March 30, 2026

Baebies Inc
Vijay Srinivasan
Official Correspondent
25 Alexandria Way
Durham, North Carolina 27519

Re: K252269
Trade/Device Name: FINDER Flu A&B/SARS-CoV-2 Test
Regulation Number: 21 CFR 866.3981
Regulation Name: 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
Regulatory Class: Class II
Product Code: QOF
Dated: July 21, 2025
Received: July 21, 2025

Dear Vijay Srinivasan:

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

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

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

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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

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

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

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

the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

JOSEPH BRIGGS -S

Joseph Briggs, Ph.D
Deputy Division Director
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252269

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

Indications for Use *(Describe)*
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.

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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1. Administrative Information

A. Applicant: Baebies Inc

B. Address: 25 Alexandria Way, Durham NC 27703

C. Phone Number: 919-891-0432

D. Contact Person: Vijay Srinivasan

E. Date Prepared: March 23, 2026

2. Submission/Device Overview

A. Name of Device: FINDER Flu A&B/SARS-CoV-2 Test

B. Common Name: Same

C. Classification name: Multi-Target Respiratory Specimen Nucleic Acid Test Including Sars-Cov-2 And Other Microbial Agents

D. Regulatory Classification: Class II

E. Regulation: 21 CFR 866.3981

F. Primary Product Code: QOF

3. 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 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.

4. Device/System Characteristics

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 from influenza A, influenza B, and severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), from nasopharyngeal samples.

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 required 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.

The FINDER Flu A&B/SARS-CoV-2 Test commences with the collection of a nasopharyngeal swab 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. The second droplet is mixed with reagents to amplify and detect influenza A and influenza B. 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 an annealing zone and 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.

5. Substantial Equivalence Information

A. Predicate Device Name(s): DiaSorin Molecular Simplexa COVID-19 & Flu A/B Direct
B. Predicate 510(k) Number(s): K220963
C. Comparison with Predicate(s):

Device & Predicate Device	**Subject Device**	**K220963**
Device Trade Name	FINDER Flu A&B/SARS-CoV-2 Test	Simplexa COVID-19 & Flu A/B Direct
General Device Characteristic Similarities	**Subject Device**	**K220963**
Product Code	Same	QOF
Regulation Number	Same	21 CFR 866.3981
Prescription Use Only	Same	Yes
Device Technology	Same	Real-time Reverse Transcription Polymerase Chain Reaction (RTPCR)
Detection	Same	Qualitative
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 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	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 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

	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.	PCR and in vitro diagnostic procedures.
Specimen Type	Same	Nasopharyngeal swab
Target Pathogens	Same	Influenza A, Influenza B, SARS-CoV-2
Assay Results	Same	Qualitative
Sample answer system	Same	Automated
General Device Characteristic Differences	**Subject Device**	**(K220963)**
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

6. Performance Characteristics

6.1. Expected Values

Performance evaluation of the FINDER Flu A&B/SARS-CoV-2 included 527 prospectively collected nasopharyngeal specimens. The number and percentages of cases positive for influenza A, influenza B, and SARS-CoV-2 as determined by an FDA cleared molecular diagnostic comparator device are shown by age in Table 1 and by site in Table 2 below.

Table 1: Positivity by Age

Age	N (%)	Positivity Rate (Number Positive / Number 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[1])
≥ 60	38 (7.2%)	15.8% (6/38)	2.6% (1/38)	10.5% (4/38)
Total	527 (100%)	**12.3% (65/527)**	**4.7% (25/527)**	**7.8% (41/526[1])**

[1] – one sample did not have a valid SARS-COV-2 result on the comparator device

Table 2: Positivity by Site

Site	Influenza A		Influenza B		SARS-CoV-2	
	# of positives	% positivity	# of positives	% positivity	# of positives	% positivity
AL	10	9.2% (10/109)	4	3.7% (4/109)	19	17.4% (19/109)
CT	4	6.9% (4/58)	7	12.1% (7/58)	0	0.0% (0/58)
OH Site 1	15	17.2% (15/87)	5	5.7% (5/87)	8	9.3% (8/86)
TX	7	8.4% (7/83)	3	3.6% (3/83)	2	2.4% (2/83)
LA	16	16.2% (16/99)	2	2.0% (2/99)	4	4.0% (4/99)
OH Site 2	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)

6.2. Clinical Performance

Performance of the FINDER Flu A&B/SARS-CoV-2 Test was characterized during the 2024–2025 respiratory virus season. The study was conducted across 6 geographically diverse POC investigational sites within the United States with testing performed by CLIA Waived operators. Specimens were collected from subjects exhibiting signs and symptoms associated with respiratory infection. The performance of the FINDER Flu A&B/SARS-CoV-2 Test was compared to FDA cleared molecular diagnostic tests.

A total of 559 prospectively collected nasopharyngeal specimens were collected. Demographic data from the individuals from whom specimens were collected are presented in Table 3. Specimens were excluded from the data analysis due to delay in FINDER testing (n=6), lack of a valid comparator result (n=1 only for SARS-CoV-2), a lack of a valid FINDER Flu A&B/SARS-CoV-2 Test result (n=19), improper specimen collection (n=4), and inadequate sample for the comparator (due to tube leakage, n=3). This yielded 527 specimens for influenza A and influenza B performance evaluation & 526 specimens for SARS-CoV-2 performance evaluation.

The initial invalid rate for FINDER Flu A&B/SARS-CoV-2 was 10.8% and the final invalid rate was 3.5% after retesting.

The positive percent agreement (PPA) and negative percent agreement (NPA) are shown in Table 4 below.

Table 3: Demographic summary for 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 4: FINDER Flu A&B/SARS-CoV-2 Performance Results - PPA and NPA

	TP	FP	TN	FN	PPA (95% CI)	NPA (95% CI)
Influenza A	62	13[1]	449	3[2]	95.4% (87.3%-98.4%)	97.2% (95.2%-98.3%)
Influenza B	24	3[3]	499	1[4]	96% (80.5%-99.3%)	99.4% (98.3%-99.8%)
SARS-CoV-2	40	1[6]	484	1[5]	97.6% (87.4%-99.6%)	99.8% (98.8%-100%)

[1] – Discrepant testing results: 9/13 were positive; 4/13 were negative.
[2] – Discrepant testing results: 3/3 were positive.
[3] – Discrepant testing results: 2/3 were positive; 1/3 was negative.
[4] – Discrepant testing results: 1/1 was positive.
[5] – Discrepant testing results: 1/1 was negative.
[6] – Discrepant testing results: 1/1 was negative.

6.3. Within-Laboratory Precision Testing

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 LOD, a positive sample co-spiked with viral materials at 5x LOD, and a negative sample. Specimens were prepared in pooled negative nasopharyngeal 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). A total of 6 instruments were used for the testing.

Table 5 below summarizes the qualitative run results (percent agreement with expected results).

Table 5: Within-Laboratory Precision - Qualitative Results

Sample	Target	Calls	% Agreement	95% CI
Negative	Flu A	0/96	100	96.2 – 100%
	Flu B	0/96	100	96.2 – 100%
	SC2	1/96	99.0	94.3 – 99.8%
Low Positive (2x LOD)	Flu A	95/96	99.0	94.3 – 99.8%
	Flu B	95/96	99.0	94.3 – 99.8%
	SC2	96/96	100	96.2 – 100%
Moderate Positive (5x LOD)	Flu A	96/96	100	96.2 – 100%
	Flu B	96/96	100	96.2 – 100%
	SC2	96/96	100	96.2 – 100%

All moderate positive (5x LOD) runs were 100% positive for all assay targets. All low positive (2x LOD) runs were ≥99% positive for all assay targets. All negative sample runs were ≤1% positive, with one false positive for SARS-CoV-2.

Table 6 below summarizes the quantitative run results of the within-laboratory precision study (Ct signal variability analysis).

Table 6 - Within-Laboratory Precision Study - Ct Variability Results

Panel Member	Target	n	Mean Ct	Repeatability		Between Instruments		Between Days		Between Cartridge Lots		Reproducibility	
				SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)
Low Positive (2x LOD)	Flu A	95	29.7	1.74	5.9	0.16	0.5	0.35	1.2	0.43	1.4	1.83	6.2
	Flu B	95	28.5	1.64	5.7	0.53	1.9	0.38	1.3	0	0	1.76	6.2
	SARS-CoV-2	96	30.5	0.89	2.9	0	0	0.10	0.3	0.19	0.6	0.92	3.0
Moderate Positive (5x LOD)	Flu A	96	27.9	1.15	4.1	0.28	1.0	0	0	0.32	1.1	1.23	4.4
	Flu B	96	27.6	1.2	4.4	0.25	0.9	0	0	0	0	1.23	4.5
	SARS-CoV-2	96	28.9	1.05	3.6	0.14	0.5	0	0	0.34	1.2	1.11	3.8

6.4. Reproducibility

A study was performed to evaluate the Reproducibility of the FINDER Flu A&B/SARS-CoV-2 Test. The study was conducted at 3 POC investigational sites within the United States across five non-consecutive days. Each site had 2 CLIA Waived operators who tested each panel 3 times each testing day. Results are shown in Table 7 below. Three instruments were tested at each site.

Table 7: Reproducibility

Sample	Site 1	Site 2	Site 3	Total Agreement	
	% Agreement (Count)	% Agreement (Count)	% Agreement (Count)	% Agreement (Count)	95% CI
Negative	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)	95.9 - 100%
Influenza A Low Positive	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)	95.9 - 100%
Influenza A Moderate Positive	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)	95.9 - 100%
Influenza B Low Positive	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)	95.9 - 100%
Influenza B Moderate Positive	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)	95.9 - 100%
SARS-CoV-2 Low Positive	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)	95.9 - 100%
SARS-CoV-2 Moderate Positive	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)	95.9 - 100%

6.5. Analytical Sensitivity

The sensitivity of the FINDER Flu A&B/SARS-CoV-2 Test was evaluated using virus spiked into pooled negative nasopharyngeal matrix collected in FINDER RVP Buffer. An initial estimate of the Limit of Detection (LoD) was determined during a range-finding study in which 3-fold dilutions of the sample were tested in triplicate. The estimated LoD was the lowest concentration in which 100% of the samples were detected. The LoD was verified by detecting at least 19 out of 20 replicates at the estimated LoD in 3 independent test lots. The verified LoD results are summarized in Table 8 below.

Table 8: LoD Results

Target	Strain	Confirmed LoD
Influenza A	A/Switzerland/9715293/13	3.024 TCID50/mL
	H1N1, Brisbane/02/18	0.670 TCID50/mL
Influenza B	Victoria, B/Brisbane/33/08	0.050 TCID50/mL
	Phuket/3073/13	0.150 TCID50/mL
SARS-CoV-2	USA/MD-HP24556/2022	0.038 TCID50/mL
	First WHO Int. Std. for SC2	2.31E+06 IU/mL
	2006 Isolate	0.059 TCID50/mL

6.6. Analytical Reactivity (Inclusivity)

The reactivity of FINDER Flu A&B/SARS-CoV-2 Test was evaluated with clinically relevant strains of influenza A, influenza B, and SARS-CoV-2. In total 28 strains of influenza A, 12 strains of influenza B, and 12 strains of SARS-CoV-2 were evaluated. The virus under evaluation was spiked into pooled negative nasopharyngeal matrix collected in FINDER RVP Buffer at levels near the analytical LoD. The samples were tested in triplicate for each strain. All strains tested positive for all 3 replicates at the concentrations summarized in Table 9 below.

Table 9: Inclusivity Test Concentrations

Viral Target	Subtype	Strain	Titer (TCID50/mL)
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	3.0375
	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
Influenza A	H1N1	A/New Caledonia/20/1999	2.01
		A/New Jersey/8/76	18.09 (CEID50/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 (CEID50/mL)
		Victoria/361/2011	9.072
		A/Port Chalmers/1/73	9.072 (CEID50/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/white-tailed eagle/Japan/OU-1/2022	5400 cp/mL
	H7N9	A/Shanghai/4664T/2013	59000 cp/mL
Influenza B	Victoria	B/Hong Kong/5/72	109.35 (CEID50/mL)
		2506/Malaysia/2004	0.15
		1/Ohio/2005	109.35 (CEID50/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	0.45

6.7. In Silico Reactivity (Inclusivity) Analysis

The FINDER Flu A&B/SARS-CoV-2 Test was evaluated for SARS-CoV-2, influenza A and influenza B inclusivity.

SARS-CoV-2

Based on analysis of 5,740,183 SARS-CoV-2 genomes in the GISAID Database submitted between November 2019 and June 2024, 100,101 SARS-CoV-2 genomes in the NCBI repository submitted between July 2024 and May 2025, it is predicted that the FINDER Flu A&B/SARS-CoV-2 Test will detect >99.9% of the SARS-CoV-2 genome sequences.

Influenza A

Based on analysis of 399,012 influenza A genomes in the GISAID Database submitted between January 1997 and June 2025, it is predicted that the FINDER Flu A&B/SARS-CoV-2 Test will detect ~99.8% of the influenza A genome sequences.

Influenza B

Based on analysis of 103,792 influenza B genomes in the GISAID Database submitted between January 1997 and June 2025, it is predicted that the FINDER Flu A&B/SARS-CoV-2 Test will detect >99.1% of the influenza B genome sequences.

6.8. Cross-Reactivity and Microbial Interference

The FINDER Flu A&B/SARS-CoV-2 Test was evaluated for potential interference from related pathogens, high prevalence disease agents, and normal or pathogenic flora reasonably likely to be encountered in a clinical sample. Potential cross-reactivity was evaluated by adding organisms into a pooled negative nasopharyngeal matrix collected in FINDER RVP Buffer. Similarly, microbial interference was evaluated by adding the same organisms into the same sample pool, with each viral target added at 3x the Limit of Detection. No cross-reactivity or microbial interference was observed at the concentrations tested in Table 10 below.

Table 10: Cross-reactivity and Microbial interference

Pool	Microorganism	Concentration	Category	Cross Reactivity	Microbial Interference
1	Adenovirus type 1	$1x10^5$ $TCID_{50}$/mL	Virus	0/3	3/3
	Adenovirus type 7	$1x10^5$ $TCID_{50}$/mL	Virus		
2	Adenovirus type 4	$1x10^5$ $TCID_{50}$/mL	Virus	0/3	3/3
3	Cytomegalovirus	$4.21x10^4$ $TCID_{50}$/mL	Virus	0/3	3/3

4	Herpes simplex virus Type 1	$1x10^5$ $TCID_{50}$/mL	Virus	0/3	3/3
	Varicella-zoster virus	$1x10^5$ cp/mL	Virus		
5	Epstein Barr Virus	$1x10^5$ cp/mL	Virus	0/3	3/3
6	Enterovirus (Coxsackie)	$1x10^5$ $TCID_{50}$/mL	Virus	0/3	3/3
	Enterovirus (echovirus)	$1x10^5$ $TCID_{50}$/mL	Virus		
7	Human parainfluenza 1	$1x10^5$ $TCID_{50}$/mL	Virus	0/3	3/3
	Human parainfluenza 3	$1x10^5$ $TCID_{50}$/mL	Virus		
8	Human parainfluenza 2	$1x10^5$ $TCID_{50}$/mL	Virus	0/3	3/3
9	Human parainfluenza 4	$1x10^5$ $TCID_{50}$/mL	Virus	0/3	3/3
10	Coronavirus HKU1	$1x10^6$ cp/mL	Virus	0/3	3/3
11	Coronavirus 229E	$4.17x10^4$ $TCID_{50}$/mL	Virus	0/3	3/3
12	Coronavirus OC43	$4.17x10^4$ $TCID_{50}$/mL	Virus	0/3	3/3
13	Coronavirus NL63	$3.55x10^4$ $TCID_{50}$/mL	Virus	0/3	3/3
14	Measles	$1x10^5$ $TCID_{50}$/mL	Virus	0/3	3/3
	Mumps virus	$1x10^5$ $TCID_{50}$/mL	Virus		
15	Human metapneumovirus A1	$1.41x10^4$ $TCID_{50}$/mL	Virus	0/3	3/3
16	Human metapneumovirus A2	$3.55x10^4$ $TCID_{50}$/mL	Virus	0/3	3/3
17	Rhinovirus Type 1A	$1.41x10^4$ $TCID_{50}$/mL	Virus	0/3	3/3
18	Aspergillus flavus	$1x10^6$ CFU/mL	Fungi	0/3	3/3
	Bordetella pertussis	$1x10^6$ CFU/mL	Bacteria		
	Bordetella parapertussis	$1x10^6$ CFU/mL	Bacteria		
19	Chlamydia pneumoniae	$1x10^6$ CFU/mL	Bacteria	0/3	3/3
	Corynebacterium amycolatum	$1x10^6$ CFU/mL	Bacteria		
	Escherichia coli	$1x10^6$ CFU/mL	Bacteria		
20	Fusobacterium necrophorum	$1x10^6$ CFU/mL	Bacteria	0/3	3/3
21	Hemophilus influenzae	$1x10^6$ CFU/mL	Bacteria	0/3	3/3
22	Lactobacillus oris	$1x10^6$ CFU/mL	Bacteria	0/3	3/3
23	Legionella pneumophila	$1x10^6$ CFU/mL	Bacteria	0/3	3/3
24	Moraxella catarrhalis	$1x10^6$ CFU/mL	Bacteria	0/3	3/3
25	Mycobacterium tuberculosis avirulent	$1x10^4$ cp/mL	Bacteria	0/3	3/3
26	Mycoplasma pneumoniae	$1x10^6$ CCU/mL	Bacteria	0/3	3/3

	Mycoplasma genitalium	$1.85x10^5$ Bacteria/mL	Bacteria		
27	Neisseria meningitides	$1x10^6$ CFU/mL	Bacteria	0/3	3/3
	Neisseria cinerea	$1x10^6$ CFU/mL	Bacteria		
28	Pneumocystis jirovecii	$1x10^6$ CFU/mL	Fungi	0/3	3/3
	Pseudomonas aeruginosa	$1x10^6$ CFU/mL	Bacteria		
29	Staphylococcus aureus	$1x10^6$ CFU/mL	Bacteria	0/3	3/3
	Staphylococcus epidermis	$1x10^6$ CFU/mL	Bacteria		
30	Streptococcus pneumoniae	$1x10^6$ CFU/mL	Bacteria	0/3	3/3
	Streptococcus pyogenes	$1x10^6$ CFU/mL	Bacteria		
	Streptococcus salivarius	$1x10^6$ CFU/mL	Bacteria		
31	SARS-CoV-1	$1x10^4$ cp/mL	Virus	0/3	3/3
32	Candida albicans	$1x10^6$ CFU/mL	Fungi	0/3	3/3
33	MERS-coronavirus	10% v/v	Virus	0/3	3/3
34	Human genomic DNA	$3.71x10^6$ cp/mL	n/a	0/3	3/3
35	Pooled human nasal wash	10% v/v	n/a	0/3	3/3
n/a	Respiratory syncytial virus	$1x10^5$ $TCID_{50}$/mL	Virus	0/3	3/3

6.9. In Silico Specificity (Exclusivity) Analysis

In addition to the cross-reactivity testing above, the FINDER Flu A&B/SARS-CoV-2 Test was evaluated for potential cross-reactivity of eleven additional microorganisms reasonably likely to be encountered in a clinical sample using *in silico* analysis. Each oligonucleotide used in the assay was compared against the reference genome for each organism. No significant homology was found with any of the analyzed organisms listed below that are predicted to cause false positive results on the FINDER Flu A&B/SARS-CoV-2 Test.

1. Human Adenovirus Type 2
2. Human Adenovirus Type 3
3. Human Adenovirus Type 5
4. Human Adenovirus Type 11
5. Human Adenovirus Type 14
6. Human Adenovirus Type 22
7. Human Adenovirus Type 35
8. Human Adenovirus Type 41
9. Human Meta-pneumovirus B1
10. Human Meta-pneumovirus B2
11. Human Cytomegalovirus (taxid:10359)

6.10. Interfering Substances

The FINDER Flu A&B/SARS-CoV-2 Test was evaluated for potential interference from exogenous/endogenous interferents that may be found in clinical samples. Negative samples were

prepared by adding potentially interfering substances to pooled negative nasopharyngeal matrix collected in FINDER RVP Buffer. Positive samples were created in the same manner but included a virus spiked at 3x the established Limit of Detection. All samples were tested in triplicate. Table 11 below shows the highest concentration for each substance at which no interference was observed. Interference was observed at higher concentrations for Zicam (5%), budesonide (1%), Nasacort (2.5%), Fluticasone (2.5%) and Nasonex (2.5%).

Table 11: Interfering substances

Substance/Active Ingredient[1]	**Concentration**
Mucin	5 mg/ml
Whole Blood (Capillary)	2% (v/v)
Leukocytes (Human Buffy Coat)	1% (v/v)
Oxymetazoline (Afrin)	5% (v/v)
Saline nasal spray	10% (v/v)
Phenylephrine (1%)	10% (v/v)
Zinc (Zinc Acetate Dihydrate)	1 mg/mL
Luffa opperculata, sulfur (Zicam)	2.5% (v/v)
Benzocaine Menthol (Cepacol)	5% (v/v)
Zanamivir	5 mg/mL
Oseltamivir	7.5 mg/mL
Tobramycin	4 ug/mL
Mupirocin	5 mg/mL
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)
Histaminum hydrochloricum	10 mg/mL
DMSO	10% (v/v)
Ethanol	10% (v/v)
0.1N NaOH	10% (v/v)

[1] **FluMist was not evaluated.**

6.11. Competitive Interference

Competitive interference of the FINDER Flu A&B/SARS-CoV-2 Test caused by co-infections was evaluated by testing contrived samples of individual SARS-CoV-2, influenza A, or influenza B strains at 3x LoD in the presence of different target strains at a higher concentration (10^5 TCID50/mL) in nasopharyngeal sample matrix. Three replicates were tested for each combination of target strain and competing strain. Competitive interference was considered absent if 3 of 3 replicates for the target strain were correctly detected in the presence of the competing virus. The results demonstrated no competitive inhibitory effects from co-infecting viruses at the concentrations tested. The results of the competitive interference study are summarized in Table 12.

Table 12: Competitive Interference Samples

Viral Target (3X LOD)	**Co-infection target** (10^5 $TCID_{50}$/mL)	**# Calls/Runs**		
		Flu A	**Flu B**	**SC2**
Influenza A (9.072 $TCID_{50}$/mL)	Influenza B	3/3	3/3	0/3
	SARS-CoV-2	3/3	0/3	3/3
Influenza B (0.150 $TCID_{50}$/mL)	Influenza A	3/3	3/3	0/3
	SARS-CoV-2	0/3	3/3	3/3
SARS-CoV-2 (0.113 $TCID_{50}$/mL)	Influenza A	3/3	0/3	3/3
	Influenza B	0/3	3/3	3/3

6.12. Carry-over Contamination

A cross contamination (carry-over) study was conducted to demonstrate that specificity was maintained for runs following positive results. A strongly positive sample was prepared with concentrations per Table 13 below. Runs of the strongly positive sample were directly followed by a negative sample. This cycle was performed 8 times on 5 different FINDER instruments resulting in 40 expected positive and 40 expected negative runs for each virus. No specimen or amplificon contamination was observed.

Table 13: Carry-over Contamination

Viral Target	**Strain**	**Analyte Level**
SARS-CoV-2	USA/MD-HP24556/2022	7.5e2 $TCID_{50}$/mL
Influenza A	H3N2/ A/Switzerland/9715293/13	2.5e4 $TCID_{50}$/mL
Influenza B	B/Brisbane/33/08	1.0e3 $TCID_{50}$/mL

7. Specimen Stability

Storage Stability

A study was performed to determine the storage stability of nasopharyngeal swab specimens collected in FINDER RVP Buffer to be analyzed on the FINDER Flu A&B/SARS-CoV-2 Test. Nasopharyngeal swabs were collected in FINDER RVP Buffer and the media were pooled. Storage stability was evaluated at

refrigerated (2-8°C) and room temperature (30°C) conditions, using both a positive sample (co-spiked with viral materials at 3x LOD) and a negative sample. Eight replicates of each specimen were tested at each timepoint. Results of this testing support that samples collected in FINDER RVP Buffer may be stored:

- Up to 5 hours at room temperature (15-30°C)
- Up to 72 hours refrigerated (2-8°C)

Freeze/thaw Testing

The equivalency of fresh and frozen specimens on the FINDER Flu A&B/SARS-CoV-2 Test was evaluated. Nasopharyngeal swabs were collected in FINDER RVP Buffer and the media were pooled. A negative sample as well as two positive samples (co-spiked with viral material at either 2x LOD or 5x LOD) were evaluated; ten replicates of the negative and 5x LOD sample were tested and 30 replicates of the 2x LOD sample were tested at each timepoint. All samples were tested fresh and after multiple freeze-thaws following -80°C storage. Results of this testing support that samples collected in FINDER RVP Buffer may be frozen at -80°C and undergo up to 2 freeze/thaw cycles before testing on the FINDER Flu A&B/SARS-CoV-2 Test.

8. Flex Testing

Flex studies were conducted to evaluate the robustness and reliability of the FINDER Flu A&B/SARS-CoV-2 Test when used under conditions that may occur in real-world CLIA-waived settings. These studies are designed to demonstrate that the FINDER system can maintain clinical accuracy and safety despite common user errors and environmental variability.

8.1. Study Design

Flex studies were conducted using both positive and negative samples and with either pooled patient matrix or external run controls. For most testing, presumed negative nasopharyngeal swab media was collected and pooled. The negative pooled matrix was verified as negative for SARS-CoV-2, influenza A, and influenza B by testing on a high sensitivity method. Positive samples were contrived by spiking viral specimens into the above negative pooled matrix at a concentration of 2x the FINDER Flu A&B/SARS-CoV-2 Test Limit of Detection for each viral target. For the test conditions where a swab is required, the recommended external positive and negative control swabs (Cat # 100-000077 and Cat # 100-000078 respectively) were used.

Replicates of 5 positive samples and 5 negative samples were used for each flex condition. Across all studies, a total of 5 trained operators were used. Sample pedigree was blinded to the user.

8.2. Flex Conditions Evaluated

The following flex conditions were selected based on FDA guidance for CLIA waiver submissions, precedent from previously waived molecular diagnostics, and foreseeable user errors as indicated from risk analysis:

Environment	a) Vibrations from common lab equipment installed near the instrument. b) Bumping the instrument during a test. c) Instrument moved during testing. d) Temperature and Humidity extremes. e) High altitude
Instrument Installation	a) Instrument installed on a non-level surface. b) Instrument installed such that airflow is impeded.
Specimen Integrity and Handling	a) FINDER RVP Buffer light exposure b) Insufficient incubation of sample in FINDER RVP Buffer c) Incorrect Storage of Sample
Human Factors/Operator Errors	a) Incorrect handling (equilibration) of sample b) Incorrect handling (equilibration) of FINDER RVP Buffer c) Incorrect handling (equilibration) of cartridge d) Incorrect handling of cartridge preparation (removal from pouch) e) Incorrect timing of cartridge preparation f) Incorrect mixing of sample g) Incorrect sample volume h) Incorrect pipette technique i) Incorrect timing of sample introduction j) Incorrect test steps (closing of sample cap) k) Interference with test equipment (Power Cycling during test)

8.3. Flex conditions test results

Condition	NEGATIVE	POSITIVE	INVALID or NO RESULT	Erroneous Results
Control	5/5	5/5	0/10	0/10
Vibration: 9,500 RPM centrifuge within 1'	5/5	5/5	0/10	0/10
Jostling: >1.5g facing instrument	5/5	5/5	0/10	0/10
Instrument moved 1' backwards during test	5/5	5/5	0/10	0/10
Environmental extreme: 15°C / 50% RH	5/5	5/5	0/10	0/10
Environmental extreme: 30°C / 20% RH	5/5	5/5	0/10	0/10
Environmental extreme: 30°C / 80% RH	5/5	5/5	0/10	0/10
Environmental extreme: 10°C / 90-95% RH	5/5	5/5	0/10	0/10

Condition	NEGATIVE	POSITIVE	INVALID or NO RESULT	Erroneous Results
Environmental extreme: 13°C / 90-95% RH	5/5	5/5	0/10	0/10
Environmental extreme: 35°C / 90-95% RH	5/5	5/5	0/10	0/10
Environmental extreme: 40°C / 90-95% RH	3/5	5/5	2/10	0/10
Environmental extreme: 8°C / 5-15% RH	5/5	5/5	0/10	0/10
Environmental extreme: 13°C / 5-15% RH	5/5	5/5	0/10	0/10
Environmental extreme: 35°C / 5-15% RH	5/5	5/5	0/10	0/10
Environmental extreme: 40°C / 5-15% RH	5/5	5/5	0/10	0/10
High altitude: 1500 m	5/5	5/5	0/10	0/10
High altitude: 1700 m	5/5	5/5	0/10	0/10
High altitude: 2000 m	3/5	3/5	4/10	0/10
High altitude: 3000 m	1/5	3/5	6/10	0/10
Instrument non-level: +2° Pitch, 0° Roll	5/5	5/5	0/10	0/10
Instrument non-level: -2° Pitch, 0° Roll	5/5	5/5	0/10	0/10
Instrument non-level: 0° Pitch, -2° Roll	3/5	4/5	3/10	0/10
Instrument non-level: 0° Pitch, +2° Roll	5/5	4/5	1/10	0/10
Instrument exhaust blocked	5/5	5/5	0/10	0/10
RVP buffer left under room light	5/5	5/5	0/10	0/10
Sample swab incubated for <20s	5/5	5/5	0/10	0/10
Sample stored at 4C for 7 days	5/5	5/5	0/10	0/10
Sample stored at 30C for 8 hours	5/5	5/5	0/10	0/10
Sample stored at 37C for 4 hours	5/5	5/5	0/10	0/10
Sample not equilibrated after refrigeration	5/5	5/5	0/10	0/10
RVPB not equilibrated after refrigeration	5/5	5/5	0/10	0/10
Cartridge not equilibrated after refrigeration	5/5	5/5	0/10	0/10
Cartridge outside pouch for 2 hours	5/5	5/5	0/10	0/10
Cartridge idled after initialization for 15 min	5/5	5/5	0/10	0/10
Sample swab not mixed in RVP	4/5	5/5	1/10	0/10
25% of sample loaded (50 uL)	1/5	0/5	9/10	0/10

Condition	NEGATIVE	POSITIVE	INVALID or NO RESULT	Erroneous Results
50% of sample loaded (100 uL)	5/5	4/5	1/10	0/10
200% of sample loaded (400 uL)	1/5	2/5	7/10	0/10
Pipette action repeated 5x	5/5	5/5	0/10	0/10
Pipette pushed deep, strongly dispensed	5/5	4/5	1/10	0/10
Sample loaded before initialization completes	3/5	3/5	4/10	0/10
Sample loaded after main protocol start	5/5	5/5	0/10	0/10
Sample cap not closed	5/5	5/5	0/10	0/10
Instrument power cycled	0/5	0/5	10/10	0/10
Tablet power cycled	5/5	5/5	0/10	0/10

8.4. Flex Testing Conclusions

Overall, the FINDER FLU A&B/SARS-CoV-2 Test as tested on the FINDER Instrument exhibited strong resilience to a range of flex conditions foreseeably present in a CLIA waived test environment. All conditions either generated expected results or triggered intended fail-safe mechanisms. No incorrect results were reported for any condition tested.

9. Conclusion

The analytical and clinical studies have demonstrated that the FINDER Flu A&B/SARS-CoV-2 Test is substantially equivalent to the predicate device (K220963).