January 13, 2025

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

Re: K243262

Trade/Device Name:	QuickFinder COVID-19/Flu Antigen Self Test / QuickFinder COVID-19/Flu Antigen Pro Test
Regulation Number:	21 CFR 866.3987
Regulation Name:	Multi-Analyte Respiratory Virus Antigen Detection Test
Regulatory Class:	Class II
Product Code:	SCA
Dated:	October 14, 2024
Received:	October 15, 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: 2025.01.13 19:58:26 -05'00'

Silke Schlottmann
Branch Chief
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)*
K243262

Device Name
QuickFinder COVID-19/Flu Antigen Self Test
QuickFinder COVID-19/Flu Antigen Pro Test

Indications for Use *(Describe)*

QuickFinder COVID-19/Flu Antigen Self Test

The QuickFinder™ COVID-19/Flu Antigen Self 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 protein 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.

QuickFinder COVID-19/Flu Antigen Pro Test

The QuickFinder™ COVID-19/Flu Antigen Pro 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 protein 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 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.

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.

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QuickFinder™ COVID-19/Flu Antigen Self Test

QuickFinder™ COVID-19/Flu Antigen Pro Test

510(k) Summary

In accordance with 21 CFR 807.87(h) and 21 CDR 807.92, the following 510(k) Summary for QuickFinder™ COVID-19/Flu Antigen Self Test / QuickFinder™ COVID-19/Flu Antigen Pro Test is provided:

Submitter Information

Applicant/Submitter:	OSANG Healthcare Co. Ltd. 132, Anyangcheondong-Ro Dongan-Gu Anyang Gyeonggi, Republic of Korea 14040 Phone: 82-31-4600415
Date Prepared:	January 10, 2025
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:	QuickFinder™ COVID-19/Flu Antigen Self Test QuickFinder™ COVID-19/Flu Antigen Pro Test
Common Name:	Multi-analyte respiratory virus antigen detection test
Classification Name	Multi-analyte respiratory virus antigen detection test 21 C.F.R. 866.3987
Product Code:	SCA
Device Class:	Class II

Predicate Device(s)

Predicate Device(s):	Healgen Rapid Check COVID-19/Flu A & B Antigen Test (DEN240029)

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Intended Use/ Indications for Use

QuickFinder™ COVID-19/Flu Antigen Self Test

The QuickFinder™ COVID-19/Flu Antigen Self 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 protein 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.

QuickFinder™ COVID-19/Flu Antigen Pro Test

The QuickFinder™ COVID-19/Flu Antigen Pro 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 protein 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 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.

Device Description

The QuickFinder™ COVID-19/Flu Antigen Self Test / QuickFinder™ COVID-19/Flu Antigen Pro Test is a rapid lateral flow test for the qualitative detection of the SARS-CoV-2, Influenza A and Influenza B using anterior nares nasal swab samples from those who are suspected of COVID-19, Influenza A, and Influenza B. The QuickFinder™ COVID-19/Flu Antigen Self Test / QuickFinder™ COVID-19/Flu Antigen Pro Test is validated for testing direct samples without transport media.

The lateral flow test is for:

- Self-collected anterior nasal (nares) swab specimens from individuals aged 14 years and older with symptoms of COVID-19 within the first 4 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 4 days of symptom onset.

The QuickFinder™ COVID-19/Flu Antigen Self Test / QuickFinder™ COVID-19/Flu Antigen Pro Test is a lateral flow test. The cassette contains membranes which are pre-coated with anti-SARS-CoV-2 nucleocapsid protein monoclonal antibodies, anti-influenza A nucleoprotein monoclonal antibodies and anti-influenza B nucleoprotein monoclonal antibodies on the test lines. Another anti-SARS-CoV-2 nucleocapsid protein monoclonal antibodies, anti-influenza A nucleoprotein monoclonal antibodies and anti-influenza B nucleoprotein monoclonal antibodies are each bound to the beads. When the sample is put into the sample well, the antibodies bound to the beads and the antigen in the sample bind to form complexes and migrate to the membrane. The complexes will be captured by coated antibodies on the membrane, and then the line will form a visible line. The presence of SARS-CoV-2, influenza A and influenza B antigens are indicated by lines visible in the S-marked position, A-marked position, and B-marked position in the results window, respectively. If no colored line appears on the control line (C), it implies that the test has not worked as intended.

Substantial Equivalence

The proposed QuickFinder™ COVID-19/Flu Antigen Self Test / QuickFinder™ COVID-19/Flu Antigen Pro Test have similar indications for use to, and use the same fundamental technology as, the legally marketed predicate device to which substantial equivalence is claimed, the Healgen Rapid Check COVID-19/Flu A & B Antigen Test (DEN240029).

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

Specification	**Proposed Device:** **QuickFinder™ COVID-19/Flu Antigen Self Test / QuickFinder™ COVID-19/Flu Antigen Pro Test**	**Predicate Device:** **Heaglen Rapid Check COVID-19/Flu A & B Antigen Test** **DEN240029**
Intended Use	Over-the-counter test to detect SARS-CoV-2 and Influenza A and B from clinical specimens.	Over-the-counter test to detect SARS-CoV-2 and Influenza A and B from clinical specimens.
Indications for Use	QuickFinder™ COVID-19/Flu Antigen Self Test The QuickFinder™ COVID-19/Flu Antigen Self 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 protein 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	The Healgen Rapid Check COVID-19/Flu 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-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

Specification	Proposed Device: QuickFinder™ COVID-19/Flu Antigen Self Test / QuickFinder™ COVID-19/Flu Antigen Pro Test	Predicate Device: Heaglen Rapid Check COVID-19/Flu A & B Antigen Test DEN240029
	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. QuickFinder™ COVID-19/Flu Antigen Pro Test The QuickFinder™ COVID-19/Flu Antigen Pro 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 protein 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 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	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.

Specification	Proposed Device: QuickFinder™ COVID-19/Flu Antigen Self Test / QuickFinder™ COVID-19/Flu Antigen Pro Test	Predicate Device: Heaglen Rapid Check COVID-19/Flu A & B Antigen Test DEN240029
	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 therefor do not substitute for a visit to a healthcare provider for appropriate follow-up.	
Prescription Use or Over the Counter	Over the counter (OTC)	Over the counter (OTC)
End User	Lay User or professional use	Lay User
Environment of Use	Home or similar environment (e.g., point of care facility)	Home or similar environment
Disease	COVID-19 and Influenza A and B	COVID-19 and Influenza A and B
Intended Use Population	Symptomatic individuals 14 years of age and older testing themselves and adults testing individuals aged 2 years and older within 4 days post symptom onset.	Symptomatic individuals 14 years of age and older testing themselves and adults testing individuals aged 2 years and older within 5 days post symptom onset.
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 Influenza A and B	SARS-CoV-2 Influenza A and B
Format	Test cassette	Test cassette
Controls	Internal control	Internal control
Time to Result	15 minutes	15 minutes
Results	Positive, Negative, or Invalid	Positive, Negative, or Invalid
Interpretation	Visually read	Visually read

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Technological Characteristics

As shown in the **Table 1** above, the proposed device, QuickFinder™ COVID-19/Flu Antigen Self Test / QuickFinder™ COVID-19/Flu Antigen Pro Test, and the predicate device have the same intended use and similar indications for use. The proposed device, QuickFinder™ COVID-19/Flu Antigen Self Test / QuickFinder™ COVID-19/Flu Antigen Pro 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 and the Influenza A and B nucleoprotein from a user collected anterior swab specimen from individuals with signs and symptoms of COVID-19 or Influenza.

Performance Data

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

Limit of Detection:

Single Analyte LoD:

The Limit of Detection (LoD) of the QuickFinder™ COVID-19/Flu Antigen Self Test / QuickFinder™ COVID-19/Flu Antigen Pro Test was determined using serial dilutions of one strain of UV inactivated SARS-CoV-2 (USA-WA1/202) and two live strains of Influenza A and Influenza B. Contrived samples were prepared by spiking the strain into pooled human negative swab matrix (PNSM) obtained from healthy volunteers confirmed negative by RT-PCR. The preliminary LoD initially determined by testing ten-fold serial dilution series of three (3) replicates was confirmed by testing twenty (20) replicates. The confirmed LoD for the QuickFinder™ COVID-19/Flu Antigen Self Test / QuickFinder™ COVID-19/Flu Antigen Pro Test is shown in **Table 2** below.

Table 2. Limit of Detection

Virus Strain	Stock Concentration ($TCID_{50}$/mL)	LoD Concentration ($TCID_{50}$/mL)	$TCID_{50}$/Swab	#Positive/ #Total Tested	Percent Detected (%)
SARS-CoV-2 (USA-WA1/2020)	3.16×10^6	**1.58×10^3**	7.90×10^1	20/20	100%
Influenza A H1N1pdm09: A/Victoria/4897/2022	2.02×10^5	**2.02×10^2**	1.01×10^1	20/20	100%
Influenza A H3N2: A/Darwin/6/2021	4.17×10^5	**2.09×10^2**	1.04×10^1	20/20	100%
Influenza B Victoria: B/Washington/02/2019	3.16×10^5	**3.16×10^3**	1.58×10^2	20/20	100%
Influenza B Yamagata: B/Florida/4/2006	1.17×10^5	**2.93×10^1**	1.46	20/20	100%

Co-spiked LoD:

After the single analyte LoDs were established for the device, co-spiked LoD equivalency testing with all three test analytes present in the sample, was conducted to characterize the

performance with samples that contain more than one analyte at low concentrations. All analytes that were successfully detected by the device when co-spiked at their single analyte LoD, may be co-spiked into positive sample(s) used in the analytical studies.

Based on the individual analyte specific 1x LoDs, co-spiked samples were prepared by mixing all three viruses (one strain of SARS-CoV-2, Flu A and Flu B). The 1x LoD concentration was tested with the device in twenty (20) replicates and considered confirmed (i.e., equivalent to the established single analyte LoD) if ≥19/20 replicates were positive for the concentrations within 2x LoD of the established single analyte LoD.

The QuickFinder™ COVID-19/Flu Antigen Self Test / QuickFinder™ COVID-19/Flu Antigen Pro Test demonstrated co-spike equivalency for all analytes, SARS-CoV-2, Flu A, and Flu B, to their respective established single analyte 1x LoD. The confirmed co-spike LoD is shown in the **Table 3** below.

Table 3. 1x LoD Co-Spike Results

Virus	LoD	LoD Concentration ($TCID_{50}$/mL)	LoD Concentration per Swab ($TCID_{50}$/mL)	# Positive Replicates
SARS-CoV-2 (USA-WA1/2020)	1x LoD	**1.58×10^3**	7.90×10^1	20/20 (100%)
Influenza A H1N1pdm09: A/Victoria/4897/2022	1x LoD	**2.02×10^2**	1.01×10^1	20/20 (100%)
Influenza B Yamagata: B/Florida/4/2006	1x LoD	**2.93×10^1**	1.46	20/20 (100%)

Inclusivity (Analytical Reactivity):
Analytical reactivity for QuickFinder™ COVID-19/Flu Antigen Self Test / QuickFinder™ COVID-19/Flu Antigen Pro Test was demonstrated using a selection of temporal, geographic and genetically diverse Influenza and SARS-CoV-2 strains. Individual virus strains were diluted in pooled negative swab matrix (PNSM) at 10-fold dilution and tested in triplicate. After a 10-fold break point was established testing two-fold dilutions points of the lowest positive 10-fold dilution was completed. The lowest 10-fold or 2-fold dilution that demonstrated three (3) positive replicates was identified. The reactivity of the QuickFinder™ COVID-19/Flu Antigen Self Test / QuickFinder™ COVID-19/Flu Antigen Pro Test with the different virus strains is summarized below in **Table 4** with the lowest concentration that returned 100% positive replicates.

Table 4. Summary of QuickFinder™ COVID-19/Flu Antigen Self Test / QuickFinder™ COVID-19/Flu Antigen Pro Test's reactivity with different virus strains of SARS-CoV-2, Flu A and Flu B.

Virus	Virus Strain	Concentration	Units
SARS-CoV-2	XBB 1.5 (Omicron) Heat Inactivated	4.0×10^2	$TCID_{50}$/mL
Flu A H1N1	A/California/04/2009	2.8×10^3	$TCID_{50}$/mL
	A/Brisbane/02/2018	1.9×10^2	$TCID_{50}$/mL
	A/Michigan/45/2015	1.9×10^1	$TCID_{50}$/mL
	A/Guangdong-Moanan/SWL 1536/19	1.0×10^3	$TCID_{50}$/mL
	A/NY/03/2009	4.6×10^4	$TCID_{50}$/mL
	A/Indiana/02/2020	9.7×10^6	$CEID_{50}$/mL
	A/Wisconsin/588/2019	2.8×10^4	FFU/mL

Virus	Virus Strain	Concentration	Units
	A/Sydney/5/2021	6.0×10^3	$TCID_{50}$/mL
	A/Hawaii/66/2019	7.4×10^7	$CEID_{50}$/mL
	A/Wisconsin/67/2022	4.2×10^2	$TCID_{50}$/mL
Flu A H3N2	A/New York/21/2020	3.3×10^5	FFU/mL
	A/Tasmania/503/2020	1.3×10^5	FFU/mL
	A/Alaska/01/2021	3.8×10^4	FFU/mL
	A/Hong Kong/45/2019	3.8×10^4	FFU/mL
	A/Hong Kong/2671/2019	1.1×10^3	$TCID_{50}$/mL
	A/Indiana/08/2011	8.1×10^2	$TCID_{50}$/mL
Flu A H1N1	A/Ohio/09/2015	1.4×10^6	$CEID_{50}$/mL
Flu A H1N2	A/Minnesota/19/2011	8.0×10^6	$CEID_{50}$/mL
Flu A H5N1	A/mallard/Wisconsin/2576/2009	4.0×10^6	$CEID_{50}$/mL
	A/bovine/Ohio/B24OSU-439/2024	7.8×10^3	$TCID_{50}$/mL
	A/duck/Guangxi/S11002/2024	1.7×10^6	EID_{50}/mL
Flu A H5N6	A/duck/Guangxi/S10888/2024	1.7×10^6	EID_{50}/mL
Flu A H5N8	A/goose/Liaoning/S1266/2024	1.7×10^6	EID_{50}/mL
Flu A H7N3	A/northernpintail/Illinois/10O53959/2010	2.8×10^6	$CEID_{50}$/mL
Flu B Victoria Lineage	B/Brisbane/60/2008	1.6×10^o	$TCID_{50}$/mL
	B/Colorado/06/2017	2.9×10^1	$TCID_{50}$/mL
	B/Texas/02/2013	2.5×10^1	$TCID_{50}$/mL
	B/Michigan/01/2021	1.4×10^4	$TCID_{50}$/mL
Flu B Yamagata Lineage	B/Texas/06/2021	1.5×10^3	$TCID_{50}$/mL
	B/Utah/08/2014	1.3×10^3	$TCID_{50}$/mL
	B/Wisconsin/01/2010	1.8×10^2	$TCID_{50}$/mL
Flu B Non-Victoria, non-Yamagata	B/Maryland/1/1959	3.4×10^3	$CEID_{50}$/mL

NIBSC - WHO Standard Testing

The Sponsor tested the sensitivity of the test with the 1st WHO International Standard for SARS-CoV-2 antigen (NIBSC code: 21/368) spiked into pooled negative swab matrix (PNSM). The unitage of this material has an assigned value of 5,000 International Units of SARS-CoV-2 antigen per ampoule when reconstituted per instructions. A 2-fold dilution series was made to determine the preliminary LoD, which was measured using one device lot and triplicate measurements (n=3). The measurements were done by adding 50 µL of each dilution directly to the test swab and processing the sample per the test's QRI. The preliminary LoD was determined to be 1000 IU/mL (or 50 IU/swab). The LoD confirmatory study was performed using 20 replicates (n=20) per dilution. The lowest concentration at which a minimum of 95% of results were positive was confirmed to be 1000 IU/mL or 50 IU/Swab as shown below.

Table 5: WHO International Standard

Description	Source	NIBSC No.	Concentration (IU/mL)	Concentration IU/swab	# Positive Results
WHO International Standard for SARS-CoV-2	National Institute for Biological Standards and Controls	NIBSC 21/368	1,000 IU/mL	50 IU/swab	20/20

Competitive Interference:

Competitive interference testing (i.e., evaluation of potential for a high concentration of one target virus to interfere with detection of a low concentration of another target virus) for the QuickFinder™ COVID-19/Flu Antigen Self Test / QuickFinder™ COVID-19/Flu Antigen Pro Test was completed. The testing was performed with different combinations of low (3x LoD) and high concentrations of live Influenza A, live Influenza B and UV inactivated SARS-CoV-2 on the QuickFinder™ COVID-19/Flu Antigen Self Test / QuickFinder™ COVID-19/Flu Antigen Pro Test device to determine if the candidate device can detect target analytes across a variety of analyte concentrations. Refer to **Table 6**. No competitive interference/false positive results were observed for analytes not present in the sample.

Table 6. Competitive Interference

Combination	**Viral Target in Sample**			
	Influenza A	**Influenza B**	**SARS-CoV-2**	**Results**
1	High	3x LoD	Negative	No interference
2	High	Negative	3x LoD	No interference
3	High	3x LoD	3x LoD	No interference
4	3x LoD	High	Negative	No interference
5	Negative	High	3x LoD	No interference
6	3x LoD	High	3x LoD	No interference
7	3x LoD	Negative	High	No interference
8	Negative	3x LoD	High	No interference
9	3x LoD	3x LoD	High	No interference

Cross Reactivity/Microbial Interference:

The cross-reactivity and potential microbial interference were evaluated by testing various microorganisms, viruses, and negative matrix with the QuickFinder™ COVID-19/Flu Antigen Self Test /QuickFinder™ COVID-19/Flu Antigen Pro Test to determine if other respiratory pathogens/flora that could be present in the direct nasal swab samples could cause a false positive test result or interference with a true positive result. Each organism and virus were tested in three (3) replicates in the absence (cross reactivity) and presence (microbial interference) of heat-inactivated SARS-CoV-2, live Influenza A, and live Influenza B (3x co-spike equivalency LoD). No cross reactivity was observed for any of the organisms tested. No microbial interference was observed for any of the organisms tested. Refer to **Table 7** below for a summary of results.

Table 7. Cross-reactivity/Microbial Interference Study Results

Microorganism	**Concentration**	**Units**	**Cross-Reactivity**	**Microbial Interference**
Human coronavirus 229E	1.58×10^5	$TCID_{50}$/mL	No	No
Human coronavirus OC43	7.00×10^5	$TCID_{50}$/mL	No	No
Human coronavirus NL63	7.05×10^4	$TCID_{50}$/mL	No	No
Human coronavirus HKU1	1.74×10^7	GE/mL	No	No
MERS-coronavirus	1.47×10^5	$TCID_{50}$/mL	No	No

SARS-coronavirus	1.25 x 10^5	PFU/mL	No	No
Adenovirus type 1	2.23 x 10^5	$TCID_{50}$/mL	No	No
Adenovirus type 7	1.58 x 10^5	$TCID_{50}$/mL	No	No
hMPV 27 Type B2	3.50 x 10^5	$TCID_{50}$/mL	No	No
Parainfluenza virus 1	2.00 x 10^5	$TCID_{50}$/mL	No	No
Parainfluenza virus 2	1.75 x 10^5	$TCID_{50}$/mL	No	No
Parainfluenza virus 3	7.00 x 10^5	$TCID_{50}$/mL	No	No
Parainfluenza virus 4b	2.39 x 10^5	$TCID_{50}$/mL	No	No
Enterovirus type 68	2.23 x 10^5	$TCID_{50}$/mL	No	No
Respiratory syncytial virus A	3.50 x 10^5	$TCID_{50}$/mL	No	No
Respiratory syncytial virus B	2.29 x 10^5	$TCID_{50}$/mL	No	No
Rhinovirus	7.05 x 10^4	$TCID_{50}$/mL	No	No
Haemophilus influenzae type b	9.68 x 10^6	CFU/mL	No	No
Streptococcus pneumoniae	1.81 x 10^7	CFU/mL	No	No
Streptococcus pyogenes	7.50 x 10^7	CFU/mL	No	No
Candida albicans	1.21 x 10^7	CFU/mL	No	No
Mycoplasma pneumoniae	2.50 x 10^7	CFU/mL	No	No
Chlamydia pneumoniae	4.33 x 10^6	IFU/mL	No	No
Legionella pneumophila	6.50 x 10^6	CFU/mL	No	No
Staphylococcus aureus	2.60 x 10^8	CFU/mL	No	No
Staphylococcus epidermidis	9.00 x 10^7	CFU/mL	No	No
Mycobacterium tuberculosis	3.03 x 10^6	CFU/mL	No	No
P. jiroveci – S. cerevisiae	1.30 x 10^7	CFU/mL	No	No
Corynebacterium xerosis	2.30 x 10^7	CFU/mL	No	No
Escherichia coli	1.79 x 10^8	CFU/mL	No	No
Lactobacillus acidophilus	1.21 x 10^7	CFU/mL	No	No
Moraxella catarrhalis	2.50 x 10^8	CFU/mL	No	No
Neisseria meningitidis	3.43 x 10^6	CFU/mL	No	No
Neisseria elongate	2.68 x 10^8	CFU/mL	No	No
Psuedomonas aeruginosa	3.45 x 10^8	CFU/mL	No	No
Streptococcus salivarius	1.01 x 10^6	CFU/mL	No	No
Measles	8.48 x 10^5	$TCID_{50}$/mL	No	No
Mumps	8.48 x 10^5	$TCID_{50}$/mL	No	No
Epstein Barr virus	1.83 x 10^6	CP/mL	No	No
Cytomegalovirus	7.05 x 10^4	$TCID_{50}$/mL	No	No
Bordetella pertussis	2.90 x 10^8	CFU/mL	No	No
Pooled Negative Nasal Wash	N/A	N/A	No	No

Exogenous and Endogenous Interfering Substances Study:

Thirty-two (32) potentially interfering substances were evaluated with the QuickFinder™ COVID-19/Flu Antigen Self Test / QuickFinder™ COVID-19/Flu Antigen Pro Test to verify if endogenous and exogenous substances that may be present in respiratory specimens interfere with the detection of SARS-CoV-2, Influenza A and Influenza B in the QuickFinder™ COVID-19/Flu Antigen Self Test / QuickFinder™ COVID-19/Flu Antigen Pro Test. Each substance was tested in three (3) replicates in the presence and absence of SARS-CoV-2, Influenza A, and Influenza B.

The positive (3x LoD co-spike pooled nasal wash (PNW) with UV inactivated SARS-CoV-2, and live influenza A and live influenza B) and negative specimens (un-spiked) were tested with the addition of the potentially interfering substances.

The performance of the QuickFinder™ COVID-19/Flu Antigen Self Test / QuickFinder™

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COVID-19/Flu Antigen Pro Test was not affected by any of the potentially interfering substances listed in the table below at the concentration noted. With the exception of the FluMist Quadrivalent Live intranasal influenza virus vaccine, none of the substances cased a false-positive test result in un-spiked samples. While the presence of FluMist Quadrivalent Live intranasal influenza virus vaccine at 15% v/v concentration did not interfere with the detection of true positive results of the 3x LoD co-spiked samples, the vaccine also resulted in positive results for Flu A and Flu B (as expected based on the composition of the vaccine). Hand soap liquid gel at 10% w/v showed false negative results for Flu B, but detected all analytes at 0.05% w/v. Refer to **Table 8** for the interfering substances evaluated.

Table 8. Interfering Substances Study Results

Interfering Substance	**Concentration**	**Cross-Reactivity (no analyte) (#pos/ #total)**			**Interference (3x co-spiked analyte LoD) (#pos/ #total)**		
		SARS-CoV-2	**Flu A**	**Flu B**	**SARS-CoV-2**	**Flu A**	**Flu B**
Human Whole Blood (EDTA tube)	4% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Leukocytes	2.85 x 10^6 cells/mL	0/3	0/3	0/3	3/3	3/3	3/3
Throat lozenges (Menthol/Benzocaine)	3.0 mg/mL	0/3	0/3	0/3	3/3	3/3	3/3
Mucin (bovine submaxillary glands Type I-S)	2.5 mg/mL	0/3	0/3	0/3	3/3	3/3	3/3
Naso GEL (NeilMed)	5% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Nasal gel (Zicam (Galphimia glauca, Histanium hydrocloricum, Luffa operculate, Sulfur))	1.25% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Nasal Drops (Phenylephrine)	15% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Nasal Spray (Oxymetazoline)	15% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Nasal Spray (Cromolyn)	15% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Nasal spray (Saline)	15% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Zicam Nasal spray (Galphimia glauca, luffa operculate)	15% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Nasal spray (Alkalol)	15% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Homeopathic allergy relief	15% v/v	0/3	0/3	0/3	3/3	3/3	3/3

Interfering Substance	Concentration	Cross-Reactivity (no analyte) (#pos/ #total)			Interference (3x co-spiked analyte LoD) (#pos/ #total)		
		SARS-CoV-2	Flu A	Flu B	SARS-CoV-2	Flu A	Flu B
(Histaminum hydrochloricum)							
TheraZinc Throat Spray (Zinc)	15% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Sore Throat Spray (Phenol)	15% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Antibiotic (Tobramycin)	4 µg/mL	0/3	0/3	0/3	3/3	3/3	3/3
Antibiotic, nasal ointment (Mupirocin)	10 mg/mL	0/3	0/3	0/3	3/3	3/3	3/3
Nasal corticosteroid (Fluticasone)	15% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Nasal corticosteroid (Triamcinolone)	15% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Nasal corticosteroid (Dexamethasone)	1mg/mL	0/3	0/3	0/3	3/3	3/3	3/3
Tamiflu (Oseltamivir Phosphate)	5 mg/mL	0/3	0/3	0/3	3/3	3/3	3/3
FluMist/FluMist Quadrivalent Live intranasal influenza virus vaccine	15% v/v	0/3	3/3	3/3	3/3	3/3	3/3
	1.5% v/v	0/3	0/3	0/3	NA	NA	NA
Zanamivir	282 ng/mL	0/3	0/3	0/3	3/3	3/3	3/3
Remdesivir	10 mg/mL	0/3	0/3	0/3	3/3	3/3	3/3
Biotin	3,500 ng/mL	0/3	0/3	0/3	3/3	3/3	3/3
Body and Hand Lotion	0.5% w/v	0/3	0/3	0/3	3/3	3/3	3/3
Body Lotion with 1.2% dimethicone	0.5% w/v	0/3	0/3	0/3	3/3	3/3	3/3
Hand Lotion	5% w/v	0/3	0/3	0/3	3/3	3/3	3/3
Hand Sanitizer with Aloe, 62% ethyl alcohol	5% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Hand Sanitizer with cream lotion	15% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Hand Sanitizer, 80% ethanol, fast drying	15% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Hand soap liquid gel	10% w/v	0/3	0/3	0/3	3/3	3/3	0/3
	0.05% w/v	NA	NA	NA	3/3	3/3	3/3

Hook Effect:

To ensure that a high concentration of SARS-CoV-2, Influenza A and Influenza B antigens do not interfere with a positive reaction in the QuickFinder™ COVID-19/Flu Antigen Self Test / QuickFinder™ COVID-19/Flu Antigen Pro Test, a hook effect study was conducted. No high dose hook effect was observed with the QuickFinder™ COVID-19/Flu Antigen Self Test / QuickFinder™ COVID-19/Flu Antigen Pro Test when high concentrations of SARS-CoV-2, Influenza A and Influenza B were tested as noted in **Table 9** below.

Table 9. High Dose Hook Effect

Analyte	**Strain**	**Lineage**	**Concentration ($TCID_{50}$/mL)**	**Concentration ($TCID_{50}$/swab)**
SARS-CoV-2	USA-WA1/2020	SARS-CoV-2	3.16×10^6	1.58×10^5
Influenza A (H1N1)	A/Victoria/4897/2022	H1N1 pdm09	2.02×10^5	1.01×10^4
Influenza A (H3N2)	A/Darwin/6/2021	H3N2	4.17×10^5	2.09×10^4
Influenza B (Victoria)	B/Washington/02/2019	Victoria	3.16×10^6	1.58×10^5
Influenza B (Yamagata)	B/Florida/04/2006	Yamagata	1.17×10^5	5.85×10^3

Stability:

Real Time Stability:
Three lots of the QuickFinder™ COVID-19/Flu Antigen Self Test / QuickFinder™ COVID-19/Flu Antigen Pro Test were subjected to room temperature (30°C) at 45% relative humidity (RH), room temperature at 95% RH, and 2°C at ambient humidity. The test panel comprised of negative clinical matrix, 1x LoD and 4x LoD of SARS-CoV-2, Flu A and Flu B viruses. Testing was performed at time 0 (baseline) and month 1, 2, 3, 4, 5, 6, 10, 12, 13, 18 and 19. All study data are 100% concordant with expected results and support shelf life of up to 18 months. The shelf life will be updated as additional passing timepoints become available.

Open Kit Stability:
In this study, the amount of time a test device can be left outside of its packaging was assessed using a test panel comprised of five (5) negative samples (PNW) and five (5) co-spiked low positive samples (2x single analyte LoD of SARS-CoV-2, Flu A, and Flu B co-spiked together into PNW). PNW was demonstrated to be equivalent to negative nasal swab matrix in a matrix equivalency study. Device packaging was opened, and testing was performed at zero (0) hours to establish a baseline. Thereafter the devices were stores for one (1) hour and two (2) hours at room temperature. All study data before and after storage of the open kits were 100% concordant with expected results.

Transport Stability:
Simulated winter and summer transport temperature conditions were used to evaluate the worst-case shipping and handling of components of the QuickFinder™ COVID-19/Flu Antigen Self Test / QuickFinder™ COVID-19/Flu Antigen Pro Test over an extended period of time. The functional performance of the device is assessed by comparing the pre- (T0) and post-distribution (Td) result

of a test panel comprised of pooled negative nasal wash (PNW) samples and co-spiked low positive samples (3x single analyte LoD with SARS-CoV-2, Flu A, and Flu B, together in contrived PNW). All results were as expected for all timepoints.

Flex Studies:
To assess the robustness and risk of false results of the test when deviating from the IFU/QRI test steps, a series of flex studies were performed by testing QuickFinder™ COVID-19/Flu Antigen Self Test / QuickFinder™ COVID-19/Flu Antigen Pro Test that assessed all major aspects of the test procedure (sample volume, reading time, swab extraction time and procedure (delay in mixing and addition of sample), sample hold time before and during processing) and variability of environmental test conditions when in use (lighting, disturbance during use, temperature and humidity stress conditions). Testing was performed with negative pooled nasal wash (PNW) samples and low positive samples co-spiked with SARS-CoV-2, Flu A, and Flu B virus into negative PNW at 2x LoD. The various conditions as shown in **Table 10.**

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 and false results can be expected to be reasonably mitigated through labeling.

Table 10. 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	Sample stability
Result reading time	Winter/Summer Transport Conditions

Precision Studies:
The lot-to-lot precision of the QuickFinder™ COVID-19/Flu Antigen Self Test/ QuickFinder™ COVID-19/Flu Antigen Pro Test was evaluated by using three (3) production lots.

For Study 1, a series of contrived samples were prepared as negative, low positive SARS-CoV-2 (2x LoD), low positive of Influenza A (2x LoD), low positive of Influenza B (2x LoD), SARS-CoV-2 and Influenza A (2x co-spike LoD), SARS-CoV-2 and Influenza B (2x co-spike LoD), Influenza A and B (2x co-spike LoD) and SARS-CoV-2, Influenza A and Influenza B (2x co-spike LoD) using UV inactivated SARS-CoV-2, live influenza A and live influenza B isolates. Each blinded and randomized sample was tested on each device lot (total 3 lots) for each operator (two (2) operators) in two (2) runs per day over ten (10) days. The precision testing demonstrated there was no difference in results lot-to-lot and between operators. Refer to **Table 11** for a summary of results of Study 1.

Study 2 was specifically conducted to further evaluate potential differences between lots. The study used negative samples (without the virus analyte) and very low positive samples at 0.75x LoD, commonly referred to as a high negative sample. Samples were prepared near the C95 concentration for all three analytes and were randomized and blinded. This supplemental precision testing was carried out over 3 days only, but otherwise followed the same study design as above. This resulted in 72 total tests per analyte and sample level (24 replicates for each analyte with each lot). Data from this testing are integrated into **Table 11** below. The random errors of the testing procedure across different days and runs, paired with an operator's

ability to read the line intensity for samples with very low analyte concentration (commonly referred to as 'high negative samples') is expected to confound lot-specific variability and to have a significant impact on the precision estimates for high negative samples such as the 0.75x LoD sample tested in this second part of the precision assessment. Taken together, the results of both precision assessments demonstrate a test precision and a lot-to-lot precision that are consistent with the expectations for the analyte concentration in the samples, the test's technology, and the test's LoD. The between-lot variability does not impact low concentrated samples equal to or above 2 x LoD of the test.

Table 11. Summary Results for Lot-to-Lot Precision Study (Operators Combined)

Sample	N	Lot 1		Lot 2		Lot 3		Total % Agreement	95% CI
		Count*	% Agreement	Count*	% Agreement	Count*	% Agreement		
Negative	240	80/80	100%	80/80	100%	80/80	100%	100%	96.9-100%
Negative	72	24/24	100%	24/24	100%	24/24	100%	100%	94.39-100%
0.75x LoD SARS-CoV-2 & Flu B	72**	18/24	75%	14/24	58.3%	17/24	70.8%	68.1%	56.6-77.7%
	72***	19/24	79.2%	13/24	54.2%	18/24	752%	69.4%	58.0-78.9%
0.75x LoD Flu A	72	15/24	62.5%	23/24	95.8%	17/24	70.8%	76.4%	65.4-84.7%
2x LoD SARS-CoV-2	240	80/80	100%	80/80	100%	80/80	100%	100%	96.9-100%
2x LoD Flu A	240	80/80	100%	80/80	100%	80/80	100%	100%	96.9-100%
2x LoD Flu B	240	80/80	100%	80/80	100%	80/80	100%	100%	96.9-100%
2x LoD SARS-CoV-2 & Flu A	240	80/80	100%	80/80	100%	80/80	100%	100%	96.9-100%
2x LoD SARS-CoV-2 & Flu B	240	80/80	100%	80/80	100%	80/80	100%	100%	96.9-100%
2x LoD Flu A & Flu B	240	80/80	100%	80/80	100%	80/80	100%	100%	96.9-100%
2x LoD SARS-CoV-2 & Flu A & Flu B	240	80/80	100%	80/80	100%	80/80	100%	100%	96.9-100%

*The total number of replicates included in this table is different for the different sample concentrations due to the study being performed in two parts. Please refer the study description above for additional details.
**SARS-CoV-2 Result
***Influenza B Result

Clinical Evaluation:

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A performance of the QuickFinder™ COVID-19/Flu Antigen Self Test / QuickFinder™ COVID-19/Flu Antigen Pro Test was compared to a SARS-CoV-2 molecular assay and an Influenza A and B molecular study in a prospective clinical study completed at six (6) sites in the United States from October 2023 to June 2024. Samples were collected by lay users from themselves or collected for a household member. A total of 788 evaluable subjects (58.6% female and 41.4% male) were enrolled and each were currently experiencing symptoms associated with COVID-19 or Influenza, within 4 days of symptom onset. The QuickFinder™ COVID-19/Flu Antigen Self Test / QuickFinder™ COVID-19/Flu Antigen Pro Test detected SARS-CoV-2 with a Positive Percent Agreement (PPA) of 90.6% and a Negative Percent Agreement (NPA) of 99.4% in symptomatic individuals as compared to a highly sensitive molecular FDA 510(k) cleared SARS-CoV-2 assay. The QuickFinder™ COVID-19/Flu Antigen Self Test / QuickFinder™ COVID-19/Flu Antigen Pro Test detected Influenza A with a Positive Percent Agreement (PPA) of 89.7% and a Negative Percent Agreement (NPA) of 98.8% as compared to a highly sensitive molecular FDA 510(k) cleared Influenza A assay. The QuickFinder™ COVID-19/Flu Antigen Self Test / QuickFinder™ COVID-19/Flu Antigen Pro Test detected Influenza B with a Positive Percent Agreement (PPA) 86.0% and a Negative Percent Agreement (NPA) of 99.7% in symptomatic individuals as compared to a highly sensitive molecular FDA 510(k) cleared Influenza B assay. Results are provided in **Tables 13** - **16** below. The subject demographics are provided in **Table 12** below.

Table 12. Subject Demographics

	Subjects (by lay-user collection and testing) (N=111)	**Self-collecting and testing (N=677)**	**Overall (N=788)**
Mean (SD)	11.1 (12.1)	38.4 (16.3)	34.4 (18.4)
Median [Min, Max]	9 [2, 74]	36 [14, 80]	32 [2, 80]
Age Group			
≥2-<14 years of age	104 (93.7%)	0 (0.0%)	104 (13.2%)
14-24 years of age	2 (1.8%)	176 (26.0%)	178 (22.6%)
>24-64 years of age	1 (0.9%)	445 (65.7%)	446 (56.6%)
≥65 years of age	4 (3.6%)	56 (8.3%)	60 (7.6%)
Sex at Birth			
Female	48 (43.2%)	414 (61.2%)	462 (58.6%)
Male	63 (56.8%)	263 (38.8%)	326 (41.4%)
Ethnicity			
Hispanic/Latino	5 (4.5%)	109 (16.1%)	114 (14.5%)
Not Hispanic/Latino	106 (95.5%)	568 (83.9%)	674 (85.5%)
Race			
American Indian or Alaskan Native	0 (0.0%)	0 (0.0%)	0 (0.0%)
Asian	0 (0.0%)	11 (1.6%)	11 (1.4%)
Black or African American	4 (3.6%)	54 (8.0%)	58 (7.4%)
Native Hawaiian/Pacific Islander	0 (0.0%)	5 (0.7%)	5 (0.6%)

	Subjects (by lay-user collection and testing) (N=111)	Self-collecting and testing (N=677)	Overall (N=788)
White	100 (90.1%)	596 (88.0%)	696 (88.3%)
Unknown/Prefer not to answer	0 (0.0%)	2 (0.3%)	2 (0.3%)
Other (Mixed race/biracial)	7 (6.3%)	9 (1.3%)	16 (2.0%)

Table 13. QuickFinder™ COVID-19/Flu Antigen Self Test /QuickFinder™ COVID-19/Flu Antigen Pro Test Performance Compared to SARS-CoV-2 Molecular Assay

QuickFinder™ COVID-19/Flu Antigen Self Test/ Pro Test	**Comparator**		**Total**
	Positive	**Negative**	
Positive	116	4	120
Negative	12	656	668
Total	**128**	**660**	**788**

Positive Percent Agreement = (116/128) x 100% = **90.6%** (95% CI: 84.3%-94.6%)
Negative Percent Agreement = (656/660) x 100% = **99.4%** (95% CI: 98.5%-99.8%)

Table 14. QuickFinder™ COVID-19/Flu Antigen Self Test / QuickFinder™ COVID-19/Flu Antigen Pro Test Cumulative PPA results by Days Post Symptom Onset (DPSO) for SARS-CoV-2.

Days Post Symptom Onset	**Number of Subjects Samples Tested**	**QuickFinder™ COVID-19/Flu Antigen Self Test/ Pro Test Positives***	**Comparator Positives**	**PPA**
Day 0	19	0	0	N/A
Day 1	180	27	31	87.1%
Day 2	274	39	45	86.7%
Day 3	185	32	33	97.0%
Day 4	130	18	19	94.7%
Total	788	116	128	90.6%

**NOTE: Four false positives yielded a false positive result on the QuickFinder™ COVID-19/Flu Antigen Self Test/ QuickFinder™ COVID-19/Flu Antigen Pro Test and were excluded from the analysis above.*

Table 15. QuickFinder™ COVID-19/Flu Antigen Self Test /QuickFinder™ COVID-19/Flu Antigen Pro Test Performance Compared to Influenza A Molecular Assay

QuickFinder™ COVID-19/Flu Antigen Self Test/Pro Test	**Comparator**		**Total**
	Positive	**Negative**	
Positive	52	9	61

Negative	6	721	727
Total	**58**	**730**	**788**

Positive Percent Agreement = (52/58) x 100% = **89.7%** (95% CI: 79.2%-95.2%)
Negative Percent Agreement = (721/730) x 100% = **98.8%** (95% CI: 97.7%-99.4%)

Table 16. QuickFinder™ COVID-19/Flu Antigen Self Test / QuickFinder™ COVID-19/Flu Antigen Pro Test Performance Compared to Influenza B Molecular Assay

QuickFinder™ COVID-19/Flu Antigen Self Test/ Pro Test	**Comparator**		**Total**
	Positive	**Negative**	
Positive	37	2	39
Negative	6	743	749
Total	**43**	**745**	**788**

Positive Percent Agreement = (37/43) x 100% = **86.0%** (95% CI: 72.7%-93.4%)
Negative Percent Agreement = (743/745) x 100% = **99.7%** (95% CI: 99.0%-99.9%)

Clinical Sensitivity:
Refer to Clinical Evaluation section (above) for the clinical validation. The PPA for the test for each analyte is as follows:
SARS-CoV-2: 90.6% (95% CI: 84.3%-94.6%)
Flu A: 89.7% (95% CI: 79.2%-95.2%)
Flu B: 86.0% (95% CI: 72.7%-93.4%)

Clinical Specificity:
Refer to the Clinical Evaluation section (above) for the clinical validation. The NPA for the test for each analyte is as follows:
SARS-CoV-2 99.4% (95% CI: 98.5%-99.8%)
Flu A 98.8% (95% CI: 97.7%-99.4%)
Flu B 99.7% (95% CI: 99.0%-99.9%)

Usability Assessment:
A usability study was conducted to evaluate the usability of the QuickFinder™ COVID-19/Flu Antigen Self Test / QuickFinder™ COVID-19/Flu Antigen Pro Test and to evaluate the labeling and comprehension of the QRI when performed by lay users in a simulated home environment. The study was conducted as part of the clinical study from October 2023 to November 2023. Fifty subjects (including subjects that self-collected and subjects collecting a sample and performing the testing on another subject (child or adult), participated in the human factors assessment where the study personnel or a healthcare provider evaluated the subject/tester's ability to correctly prepare the test components for testing, collect a sample, perform the test, and interpret the test results. All subjects participating in the human factors assessment also completed a labeling and comprehension questionnaire and were provided with a mock panel with different test results for interpretation. The demographics of the usability study are shown below in **Table 17**.

Table 17. Demographics of Usability Study Population

	Lay-user (Tester collection and testing) (N=25)	Self-collecting and testing (N=25)	Overall (N=50)
Mean (SD)	19.5 (23.1)	35.2 (14.9)	27.4 (20.8)
Median [Min, Max]	10 [2, 74]	33 [19, 65]	21 [2, 74]
Age Group			
≥2-<14 years of age	20 (80%)	0 (0%)	20 (40%)
14-24 years of age	0 (0%)	9 (36%)	9 (18%)
>24-64 years of age	1 (4%)	15 (60%)	16 (32%)
≥65 years of age	4 (16%)	1 (4%)	5 (10%)
Sex at Birth			
Female	11 (44%)	17 (68%)	28 (56%)
Male	14 (56%)	8 (32%)	22 (44%)

The human factors assessment portion of the study was competed per the protocol. Fifty (50) subjects (25 self-collecting and 25 lay-users collecting and testing from another) were enrolled in the human factors assessment. Evaluation of the human user experience indicated high usability of the QuickFinder™ COVID-19/Flu Antigen Self Test/ QuickFinder™ COVID-19/Flu Antigen Pro Test. 94% of the subjects who participated found the instructions to be clear and easy to follow with 100% of the subjects finding the sample collection instructions easy to follow. 98% of the subjects found sample collection easy to perform, as well as having no difficulty reading the test results. Overall, 92.5% of all critical tasks associated with sample collection and running the QuickFinder™ COVID-19/Flu Antigen Self Test / QuickFinder™ COVID-19/Flu Antigen Pro Test were performed correctly. Additionally, 88% of all non-critical tasks were performed correctly. The human factors assessment met the targets for percentage of critical and non-critical tasks performed correctly as shown in the **Table 18** below.

Table 18. Critical vs Non-Critical Tasks Correctly Performed

Steps	Tasks performed correctly	Total number of tasks	Percentage of tasks
Critical	370	400	92.5%
Non-Critical	176	200	88.0%
Total	546	600	91.0%

Lay User Readability Assessment:
All fifty (50) subjects who participated in the human factors assessment (Usability Assessment) also interpreted a panel of mock devices with various results that reflected the test concentrations at 1.9x and 5x the limits of detection (LoD) in a blinded and random fashion. Each panel of mock tests included 16 tests with various negative and positive results for each analyte. The percentage of human factors subjects with vision impairment is 14% (7/50). The vision impairments encountered in the study subjects are listed in the **Table 19** with their

respective frequency of occurrence.

Table 19. Vision Impairment of Readability Study Subjects

Type of Vision Impairment	# of Study Subjects	Percentage of total human factors subjects with vision impairment (N=50)
Near sightedness only (with lens prescription)	1	2%
Far sightedness only (with lens prescription)	3	6%
Astigmatism	2	4%
Glaucoma	1	2%
Total Subjects with Vision Impairment	7	14%

The comparison of the result interpretation data between lay users with and without visual impairment is included in **Table 20** below.

Table 20. Lay User Readability Study Results

Mock Results Type	Accuracy of Mock Test Interpretations [%]	
	Subjects without vision impairment (N=43)	Subjects with vision impairment (N=7)
1.9x - Flu A+ & Flu B+	100.0%	85.7%
1.9x - COV-19+/Flu A+	81.4%	100.0%
1.9x - COV-19+/Flu A+ & Flu B+	100.0%	100.0%
1.9x - COV-19+/Flu B+	81.4%	100.0%
1.9x - COV+	100.0%	100.0%
1.9x - Flu A+	93.0%	100.0%
1.9x - Flu B+	93.0%	100.0%*
5x - Flu A+ & Flu B+	97.7%	100.0%
5x - COV-19+/Flu A+	86.0%	100.0%
5x - COV-19+/Flu A+ & Flu B+	100.0%	100.0%*
5x - COV-19+/Flu B+	88.4%	85.7%
5x - COV+	95.3%	100.0%
5x - Flu A+	93.0%	100.0%
5x - Flu B+	93.0%	85.7%
Invalid	93.0%	100.0%
Negative	93.0%	100.0%
Total	93.0%	95.5%

*Subject OSC02-007 interpretation for these samples was removed from the analysis (N=6).

The overall accuracy of the results interpreted by the lay users **93.6%** (747/798): 95% CI (91.7-95.1%).

Variant Monitoring Plan:
To determine whether the QuickFinder™ COVID-19/Flu Antigen Self Test / QuickFinder™

COVID-19/Flu Antigen Pro Test can detect newly emerging variants, and/or to assess whether new mutations care impacting analytical sensitivity of the test performance, the Sponsor provided a variant monitoring plan in accordance with the Special Controls established for the device.

Risk Analysis:
A comprehensive risk analysis of the QuickFinder™ COVID-19/Flu Antigen Self Test / QuickFinder™ COVID-19/Flu Antigen Pro Test included identification of potential hazards, likelihood of occurrence, severity of potential harm, hazard control measure(s), hazard control verification, and assignment of pre- and post-control risk levels. The elements considered included operator errors (i.e., human factors), sample and device handling and storage, and environmental factors. Potential sources of error that could adversely affect system performance were identified and mitigated through labeling. The identified risks which could result in erroneous test results were evaluated in Flex Studies that evaluated the functionality of fail-safe mechanisms and stressed the functional limits of the device.

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 QuickFinder™ COVID-19/Flu Antigen Self Test / QuickFinder™ COVID-19/Flu Antigen Pro 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. The results of non-clinical and clinical testing demonstrate the device is as safe, as effective and performs as well as or better than 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 and Influenza A and B from clinical specimens therefore the QuickFinder™ COVID-19/Flu Antigen Self Test / QuickFinder™ COVID-19/Flu Antigen Pro Test can be found substantially equivalent to the predicate device.