



**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY**

I. Background Information:

A 510(k) Number

K243262

B Applicant

Osang LLC

C Proprietary and Established Names

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

D Regulatory Information

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

II. Submission/Device Overview:

A Purpose for Submission:

To obtain 510(k) clearance for the QuickFinder COVID-19/Flu Antigen Self Test / QuickFinder COVID-19/Flu Antigen Pro Test.

B Measurand:

Influenza type A and type B nucleoprotein and SARS-CoV-2 nucleocapsid antigens.

C Type of Test:

Qualitative Lateral flow Immunoassay

III. Intended Use/Indications for Use:

A Intended Use(s):

Same as Indications for Use below.

B Indication(s) for Use:

QuickFinder COVID-19/Flu Antigen Self Test:

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 antigen directly in anterior nasal swab samples from individuals with signs and symptoms of respiratory tract infection. Symptoms of respiratory infections due to SARS-CoV-2 and influenza can be similar. This test is for non-prescription home use by individuals aged 14 years or older testing themselves, or adults testing individuals aged 2 years or older.

All negative results are presumptive and should be confirmed with an FDA-cleared molecular assay when determined to be appropriate by a healthcare provider. Negative results do not rule out infection with influenza, SARS-CoV-2 or other pathogens. Individuals who test negative and experience continued or worsening respiratory symptoms, such as fever, cough and/or shortness of breath, should seek follow-up care from their healthcare provider.

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

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.

C Special Conditions for Use Statement(s):

OTC - Over The Counter

D Special Instrument Requirements:

Not applicable.

E Device/System Characteristics:

1. Device Description:

The QuickFinder COVID-19/Flu Antigen Self Test / QuickFinder COVID-19/Flu Antigen Pro Test (in the remainder of the document referred to as QuickFinder COVID-19/Flu Antigen Test) is an immunochromatographic assay that uses monoclonal antibodies to detect nucleoprotein antigens from SARS-CoV-2, influenza virus types A and B in anterior nasal swab (ANS) samples from symptomatic individuals. The test device is composed of a plastic housing, known as a cassette, that contains a test strip with the following parts: sample pad, conjugate pad, nitrocellulose membrane, and absorbent pad.

The test cassette contains a conjugate pad with anti-SARS-CoV-2 nucleocapsid protein monoclonal antibodies, anti-influenza A nucleoprotein monoclonal antibodies, and anti-influenza B nucleoprotein monoclonal antibodies bound to beads, and a nitrocellulose membrane that is pre-coated with 4 lines, three (3) test lines each containing monoclonal antibodies for one of the specific viral nucleoproteins for SARS-CoV-2, influenza A, and influenza B, and one (1) control line to verify that the test reagents are functional and the test was correctly performed.

The QuickFinder COVID-19/Flu Antigen Test is validated for testing direct samples without transport media. The QuickFinder COVID-19/Flu Antigen Test does not use biotin-Streptavidin/avidin chemistry for any of the steps.

2. Principle of Operation:

To perform the test, an ANS specimen is collected from the patient and eluted into extraction reagent in the pre-filled vial, disrupting the virus particles and exposing internal viral nucleoproteins. After disruption, the swab is removed from the vial, and the extracted sample solution is transferred to the test cassette to allow the extracted specimen to flow onto the sample pad and migrate up the membrane of the test strip.

When the sample is applied to the sample well, the conjugate antibodies will bind any antigens in the sample to form complexes and migrate to the nitrocellulose membrane. The complexes will then be captured by coated antibodies on the membrane, and the test lines 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-line position, A-line position, and B-line positions in the results window, respectively. For a valid test, the control C-line position must be visible on the test.

3. Interpretation of Results:

The qualitative results of the QuickFinder COVID-19/Flu Antigen Test are visually interpreted by the user. Examples of the positive, negative, and invalid results interpretations are provided within the “Interpretation of Results” section of the QRI.

Results interpretation is described in the figure below.

Invalid (No Result)

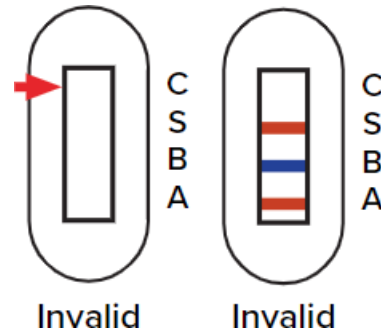
If a control line is not visible at “C” after 15 minutes, even if any other line is visible in the results window, THE TEST HAS FAILED and is considered invalid.

DO NOT CONTINUE reading the results.
Repeat the test with a new sample and new test kit materials.

STOP: If the test is invalid, repeat the test procedure using a new test kit and sample.

NOTE: The images are examples only; additional invalid outcomes are possible.

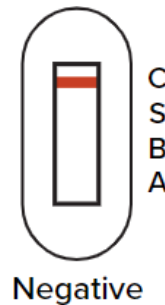
Complete set of invalid results can be found at <http://www.osangllc.com/covid-19-flu-combo-self-testing>



Negative Result

If the control line at 'C' is visible and you do not see a line at 'S', 'B', or 'A', the test is negative. It means you may not have COVID-19, Flu B or Flu A virus.

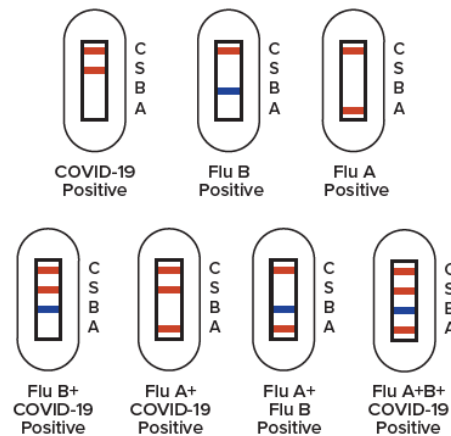
If you still have COVID-19, Flu B or Flu A symptoms, you should seek follow-up care with your healthcare provider.



Positive Result

If the control line at C is visible, and any other line or multiple lines on S, B and/or A appear, the test is positive.

This virus next to the positive line was detected in your sample.



IV. Substantial Equivalence Information:

A Predicate Device Name(s):

Healgen Rapid Check COVID-19/Flu A&B Antigen Test

B Predicate 510(k) Number(s):

DEN240029

C Comparison with Predicate(s):

Device & Predicate Device(s):	<u>K243262</u>	<u>DEN240029</u>
Device Trade Name	QuickFinder COVID-19/Flu Antigen Self Test / QuickFinder COVID-19/Flu Antigen Pro Test	Healgen Rapid Check COVID-19/Flu A & B Antigen Test
General Device Characteristic Similarities		
Intended Use	Same	Over-the-counter test to detect SARS-CoV-2 and Influenza A and B from clinical specimens.
Indications For Use	<p><u>QuickFinder COVID-19/Flu Antigen Self Test:</u></p> <p>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 antigen directly in anterior nasal swab samples from individuals with signs and symptoms of respiratory tract infection. Symptoms of respiratory infections due to SARS-CoV-2 and influenza can be similar. This test is for non-prescription home use by individuals aged 14 years or older testing themselves, or adults testing individuals aged 2 years or older.</p> <p>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</p>	<p>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 individuals aged 14 years or older testing themselves, or adults testing individuals aged 2 years or older.</p> <p>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,</p>

Device & Predicate Device(s):	K243262	DEN240029
	<p>continued or worsening respiratory symptoms, such as fever, cough and/or shortness of breath, should seek follow-up care from their healthcare provider.</p> <p>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.</p> <p><u>QuickFinder COVID-19/Flu Antigen Pro Test:</u></p> <p>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.</p> <p>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.</p>	<p>such as fever, cough and/or shortness of breath, should seek follow-up care from their healthcare provider.</p> <p>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.</p>

Device & Predicate Device(s):	<u>K243262</u>	<u>DEN240029</u>
	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.	
Prescription Use / Over-the-Counter	Same	Over-the-Counter
End user	Same	Lay user
Environment of use	Same	Home or similar environment
Disease	Same	COVID-19 Influenza A and B
Intended use population	Same	Symptomatic individuals 14 years of age and older testing themselves and adults testing individuals aged 2 years and older.
Sample	Same	Anterior nasal swab specimen
Assay principle	Same	Lateral flow
Qualitative or quantitative	Same	Qualitative
Organism detected	Same	SARS-CoV-2 Influenza A and B
Format	Same	Test cassette
Controls	Same	Internal control
Time to result	Same	15 minutes
Results	Same	Positive, negative, or invalid
Interpretation	Same	Visually read

V. Standards/Guidance Documents Referenced:

The following have been referenced for Conformity.

Document number	Title	Publishing Organization
11135:2014	Sterilization of health care products - Ethylene oxide - Requirements for development, validation and routine control of a sterilization process for medical devices	ISO
109993-7	Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals	ISO
10993-10:2010	Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization	ISO
10993-5:2009	Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity	ISO

VI. Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision:

The Precision study for the QuickFinder COVID-19/Flu Antigen Test was evaluated in two different in-house studies using the same 3 lots. The strains used for testing were UV inactivated SARS-CoV-2: USA-WA1/2020, H1N1pdm09/A/Victoria/4897/2022, and Yamagata/B/Florida/4/2006.

Study 1 was conducted by 2 trained operators who each tested eight samples with different analyte concentrations and combinations (Negative, 2X LoD SARS-CoV-2, 2X LoD Flu A, 2X LoD Flu B, 2X LoD SARS-CoV-2 & Flu A co-spiked, 2X LoD SARS-CoV-2 & Flu B co-spiked, 2X LoD Flu A & Flu B co-spiked, 2X LoD SARS-CoV-2 & Flu A & Flu B co-spiked). All samples were formulated in negative clinical matrix, pooled nasal wash (PNW). Each operator tested two sample replicates each in 2 runs for each of 3 lots of devices. Runs were performed in the morning and afternoon (or at least 4 hours apart) over 10 days. This design (2 replicates/run/lot x 2 runs/operator x 2 operators x 3 lots x 10 days) resulted in 240 total replicates per sample. All samples were randomized and blinded for each day. Results for this study are shown in Table 1 below and were concordant with the expected results; that is, all samples with analyte produced positive results, and all samples without analyte produced negative results.

Table 1: Summary Results for Lot-to-Lot Precision Study (Operators 1 and 2 Combined)

Analyte in Sample	Analyte Test Lines	Lot 1		Lot 2		Lot 3		Lot-to-Lot Agreement	95% CI**
		Count	% Amt*	Count	% Amt	Count	% Amt		
Negative	SARS-CoV-2	80/80	100%	80/80	100%	80/80	100%	100%	96.9-100%
	Flu A	80/80	100%	80/80	100%	80/80	100%	100%	96.9-100%
	Flu B	80/80	100%	80/80	100%	80/80	100%	100%	96.9-100%
SARS-CoV-2	SARS-CoV-2	80/80	100%	80/80	100%	80/80	100%	100%	96.9-100%
	Flu A	80/80	100%	80/80	100%	80/80	100%	100%	96.9-100%
	Flu B	80/80	100%	80/80	100%	80/80	100%	100%	96.9-100%
Flu A	SARS-CoV-2	80/80	100%	80/80	100%	80/80	100%	100%	96.9-100%
	Flu A	80/80	100%	80/80	100%	80/80	100%	100%	96.9-100%
	Flu B	80/80	100%	80/80	100%	80/80	100%	100%	96.9-100%
Flu B	SARS-CoV-2	80/80	100%	80/80	100%	80/80	100%	100%	96.9-100%
	Flu A	80/80	100%	80/80	100%	80/80	100%	100%	96.9-100%
	Flu B	80/80	100%	80/80	100%	80/80	100%	100%	96.9-100%
SARS-CoV-2 + Flu A	SARS-CoV-2	80/80	100%	80/80	100%	80/80	100%	100%	96.9-100%
	Flu A	80/80	100%	80/80	100%	80/80	100%	100%	96.9-100%
	Flu B	80/80	100%	80/80	100%	80/80	100%	100%	96.9-100%
SARS-CoV-2 + Flu B	SARS-CoV-2	80/80	100%	80/80	100%	80/80	100%	100%	96.9-100%
	Flu A	80/80	100%	80/80	100%	80/80	100%	100%	96.9-100%

Analyte in Sample	Analyte Test Lines	Lot 1		Lot 2		Lot 3		Lot-to-Lot Agreement	95% CI**
		Count	% Amt*	Count	% Amt	Count	% Amt		
Flu B	Flu B	80/80	100%	80/80	100%	80/80	100%	100%	96.9-100%
Flu A + Flu B	SARS-CoV-2	80/80	100%	80/80	100%	80/80	100%	100%	96.9-100%
	Flu A	80/80	100%	80/80	100%	80/80	100%	100%	96.9-100%
	Flu B	80/80	100%	80/80	100%	80/80	100%	100%	96.9-100%
SARS-CoV-2 + Flu A + Flu B	SARS-CoV-2	80/80	100%	80/80	100%	80/80	100%	100%	96.9-100%
	Flu A	80/80	100%	80/80	100%	80/80	100%	100%	96.9-100%
	Flu B	80/80	100%	80/80	100%	80/80	100%	100%	96.9-100%

*Amt = Agreement: Result matched expected result.

**95% CI = 2-sided 95% Confidence Interval

Study 2 was specifically conducted to assess between-lot variability. The study used negative samples (without virus analytes) and low positive samples at 0.75X LoD for all three analytes (0.75X LoD SARS-CoV-2 & Flu B Co-spike and 0.75X LoD Flu A). Samples were blinded and tested randomized. 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 sample level (24 replicates for each analyte with each lot). Lot and operator stratified results from this testing are included in Table 2 below.

Precision estimates for samples below the LoD, the 0.75X LoD sample, are expected to be low due to 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.

Table 2: Summary for Supplemental Precision Study (0.75xLoD for positive samples)

Analyte in Sample	Analyte Test Lines	Between Lot						Between Operator			
		Lot 1		Lot 2		Lot 3		Op-1		Op-2	
		Count	% Amt*	Count	% Amt	Count	% Amt	Count	% Amt	Count	% Amt
Negative	SARS-CoV-2	24/24	100%	24/24	100%	24/24	100%	36/36	36/36	36/36	36/36
	Flu A	24/24	100%	24/24	100%	24/24	100%	36/36	36/36	36/36	36/36
	Flu B	24/24	100%	24/24	100%	24/24	100%	36/36	36/36	36/36	36/36
SARS-CoV-2 + Flu B	SARS-CoV-2	18/24	75%	14/24	58.3%	17/24	70.8%	25/36	69.4%	24/36	66.7%
	Flu A	N/A*	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Flu B	19/24	79.2%	13/24	54.2%	18/24	75%	24/36	66.7%	26/36	72.2%
Flu A	SARS-CoV-2	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Flu A	15/14	62.5%	23/24	95.8%	17/24	70.8%	29/36	80.6%	26/36	72.2%
	Flu B	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

*Amt = Agreement: Result matched expected result.

**N/A: Not applicable because the analyte wasn't present in the tested sample and all tested replicates correctly returned negative results for these analytes (i.e., no false positive results were observed).

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 concentrations 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.

2. **Linearity:**

This is a qualitative test and linearity is not applicable.

3. **Analytical Specificity/Interference:**

a. Cross Reactivity and Microbial Interference

Cross Reactivity and Microbial Interference studies were conducted to determine if other respiratory pathogens/flora that could be present in a direct nasal swab samples could cause a false-positive test result or interfere with a true positive result. A panel of viruses, bacteria, fungi, and pooled nasal wash (PNW) was used for these studies. Final organism concentrations were targeted to be at least 1.0×10^5 PFU/mL and 1×10^5 TCID₅₀/mL for viruses, and 1.0×10^6 CFU/mL for bacteria and fungi. Where this target concentration was not achievable due to the titer of the stock culture, the highest concentration possible was tested without dilution. Dilutions for cross-reactivity testing were made in pooled negative nasal swab matrix (swabs collected in saline). Each organism was tested in replicates of three (3) without SARS-CoV-2/ Flu A/Flu B present in the sample.

Organisms that did not cause a false-positive result were further evaluated for microbial interference by testing PNW spiked with low-level UV inactivated SARS-CoV-2, live Flu A virus, and live Flu B virus isolate (3X co-spike equivalency LoD) in the presence of potentially interfering organism at a high titer in triplicate.

Neither cross-reactivity nor interference was observed for any of the organisms at the concentrations tested with the QuickFinder COVID-19/Flu Antigen Test device.

The summary of cross-reactivity and microbial interference results are shown in the table below.

Table 3: Summary of Cross-Reactivity and Microbial Interference Results

Organism	Concentration Tested	Units	Cross-Reactivity	Microbial Interference
SARS-CoV-1	1.25E+05	PFU/mL	ND*	ND
MERS-coronavirus	1.47E+05	TCID ₅₀ /mL	ND	ND
Human coronavirus OC43	7.00E+05	TCID ₅₀ /mL	ND	ND
Human coronavirus 229E	1.58E+05	TCID ₅₀ /mL	ND	ND
Human coronavirus NL63	7.05E+04	TCID ₅₀ /mL	ND	ND
Human coronavirus HKU1	1.74E+07	GE/mL	NA	ND
Adenovirus, Type 1 (Adenoid 71)	2.23E+05	TCID ₅₀ /mL	ND	ND
Adenovirus Type 7, Type 7A (Species B)	1.58E+05	TCID ₅₀ /mL	ND	ND
Cytomegalovirus, Strain AD-169	7.05E+04	TCID ₅₀ /mL	ND	ND
Epstein Barr Virus, Strain B95-8	1.83E+06	CP/mL	ND	ND
Human Metapneumovirus (hMPV), Strain TN/91-316	3.50E+05	TCID ₅₀ /mL	ND	ND
Parainfluenza virus 1, Strain FRA/29221106/2009	2.00E+05	TCID ₅₀ /mL	ND	ND

Organism	Concentration Tested	Units	Cross-Reactivity	Microbial Interference
Parainfluenza virus 2, Strain Greer	1.75E+05	TCID ₅₀ /mL	ND	ND
Parainfluenza virus 3, Strain C243	7.00E+05	TCID ₅₀ /mL	ND	ND
Parainfluenza virus 4, Strain N/A	2.39E+05	TCID ₅₀ /mL	ND	ND
Enterovirus Species D Type 68	2.23E+05	TCID ₅₀ /mL	ND	ND
Respiratory syncytial virus A, Strain A-2	3.50E+05	TCID ₅₀ /mL	ND	ND
Respiratory syncytial virus B, Strain CH93(18)-18	2.29E+05	TCID ₅₀ /mL	ND	ND
Rhinovirus 1A, Strain N/A	7.05E+04	TCID ₅₀ /mL	ND	ND
Bordetella pertussis, Strain A639	2.90E+08	CFU/mL	ND	ND
Candida albicans, Strain Z006	1.21E+07	CFU/mL	ND	ND
Chlamydomydia pneumoniae, Strain Z500	4.33E+06	IFU/mL	ND	ND
Corynebacterium xerosis	2.30E+07	CFU/mL	ND	ND
Escherichia coli, Strain mcr-1	1.79E+08	CFU/mL	ND	ND
Hemophilus influenzae, type b; Eagan	9.68E+06	CFU/mL	ND	ND
Lactobacillus sp., Lactobacillus Acidophilus, Strain Z048	1.21E+07	CFU/mL	ND	ND
Legionella spp pneumophila, Strain Philadelphia-1	6.50E+06	CFU/mL	ND	ND
Moraxella catarrhalis, Strain 59632	2.50E+08	CFU/mL	ND	ND
Mycoplasma pneumoniae, Strain PI 1428	2.50E+07	CFU/mL	ND	ND
Mycobacterium tuberculosis avirulent, Strain H37Ra-1	3.03E+06	CFU/mL	ND	ND
Neisseria meningitidis, serogroup A	3.43E+06	CFU/mL	ND	ND
Neisseria sp. Elongata Z071	2.68E+08	CFU/mL	ND	ND
Pneumocystis jirovecii, Strain W303-Pji	1.30E+07	CFU/mL	ND	ND
Pseudomonas aeruginosa, Strain N/A	3.45E+08	CFU/mL	ND	ND
Staphylococcus aureus ssp aureus	2.60E+08	CFU/mL	ND	ND
Staphylococcus epidermidis (PCI 1200)	9.00E+07	CFU/mL	ND	ND
Streptococcus salivarius, Ssp salivarius	1.01E+06	CFU/mL	ND	ND
Streptococcus pneumoniae, Strain Z022	1.81E+07	CFU/mL	ND	ND
Streptococcus pyogenes, Strain MGAS 8232	7.50E+07	CFU/mL	ND	ND
Measles, Strain Edmonston	8.48E+05	TCID ₅₀ /mL	ND	ND
Mumps (Isolate 1)	8.48E+05	TCID ₅₀ /mL	ND	ND

*ND – Not Detected

b. Competitive Interference:

Competitive interference of the test's analytes with each other was tested with different combinations of low (3x single analyte LoD) and high (1000X single analyte LoD or the highest achievable concentration) concentrations of Flu A, Flu B and SARS-CoV-2 spiked

together into the same sample. Samples were tested with one lot of QuickFinder COVID-19/Flu Antigen Test device in three replicates per test condition. The study used UV inactivated SARS-CoV-2 but live influenza A and B virus strains; virus materials were spiked into negative clinical matrix (PNW).

The table below summarizes the results of the competitive interference study. For each condition tested all three replicates tested at the low target analyte condition tested positive in the presence of a second target analyte at high concentrations. No false positive results were observed for analytes that are not present in the sample.

Table 4: Competitive Interference Results Summary

SARS-CoV-2 (USA-WA1/2020)		Influenza A Virus (H1N1pdm09) A/Victoria/4897/2022		Influenza B Virus (Yamagata Lineage) B/Florida/4/2006	
Concentration	% Agreement	Concentration	% Agreement	Concentration	% Agreement
-	100%	High	100%	Low	100%
Low	100%	High	100%	-	100%
Low	100%	High	100%	Low	100%
-	100%	Low	100%	High	100%
Low	100%	-	100%	High	100%
Low	100%	Low	100%	High	100%
High	100%	Low	100%	-	100%
High	100%	-	100%	Low	100%
High	100%	Low	100%	Low	100%

c. Exogenous and Endogenous Interference Study

The QuickFinder COVID-19/Flu Antigen Test was also evaluated for performance in the presence and absence of potentially interfering substances that might be present in a respiratory specimen. Interfering substances testing was performed using a panel of endogenous and exogenous substances tested at concentrations listed in the below table.

Negative specimens were evaluated in triplicates to confirm that the potentially interfering substances would not cause false positive results with the test.

Negative clinical matrix (pooled nasal wash) was co-spiked with SARS-CoV-2 USA WA1/2020 (UV inactivated), Flu A H1N1 Victoria/4897/2022, and Flu B Yamagata/B/Florida/4/2006, and then mixed 1:1 with interfering substance. Final concentration for each analyte was 3X LoD based on the established co-spike LoD. Negative nasal wash (PNW) has been demonstrated to be equivalent to the pooled nasal swab matrix (PNSM) in a matrix equivalency study. Testing was performed in triplicates to confirm that SARS-CoV-2, Flu A and Flu B could still be detected if the test substances were present in the sample. All testing was randomized and blinded. Test results are summarized in the table below.

With the exception of Flu Mist Quadrivalent live influenza vaccine, none of the substances caused a false-positive test result in unspiked samples. While the presence of Flu Mist Quadrivalent live influenza 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 resulted in

cross reactivity (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 all analytes were detected when its concentration was at 0.05% w/v.

Table 5: Interfering Substances Study Results

Interfering Substance	Concentration	Cross-reactivity (no analyte) (# pos/ # total)			Interference (3X LoD analyte) (# pos/ # total)		
		SCV2	Flu A	Flu B	SCV2	Flu A	Flu B
Human Whole Blood (K2-EDTA)	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 mg/mL	0/3	0/3	0/3	3/3	3/3	3/3
Mucin Type I-S bovine submaxillary glands	2.5 mg/mL	0/3	0/3	0/3	3/3	3/3	3/3
Zinc (Therazinc throat Spray)	15% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Naso GEL (NeilMed)	5%	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
Nasal Corticosteroid (Triamcinolone)	15% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Nasal Corticosteroid (Dexamethasone)	1 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 gel (Galphimia glauca, Histanium hydrochloricum, Luffa operculate, Sulfur)	1.25%	0/3	0/3	0/3	3/3	3/3	3/3
Homeopathic allergy relief (Histaminum hydrochloricum)	15% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Zicam nasal spray (Galphimia glauca, Luffa operculata)	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
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
Anti-viral drug (Remdesvir)	10 mg/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
	15% v/v	0/3	3/3	3/3	3/3	3/3	3/3

Interfering Substance	Concentration	Cross-reactivity (no analyte) (# pos/ # total)			Interference (3X LoD analyte) (# pos/ # total)		
		SCV2	Flu A	Flu B	SCV2	Flu A	Flu B
FluMist (Quadrivalent/Live)	6 % v/v	0/3	3/3	3/3	N/A	N/A	N/A
	3% v/v	0/3	3/3	3/3	N/A	N/A	N/A
	1.5 % v/v	0/3	0/3	0/3	N/A	N/A	N/A
	0.75 % v/v	0/3	0/3	0/3	N/A	N/A	N/A
Zanamivir	282 ng/mL	0/3	0/3	0/3	3/3	3/3	3/3
Biotin	3500 ng/mL	0/3	0/3	0/3	3/3	3/3	3/3
Body & 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% w/v	0/3	0/3	0/3	3/3	3/3	3/3
Hand Sanitizer 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
	1 % w/v	N/A	N/A	N/A	3/3	3/3	0/3
	0.1 % w/v	N/A	N/A	N/A	3/3	3/3	0/3
	0.05 % w/v	N/A	N/A	N/A	3/3	3/3	3/3
	0.01 % w/v	N/A	N/A	N/A	3/3	3/3	3/3

4. **Assay Reportable Range:**

This section is not applicable as this device is a qualitative assay.

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

a. Controls

i. Internal Controls:

Both the test strips enclosed in the QuickFinder COVID-19/Flu Antigen Test device independently feature an internal control, denoted directly on the user interface of the test device as "C". The internal control line needs to be present on each respective test strip to indicate that the test works adequately in each lay user performed test. The control line contains IgG antibodies that capture the excess labeled mouse antibody preloaded in the conjugate pad. These controls must be positive for all valid test results to demonstrate that the test reagents are functional, and the tests correctly performed. If the control lines are not detected, the sample result is invalid.

ii. External Controls:

External Quality Control materials are not included in the test kit but are available separately for use by professional users.

b. Stability

i. *Real Time Stability:*

Three lots of the QuickFinder COVID-19/Flu Antigen Test kits were subjected to temperatures expected for unopened kits when stored at the indicated storage condition, 2-30°C. The test kits were stored at 2°C/ambient humidity, 30°C/45% relative humidity (RH), and 30°C/95% relative humidity. The test panel comprised of un-spiked pooled nasal wash, 1X LoD and 4X LoD of inactivated SARS-CoV-2, and live Flu A and Flu B viruses, spiked into negative clinical matrix (PNW). 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 a shelf-life of up to 18 months when stored between 2-30°C.

ii. *Open Kit Stability Study:*

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 (clinical matrix: PNW) and five (5) co-spiked low positive samples (2X co-spike equivalency 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 baseline. Thereafter, devices were stored for one-hour and two-hour, respectively at 30±1°C (the worst-case condition for a room temperature storage). All study data before and after storage of the open kits were 100% concordant with the expected results establishing stability of the open kit at room temperature as indicated in the instructions for use.

iii. *Transport Stability:*

Simulated winter and summer transport temperature conditions were used to evaluate the expected worst-case shipping and handling of unopened components of the QuickFinder COVID-19/Flu Antigen Test over an extended period. The functional performance of the QuickFinder COVID-19/Flu Antigen Test kits was assessed by comparing the pre- (T0) and post-distribution (Td) results of a test panel comprised of pooled negative nasal wash (PNW) samples and co-spiked low positive samples (3X co-spike equivalency LoD with SARS-CoV-2, Flu A, and Flu B, together contrived in PNW). PNW was demonstrated to be an equivalent negative clinical matrix to negative nasal swab matrix in a matrix equivalency study. All results were as expected for all time points.

6. **Detection Limit:**

a. Single Analyte LoD:

The LoD of the device was performed to determine the lowest detectable concentration of SARS-CoV-2, influenza A and influenza B at which at least 95% of all true positive replicates are consistently detected as positive. The LoD was assessed for each analyte in two parts, a preliminary range finding study, followed by a confirmatory LoD study.

The preliminary LoD was determined by first testing serial ten-fold dilutions of live influenza A and B, and inactivated SARS-CoV-2 virus stocks diluted into either pooled negative swab matrix (PNSM) in 3 replicates per dilution and lot. Once the ten-fold LoD range was established, additional two-fold dilutions of the lowest positive ten-fold dilution

were tested in triplicate to determine the preliminary LoD of each virus. Single analyte virus dilutions (50 µL/swab) were each spiked onto dry sterile swabs and tested per the IFU. Total of three test kit lots have been tested to demonstrate LOD consistency across different device lots.

The preliminary LoD results for each individual virus strain are shown in the tables below.

Table 6: Preliminary LoD - SARS-CoV-2

Isolate/Lineage	SARS-CoV-2 (TCID ₅₀ /mL)	SARS-CoV-2 (TCID ₅₀ /Swab)	#Positive/# Total (All lots combined)
USA-WA1-2020 (UV inactivated)	3.16E+05	1.58E+04	9/9
	3.16E+04	1.58E+03	9/9
	3.16E+03	1.58E+02	9/9
	1.58E+03	7.90E+01	9/9
	7.90E+02	3.95E+01	0/9
	3.95E+02	1.98E+01	0/9
	3.16E+02	1.58E+01	0/9

Table 7: Preliminary LoD - Influenza A

Isolate/Lineage	Strain	SARS-CoV-2 (TCID ₅₀ /mL)	SARS-CoV-2 (TCID ₅₀ /Swab)	#Positive/# Total (All lots combined)
H3N2	A/Darwin/6/2021 (live)	4.17E+04	2.09E+03	9/9
		4.17E+03	2.09E+02	9/9
		4.17E+02	2.09E+01	9/9
		2.09E+02	1.04E+01	9/9
		1.04E+02	5.20E+00	0/9
		5.21E+01	2.61E+00	0/9
		4.17E+01	2.09E+00	0/9
		4.17E+04	2.09E+03	0/9
H1N1	A/Victoria/ 4897/2022 (live)	2.02E+04	1.01E+03	9/9
		2.02E+03	1.01E+02	9/9
		2.02E+02	1.01E+01	9/9
		1.01E+02	5.05E+00	0/9
		5.05E+01	2.53E+00	0/9
		2.53E+01	1.27E+00	0/9
		2.02E+01	1.01E+00	0/9

Table 8: Preliminary LoD - Influenza B

Isolate/Lineage	Strain	SARS-CoV-2 (TCID ₅₀ /mL)	SARS-CoV-2 (TCID ₅₀ /Swab)	#Positive/# Total (All lots combined)
Yamagata	B/Florida/4/2006 (live)	1.17E+04	5.85E+02	9/9
		1.17E+03	5.85E+01	9/9
		1.17E+02	5.85E+00	9/9
		5.85E+01	2.93E+00	9/9
		2.93E+01	1.46E+00	9/9
		1.46E+01	7.30E-01	0/9
		1.17E+01	5.85E-01	0/9

Isolate/Lineage	Strain	SARS-CoV-2 (TCID ₅₀ /mL)	SARS-CoV-2 (TCID ₅₀ /Swab)	#Positive/# Total (All lots combined)
Victoria	B/Washington /02/2019 (live)	3.16E+05	1.58E+04	9/9
		3.16E+04	1.58E+03	9/9
		3.16E+03	1.58E+02	9/9
		1.58E+03	7.90E+01	0/9
		7.90E+02	3.95E+01	0/9
		3.95E+02	1.98E+01	0/9
		3.16E+02	1.58E+01	0/9

LoD confirmatory testing was then performed individually for each of the viral strains by testing 20 replicates at the virus' preliminary (1X) LoD concentration, as determined above. For the LoD to be confirmed, at least 95% of the replicates ($\geq 19/20$) needed to test positive. Results of the LoD confirmation testing for each virus are summarized in the table below.

Table 9: Confirmatory LoD

Analyte	Isolate/ Lineage	Strain	LoD Concentration (TCID ₅₀ /mL)	LoD per Swab (TCID ₅₀ /swab)	#Positive/ # Total (All lots combined)
SARS-CoV-2	USA-WA1/2020 (UV inactivated)	NA	1.58E+03	7.90E+01	60/60
Flu A	H3N2	Darwin/6/21	2.09E+02	1.04E+01	60/60
	H1N1	Victoria/4897/22	2.02E+02	1.01E+01	60/60
Flu B	Yamagata	Florida/04/06	2.93E+01	1.46E+00	60/60
	Victoria	Washington/02/19	3.16E+03	1.58E+02	60/60

b. Co-spiked LoD:

After the single-analyte LoDs were established for the candidate device, co-spiked LoD equivalency testing with all three test analytes present in the same sample, was conducted to characterize performance with samples that contain more than one analyte at low concentrations.

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

The QuickFinder COVID-19/Flu Antigen Test demonstrated co-spiked LoD equivalency for all analytes, SARS-CoV-2, Flu A and Flu B, to their respective established single analyte 1X LoD concentration. Since all analytes are successfully detected by the candidate device when co-spiked at their single-analyte LoD, co-spiking of the analytes into the same positive sample/s is supported for use in the analytical studies. The summary of the co-spiked LoD is shown in the below table.

Table 10: Summary of Co-Spike LoD Equivalency Results

Virus	Fold single-analyte LoD	LoD Concentration (TCID ₅₀ /mL)	LoD per Swab (TCID ₅₀ /swab)	# Positive Replicates
SARS-CoV-2 (USA-WA1/2020)	1X	1.58 x 10 ³	7.90 x 10 ¹	20/20
Flu B Yamagata (B/Florida/4/2006)	1X	2.93 x 10 ¹	1.47 x 10 ⁰	20/20
Flu A H1N1 (pdm09:A/Victoria/4897/2022)	1X	2.09 x 10 ²	1.05 x 10 ¹	20/20

c. Detection Limit with the NIBSC 21/368 - WHO International Standard:

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). 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 50µl 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 11: LOD with the 1st WHO International Standard for SARS-CoV-2 Antigen (NIBSC code: 21/368)

Preliminary LoD			Confirmatory LoD		
Concentration (IU/ml)	IU/swab	Results	Concentration (IU/ml)	IU/swab	Results
4x10 ³	200	3/3			
2x10 ³	100	3/3	2x10 ³	100	20/20
1x10 ³	50	3/3	1x10 ³	50	20/20
4x10 ²	20	0/3	5x10 ²	25	0/20
2x10 ²	10	0/3			

7. High-Dose Hook Effect Study:

The hook effect study was conducted to evaluate if high levels of antigen present in the sample could result in a false negative test result. In this study, 50µL of the highest concentration possible for UV inactivated SARS-CoV-2 virus stock and for live influenza A and influenza B virus stocks were spiked onto sterile swabs for triplicate measurements, and swabs were tested on the device per IFU of the candidate device.

Testing showed no hook effect for SARS-CoV-2, Flu A, Flu B at the concentrations listed in the table below.

Table 12: Summary of High Dose Hook Effect Results

Virus	Strain	Subtype or Lineage	Virus Concentration [TCID ₅₀ /mL]	Virus Concentration [TCID ₅₀ /swab]	# Positive/ # Total
SARS-CoV-2	USA-WA1/2020	N/A	3.16E+06	1.58E+05	3/3
Influenza A	A/Victoria/4897/2022	H1N1pdm09	2.02E+05	1.01E+04	3/3
Influenza A	A/Darwin/6/21	H3N2	4.17E+05	2.09E+04	3/3
Influenza B	B/Washington/02/2019	Victoria	3.16E+06	1.58E+05	3/3
Influenza B	B/Florida/4/2006	Yamagata	1.17E+05	5.85+03	3/3

8. Inclusivity Study:

Analytical reactivity testing was performed for the QuickFinder COVID-19/Flu Antigen Test to determine if the device can detect the target analytes across a variety of strains. A selection of temporally, geographically, and genetically diverse SARS-CoV-2 and influenza strains were tested for inclusivity. An LoD study was conducted on a total of 23 Influenza A strains (11 H1N1, 1 H1N2, and 6 H3N2, 2 H5N1, 1 H5N6, 1 H5N8, 1 H7N3), and 10 Influenza B strains (1 non-Victoria and non-Yamagata, 4 Yamagata and 5 Victoria lineages). A series of three (3) ten-fold dilutions of each virus was spiked into PNSM and tested. Once the ten-fold LoD range was established for each strain, an additional series of 3 two-fold dilutions of the lowest positive ten-fold dilution for each virus was tested in triplicate to demonstrate inclusivity. Contemporary strains (within the past 5 years) were prioritized over older strains. Results are summarized below.

Table 13: Minimal Detectable Concentrations of SARS-CoV-2, Influenza A, and Influenza B Variants

Target Analyte	Strain	Concentration
SARS-CoV-2	USA-WA1/2020 (UV inactivated)	1.58 x 10 ³ TCID ₅₀ /mL
	Xbb 1.5 Omicron Variant (heat inactivated)	4 × 10 ² TCID ₅₀ /mL
Influenza A (H1N1pdm09)	A/California/04/2009	2.80 × 10 ³ TCID ₅₀ /mL
	A/Brisbane/02/2018	1.89 × 10 ² TCID ₅₀ /mL
	A/Michigan/45/2015	1.86 × 10 ¹ TCID ₅₀ /mL
	A/Guangdong- Maonan/SWL 1536/2019	1.04 × 10 ³ TCID ₅₀ /mL
	A/NY/03/2009	4.57 × 10 ⁴ TCID ₅₀ /mL
	A/Indiana/02/2020	9.70 × 10 ⁶ CEID ₅₀ /mL
	A/Wisconsin/588/2019	2.80 × 10 ⁴ FFU/mL
	A/Sydney/5/2021	6.00 × 10 ³ TCID ₅₀ /mL
	A/Hawaii/66/2019	7.40 × 10 ⁷ CEID ₅₀ /mL
	A/Wisconsin/67/2022	4.21 × 10 ² TCID ₅₀ /mL
Influenza A (H1N1)v	A/Ohio/09/2015	1.40 × 10 ⁶ CEID ₅₀ /mL
Influenza A (H1N2)v	A/Minnesota/19/2011	8.0 × 10 ⁶ CEID ₅₀ /mL
Influenza A (H3N2)	A/New York/21/2020	3.25 × 10 ⁵ FFU/mL
	A/Tasmania/503/2020	1.30 × 10 ⁵ FFU/mL
	A/Alaska/01/2021	3.75 × 10 ⁴ FFU/mL
	A/Hong Kong/45/2019	3.75 × 10 ⁴ FFU/mL
	A/Hong Kong/2671/2019	1.05 × 10 ³ TCID ₅₀ /mL
	A/Indiana/08/2011	8.10 × 10 ² TCID ₅₀ /mL
Influenza A (H5N1)	A/mallard/Wisconsin/2576/2009	4.0 × 10 ⁶ CEID ₅₀ /mL

Target Analyte	Strain	Concentration	
	A/bovine/Ohio/B24OSU-439/2024	7.8×10^3	TCID ₅₀ /mL
	A/duck/Guangxi/S11002/ 2024	1.69×10^6	EID ₅₀ /mL
Influenza A (H5N6)	A/duck/Guangxi/S10888/2024	1.69×10^6	EID ₅₀ /mL
Influenza A (H5N8)	A/goose/Liaoning/S1266/2021	1.69×10^6	EID ₅₀ /mL
Influenza A (H7N3)	A/northern pintail/Illinois/ 10053959/2010	2.8×10^6	CEID ₅₀ /mL
Influenza B (Victoria)	B/Brisbane/60/2008	1.61×10^0	TCID ₅₀ /mL
	B/Colorado/06/2017	2.93×10^1	TCID ₅₀ /mL
	B/Texas/02/2013	2.45×10^1	TCID ₅₀ /mL
	B/Washington/02/2019	3.16×10^3	TCID ₅₀ /mL
	B/Michigan/01/2021	1.43×10^4	TCID ₅₀ /mL
Influenza B (Yamagata)	B/Texas/06/2011	1.51×10^3	TCID ₅₀ /mL
	B/Utah/09/2014	1.26×10^3	TCID ₅₀ /mL
	B/Florida/04/2006	2.93×10^1	TCID ₅₀ /mL
	B/Wisconsin/01/2010	1.78×10^2	TCID ₅₀ /mL
Influenza B (non-Victoria, non-Yamagata)	B/Maryland/1/1959	3.38×10^3	CEID ₅₀ /mL

9. Assay Cut-Off:

Not applicable as this is a qualitative visually read assay without numeric raw data.

B Comparison Studies:

1. Method Comparison with Predicate Device:

Please refer to section VI.C (Clinical Studies) below for the clinical validation, regarding the method comparison studies.

2. Matrix Equivalency:

The candidate device is only intended for qualitative detection of nucleocapsid protein antigen from SARS-CoV-2, and nucleoprotein from Flu A and Flu B in direct anterior nasal swab specimens. As no other sample types are claimed herein, a matrix comparison study is not applicable.

However, the sponsor performed the matrix equivalency study between pooled negative nasal swab matrix (PNSM) and the surrogate pooled negative nasal wash (PNW) that was used in multiple analytical studies. The data demonstrated equivalent performance of the test with both matrices.

C Clinical Studies:

1. Clinical Performance Assessment:

A multi-center, prospective clinical study was conducted with lay users to assess the performance of the QuickFinder COVID-19/Flu Antigen Self Test in detecting nucleoprotein antigens extracted from COVID-19, influenza virus A, and influenza virus B in self-collected and self-tested anterior nasal swab samples. The study only enrolled lay user subjects with two or more symptoms of respiratory infection consistent with COVID-19 or influenza. Six clinical sites (one

site with two locations) across the U.S. conducted the study from October 9, 2023, to June 13, 2024.

Both the comparator and the candidate test used anterior nasal swab samples and the collection order was alternated by study subject. Comparator test samples were collected by health care professionals at the clinical study sites and inserted into Universal Transport Media per the IFU of the comparator test. Samples were then sent to a reference laboratory for testing with highly sensitive RT-PCR tests separately detecting SARS-CoV-2 and Flu A/B. Samples for the candidate antigen test were collected per the test's quick reference instructions and were either self-collected by a lay user aged ≥ 14 years or collected by an adult (parent/guardian) from individuals aged 2 to <14 years.

There were 794 symptomatic subjects enrolled with symptom onset between 0 and 4 days who conducted testing using the QuickFinder COVID-19/Flu Antigen Self Test summary instructions (QRI). Of those, 788 subjects were evaluable for SARS-CoV-2, Flu A, and B. The study cohort included 21% low positive samples. The age of participants ranged from 2 years old to 80 years old, with a mean of 34.6 years. The education level of subjects ranged from less than high school diploma to doctorate degree. The demographics of the subjects involved in the clinical study are shown in the table below.

Table 14. Subject Demographics

	Subjects with collection and testing by lay-caregiver (N=111)	Self-collecting and testing (N=677)	Overall (N=788)
Age			
Mean (SD)	11.1 (12.1)	38.4 (16.3)	34.6 (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%)
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%)
Education Level (testers and subjects self-collecting and testing)			
Less than high school diploma	8 (7.2%)	84 (12.4%)	92 (11.6%)

	Subjects with collection and testing by lay-caregiver (N=111)	Self-collecting and testing (N=677)	Overall (N=788)
High school diploma	63 (56.8%)	196 (29.0%)	259 (32.9%)
Some college, but no degree	24 (21.6%)	115 (17.0%)	139 (17.6%)
Associate degree (e.g., AA, AS)	3 (2.7%)	31 (4.6%)	34 (4.3%)
Bachelor's Degree (e.g., BA, BBA and BS)	7 (6.3%)	164 (24.2%)	171 (21.7%)
Master's Degree (e.g., MA, MS and Meng)	0 (0.0%)	49 (7.2%)	49 (6.2%)
Professional Degree (e.g., MD, DDS, JD)	0 (0.0%)	2 (0.3%)	2 (0.3%)
Doctorate (e.g., PhD, EdD)	0 (0.0%)	1 (0.1%)	1 (0.1%)
Other	6 (5.4%)	35 (5.2%)	41 (5.2%)
Household Income (testers and subjects self-collecting and testing)			
less than \$15,000	17 (15.3%)	143 (21.1%)	160 (20.3%)
\$15,001 to \$45,000	56 (50.5%)	178 (26.3%)	234 (29.7%)
\$45,001 to \$90,000	29 (26.1%)	164 (24.2%)	193 (24.5%)
\$90,001 to \$150,000	5 (4.5%)	107 (15.8%)	112 (14.2%)
\$150,001 to \$300,000	3 (2.7%)	47 (6.9%)	50 (6.3%)
over \$300,000	0 (0.0%)	0 (0.0%)	0 (0%)
Other	1 (0.9%)	38 (5.6%)	39 (4.9%)

Results obtained with the QuickFinder COVID-19/Flu Antigen Self Test were compared to the results obtained with highly sensitive RT-PCR comparator tests giving rise to the following performance estimates:

Table 15: Clinical Performance for Detection of SARS-CoV-2

SARS-CoV-2	Comparator Positives	Comparator Negatives	Total
Candidate Positives	116	4	120
Candidate Negatives	12	656	668
Total	128	660	788

Positive Percent Agreement = (116/128) = 90.6% (95% CI: 84.3% - 94.6%)

Negative Percent Agreement = (656/660) = 99.4% (95% CI: 98.5% - 99.8%)

Results for SARS-CoV-2 were also analyzed stratified by the number of days post symptom onset (DPSO) and are presented in Table 16 below.

Table 16: Clinical Performance for Detection of SARS-CoV-2 stratified by DPSO

DPSO*	Number of Subject samples tested	Investigational Positives	Comparator Positives	% Positive Rate (by Comparator)	PPA (95% CI)
0	19	0	0	0.0%	NA
1	180	27	31	17.2%	87.1% (71.1% - 94.9%)
2	274	39	45	16.4%	86.7% (73.8% - 93.7%)
3	185	32	33	17.8%	97.0% (84.7% - 99.8%)

DPSO*	Number of Subject samples tested	Investigational Positives	Comparator Positives	% Positive Rate (by Comparator)	PPA (95% CI)
4	130	18	19	14.6%	94.7% (75.4% - 99.7%)
Total	788	116**	128	16.2%	90.6% (84.3% - 94.6%)

* DPSO: Days Post Symptom Onset

**False positive results on the investigational device were excluded from the analysis.

Table 17: Clinical Performance for Detection of Influenza A

FLU A	Comparators Positives	Comparators Negatives	Total
Candidate Positives	52	9	61
Candidate Negatives	6	721	727
Total	58	730	788

Positive Percent Agreement = (52/58) = 89.7% (95% CI: 79.2% - 95.2%)

Negative Percent Agreement = (721/730) = 98.8% (95% CI: 97.7% - 99.4%)

Table 18: Clinical Performance for Detection of Influenza B

FLU B	Comparators Positives	Comparators Negatives	Total
Candidate Positives	37	2	39
Candidate Negatives	6	743	749
Total	43	745	788

Positive Percent Agreement = (37/43) = 86% (95% CI: 72.7% - 93.4%)

Negative Percent Agreement = (743/745) = 99.7% (95% CI: 99% - 99.9%)

Clinical Sensitivity:

Please refer to Section VI.C (Clinical Studies) above for the clinical validation. The PPA for the test for each analyte is as follows:

- SARS-CoV-2: 90.6% (116/128) - 95% CI: 84.3% - 94.6%
- Flu A: 89.7% (52/58) - 95% CI: 79.2% - 95.2%
- Flu B: 86% (37/43) - 95% CI: 72.7% - 93.4%

Clinical Specificity:

Please refer to Section VI.C (Clinical Studies) 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%)

2. Usability Study:

Usability study was conducted to evaluate the usability of the QuickFinder COVID-19/Flu Antigen Self Test and to evaluate the labeling and comprehension of the subject test QRI when performed by lay users in a simulated home environment. The study was conducted as part of the clinical study from October 11 – November 3, 2023. The first fifteen (15) or more subjects from the clinical study who were self-collecting and testing, and the first fifteen (15) or more subjects collecting a sample and performing the testing on another subject (child or adult), were selected

to participate in the human factors assessment. The demographics of the usability study is tabulated below.

Table 19: Demographics of the Usability Study Population

Factor	Lay-user (Tester) collection and testing (N=25)	Self-collecting and testing (N=25)	Overall (N=50)
Subject Age			
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]
Subject Age Group			
2-<14 years of age	20 (80.0%)	0 (0.0%)	20 (40.0%)
14-24 years of age	0 (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%)

The human factors assessment portion of the study was completed per the protocol. Fifty (50) subjects (25 self-collecting and testing, 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 investigational test. All subjects who participated found the instructions to be clear and easy to follow and found the sample collection easy to perform, as well as having no difficulty reading the test results. Overall, 93% of all critical tasks associated with sample collection and the running of the QuickFinder COVID-19/Flu Antigen Self Test Cassette (Swab) were performed correctly. Additionally, 88% of all non-critical tasks were performed correctly. The human factors assessment met the predetermined targets for the percentage of critical and noncritical tasks performed correctly as shown in the table below.

Table 20: Usability Study Results

Steps	Tasks performed correctly	Total number of tasks	Percentage of tasks performed correctly
Critical	370	400	93%
Non- Critical	176	200	88%
Total	546	600	91%

3. Lay User Readability Study:

All 50 subjects who participated in the human factors assessment (Usability study) also interpreted a panel of mock investigational tests with various results that reflected the test concentration levels at 1.9X and 5X the limits of detection (LoD) in a blinded and random fashion. Each panel of mock tests included 16 investigational tests with various negative and positive results for each analyte. Vision impairments encountered in study subjects are listed in the table below with their respective frequency of occurrence. The study did not include individuals with any of the following: macular degeneration, color blindness, diabetic retinopathy, cataracts, or amblyopia/strabismus. The percentage of total human factor subjects with vision impairment is 14% (7/50). The overall accuracy of the results interpreted by the lay users in the clinical study, with and without vision impairment, is 93.6% (747/798), 95% CI: 91.7%-95.1%.

Table 21: Vision Impairment of Readability Study Subjects

Type of vision impairment	# of testers	Percentage of total number of vision impaired testers (N=50)
Near sightedness only (with lens prescription)	1	2.0%
Far sightedness only (with lens prescription)	3	6.0%
Astigmatism	2	4.0%
Glaucoma	1	2.0%
More than one visual impairment condition	0	0.0%
Total testers with vision impairment	7	14%

The comparison of result interpretation data between lay users with and without visual impairment is tabulated below.

Table 22: Lay User Readability Study Results

Mock Results Type	LoD Equivalent of Line intensity	Percent Accuracy of Mock Test Interpretations	
		Subjects Without Visual Impairment (N=43)	Subjects with Visual Impairment (N=7)
Flu A+ & Flu B+	1.9 X LoD	100.0%	85.7%
COV-19+ /Flu A+	1.9 X LoD	81.4%	100.0%
COV-19+ /Flu A+ & Flu B+	1.9 X LoD	100.0%	100.0%
COV-19+ /Flu B+	1.9 X LoD	81.4%	100.0%
COV+	1.9 X LoD	100.0%	100.0%
Flu A+	1.9 X LoD	93.0%	100.0%
Flu B+	1.9 X LoD	93.0%	100.0%*
Flu A+ & Flu B+	5 X LoD	97.7%	100.0%
COV-19+ /Flu A+	5 X LoD	86.1%	100.0%
COV-19+ /Flu A+ & Flu B+	5 X LoD	100.0%	100.0%*
COV-19+ /Flu B+	5 X LoD	88.4%	85.7%
COV+	5 X LoD	95.3%	100.0%
Flu A+	5 X LoD	93.0%	100.0%
Flu B+	5 X LoD	93.0%	85.7%
Invalid (absent control line)	-	93.0%	100.0%
Negative (no analyte but control line present)	-	93.0%	100.0%
Total		93.0%	95.5%

*Results from one (1) subject was removed from the analysis due to protocol deviation (N=6).

D Clinical Cut-Off:

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

E Expected Values/Reference Range:

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

F Other Supportive Information:

1. Variant Monitoring Plan:

To determine whether the QuickFinder COVID-19/Flu Antigen Test can detect newly emerging variants, and/or to assess whether new mutations are impacting analytical sensitivity of the test performance, the sponsor provided the variant monitoring plan as described below:

- a. Monitoring SARS-CoV-2, Influenza A and B sequence data in GISAID database, WHO, NIH and other public health entities: The updated sequence data for SARS-CoV-2, influenza A and influenza B variants from GISAID database, WHO, NIH and other public health entities will be downloaded and analyzed bimonthly for variant mutations in the target proteins with an allele frequency of $\geq 5\%$.
- b. In silico analysis of antigenicity of the N proteins: In silico monitoring of antigen variations caused by changes in amino acid residues will be performed by analyzing epitopes through sequence alignments.
- c. If based on the in-silico analysis of a. and b. above the test recognized epitope/s is/are affected by new mutation/s, evaluation using virus culture fluid will be performed.
- d. If available, evaluation of new strains using clinical SARS-CoV-2, Influenza A, and Influenza B positive samples will be conducted.

2. Frequently Asked Questions:

To improve user label comprehension, the labeling includes a Frequently Asked Questions (FAQ) section. The FAQ section was created to provide users information to adequately understand the meaning of the test results and test types as well as the accuracy of the test. The concepts covered in the FAQ section include:

- Meaning of the test results
- When to re-test (e.g., following an invalid result)
- Difference between antigen and molecular test
- Accuracy of the test
- Follow-up for appropriate health management.

3. Hazard Analysis:

A comprehensive hazard analysis of the QuickFinder COVID-19/Flu Antigen Test included identification of the potential hazard, 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 errors that could adversely affect system performance were identified and mitigated through cautions in the 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 test system (see below).

4. Fail Safe Features:

The device features an internal control to minimize false results due to user error. The internal control monitors for grossly insufficient sample volume, adequate membrane wicking, and sample flow.

5. Flex Studies:

To assess the robustness and risk for false results of the test when deviating from the IFU/QRI test steps, flex studies were conducted that assessed all major aspects of the test procedure [e.g., sample volume, reading time, swab extraction time and procedure (delay in mixing and addition of the sample), sample hold time before and during processing] and variability of environmental test conditions that the test may be subjected to when in use (e.g., lighting, disturbance during use, temperature and humidity stress conditions). Testing was performed with negative 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 results demonstrated that the test system is robust and that false results can be expected to be reasonably mitigated through labeling.

VII. Proposed Labeling:

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

VIII. Conclusion:

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