for the rapid, qualitative detection of SARS-CoV-2 virus nucleocapsid protein antigen directly in anterior nasal swab specimens from individuals with signs and symptoms of 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

Specification	Proposed Device: OHC COVID-19 Antigen Self Test	Predicate Device: Flowflex COVID-19 Antigen Home Test K230828
	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.	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.
Prescription Use or Over-the-Counter	Over-the-counter (OTC)	Over-the-counter (OTC)
End User	Lay User	Lay User
Disease	COVID-19	COVID-19
Intended Use Population	Symptomatic individuals 14 years of age and older testing themselves and adults testing individuals aged 2 years and older.	Symptomatic individuals 14 years of age and older testing themselves and adults testing individuals aged 2 years and older
Sample	Anterior nasal swab specimen	Anterior nasal swab specimen
Assay Principle	Lateral Flow	Lateral Flow
Qualitative or Quantitative	Qualitative	Qualitative
Organism detected	SARS-CoV-2	SARS-CoV-2
Format	Test cassette	Test cassette
Controls	Internal control	Internal control
Time to Result	15 minutes	15-30 minutes
Results	Positive, Negative, or Invalid	Positive, Negative, or Invalid
Interpretation	Visually read	Visually read

Technological Characteristics

As shown in **Table 1** above, the proposed device, OHC COVID-19 Antigen Self Test, and the predicate device have the same intended use and similar indications for use. The proposed device, OHC COVID-19 Antigen Self Test and the predicate device have the same technological characteristics. Both devices are lateral flow immunoassays which are visually read and require no instrumentation or mobile applications. Both devices detect the SARS-CoV-2 nucleocapsid protein from a lay user collected anterior swab specimen from individuals with signs and

symptoms of COVID-19.

Performance Data

Numerous studies were undertaken to document the performance characteristics and the substantial equivalence of the proposed device, OHC COVID-19 Antigen Self Test and the predicate device. The performance studies included:

Limit of Detection:

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 a negative standard material (pooled nasal wash). 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 phases.

Preliminary LoD Study:

Five serial dilutions were made from heat-inactivated SARS-CoV-2 virus (isolate USA/MD-HP20874/2021) into negative standard material (pooled nasal wash). Five replicates of each serial dilution were tested on 3 lots of the assay 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 2:

Table 2. Preliminary LoD

Concentration of SARS-CoV-2 (USA/MD-HP20874/2021) applied to dry swab	**Lot 1: O1SHY004**	**Lot 2: 01SHZ005**	**Lot 3: 01SHY006**
5.01 x 10^4 $TCID_{50}$/mL	5/5	5/5	5/5
5.01 x 10^3 $TCID_{50}$/mL	5/5	5/5	5/5
2.51 x 10^3 $TCID_{50}$/mL	**5/5**	**0/5**	**5/5**
5.01 x 10^2 $TCID_{50}$/mL	0/5	5/5	0/5
1.26 x 10^3 $TCID_{50}$/mL	0/5	0/5	0/5
0.63 x 10^3 $TCID_{50}$/mL	0/5	0/5	0/5

Confirmatory LoD Study:

The Preliminary LoD concentration and at concentrations above and below the LoD were tested with a total of twenty (20) replicates of the same heat-inactivated SARS-CoV-2 material for each of 3 kit lots. To confirm the LoD for each lot, at least 19 of the 20 replicates should be positive. The final confirmation data set included the confirmed LoD level with at least on 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 below in **Table 3**:

Table 3. Confirmatory LoD

Concentration of SARS-CoV-2 (USA/MD-HP20874/2021) applied to dry swab	**Lot 1: O1SHY004**	**Lot 2: 01SHZ005**	**Lot 3: 01SHY006**
1.00×10^4 $TCID_{50}$/mL (4x LoD)	20/20	20/20	20/20
5.01×10^3 $TCID_{50}$/mL (2x LoD)	20/20	20/20	20/20
2.51×10^3 $TCID_{50}$/mL (1x LoD)	**20/20**	**20/20**	**20/20**
1.26×10^3 $TCID_{50}$/mL (0.5x LoD)	0/20	0/20	0/20
0.63×10^3 $TCID_{50}$/mL (0.25x LoD)	0/20	0/20	0/20

The limit of detection for the OHC COVID-19 Antigen Self Test was determined to be 2.51×10^3 $TCID_{50}$/mL.

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

In addition, the limit of detection (LoD) was evaluated using the International Standard for SARS-CoV-2 antigen (NIBSC code: 21/368) following the same procedure. The confirmed limit of detection (LoD) using this standard was 1,000 IU/mL. This is equivalent to 50 IU/swab.

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 negative standard material (pooled nasal wash) at different concentrations. Each concentration was tested with replicates of 5 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 4** with the lowest concentration that returned 100% positive replicates (i.e., 5/5).

Table 4. Summary of OHC COVID-19 Antigen Self Test's reactivity with SARS-CoV-2 variants

SARS-CoV-2 Variants	**Lowest Variant Concentration with 5/5 positive replicates** ($TCID_{50}$/mL)
Wild-Type (USA-WA1/2020)	2.88×10^4
Wild-Type (Hong Kong/VM20001061/2020)	1.38×10^4
Wild-Type (Italy-INMI1)	1.28×10^5
Alpha (B.1.1.7)	5.25×10^3
Beta (B.1.351)	1.14×10^4
Gamma (P.1)	1.26×10^3
Delta (B.1.617.2)	1.25×10^3
Kappa (B.1.617.1)	6.15×10^5
Omicron (BA.2.3)	5.85×10^2

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Wet Testing JN.1:

The JN.1 live pool 1, derived from Emory University clinical samples was diluted and five (5) replicates of OHC COVID-19 Antigen Self Test were evaluated according to the instructions for use. Results are shown in **Table 5** below.

Table 5. Wet Testing Results

Sample	Dilution	Ct Value	Positive Results
JN.1 Live Pool 1-1	Dilution 1	22.9 +/- 0.43	5/5
JN.1 Live Pool 1-2	Dilution 2	24.0 +/- 0.11	5/5
JN.1 Live Pool 1-3	Dilution 3	25.6 +/- 0.34	5/5
JN.1 Live Pool 1-4	Dilution 4	25.4 +/- 0.57	0/5
JN.1 Live Pool 1-5	Dilution 5	26.4 +/- 0.45	0/5
JN.1 Live Pool 1-6	Dilution 6	27.9 +/- 0.75	0/5
JN.1 Live Pool 1-7	Dilution 7	29.8 +/- 0.37	0/5
JN.1 Live Pool 1-8	Dilution 8	30.3 +/- 0.46	0/5
JN.1 Live Pool 1-9	Dilution 9	32.4 +/- 0.59	0/5
JN.1 Live Pool 1-10	Dilution 10	33.1 +/- 0.11	0/5
JN.1 Live Pool 1-11	Dilution 11	33.9 +/- 0.48	0/5
JN.1 Live Pool 1-12	Dilution 12	35.5 +/- 0.76	0/5

Cross Reactivity/Microbial Interference:

The cross-reactivity and potential interference were evaluated by testing various microorganisms, viruses, and negative matrix with the OHC COVID-19 Antigen Self Test. Each organism and virus were tested in three (3) replicates in the absence and presence of 5.01 x 10^3 $TCID_{50}$/mL of heat-inactivated SARS-CoV-2 (isolate USA/MD-HP20874/2021). No cross-reactivity or microbial interference was observed, except with SARS-coronavirus (rAg), which showed cross-reactivity and microbial interference at 1 µg/mL. A titration study determined that cross-reactivity and microbial interference was no longer observed for SARS-coronavirus(rAg) at 0.001 µg/mL.

Table 6. Cross-reactivity/Microbial Interference Study Results

Virus/Microorganism	Concentration	Units	Cross-Reactivity	Microbial Interference
Human coronavirus 229E	1.43 x 10^5	$TCID_{50}$/mL	No	No
Human coronavirus OC43	1.43 x 10^5	$TCID_{50}$/mL	No	No
Human coronavirus NL63	7.05 x 10^4	$TCID_{50}$/mL	No	No
Human coronavirus HKU1 (rAg)*	1	µg/mL	No	No
MERS-coronavirus	1.43 x 10^5	$TCID_{50}$/mL	No	No
SARS-coronavirus (rAg)*	1	µg/mL	Yes	Yes
	0.1	µg/mL	No	No
	0.01	µg/mL	No	No
	0.001	µg/mL	No	No
Adenovirus type 1	1.29 x 10^5	$TCID_{50}$/mL	No	No
Adenovirus type 2	1.43 x 10^5	$TCID_{50}$/mL	No	No
Adenovirus type 3	1.43 x 10^5	$TCID_{50}$/mL	No	No
Adenovirus type 5	1.43 x 10^5	$TCID_{50}$/mL	No	No
Adenovirus type 7A	7.05 x 10^4	$TCID_{50}$/mL	No	No
Adenovirus Type 21	8.50 x 10^4	$TCID_{50}$/mL	No	No
hMPV 27 Type A2	1.43 x 10^5	$TCID_{50}$/mL	No	No
Parainfluenza virus 1	1.43 x 10^5	$TCID_{50}$/mL	No	No
Parainfluenza virus 2	1.43 x 10^5	$TCID_{50}$/mL	No	No
Parainfluenza virus 3	1.43 x 10^5	$TCID_{50}$/mL	No	No
Parainfluenza virus 4a	1.43 x 10^5	$TCID_{50}$/mL	No	No
Parainfluenza virus 4b	1.43 x 10^5	$TCID_{50}$/mL	No	No
Influenza type A	1.43 x 10^5	$TCID_{50}$/mL	No	No
Influenza type B	1.43 x 10^5	$CEID_{50}$/mL	No	No

Enterovirus type 68	1.43×10^5	$TCID_{50}$/mL	No	No
Enterovirus type 71	1.43×10^5	$TCID_{50}$/mL	No	No
Respiratory syncytial virus A	1.43×10^5	$TCID_{50}$/mL	No	No
Respiratory syncytial virus B	7.75×10^3	$TCID_{50}$/mL	No	No
Rhinovirus	1.43×10^5	$TCID_{50}$/mL	No	No
Haemophilus influenzae type b	1.00×10^6	CFU/mL	No	No
Streptococcus pneumoniae	1.00×10^6	CFU/mL	No	No
Streptococcus pyogenes	1.00×10^6	CFU/mL	No	No
Candida albicans	1.00×10^6	CFU/mL	No	No
Mycoplasma pneumoniae	1.00×10^6	CFU/mL	No	No
Chlamydia pneumoniae	2.90×10^7	IFU/mL	No	No
Legionella pneumophila	1.00×10^6	CFU/mL	No	No
Staphylococcus aureus	1.00×10^6	CFU/mL	No	No
Staphylococcus epidermidis	1.00×10^6	CFU/mL	No	No
Bordetella pertussis	1.00×10^6	CFU/mL	No	No
Nasal Human Nasal Cavity Wash (representative of normal respiratory microbial flora)	N/A	N/A	No	No

*Human coronavirus HKU1 and SARS-coronavirus were tested using recombinant antigens.

*Wet testing for SARS-coronavirus and HKU1 was not conducted, and cross-reactivity cannot be ruled out.

Interfering Substances:

Twenty-five (25) potentially interfering substances were evaluated with the OHC COVID-19 Antigen Self Test to verify if endogenous and exogenous substances that may be present in respiratory specimens interfere with the detection of SARS-CoV-2 in the OHC COVID-19 Antigen Self Test. Each substance was tested in three (3) replicates in the presence and absence of 5.01×10^3 $TCID_{50}$/mL of heat-inactivated SARS-CoV-2 (isolate USA/MD-HP20874/2021). None of the substances listed in **Table 7** interfered with the assay at the levels shown.

Table 7. Interfering Substances Study Results

Interfering Substance	Concentration
Human whole blood (Anticoagulant: K2-EDTA)	2.5 %v/v
Leukocytes	5.0×10^6 cells/mL
Mucin	2.5 mg/mL
Throat Lozenges (Menthol/Benzocaine)	3 mg/mL
Nasal spray or drops (Sodium chloride with preservatives)	15 %v/v
Nasal spray or drops (Phenylephrine)	15 %v/v
Nasal spray or drops (Oxymetazoline)	15 %v/v
Nasal spray or drops (Cromolyn)	15 %v/v
Nasal gel (Luffa opperculata, Galphimia glauca, Histaminum hydrochloricum, Sulphur)	15 %v/v
Homeopathic Allergy relief, or nasal wash (Menthol, Eucalytol, Thymol, Camphor, Benzoin, etc.)	15 %v/v
Sore Throat Spray (Phenol)	15 %v/v
Antibiotic (Tobramycin)	4 µg/mL
Antibiotic, nasal ointment (Mupirocin)**	5 mg/mL
Anti-viral drugs (Tamiflu)	5 mg/mL
Nasal corticosteroids (Beclomethasone)*	15 %v/v
Nasal corticosteroids (Budesonide)	15 %v/v
Nasal corticosteroids (Dexamethasone)*	15 %v/v
Nasal corticosteroids (Flunisolide)*	15 %v/v
Nasal corticosteroids (Fluticasone)	15 %v/v
Nasal corticosteroids (Mometasone)	15 %v/v
Nasal corticosteroids (Triamcinolone)	15 %v/v
Body lotion	10 %v/v
Hand soap	10 % v/v
Hand sanitizer	10 %v/v
Anti-viral drugs (Remdesivir)	10mg/mL

*Active ingredients were prepared in the same concentration as commercial medication and used in the test.

**While there was no interference with Nasal antibiotic ointment, Mupirocin, at 10mg/mL in SARS-CoV-2 negative samples, in the presence of SARS-CoV-2, false negative results were observed when tested 10 mg/mL. Mupirocin did not interfere at the testing

concentration of 5mg/mL and the samples were positive as expected.

Hook Effect:
To ensure that a high concentration of SARS-CoV-2 antigen does not interfere with a positive reaction in the OHC COVID-19 Antigen Self Test, 50 µl of heat-inactivated SARS-CoV-2 (isolate USA/MD-HP20874/2021) was added onto each of five (5) swabs and tested on the OHC COVID-19 Antigen Self Test. The testing was conducted according to the Instructions for Use for the test. The results demonstrated that the OHC COVID-19 Antigen Self test did not display a Hook Effect when tested with concentrations up to 5.01 x 10^5 $TCID_{50}$/mL of heat-inactivated SARS-CoV-2 virus.

Flex Studies:
A series of flex studies were performed by testing SARS-CoV-2 negative sample and SARS-CoV-2 positive sample (2xLoD) at various conditions as shown in **Table 8** when use-related errors occur. The results demonstrate the robustness of the assay in the intended use condition and the assay does not present a significant risk of erroneous results when performed by a lay user.

Table 8. Flex Studies

Flex Studies	
Placement of the device on non-level surface	Temperature and Humidity Extremes
Swab mixing expression variability	Variety of Light Conditions
Sample volume variability	Open cassette pouch stability
Touching or moving test cassette during test	High Humidity
Result reading time	Extraction buffer spill

Precision:
The lot-to-lot precision of the OHC COVID-19 Antigen Self Test was evaluated by using three (3) product lots (Study 1). A series of contrived samples were prepared as negative, low positive (1xLoD), and moderate positive (4xLoD) using heat-inactivated SARS-CoV-2 (isolate USA/MD-HP20874/2021). Each sample was tested in triplicate in two (2) events per day over ten (10) days with two (2) operators. The precision testing demonstrated there was no difference in results lot-to-lot and between operators. Refer to **Table 9** for a summary of results for Study 1.

Table 9. Precision Study Results (Study 1)

Lot	**Negative**		**Low Positive (1xLoD)**		**Moderate Positive (4xLoD)**	
	Reader 1	**Reader 2**	**Reader 1**	**Reader 2**	**Reader 1**	**Reader 2**
1	60/60	60/60	60/60	60/60	60/60	60/60
2	60/60	60/60	60/60	60/60	60/60	60/60
3	60/60	60/60	60/60	60/60	60/60	60/60
Total	180/180	180/180	180/180	180/180	180/180	180/180
% Agreement	100%	100%	100%	100%	100%	100%

Study 2 was specifically designed to evaluate between-lot variability. The study utilized a test panel consisting of three randomized sample types 0.75X LoD, 4X LoD, and a negative sample. This supplemental precision testing was conducted over three consecutive days, following the structure: 3 lots x 2 operators per lot x 3 days per operator x 2 runs per day x 2 replicates per run, resulting in 72 total tests per sample level (i.e., 24 replicates per analyte for each lot). Refer to **Table 10** for a summary of results for Study 2.

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Table 10. Precision Study Results (Study 2)

Lot	Negative		Low Positive (0.75xLoD)		Moderate Positive (4xLoD)	
	Reader 1	Reader 2	Reader 1	Reader 2	Reader 1	Reader 2
1	12/12	12/12	8/12	8/12	12/12	12/12
2	12/12	12/12	9/12	9/12	12/12	12/12
3	12/12	12/12	8/12	9/12	12/12	12/12
Total	36/36	36/36	25/36	26/36	36/36	36/36
% Agreement	100%	100%	69.4%	72.2%	100%	100%

Clinical Evaluation:

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 709 evaluable subjects (59.4% female and 40.6% male) were enrolled and each were currently experiencing symptoms associated with COVID-19, within 6 days of symptom onset. 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 sensitivity molecular FDA 510(k) cleared SARS-CoV-2 assay. Results re provided in **Table 11** and **Table 12**.

Table 11. OHC COVID-19 Antigen Self Test Performance Compared to SARS-CoV-2 Molecular Assay

OHC COVID-19 Antigen Self Test	Comparator		Total
	Positive	Negative	
Positive	110	4	114
Negative	19	576	595
Total	129	580	709

Positive Percent Agreement = (110/129) x 100% = **85.3%** (95% CI: 78.1%-90.4%)
Negative Percent Agreement = (576/580) x 100 = **99.3%** (95% CI: 98.2%-99.7%)

Table 12. OHC COVID-19 Antigen Self Test PPA results by Days Post Symptom Onset (DPSO)

Days from COVID-19 Symptom Onset	Number of Subjects Samples Tested	OHC COVID-19 Antigen Self Test Positives	Comparator Positives	PPA
Day 0	20	5	6	83.3%
Day 1	58	4	5	80.0%
Day 2	165	15	22	68.2%
Day 3	173	17	20	85.0%
Day 4	133	18	20	90.0%
Day 5	115	34	37	91.9%
Day 6	45	17	19	89.5%
Total	**709**	**110**	**129**	**85.3%**

Conclusion:
The submitted information in this premarket notification is complete and supports a substantial equivalence decision. Based on the comparison of technological features and intended use, and as a result of the non-clinical and clinical performance testing completed on OSANG's OHC COVID-19 Antigen Self Test, the proposed device does not raise new questions of safety and effectiveness and supports the conclusion that the proposed device is substantially equivalent to the predicate device. OSANG has demonstrated that the proposed device complies with applicable Special Controls for over-the- counter (OTC) test to detect SARS-CoV-2 from clinical specimens therefore OHC COVID-19 Antigen Self Test can be found substantially equivalent to the predicate device.