CLIA Waiver by Application Approval Determination
Decision Summary

I. Document Number

CW250011

II. Parent Document Number

K252269

III. CLIA Waiver Type

Dual 510(k) and CLIA Waiver by Application (Dual Submission)

IV. Applicant

Baebies Inc

V. Proprietary and Established Names

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

VI. Measurand (analyte)

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

VII. Sample Type(s)

Nasopharyngeal swab collected in FINDER RVP Buffer

VIII. Type of Test

Qualitative reverse transcriptase polymerase chain reaction (RT-PCR)

IX. Test System Description

A Overview

The FINDER Flu A&B/SARS-CoV-2 Test is an automated RT-PCR test intended for the qualitative detection and differentiation of viral RNA from influenza A, influenza B, and severe acute respiratory syndrome coronavirus 2. The FINDER Flu A&B/SARS-CoV-2 Test is performed on the FINDER Instrument, a fully automated, bench-top instrument designed for point-of-care settings.

The FINDER Flu A&B/SARS-CoV-2 Test uses nasopharyngeal swab specimens collected in FINDER RVP Buffer. The sample is transferred into a single-use, self-contained cartridge using a provided single-use exact-volume transfer pipette. The cartridge contains all sample preparation reagents, nucleic acid extraction components, and amplification reagents.

All assay steps, from nucleic acid extraction to real-time reverse transcription PCR (RT-PCR) and result interpretation, are executed automatically by the FINDER Instrument. After the test is complete, results are displayed to the user as either Negative, Positive, or Invalid for each viral RNA target.

B Test System Components

Test Components:

- FINDER Flu A&B/SARS-CoV-2 Test Cartridge (single-use, box of 10)
- Each box includes (12) individually packaged disposable exact-volume transfer pipettes
- FINDER RVP Buffer (pre-measured 1.5mL vials, box of 60)
- FINDER Instrument

X. Specific Contents for CLIA Waiver

A Demonstrating “Simple”:

- The FINDER Flu A&B/SARS-CoV-2 Test cartridge is single-use and self-contained, with all reagents required to perform the test included within the test cartridge.
- The FINDER Flu A&B/SARS-CoV-2 Test is performed on unprocessed nasopharyngeal swab.
- The FINDER Flu A&B/SARS-CoV-2 Test does not require technique-dependent specimen manipulation. An inversion of the FINDER RVP Buffer is performed prior to sample transfer.
- All reagent manipulation is performed automatically on cartridge with no user technique required.
- Analysis is performed automatically by FINDER Instrument software.
- In the event of a system or test error, direct user actions are clearly recommended on the screen. No training or interpretation is required from the user.
- Recommended maintenance of the FINDER Instrument is limited to general cleaning to reduce the risk of work-surface cross-contamination.
- The FINDER instrument automatically reports results as “Positive”, “Negative” or “Invalid” for each viral RNA target. The operator does not need to perform any additional result calculations or interpretations.
- The FINDER Flu A&B/SARS-CoV-2 Test includes a Quick Reference Guide that is written at no higher than a 7th grade reading level. The Quick Reference Guide was validated as appropriate for the intended user.

B Demonstrating "Insignificant Risk of an Erroneous Result"- Failure Alerts and Fail-Safe Mechanisms

1. Risk Analysis:
   A structured risk assessment to identify hazards and hazardous situations relevant to the intended use of the FINDER System in non-laboratory settings was conducted. Risks evaluated included:
   - Operator errors or misuse (e.g., incorrect sample handling or loading)
   - Environmental factors (e.g., out-of-specification temperature or humidity)
   - Cartridge and device integrity (e.g., expired or degraded components)
   - Hardware/software failures
   - Sample cross-contamination or carryover
   - Inadequate specimen volume or improper sample handling
   - Unintended interruption during test run

   Each identified risk was addressed through a combination of design mitigation (e.g., lockouts, interlocks), instructional labeling, and real-time system monitoring. All residual risks were determined to be low or negligible.

2. Fail-Safe and Failure Alert Mechanisms:
   The FINDER System incorporates multiple fail-safe and failure alert mechanisms to prevent invalid or inaccurate results:

   Table 18: Fail-Safe and failure alert mechanisms for the FINDER Flu A&B/SARS-CoV-2 Test

Design Feature	Description
Operator Lockouts	• User authentication is required to initiate a test. The instrument will prevent a run from proceeding if the user does not have sufficient privileges. • A cartridge barcode is required to be scanned by the Instrument to initiate a test. The instrument will not start a test workflow if the cartridge is expired. • The instrument checks to ensure proper cartridge insertion has been performed. A test is prevented from running if a cartridge is missing or mis-inserted.
Environmental Sensors	• The instrument interface to the cartridge is heated above standard lab temperatures to eliminate the impact of ambient temperature variation. The instrument monitors interface temperatures and will prevent a run from proceeding if specifications are not met.
Cartridge Integrity Detection	• The instrument checks cartridge integrity prior to sample insertion. The test is prevented from proceeding if cartridge health specifications are not met. Cartridges that have previously been used will also be prevented from proceeding.
Automated Error Messaging	• On-screen instructions guide users through resolution steps if an error occurs. Most errors result in a prompt to repeat the test.
One-test-at-a-time Control	• The instrument allows only one active test per instrument, reducing the risk of confusion or cross-contamination.
Run Interruption Detection	• Critical run failures, including instrument loss of function or complete power loss, automatically halt the test and prevent a run result from being reported.

Automated Interpretation	• Results are generated and interpreted by onboard algorithms, eliminating opportunities for user error. • Valid results are reported as "Positive" or "Negative", eliminating user subjectivity or misreading of results.
Result Flags and Retest Guidance	• Run health is monitored during the test for abnormalities in fluidics, sample concentration, reagent availability, and thermal cycling. In the event that a run health flag is generated, the test is reported as "Invalid" with clear on-screen language provided to repeat the test.
Quick Reference Guide with Troubleshooting	• Provides plain-language steps for corrective actions in response to error messages.
Internal RPP30 Controls	• Confirm the adequacy of specimen collection by verifying the presence of human cellular material. • Monitor the entire analytical workflow within each reaction, including lysis, nucleic acid extraction, amplification, and detection. • Detect potential inhibition of PCR amplification. • Identify test failures on a per-sample basis, ensuring invalid results are recognized and not misinterpreted.
External Controls	• Monitor the entire test process, including nucleic acid extraction, amplification, and detection steps. • Detect potential FINDER RVP buffer or Cartridge degradation or assay drift over time. • Monitor for contamination and non-specific assay reactivity. • Verify that the test system continues to perform as expected during routine use. • Provide confidence in test results, particularly in non-laboratory settings with minimally trained users.

3. Flex Studies:

Flex studies were conducted to evaluate the robustness and reliability of the FINDER Flu A&B/SARS-CoV-2 Test when used under non-ideal 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. Flex studies were conducted using both positive and negative samples. Positive samples were created by spiking virus at 2x LoD into pooled negative NPS matrix in FINDER RVP Buffer. Negative samples were created using negative pooled NPS matrix in FINDER RVP Buffer. For test conditions where a swab is specified, the negative or positive control swab was used. Replicates of 5 positive samples and 5 negative samples were tested for each flex condition. Across all studies, a total of 5 trained operators were used. Test samples were randomized and blinded to the operators running the FINDER Flu A&B/SARS-CoV-2 Test. The effect of the following conditions on the performance of the test was evaluated, organized by the potential type of error source:

Table 19: Flex conditions evaluated for the FINDER Flu A&B/SARS-CoV-2 Test

Environmental Conditions	• Vibrations from common lab equipment installed near the instrument. • Bumping the instrument during a test. • Instrument moved during testing. • Temperature and humidity extremes. • High altitude.
Instrument Installation	• Instrument installed on a non-level surface. • Instrument installed such that airflow is impeded.

Specimen Integrity and Handling	• FINDER RVP Buffer light exposure. • Insufficient incubation of sample in FINDER RVP Buffer. • Incorrect storage of Sample.
Human Factors/Operator Error	• Incorrect handling (equilibration) of sample. • Incorrect handling (equilibration) of FINDER RVP Buffer. • Incorrect handling (equilibration) of cartridge. • Incorrect handling of cartridge preparation (removal from pouch). • Incorrect timing of cartridge preparation. • Incorrect mixing of sample. • Incorrect sample volume. • Incorrect pipette technique. • Incorrect timing of sample introduction. • Incorrect test steps (closing of sample cap). • Interference with test equipment (Power Cycling during test).

Environmental Conditions

a) Vibrations from common lab equipment

This study evaluated the effect of using a centrifuge adjacent to the FINDER Instrument while a test is in progress. The centrifuge was installed within one (1) foot of the FINDER instrument. A FINDER run was initiated following the normal instructions for use. While the test was in progress, the lab centrifuge was turned on at 9,500 RPM for the duration of the test. All samples generated expected results demonstrating that risks of erroneous results due to environmental vibrations while operating the FINDER Instrument in the lab environment is low. As a precaution, the FINDER Instrument manual includes clear labeling which informs the user that the use of the FINDER instrument adjacent to or stacked with other equipment should be avoided.

b) Bumping the instrument during test

This study evaluated the effect of accidentally jarring the FINDER Instrument while a test is in progress. A FINDER run was initiated following the normal instructions for use. While the test was in progress, a force sufficient to induce an acceleration of >1.5g was introduced to the system. All samples generated expected results demonstrating that risks of erroneous results due to bumping the FINDER Instrument while operating the FINDER Instrument in the lab environment is low. As a precaution, the FINDER Instrument manual includes clear labeling which cautions the user not to disrupt the FINDER instrument while testing is performed.

c) Instrument moved during test

This study evaluated the effect of repositioning the FINDER Instrument while a test is in progress. A FINDER run was initiated following the normal instructions for use. While the test was in progress, the FINDER Instrument was picked up and moved 12” further back on the bench surface. All samples generated expected results demonstrating that risks of erroneous results due to instrument disruption while operating the FINDER Instrument in the lab environment is low. As a precaution, the FINDER Instrument manual includes clear labeling which cautions the user not to disrupt the FINDER instrument while testing is performed.

d) Temperature and Humidity Extremes

This study evaluated the effect of installing the FINDER Instrument at the extremes of temperature and humidity conditions anticipated from a professional healthcare facility. The

FINDER Flu A&B/SARS-CoV-2 Test and the FINDER Instrument were allowed to sit for at least 20 minutes at the environmental condition being tested. The FINDER runs were then initiated following the normal instructions for use. Conditions tested included 15°C /50% RH, 30°C /20% RH, and 30°C /80% RH. All samples generated expected results for this initial testing.

Additional testing was performed at more extreme conditions outside of those anticipated for a professional healthcare facility, including: 10°C /95% RH, 13°C /95% RH, 35°C /95% RH, 40°C /95% RH, 10°C /5% RH, 13°C /5% RH, 35°C /5% RH, 40°C /5% RH. All samples generated expected results, except for the 40°C /95% condition, where 8/10 runs produced expected results, and 2/10 results generated a fail-safe "invalid" result. No incorrect results were reported for any condition tested.

The risk of incorrect results is determined to be appropriately mitigated by fail-safe mechanisms for cases where the FINDER Instrument is operated above both its stated temperature range and its stated humidity range. The risk of instrument error due to extreme temperature and humidity conditions are further mitigated by clear labeling which instructs the user to operate the FINDER Instrument at 15°C to 30°C and relative humidity of 20%–80%.

Instrument Installation

a) Instrument installed on a non-level surface

This study evaluated the effect of installing the FINDER Instrument on a non-level work surface. The FINDER Instrument was installed at the following conditions: +2° pitch, -2° pitch, +2° roll, -2° roll. For each condition, FINDER Flu A&B/SARS-CoV-2 Test runs were initiated following the normal instructions for use.

All samples generated expected results when the instrument was non-level in pitch. In the non-level -2° roll orientation, 7/10 replicates results generated expected results while the remaining 3 replicates resulted in a fail-safe mechanism "Invalid" result. In the non-level +2° roll orientation, 9/10 replicates results generated expected results while the remaining replicate resulted in a fail-safe mechanism "Invalid" result. No incorrect results were reported for any condition tested.

The risk of incorrect results is determined to be appropriately mitigated by fail-safe mechanisms when the instrument is installed on a significantly non-level surface. Elevated invalid rate is mitigated by software lockout until an initial level is completed at first device setup. Risk of elevated invalid rates is additionally mitigated by FINDER Instrument labeling that clearly states that testing should be performed on a flat surface.

b) Instrument installed such that airflow is impeded

This study evaluated the effect of installing the FINDER Instrument such that the rear exhaust of the instrument was impeded. The FINDER instrument was installed such that the rear of the instrument was directly touching a wall. The instrument was left to sit idle for at least 10 minutes. A FINDER run was initiated following the normal instructions for use. All samples generated expected results, demonstrating that risks of erroneous results due to impeded air flow while operating the FINDER Instrument in the lab environment is low. As a precaution, the FINDER Instrument manual includes clear labeling which informs the user that instrumentation should not be operated while the rear of the instrument is obstructed.

Specimen Integrity and Handling

a) FINDER RVP Buffer light exposure

This study evaluated the effect of exposing the FINDER RVP Buffer to lab lighting for an extended amount of time. The FINDER RVP Buffer was removed from shelf packaging and allowed to sit under bright lab lighting for 24 hours. A swab was then introduced into the FINDER RVP Buffer then tested according to the instructions of use. All samples generated expected results, demonstrating that risks of erroneous results due to extended light exposure of the FINDER RVP Buffer is low. As a precaution, a light-protection symbol is included on the packaging to indicate that the FINDER RVP Buffer should be shielded from light exposure.

b) Insufficient elution of sample in FINDER RVP Buffer

This study evaluated the effect of insufficient elution of swab material into FINDER RVP Buffer. A swab was introduced into FINDER RVP Buffer for no more than 20 seconds and then discarded. No agitation of the swab was performed while inserted into the FINDER RVP Buffer. Testing proceeded following the normal instructions for use. All samples generated expected results demonstrating that risks of erroneous results due to insufficient elution of sample in FINDER RVP Buffer is low. As a precaution, the FINDER Flu A&B/SARS-CoV-2 Test Instructions for Use instructs the user to mix the FINDER RVP Buffer after the sample swab is added and to leave the swab in the FINDER RVP Buffer after inoculation.

c) Incorrect Storage of Sample

This study evaluated the effect of improper storage of swab material in FINDER RVP Buffer. A swab was collected into RVP Buffer following the normal instructions for use. The sample was stored at the condition under consideration before proceeding to testing following the normal instructions for use. The conditions tested were as follows: 4°C storage for 7 days, 30°C storage for 8 hours, 37°C for 4 hours. All samples generated expected results demonstrating that risks of erroneous results due to incorrect sample storage is low. As a precaution, the FINDER Flu A&B/SARS-CoV-2 Test Instructions for Use clearly state sample storage parameters.

Human Factors/Operator Errors

a) Incorrect handling (equilibration) of sample

This study evaluated the effect of testing a collected sample immediately after removal from refrigerated conditions. The sample was stored at 4°C for at least 1 hour, removed, and then transferred into the cartridge within 3 minutes. Testing continued following the normal instructions for use. All samples generated expected results demonstrating that risks of erroneous results due to incorrect sample handling after refrigeration is low. As a precaution, the Quick Reference Guide clearly states that samples stored at refrigerated temperatures should be removed at least five minutes prior to testing.

b) Incorrect handling (equilibration) of RVP Buffer

This study evaluated the effect of collecting a sample immediately into FINDER RVP Buffer after removal from refrigerated conditions. The FINDER RVP Buffer was stored at 4°C for at least 1 hour, removed from cold storage, and within 3 minutes, a swab was inserted and a sample transferred into the cartridge. Testing continued following the normal instructions for use. All samples generated expected results demonstrating that risks of erroneous results due

to incorrect handling of FINDER RVP Buffer is low. As a precaution, the packaging of the FINDER RVP Buffer clearly describes the correct FINDER RVP Buffer handling procedure.

c) Incorrect handling (equilibration) of cartridge

This study evaluated the effect of using a FINDER Flu A&B/SARS-CoV-2 Test cartridge immediately after removal from refrigerated conditions. The cartridge was stored at 4°C for at least 1 hour, removed, and testing initiated on the instrument within 3 minutes and following the normal instructions for use. All samples generated expected results demonstrating that risks of erroneous results due to incorrect test cartridge handling after refrigeration is low. As a precaution, the Quick Reference Guide clearly states that test cartridges should be removed at least five minutes prior to testing.

d) Incorrect handling of cartridge (pouch removal)

This study evaluated the effect of not removing a FINDER Flu A&B/SARS-CoV-2 Test cartridge from its pouch immediately before use. The cartridge was removed from the pouch and left exposed to room conditions for at least 2 hours. Testing followed the normal instructions for use. All samples generated expected results demonstrating that risks of erroneous results due to incorrect removal of the test cartridge from the foil pouch is low. As a precaution, the FINDER Flu A&B/SARS-CoV-2 Test Instructions for Use indicate that test cartridges should be used within one hour of opening.

e) Incorrect timing of cartridge preparation

This study evaluated the effect of not immediately starting a test after cartridge initialization has completed. The cartridge was inserted into the FINDER Instrument and a test was started following the normal instructions for use. After initialization, a 15-minute timer will appear on the screen indicating the window of time to transfer sample into the cartridge. Sample was transferred at the end of the timer but before software lockout. All samples generated expected results demonstrating that risks of erroneous results due to incorrect timing of cartridge preparation is low. As a precaution, the FINDER Flu A&B/SARS-CoV-2 Test Instructions for Use indicate that samples should be added to the cartridge within 15 minutes of initializing or the run will auto-cancel.

f) Incorrect mixing of sample

This study evaluated the effect of not mixing the sample prior to transfer into the cartridge. A swab was introduced into RVP Buffer for at least 5 minutes and then discarded. No agitation of the swab was performed while inserted into the FINDER RVP Buffer. FINDER RVP Buffer was not inverted or otherwise intentionally disturbed. Testing proceeded following the normal instructions for use. 9/10 replicates generated expected results. 1 result generated a fail-safe mechanism “Invalid” result. No incorrect results were reported for any condition tested.

The risk of incorrect results is determined to be appropriately mitigated by fail-safe mechanisms when sample is not mixed. The risk of elevated invalid rates due to incorrect mixing of the sample are additionally mitigated by clear and concise direction to invert the sample in the FINDER Flu A&B/SARS-CoV-2 Test Instructions for Use and Quick Reference Instructions.

g) Incorrect sample volume

This study evaluated the effect of transferring the incorrect volume of sample into the FINDER Flu A&B/SARS-CoV-2 Test cartridge. The following volumes of sample were transferred as part of this testing: 50µL (25% load), 100µL (50% load), 400µL (200% load). Testing proceeded following the normal instructions for use. In the 50µL condition, one (1) replicate generated expected results while the remaining 9 replicates resulted in a fail-safe mechanism "Invalid" result. In the 100µL condition, 9/10 replicates generated expected results while the remaining replicate generated a fail-safe mechanism "Invalid" result. In the 400µL condition, 3/10 replicates generated expected results while the remaining 7 replicates generated fail-safe mechanism "Invalid" results. No incorrect results were reported for any condition tested.

The risk of incorrect results is determined to be appropriately mitigated by fail-safe mechanisms when the transferred sample volume is incorrect. The risk of elevated invalid rates due to incorrect sample volume are additionally mitigated by clear and concise direction to fill the stem of the exact-volume transfer pipette in the FINDER Flu A&B/SARS-CoV-2 Test Instructions for Use and Quick Reference Instructions.

h) Incorrect pipette technique

This study evaluated the effect of incorrect pipetting technique when transferring sample into the FINDER Flu A&B/SARS-CoV-2 Test cartridge. The first condition, where the pipette bulb was squeezed 5 times during sample addition, generated expected results for all samples. The second condition, where the pipette was pushed deep into the cartridge and strongly squeezed, generated expected results for 9/10 replicates, with the remaining replicate generating a fail-safe mechanism "Invalid" result. No incorrect results were reported for any condition tested in this study.

The risk of incorrect results is determined to be appropriately mitigated by fail-safe mechanisms when pipette transfer technique is incorrect. As a precaution, the FINDER Flu A&B/SARS-CoV-2 Test Instructions for Use provide clear and concise direction of the proper pipetting technique.

i) Incorrect timing of sample introduction

This study evaluated the effect of transferring sample into the FINDER Flu A&B/SARS-CoV-2 Test cartridge at the wrong step. Two conditions were tested as part of this study. For the first condition, sample was loaded early, during the cartridge initialization step before on-board liquid reagents completed loading. This resulted in 6/10 replicates with expected results and 4/10 replicates with fail-safe mechanism "Invalid" results. For the second condition, sample was loaded late, up to 60 seconds after the test began (requiring that the instrument lid closure was manually prevented). For this condition all samples generated expected results. No incorrect results were reported for any condition tested in this study.

The risk of incorrect results is determined to be appropriately mitigated by fail-safe mechanisms when the sample is loaded early. Risk of elevated invalid rate due to incorrect timing of sample introduction are additionally mitigated by clear and concise direction provided on-screen for when to transfer sample into the cartridge.

j) Incorrect test steps (closing of sample cap)

This study evaluated the effect of failing to close the FINDER Flu A&B/SARS-CoV-2 Test sample cap. During the sample loading step, the instruction to close the cartridge sample cap

was ignored and the sample cap was left open for the remainder of the test. All samples generated expected results demonstrating that the risk of incorrect results due to failure to close the sample cap is low. As a precaution, the FINDER Flu A&B/SARS-CoV-2 Test Instructions for Use provides clear instructions for proper sample loading.

k) Interference with test equipment (Power Cycling during test).
This study evaluated the effect of power cycling the FINDER Instrument during a test. After starting a test following the normal instructions for use, two conditions were evaluated. For the first condition, power was removed from the base unit by toggling the power switch on the rear of the instrument, which caused a fail-safe mechanism to trigger for all 10 replicates. For the second condition, power was removed from the user interface hardware by initiating a shutdown on the screen. For this condition all samples generated expected results. No incorrect results were reported for any condition tested in this study.

The risk of incorrect results is determined to be appropriately mitigated by fail-safe mechanisms when the instrument base is power cycled mid-run.

C Demonstrating "Insignificant Risk of an Erroneous Result" - Accuracy

1. Comparison Study
   Study Design
   (1) Study Sites and Duration
   Clinical performance of the FINDER Flu A&B/SARS-CoV-2 Test was evaluated across six clinical testing sites throughout the US from February 2025 – April 2025. The sites consisted of urgent care settings and a family medicine setting.

   (2) Operators
   Twelve (12) operators representative of intended CLIA waived users across the six clinical testing sites participated in the study, with between one and four operators at each site. The test operators who participated in the study were not trained laboratory technicians.

   (3) Instructions for Use
   Operators who participated in evaluating the clinical performance of the FINDER Flu A&B/SARS-CoV-2 Test did not receive any training on how to perform the assay and were instructed to refer to the FINDER Flu A&B/SARS-CoV-2 Test Quick Reference Guide.

   (4) Subjects (Patients)
   The subjects were enrolled according to the study protocol Inclusion or Exclusion criteria from symptomatic patients.

   (5) Samples
   The clinical performance of the FINDER Flu A&B/SARS-CoV-2 Test testing nasopharyngeal swab (NPS) specimens collected in FINDER RVP Buffer was established during a prospective multi-center study. Six geographically distinct study sites located in the US and representative of the intended use setting participated in this study from February 2025 to April 2025.

A total of 559 NPS specimens were enrolled in the prospective clinical study. Thirty-two specimens were excluded for influenza A and influenza B while 33 specimens were excluded for SARS-CoV-2. Of the excluded samples, six samples were excluded due to a delay in FINDER testing, one for the lack of a valid comparator result (SARS-CoV-2 only), nineteen for the lack of valid FINDER Flu A&B/SARS-CoV-2 Test results, four for improper specimen collection, and three 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 a FDA-cleared assay. There were no co-infections detected during the clinical study.

(6) Results and Analysis
The clinical performance of the FINDER Flu A&B/SARS-CoV-2 Test when used by untrained operators, testing prospectively collected NPS specimens from patients with signs and symptoms of respiratory tract infections is shown in **Table 20.**

Table 20: 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

(7) Invalid rate for clinical evaluation samples
A total of 559 tests were performed on nasopharyngeal swab specimens from prospective subjects. A total of 59 tests did not complete on the initial run for an overall success rate for initial specimen testing was 89.2% (487/546). All invalid specimens were repeated to produce a final success rate of 96.5% (527/546).

2. Device Performance with Analyte Concentrations Near the Assay LoD:
The performance of the FINDER Flu A&B/SARS-CoV-2 Test with samples at viral concentrations near the assay LoD were evaluated during a reproducibility study, which included a sample with low concentrations of the virus (2x LoD) and a negative sample. The FINDER Flu A&B/SARS-CoV-2 Test was evaluated at three CLIA waived sites. Each site conducted testing over five days with two operators, and three replicates for each panel for a total of 90 replicates per panel member. Each site used three FINDER instruments. Panels were created by spiking cultured influenza A and influenza B and inactivate SARS-CoV-2 of known titer into pooled negative NPS specimen collected in FINDER RVP Buffer. The negative samples were comprised of pooled negative NPS specimen collected in FINDER RVP Buffer without target analytes. The results are presented in **Table 21**.

Table 21: 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	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)
Influenza B	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	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)

Overall, the %CV for all targets was ≤7.4%. In general, the variability between users, between days, and between sites was low. These results are summarized in **Table 22.**

Table 22: 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

3. Operator Questionnaire

Upon completion of the clinical study, the operators at each site were asked to complete an operator questionnaire that covered two categories: 1) system set-up and operation for QCs and patient samples, and 2) results interpretation. The responses were rated on an agreement scale (1 = strongly disagree, 5 = strongly agree). Across all participants, the average score for system set-up and operation was 4.9 for QCs and 4.84 for patient samples. For results interpretation and instructional materials, the average score was 5.00. Based on the study operator responses, the FINDER Flu A&B/SARS-CoV-2 Test was easy to set up and use by following the instructions provided in the QRG.

D Labeling for Waived Devices

1. The labeling consists of:
   a. FINDER Flu A&B/SARS-CoV-2 Test Quick Reference Guide
   b. FINDER Flu A&B/SARS-CoV-2 Test Instructions for Use
   c. FINDER Instrument Operator's Manual
   d. FINDER Flu A&B/SARS-CoV-2 Test components and kit labels

2. The following elements are appropriately present:
   - The FINDER Flu A&B/SARS-CoV-2 Test specifies the environmental operating conditions under which testing may be performed.
   - The FINDER Flu A&B/SARS-CoV-2 Test User Guide and FINDER Flu A&B/SARS-CoV-2 Test Instructions for Use are clear and easy to understand.
   - The FINDER Flu A&B/SARS-CoV-2 Test Instructions for Use and Quick Reference Instructions identify the test as CLIA Waived.
   - The FINDER Flu A&B/SARS-CoV-2 Test Instructions for Use:
     - Indicate that laboratories with a Certificate of Waiver must follow the manufacturer's instructions for performing the test.
     - Include step-by-step instructions for performing the test.
     - Include safety considerations applicable for untrained users.
     - Specify the actions to be taken if an invalid test result is obtained.
     - Include a summary of the studies performed to support CLIA Waiver.
     - Include appropriate warnings and/or limitations pertaining to clinical interpretation of test results.
     - Include recommendations for Quality Control testing including the source of appropriate control materials and the frequency of testing.

   - The labeling is sufficient and satisfies the requirements of 21 CFR Part 809.10.

XI. Conclusion

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