510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

I Background Information:

A 510(k) Number

K252269

B Applicant

Baebies Inc

C Proprietary and Established Names

FINDER Flu A&B/SARS-CoV-2 Test

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
QOF	Class II	21 CFR 866.3981 - Device To Detect And Identify Nucleic Acid Targets In Respiratory Specimens From Microbial Agents That Cause The SARS-Cov-2 Respiratory Infection And Other Microbial Agents When In A Multi-Target Test	MI - Microbiology

II Submission/Device Overview:

A Purpose for Submission:

The purpose of this submission is to show that the FINDER Flu A&B/SARS-CoV-2 Test on the FINDER Instrument is substantially equivalent to the DiaSorin Molecular Simplexa COVID-19 & Flu A/B Direct (K220963) and to obtain clearance for the FINDER Flu A&B/SARS-CoV-2 Test.

B Measurand:

- Influenza A RNA

- Influenza B RNA
- Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) RNA

C Type of Test:

Qualitative reverse transcriptase polymerase chain reaction (RT-PCR)

III Intended Use/Indications for Use:

A Intended Use(s):
See Indications for Use below.

B Indication(s) for Use:
The FINDER Flu A&B/SARS-CoV-2 Test is an automated, multiplexed, real-time RT-PCR test performed on the FINDER instrument and is intended for the simultaneous qualitative detection and differentiation of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), influenza A, and influenza B viral nucleic acid in nasopharyngeal swab (NPS) specimens from individuals with signs and symptoms of respiratory tract infection. Clinical signs and symptoms of respiratory tract infection due to SARS-CoV-2 and influenza can be similar.

The FINDER Flu A&B/SARS-CoV-2 Test is intended for use as an aid in the differential diagnosis of SARS-CoV-2, influenza A, and/or influenza B infection if used in conjunction with other clinical and epidemiological information, and laboratory findings. SARS-CoV-2, influenza A and influenza B viral nucleic acid are generally detectable in NPS specimens during the acute phase of infection.

Positive results do not rule out co-infection with other organisms. The agent(s) detected by the FINDER Flu A&B/SARS-CoV-2 Test may not be the definite cause of disease.

Negative results do not preclude SARS-CoV-2, influenza A, and/or influenza B infection. The results of this test should not be used as the sole basis for diagnosis, treatment, or other patient management decisions.

C Special Conditions for Use Statement(s):
Rx - For Prescription Use Only

For In Vitro Diagnostic Use Only

D Special Instrument Requirements:

For use with the FINDER Instrument.

IV Device/System Characteristics:

A Device Description:

The FINDER Flu A&B/SARS-CoV-2 Test is an automated, multiplexed, real-time RT-PCR test intended for the qualitative detection of viral RNA of influenza A, influenza B, and SARS-CoV-2 viruses in NPS samples collected from individuals with signs and symptoms of respiratory tract infection.

The FINDER Flu A&B/SARS-CoV-2 Test is performed using a single-use test cartridge that contains all the reagents necessary to perform the test. The cartridge uses electrowetting-based digital microfluidics to integrate and automate all the sample and reagent handling steps required to perform the multiplexed, real-time RT-PCR test. The time to result is approximately 20 minutes from sample introduction.

The FINDER Flu A&B/SARS-CoV-2 Test is run on the FINDER Instrument. The instrument is supplied with all the hardware and software required for the electrowetting control, thermal control, and multicolor fluorescence detection capabilities that are needed to perform the test. The instrument also features a touch-screen user interface and the software application that performs the test and reports the results.

B Principle of Operation:

The FINDER Flu A&B/SARS-CoV-2 Test is performed on the FINDER instrument. NPS samples are collected in a sample collection media (FINDER RVP Buffer) provided by Baebies. To perform a test, the operator inserts the test cartridge into the instrument, follows the onscreen instructions to setup a test and then loads a 200µL sample using the provided exact-volume transfer pipette.

The instrument automatically performs all sample preparation steps once the sample is introduced on the test cartridge. The sample is lysed in a chaotropic (guanidine) lysis reagent in the FINDER RVP Buffer and is further lysed using proteinase K on the cartridge. Paramagnetic beads and a binding buffer (with ethyl alcohol) are added to the lysed sample to precipitate the nucleic acid onto the beads. The beads are then washed and eluted in a buffer.

The eluate is split into two droplets. One droplet is mixed with reagents to amplify and detect SARS-CoV-2 nucleic acid. The second droplet is mixed with reagents to amplify and detect influenza A and influenza B nucleic acid. An internal control (RPP30) is also amplified and detected in each droplet to verify that the test system is working as expected and that sufficient specimen was added.

Reverse transcription (RT) is performed on both droplets. This is followed by Polymerase Chain Reaction (PCR) by shuttling the droplets between the annealing zone and the denaturing zone on the cartridge. Reactions are performed in parallel on both droplets under the two multicolor detectors. The fluorescence is measured at each cycle and the cycle threshold (Ct) is automatically calculated for each target using software algorithms. Within droplets, multiple target reactions produce fluorescence at different wavelengths, allowing analysis of multiple viral targets in parallel.

After the test is complete, the software computes test results which are then displayed to the user and optionally printed.

C Instrument Description Information:

1. Instrument Name:
   FINDER Instrument

2. Specimen Identification:
   Specimen identification is either entered manually or via barcode

3. Specimen Sampling and Handling:
   Nasopharyngeal swab collected in FINDER RVP Buffer

4. Calibration:
   Not applicable

5. Quality Control:
   Internal Controls
   The FINDER Flu A&B/SARS-CoV-2 Test includes an internal control, which utilizes primers and probes for the human RPP30 gene. Amplification of the RPP30 control indicates that adequate sample collection and the reaction steps were completed successfully on the cartridge.

   External Controls
   External Positive and Negative controls are packaged and sold separately from the assay kit. The positive control contains non-infectious intact viral particles representative of multiple pathogens included in the respiratory panel (e.g., influenza A, influenza B, SARS-CoV-2 viruses) dried on a swab. The negative control contains human A-549 cells dried on a swab and is free from target nucleic acids. External controls may be performed to conform with internal Quality Control procedures, or with local, state, or federal regulations. The external controls were evaluated in the analytical, clinical, and flex studies.

V Substantial Equivalence Information:

A Predicate Device Name(s):
Simplexa COVID-19 & Flu A/B Direct

B Predicate 510(k) Number(s):
K220963

C Comparison with Predicate(s):

Device & Predicate Device(s):	K252269	K220963
Device Trade Name	FINDER Flu A&B/SARS-CoV-2	Simplexa COVID-19 & Flu A/B Direct

	Test	
General Device Characteristic Similarities		
Intended Use/Indications For Use	The FINDER Flu A&B/SARS-CoV-2 Test is an automated, multiplexed, real-time RT-PCR test performed on the FINDER instrument and is intended for the simultaneous qualitative detection and differentiation of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), influenza A, and influenza B viral nucleic acid in nasopharyngeal swab (NPS) specimens from individuals with signs and symptoms of respiratory tract infection. Clinical signs and symptoms of respiratory tract infection due to SARS-CoV-2 and influenza can be similar. The FINDER Flu A&B/SARS-CoV-2 Test is intended for use as an aid in the differential diagnosis of SARS-CoV-2, influenza A, and/or influenza B infection if used in conjunction with other clinical and epidemiological information, and laboratory findings. SARS-CoV-2, influenza A and influenza B viral nucleic acid are	The DiaSorin Molecular Simplexa COVID-19 & Flu A/B Direct is a real-time RT-PCR assay intended for use on the LIAISON MDX instrument for the in vitro qualitative detection and differentiation of nucleic acid from severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), influenza A virus and influenza B virus in nasopharyngeal swabs (NPS) from individuals with signs and symptoms of respiratory tract infection. The Simplexa COVID-19 & Flu A/B Direct assay is intended for use as an aid in the differential diagnosis of SARS-CoV-2, influenza A and influenza B infection. Negative results do not preclude SARS-CoV-2, influenza A or influenza B infection and should not be used as the sole basis for patient management decisions. Positive results do not rule out coinfections with other organisms. Results should be combined with clinical observations, patient history, and epidemiological information. The

	generally detectable in NPS specimens during the acute phase of infection. Positive results do not rule out co-infection with other organisms. The agent(s) detected by the FINDER Flu A&B/SARS-CoV-2 Test may not be the definite cause of disease. Negative results do not preclude SARS-CoV-2, influenza A, and/or influenza B infection. The results of this test should not be used as the sole basis for diagnosis, treatment, or other patient management decisions.	Simplexa COVID-19 & Flu A/B Direct assay is intended for use by qualified and trained clinical laboratory personnel specifically instructed and trained in the techniques of real-time PCR and in vitro diagnostic procedures.
Specimen Type	Same	Nasopharyngeal swab
Target Pathogens	Same	Influenza A, Influenza B, SARSCoV-2
Assay Results	Same	Qualitative
General Device Characteristic Differences		
Instrumentation	FINDER Instrument	LIAISON MDX
Time to Result	Approximately 20 minutes	Approximately 90 minutes
Sample Preparation	Uses magnetic-bead based solid-phase extraction chemistry for sample preparation	Extraction free chemistry

VI Standards/Guidance Documents Referenced:

- Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements. IEC 61010-1 Edition 3.1 2017-01 CONSOLIDATED VERSION
- Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements. IEC 61326-1 Edition 3.0 2020-10

- Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical electrical equipment. IEC 61326-2-6 Edition 3.0 2020-10
- Medical devices – Application of risk management to medical devices. ISO 14971 Third Edition 2019-12
- Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements. ISO 15223-1 Fourth Edition 2021-07
- Evaluation of Precision of Quality Measurement Procedures; Approved Guideline – Third Edition. CLSI EP05-A3 (Reaffirmed: September 2019)
- Evaluation of Stability of In Vitro Medical Laboratory Test Reagents. CLSI EP25 2nd Edition.

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

Precision

Within-laboratory precision of the FINDER Flu A&B/SARS-CoV-2 Test was evaluated at a single site using a panel of three samples: a positive sample co-spiked with viral materials at 2x Limit of Detection (LoD), a positive sample co-spiked with viral materials at 5x LoD, and a negative sample. Specimens were prepared in pooled negative NPS media collected in FINDER RVP Buffer. The study was conducted with two operators over the course of 12 non-consecutive days. Two replicates of each panel member were tested in two sessions per testing day, for a total of 96 replicates of each sample (1 site x 2 operators x 12 days x 2 sessions per day x 2 replicates per session). Three cartridge lots were used during the study. Results are summarized in **Tables 1-2**. All moderate positive (5x LoD) runs were 100% positive for all three assay targets. All low positive (2x LoD) runs were ≥99% positive for all three assay targets. One false positive result for SARS-CoV-2 was observed. The results of the study demonstrate acceptable test variability.

Table 1: Precision Study Results

Panel Member	Target	Strain	N Positive/N Valid Tested	% Agreement with Expected Results (95% CI)
Negative	Influenza A	NA	0/96	100.0% (96.2%-100.0%)
	Influenza B	NA	0/96	100.0% (96.2%-100.0%)
	SARS-COV-2	NA	1/96	99.0% (94.3%-99.8%)
Low Positive (2x LoD)	Influenza A	H3N2/A/Switzerland/ 9715293/13	95/96	99.0% (94.3%-99.8%)
	Influenza B	B/Brisbane/33/08	95/96	99.0% (94.3%-99.8%)
	SARS-COV-2	USA/MD-HP24556/2022	96/96	100.0% (96.2%-100.0%)
	Influenza A	H3N2/A/Switzerland/ 9715293/13	96/96	100.0% (96.2%-100.0%)

Moderate Positive (5x LoD)	Influenza B	B/Brisbane/33/08	96/96	100.0% (96.2%-100.0%)
	SARS-COV-2	USA/MD-HP24556/2022	96/96	100.0% (96.2%-100.0%)

Table 2: Precision Study – Ct Analysis Results

Panel Member	Target	n	Mean Ct	Repeatability		Between Instruments		Between Days		Between Lots		Reproducibility	
				SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)
Low Positive (2x LoD)	Influenza A	95	29.7	1.74	5.9	0.16	0.5	0.35	1.2	0.43	1.4	1.83	6.2
	Influenza B	95	28.5	1.64	5.7	0.53	1.9	0.38	1.3	0.00	0.0	1.76	6.2
	SARS-COV-2	96	30.5	0.89	2.9	0.00	0.0	0.10	0.3	0.19	0.6	0.92	3.0
Moderate Positive (5x LoD)	Influenza A	96	27.9	1.15	4.1	0.28	1.0	0.00	0.0	0.32	1.1	1.23	4.4
	Influenza B	96	27.6	1.20	4.4	0.25	0.9	0.00	0.0	0.00	0.0	1.23	4.5
	SARS-COV-2	96	28.9	1.05	3.6	0.14	0.5	0.00	0.0	0.34	1.2	1.11	3.8

SD = standard deviation; CV(%) = percent coefficient of variation.; n = total number of samples

Reproducibility

Assay reproducibility of the FINDER Flu A&B/SARS-CoV-2 Test was evaluated at three US sites using one negative and two positive panel members with one lot of assay reagents and three instruments. Each site tested over five days with two operators, and three replicates for each panel for a total of 90 replicates per panel member. Three instruments at each site were used. A negative panel member was created using pooled negative NPS media (negative NPS specimens collected in FINDER RVP Buffer). Positive panel members were created by spiking inactivated (SARS-CoV-2) and live viral targets at low positive (2x LoD) concentrations and moderate positive (5x LoD) concentrations into pooled negative NPS media. Results are summarized in **Table 3 – 4.** All low positive (2x LoD) and all moderate positive (5x LoD) sample runs were positive for all assay targets (100% positive agreement). All negative sample runs were negative for all targets (100% negative agreement). The results of the study demonstrate acceptable test reproducibility.

Table 3: Reproducibility Study Results

Analyte	Panel Description	% Agreement with Expected Results (n Agreement/N Valid Tested) (95% CI)			
		Site 1	Site 2	Site 3	Overall
Influenza A (H3N2/A/Switzerland/9715293/13)	Moderate Positive (5x LoD)	100% (30/30) (88.7-100.0)	100% (30/30) (88.7-100.0)	100% (30/30) (88.7-100.0)	100% (90/90) (95.9-100.0)
	Low Positive (2x LoD)	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)

		(88.7-100.0)	(88.7-100.0)	(88.7-100.0)	(95.9-100.0)
	Negative	100% (30/30) (88.7-100.0)	100% (30/30) (88.7-100.0)	100% (30/30) (88.7-100.0)	100% (90/90) (95.9-100.0)
Influenza B (B/Brisbane/33/08)	Moderate Positive (5x LoD)	100% (30/30) (88.7-100.0)	100% (30/30) (88.7-100.0)	100% (30/30) (88.7-100.0)	100% (90/90) (95.9-100.0)
	Low Positive (2x LoD)	100% (30/30) (88.7-100.0)	100% (30/30) (88.7-100.0)	100% (30/30) (88.7-100.0)	100% (90/90) (95.9-100.0)
	Negative	100% (30/30) (88.7-100.0)	100% (30/30) (88.7-100.0)	100% (30/30) (88.7-100.0)	100% (90/90) (95.9-100.0)
SARS-CoV-2 (USA/MD-HP24556/2022)	Moderate Positive (5x LoD)	100% (30/30) (88.7-100.0)	100% (30/30) (88.7-100.0)	100% (30/30) (88.7-100.0)	100% (90/90) (95.9-100.0)
	Low Positive (2x LoD)	100% (30/30) (88.7-100.0)	100% (30/30) (88.7-100.0)	100% (30/30) (88.7-100.0)	100% (90/90) (95.9-100.0)
	Negative	100% (30/30) (88.7-100.0)	100% (30/30) (88.7-100.0)	100% (30/30) (88.7-100.0)	100% (90/90) (95.9-100.0)

Table 4: Reproducibility Study – Ct Analysis Results

Panel Member	Target	n	Mean Ct	Repeatability		Between Users		Between Days		Between Sites		Reproducibility	
				SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)
Low Positive (2x LoD)	Influenza A	90	29.2	0.997	3.4	0.119	0.4	0.000	0.0	0.221	0.8	1.029	3.5
	Influenza B	90	28.1	0.844	3.0	0.000	0.0	0.000	0.0	0.000	0.0	0.844	3.0
	SARS-COV-2	90	30.0	0.501	1.7	0.464	1.5	0.190	0.6	0.249	0.8	0.751	2.5
Moderate Positive (5x LoD)	Influenza A	90	27.5	1.786	6.5	0.797	2.9	0.000	0.0	0.547	2.0	2.031	7.4
	Influenza B	90	27.4	0.929	3.4	0.000	0.0	0.000	0.0	0.357	1.3	0.996	3.6
	SARS-COV-2	90	28.5	0.572	2.0	0.473	1.7	0.130	0.5	0.496	1.7	0.902	3.2

SD = standard deviation; CV(%) = percent coefficient of variation.; n = total number of samples

2. Linearity:

Not applicable.

3. Analytical Specificity/Interference:

Wet Testing

This study was performed to determine the analytical reactivity of the FINDER Flu A&B/SARS-CoV-2 Test with clinically relevant strains of influenza A, influenza B, and SARS-CoV-2 virus. Samples were created by spiking viral strains at concentrations of 3x LoD in pooled negative NPS samples collected in FINDER RVP Buffer. Samples that were not detected in all replicates were tested at higher concentrations, increasing by a factor of 3x until all three replicates were detected. Results from the lowest concentration that achieved 100% detection are shown in **Table 5** below. The results from this study demonstrate that the FINDER Flu A&B/SARS-CoV-2 Test is capable of detecting multiple strains of influenza A, influenza B and SARS-CoV-2 virus at the concentrations tested.

Table 5: Inclusivity Wet Testing Results

Analyte	Subtype	Strain/Isolate Name	Test Concentration ($TCID_{50}$/mL)
Influenza A	H1N1	A/New Caledonia/20/1999	2.01
		A/New Jersey/8/76	18.09 ($CEID_{50}$/mL)
		Brisbane/59/2007	2.01
		Pdm Netherlands/2629/2009	2.01
		pdm NY/01/09	2.01
		Solomon Islands/03/06	2.01
		pdm Victoria/2570/19	2.01
		Michigan/45/15	2.01
		Guangdong-Maonan/SWL1536/19	6.03
		Taiwan/42/06	6.03
		pdm California/07/09	2.01
		pdm Mexico/4108/09	54.27
		Singapore/63/04	54.27
	H3N2	Wisconsin/67/2005	9.072
		Brisbane/10/2007	9.072
		Victoria/3/1975	27.216 ($CEID_{50}$/mL)
		Victoria/361/2011	9.072
		A/Port Chalmers/1/73	9.072 ($CEID_{50}$/mL)
		Texas/50/2012	9.072
		Kansas/14/17	9.072
		Hong Kong/2671/19	9.072
		Singapore/INFIMH-16-0019/16	9.072
		Darwin/6/21	9.072
		Perth/16/09	9.072
		South Australia/55/14	9.072
		Stockholm/6/14	9.072
	H5N1[a]	A/white-tailed eagle/Japan/OU-1/2022	5400 (cp/mL)
	H7N9[a]	A/Shanghai/4664T/2013	59000 (cp/mL)
Influenza B	Victoria	B/Hong Kong/5/72	109.35 ($CEID_{50}$/mL)
		2506/Malaysia/2004	0.15
		1/Ohio/2005	109.35 ($CEID_{50}$/mL)
		Alabama/2/17	0.45
		Colorado/06/17	0.15
		Austria/1359417/21	0.15
		B/New York/1056/2003	1.35

	Yamagata	Florida/07/04	0.45
		Florida/04/06	0.45
		Wisconsin/1/10	0.45
		Massachusetts/2/12	1.35
		Utah/9/14	1.45
SARS-CoV-2	A	Hong Kong/VM20001061/2020	0.1125
	A	USA-WA1/2020	1.0125
	GISAID Clade O	Italy-INMI1	3.0375
	B.1	USA/NY-Wadsworth-103677-01/2020	0.1125
	Beta B.1.351	South_Africa/KRISP-K005325/2020	0.1125
	Delta B.1.617.2	USA/PHC658/2021	0.3375
	Zeta P.2	NY-Wadsworth-21006055-01/2021	0.3375
	Iota B.1.526	NY-Wadsworth-21018781-01/2021	1.0125
	Omicron XBB	USA/CA-Stanford-109_S21/2022	1.0125
	Gamma P.1	Japan/TY7-503/2021	0.1125
	Kappa B.1.617.1	USA/CA-Stanford-15_S02/2021	0.3375
	Omicron BQ.1.1	USA/MD-HP38861/2022	0.1125

$CEID_{50}$/mL = median chicken embryo infectious dose/mL; cp/mL = copies/mL
[a] Synthetic RNA

In Silico Assessment

Inclusivity of the FINDER Flu A&B/SARS-CoV-2 Test was also evaluated using *in-silico* analysis of the assay primer and probes with sequences available in GISAID and NCBI databases. SARS-CoV-2 primer and probes were evaluated against 5,740,183 SARS-CoV-2 genomes in the GISAID database submitted between November 2019 and June 2024 and 100,101 SARS-CoV-2 genomes in the NCBI database submitted between July 2024 and May 2025. Results of the *in-silico* analysis predict that the FINDER Flu A&B/SARS-CoV-2 Test will detect greater than 99.9% of SARS-CoV-2 variants.

Cross Reactivity/Microbial Interference

This study evaluated the cross-reactivity and microbial interference for the FINDER Flu A&B/SARS-CoV-2 Test in the presence of related pathogens, high prevalence disease agents, and normal or pathogenic flora reasonably likely to be present in a clinical NPS sample. A total of 35 pools of microorganisms were tested, microorganisms were added to pooled clinical negative NPS matrix in FINDER RVP Buffer, for final concentrations of 10^5 units/mL for viruses and fungi, 10^6 units/mL for bacteria, and 10% v/v of pooled human nasal wash. To evaluate cross-reactivity, each panel member was evaluated in triplicate in the absence of the target organism. To evaluate microbial interference, each panel was tested in triplicate in the presence of 3x LoD of each test analyte. The organisms evaluated are shown below in **Table 6**. No cross-reactivity or microbial interference was observed at the concentrations tested.

Table 6: Organisms Evaluated in Cross-Reactivity and Microbial Interference Study by Wet-Testing

Viruses	Concentration[1]	Bacteria/Fungi	Concentration[1]
Adenovirus type 1	$1x10^5$ $TCID_{50}$/mL	*Aspergillus flavus*	$1x10^6$ CFU/mL
Adenovirus type 7	$1x10^5$ $TCID_{50}$/mL	*Bordetella parapertussis*	$1x10^6$ CFU/mL
Adenovirus type 4	$1x10^5$ $TCID_{50}$/mL	*Bordetella pertussis*	$1x10^6$ CFU/mL
Cytomegalovirus	$4.21x10^4$ $TCID_{50}$/mL[a]	*Chlamydia pneumoniae*	$1x10^6$ CFU/mL

Herpes Simplex Virus Type 1	$1x10^5$ $TCID_{50}$/mL	*Corynebacterium amycolatum*	$1x10^6$ CFU/mL
Varicella Zoster Virus	$1x10^5$ cp/mL[b]	*Escherichia coli*	$1x10^6$ CFU/mL
Epstein Barr Virus	$1x10^5$ cp/mL[b]	*Fusobacterium necrophorum*	$1x10^6$ CFU/mL
Enterovirus (Coxsackie)	$1x10^5$ $TCID_{50}$/mL	*Haemophilus influenzae*	$1x10^6$ CFU/mL
Enterovirus (echovirus)	$1x10^5$ $TCID_{50}$/mL	*Lactobacillus ORIS*	$1x10^6$ CFU/mL
Parainfluenza virus 1	$1x10^5$ $TCID_{50}$/mL	*Legionella pneumophila*	$1x10^6$ CFU/mL
Parainfluenza virus 2	$1x10^5$ $TCID_{50}$/mL	*Moraxella catarrhalis*	$1x10^6$ CFU/mL
Parainfluenza virus 3	$1x10^5$ $TCID_{50}$/mL	*Mycobacterium tuberculosis* avirulent	$1x10^4$ CFU/mL[d]
Parainfluenza virus 4	$1x10^5$ $TCID_{50}$/mL	*Mycoplasma pneumoniae*	$1x10^6$ CFU/mL
Human coronavirus HKU1	$1x10^6$ cp/mL	*Mycoplasma genitalium*	$1.85x10^5$ CFU/mL[a]
Human coronavirus 229E	$4.17x10^4$ $TCID_{50}$/mL[a]	*Neisseria meningitides*	$1x10^6$ CFU/mL
Human coronavirus OC43	$4.17x10^4$ $TCID_{50}$/mL[a]	*Neisseria cinerea*	$1x10^6$ CFU/mL
Human coronavirus NL63	$3.55x10^4$ $TCID_{50}$/mL[a]	*Pneumocystis jirovecii (PJP)*	$1x10^6$ CFU/mL
Mumps	$1x10^5$ $TCID_{50}$/mL	*Pseudomonas aeruginosa*	$1x10^6$ CFU/mL
Measles	$1x10^5$ $TCID_{50}$/mL	*Staphylococcus aureus*	$1x10^6$ CFU/mL
Human Metapneumovirus A1	$1.41x10^4$ $TCID_{50}$/mL[a]	*Staphylococcus epidermis*	$1x10^6$ CFU/mL
Human Metapneumovirus A2	$3.55x10^4$ $TCID_{50}$/mL[a]	*Streptococcus pneumoniae*	$1x10^6$ CFU/mL
Rhinovirus Type 1A	$1.41x10^4$ $TCID_{50}$/mL[a]	*Streptococcus pyogenes*	$1x10^6$ CFU/mL
SARS-coronavirus[2]	$1x10^4$ cp/mL[d]	*Streptococcus salivaris*	$1x10^6$ CFU/mL
MERS-coronavirus	$1x10^4$ $TCID_{50}$/mL	*Candida albicans*	$1x10^6$ CFU/mL
Respiratory Syncytial Virus	$1x10^5$ $TCID_{50}$/mL	Pooled human nasal wash	10% v/v
Human genomic DNA	$3.71x10^6$ cp/mL[c]		

$TCID_{50}$ = Median Tissue Culture Infectious Dose; cp/mL = copies/mL

[a] The concentrations of some components were reduced to the values shown in the table to maintain a ≥90% concentration of matrix.

[b] Varicella Zoster Virus and Epstein Barr Virus were inadvertently tested at $1x10^5$ cp/mL rather than $1x10^6$ cp/mL.

[c] Human genomic DNA was inadvertently tested at $3.71x10^6$ cp/mL rather than the intended 10^4 cp/mL.

[d] Mycobacterium tuberculosis avirulent and SARS-CoV-1 were inadvertently tested at $1x10^4$ cp/mL rather than the intended $1x10^6$ cp/mL.

Interfering Substances

This study evaluated the performance of the FINDER Flu A&B/SARS-CoV-2 Test in the presence of potentially interfering endogenous and exogenous substances that may be commonly found in a NPS sample. The assay was evaluated with potentially interfering substances in the presence and absence of the target analyte. For analyte negative samples, potential interfering substances were added to pooled clinical negative NPS matrix in FINDER RVP Buffer. For analyte positive samples, potentially interfering substances were spiked into analyte positive samples at concentrations of 3x LoD. All samples were tested in triplicate. The concentration of each substance tested can be found in **Table 8**. Interference was found at the initial testing concentration for the following substances: Zicam,

Budesonide, Nasacort, Fluticasone, and Nasonex. Testing with these substances were repeated at a lower concentration until 100% detection was obtained.

Table 8: Interfering Substance and Concentrations Tested

Potentially Interfering Substance Category	Substance/Active Ingredient	Concentration Tested with No Interference
Biologicals	Mucin	5 mg/ml
	Whole Blood (capillary)	2% (v/v)
	Leukocytes (Human Buffy Coat)	1% (v/v)
Nasal spray/drops	Oxymetazoline (Afrin)	5% (v/v)
	Saline nasal spray	10% (v/v)
	Phenylephrine (1%)	10% (v/v)
	Zinc (Zinc Acetate Dihydrate)	1 mg/mL
Nasal gel	Luffa opperculata, sulfur (Zicam)	2.5% (v/v)*
Throat lozenge	Benzocaine Menthol (Cepacol)	5% (v/v)
Antiviral drugs	Zanamivir	5 mg/mL
	Oseltamivir	7.5 mg/mL
Antimicrobial, systemic	Tobramycin	4 ug/mL
Antibiotic nasal ointment	Mupirocin	5 mg/mL
Nasal corticosteroids	Beclomethasone	2 mg/mL
	Dexamethasone	1.5 mg/mL
	Flunisolide	2 mg/mL
	Budesonide, 32 mcg/spray	0.5% (v/v)*
	Triamcinolone (Nasacort)	0.63% (v/v)*
	Fluticasone	1.25% (v/v)*
	Mometasone (Nasonex)	1.25% (v/v)*
Homeopathic allergy relief	Histaminum hydrochloricum	10 mg/mL
Solvent controls	DMSO	10% (v/v)
	Ethanol	10% (v/v)
	0.1N NaOH	10% (v/v)

* Interference was observed in these substances. The highest concentration at which no interference was observed is presented in this table.

Competitive Interference

The purpose of this study was to evaluate potential competitive interference between target analytes of the FINDER Flu A&B/SARS-CoV-2 Test. Six panels were used for this study, each consisting of one analyte at low concentrations (3x LoD) and one analyte at high concentrations of $1x10^5$ $TCID_{50}$/mL added to pooled negative NPS matrix in FINDER RVP Buffer. Each panel was tested in replicates of three. The viral strains used to prepare the panels and the results of the study are shown in **Table 9 and Table 10**. No competitive interference was observed for all analytes prepared at 3x LoD.

Table 9: Viral Strains and Concentrations Used in the Competitive Interference Study

Viral Target	Level	Strains Tested	Concentration Tested ($TCID_{50}$/mL)
SARS-CoV-2	Low	USA/MD-HP24556/2022	0.113 $TCID_{50}$/mL
	High	USA/CA-Stanford-109_S21/2022	$1x10^5$ $TCID_{50}$/mL
Influenza A	Low	A/Switzerland/9715293/13	9.072 $TCID_{50}$/mL
	High	A/Switzerland/9715293/13	$1x10^5$ $TCID_{50}$/mL
Influenza B	Low	B/Brisbane/33/08	0.150 $TCID_{50}$/mL
	High	B/New York/1056/2003	$1x10^5$ $TCID_{50}$/mL

Table 10: Competitive Interference of the FINDER Flu A&B/SARS-CoV-2 Test

Target Analyte	Interferent	Interferent Conc.	Flu A Detection[a] Rate	Flu A Mean CT	Flu B Detection[a] Rate	Flu B Mean CT	SARS-CoV-2 Detection[a] Rate	SARS-CoV-2 Mean CT
Influenza A	Influenza B	$1x10^5$ $TCID_{50}$/mL	3/3	29.3	3/3	17.4	NA	NA
	SARS-CoV-2	$1x10^5$ $TCID_{50}$/mL	3/3	29.0	NA	NA	3/3	13.7
Influenza B	Influenza A	$1x10^5$ $TCID_{50}$/mL	3/3	14.2	3/3	30.8	NA	NA
	SARS-CoV-2	$1x10^5$ $TCID_{50}$/mL	NA	NA	3/3	28.3	3/3	14.0
SARS-CoV-2	Influenza A	$1x10^5$ $TCID_{50}$/mL	3/3	13.5	NA	NA	3/3	30.2
	Influenza B	$1x10^5$ $TCID_{50}$/mL	NA	NA	3/3	17.0	3/3	28.4

[a] Detection Rate is defined as # of positive tests/# valid tests
NA = Not applicable

4. Assay Reportable Range:
   Not applicable, this is a qualitative assay.

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):
   a. Controls
      See Section **IV.C.5.Quality Control**.

   b. Sample Stability
      The purpose of this study was to demonstrate the stability of NPS specimens collected in FINDER RVP Buffer when stored under recommended temperature conditions and durations for the FINDER Flu A&B/SARS-CoV-2 Test. Study results support that NPS samples in FINDER RVP Buffer are stable at 2-8°C for up to 72 hours and at 15-30°C for up to 5 hours.

   c. Freeze/Thaw Stability
      The purpose of this study was to demonstrate the effects of freeze/thaw cycles on NPS specimens collected in FINDER RVP Buffer. The results of this study support that NPS samples collected in FINDER RVP Buffer are stable when frozen at -80°C and undergo up to two freeze/thaw cycles.

   d. Kit Stability
      The purpose of this study was to evaluate the storage and in-use stability of the FINDER Flu A&B/SARS-CoV-2 Test. The study data supports the storage and in-use stability storage conditions of the FINDER Flu A&B/SARS-CoV-2 Test which are listed below:
      - FINDER Flu A&B/SARS-CoV-2 Test is stable for 6 months when stored at 2-8°C.

- After removing from refrigerated storage, FINDER Flu A&B/SARS-CoV-2 Test may be stored at room temperature for up to two weeks.

6. Detection Limit:
The Limit of Detection (LoD) for the FINDER Flu A&B/SARS-CoV-2 Test was determined by spiking inactivated SARS-CoV-2, and live influenza A and influenza B viruses into pooled negative NPS matrix in FINDER RVP Buffer. To determine the preliminary LoD, three-fold dilutions of each target virus were tested with four replicates each for three reagent lots. The lowest concentration for which all four replicates were detected was considered the preliminary LoD. The LoD was confirmed by testing 20 replicates at the preliminary LoD. If fewer than 19/20 replicates or 20 replicates were detected, three-fold dilutions were prepared above or below the tested concentration until 19/20 positive replicates was detected. The LoD was determined as the lowest concentration at which greater than or equal 95% of all replicates tested positive, as summarized in **Table 13**.

Table 13: Confirmatory Limit of Detection Study Results

Target	Strain	LoD ($TCID_{50}$/mL)	Detection Rate (n Positive/n Tested)	Average Ct
Influenza A	A/Switzerland/9715293/13	1.008	16/20	34.4
		3.024	20/20	30.5
	H1N1, Brisbane/02/18	0.670	19/20	31.9
Influenza B	Victoria, B/Brisbane/33/08	0.050	19/20	28.9
	Phuket/3073/13	0.150	19/20	28.9
SARS-CoV-2	USA/MD-HP24556/2022	0.013	15/20	34.2
		0.038	20/20	32.4
	England/02/2020	2.57E+05	2/20	36.4
		7.70E+05	15/20	33.4
		2.31E+06	19/20	32.1

The LoD for co-analyte spiked samples was also evaluated and shown to be equivalent to single analyte spiked samples.

7. Assay Cut-Off:
The FINDER Instrument has two multi-color fluorescence detectors and an algorithm that is utilized for detection of the targets. The Ct threshold for the test is 42, same as the total number of PCR cycles. If fluorescence signal generated at each PCR cycle satisfied the algorithm criteria before completion of all 42 PCR cycles, a 'Detected" result will be reported. "Not Detected" targets can only be reported after all 42 PCR cycles are completed and analyzed. An invalid result is generated when the assay signals do not meet the predefined quality criteria required for a valid result interpretation.

8. Accuracy (Instrument):
Not applicable

9. Carry-Over:
The purpose of this study was to determine the carryover contamination rate of the FINDER Flu A&B/SARS-CoV-2 Test. The carryover contamination rate was established by testing

high titer panels of influenza A, influenza B, and SARS-CoV-2 viruses alternating with negative panels. High titer panels were prepared by spiking inactivated SARS-CoV-2 and live influenza A and influenza B viruses into pooled negative NPS samples collected in FINDER RVP Buffer. Negative panels consisted of pooled negative NPS samples in FINDER RVP Buffer. Testing was conducted on five FINDER instruments with one lot of FINDER Flu A&B/SARS-CoV-2 Test reagents. The high titer positive and negative samples were tested in alternating runs for a total of eight replicates of each per instrument, and 40 runs total per sample. Two instruments started the first round of testing with a positive sample, and three instruments started the first round with a negative sample. All high titer positive panel samples tested positive for all analytes and all negative samples tested negative for all analytes and no carry-over contamination was observed.

B Comparison Studies:

1. Method Comparison with Predicate Device:
   Not applicable

2. Matrix Comparison:
   The FINDER Flu A&B/SARS-CoV-2 Test is to be used with the FINDER RVP Buffer only. No additional collection devices have been evaluated for use with the device.

C Clinical Studies:

1. Clinical Sensitivity:
   The clinical performance of the FINDER Flu A&B/SARS-CoV-2 Test was evaluated in a prospective clinical study using NPS in FINDER RVP Buffer collected from individuals with signs and symptoms of upper respiratory viral infection. Testing of clinical samples was performed with the FINDER Flu A&B/SARS-CoV-2 Test in six (6) geographically distinct CLIA waived healthcare facilities (e.g. urgent care centers and primary care/outpatient clinics) located in the US with 12 untrained test operators.

   A total of 559 NPS specimens were enrolled in the prospective clinical study from February 2025 to April 2025. Thirty-two (32) specimens were excluded for the performance analysis of influenza A and influenza B virus and 33 specimens were excluded for the performance analysis of SARS-CoV-2 virus. Of the excluded samples, six (6) samples were excluded due to a delay in FINDER testing, one (1) for the lack of a valid comparator result (SARS-CoV-2 only), nineteen (19) for the lack of valid FINDER Flu A&B/SARS-CoV-2 Test results, four (4) for improper specimen collection, and three (3) for inadequate sample volume for comparator testing. The performance of the FINDER Flu A&B/SARS-CoV-2 Test was evaluated by comparing the test results with those from an FDA-cleared RT-PCR assay. The demographics and performance of the FINDER Flu A&B/SARS-CoV-2 Test observed in the clinical study are summarized in **Table 14** and **Table 15** below.

   The initial invalid rate for the FINDER Flu A&B/SARS-CoV-2 Test was 10.8% (59/546), and the final invalid rate was 3.5% (19/546) after retesting.

Table 14: Demographic Summary for the FINDER Flu A&B/SARS-CoV-2 Test Prospective Clinical Evaluation

Prospectively Collected Clinical Samples	N=559	
Gender		
Female	343	61.4%
Male	216	38.6
Age Group (Years)		
≤5 years	24	4.3%
6-21 years	118	21.1%
22-59 years	377	67.4%
60+ years	40	7.2%
Race		
Asian	7	1.3%
Black or African American	137	24.5%
Black or African American, American Indian or Alaska Native	1	0.2%
Black or African American, Hispanic	6	1.1%
Hispanic	36	6.4%
White	275	49.2%
White, Asian	4	0.7%
White, Black or African American	4	0.7%
While, Black or African American, American Indian or Alaska Native	1	0.2%
White, Hispanic	88	15.7%

Table 15: FINDER Flu A&B/SARS-CoV-2 Test Prospective Clinical Performance Summary for NPS

Analyte					Positive Percent Agreement			Negative Percent Agreement		
	TP	FP	FN	TN	TP/ (TP+FN)	%	95% CI	TN/ (TN+FP)	%	95% CI
SARS-CoV-2	40	1	1	484	40/41	97.6	87.4-99.6	484/485	99.8	98.8-100.0
Influenza A	62	13	3	449	62/65	95.4	87.3-98.4	449/462	97.2	95.2-98.3
Influenza B	24	3	1	499	24/25	96.0	80.5-99.3	499/502	99.4	98.3-99.8

2. Clinical Specificity:
   See Clinical Sensitivity above

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):
   Not applicable

D Clinical Cut-Off:

Not applicable

E Expected Values/Reference Range:

The FINDER Flu A&B/SARS-CoV-2 Test prospective clinical study included a total of 527 evaluable prospectively collected NPS specimens. The number and percentage of cases positive for influenza A, influenza B, and SARS-CoV-2 as determined by the FINDER Flu A&B/SARS-CoV-2 Test are presented below in **Tables 16** and **17**.

Table 16: FINDER Flu A&B/SARS-CoV-2 Test Expected values for NPS Specimens by Age

Age	N(%)	Positivity Rate (N Positive/N Tested)		
		Influenza A	Influenza B	SARS-CoV-2
1-5	24 (4.6%)	12.5% (3/24)	4.2% (1/24)	0.0% (0/24)
6-21	112 (21.2%)	14.3% (16/112)	11.6% (13/112)	5.4% (6/112)
22-59	353 (67.0%)	11.3% (40/353)	2.8% (10/353)	8.8% (31/352)[a]
≥60	38 (7.2%)	15.8% (6/38)	2.6% (1/38)	10.5% (4/38)
Total	527 (100.0%)	12.3% (65/527)	4.7% (25/527)	7.8% (41/526)[a]

N = Total number of samples

[a] one sample did not have a valid SARS-CoV-2 Result on the comparator device.

Table 17: FINDER Flu A&B/SARS-CoV-2 Test Expected values for NPS Specimens by Collection Site

Site	Influenza A		Influenza B		SARS-CoV-2	
	# of positives	% positivity	# of positives	% positivity	# of positives	% positivity
Site 1	10	9.2 (10/109)	4	3.7 (4/109)	19	17.4 (19/109)
Site 2	4	6.9 (4/58)	7	12.1 (7/58)	0	0.0 (0/58)
Site 3	15	17.2 (15/87)	5	5.7 (5/87)	8	9.3 (8/86)[a]
Site 4	7	8.4 (7/83)	3	3.6 (3/83)	2	2.4 (2/83)
Site 5	16	16.2 (16/99)	2	2.0 (2/99)	4	4.0 (4/99)
Site 6	13	14.3 (13/91)	4	4.4 (4/91)	8	8.8 (8/91)
Total	65	12.3 (65/528)	25	4.7 (25/528)	41	7.8 (41/527)[a]

[a] one sample did not have a valid SARS-CoV-2 Result on the comparator device.

F Other Supportive Instrument Performance Characteristics Data:

Not applicable.

VIII Proposed Labeling:

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

IX Conclusion:

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

The submitted information in this CLIA waiver application supports a CLIA waiver approval decision.