# 510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
# DECISION SUMMARY
ASSAY AND INSTRUMENT

## I Background Information:

### A 510(k) Number

K261837

### 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 (modified design) is substantially equivalent to the FINDER Flu A&B/SARS-CoV-2 Test (K252269).

### 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 set up 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):**
FINDER Flu A&B/SARS-CoV-2 Test

**B Predicate 510(k) Number(s):**
K252269

**C Comparison with Predicate(s):**

| **Device & Predicate Device(s):** | K261837 | K252269 |
|---|---|---|
| Device Trade Name | FINDER Flu A&B/SARS-CoV-2 Test | FINDER Flu A&B/SARS-CoV-2 Test |

| General Device Characteristic Similarities | | |
|---|---|---|
| Intended Use/Indications For Use | Same | 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.<br>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.<br>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.<br>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. |
| Specimen Type | Same | Nasopharyngeal Swab |
| Target Pathogens | Same | Influenza A, Influenza B, SARS-CoV-2 |
| Assay Results | Same | Qualitative |
| Sample Answer System | Same | Automated |
| Time to Result | Same | Approximately 20 minutes |
| Sample Preparation | Same | Uses magnetic-bead based solid-phase extraction chemistry for sample preparation |
| **General Device Characteristic Differences** | | |
| Instrument | FINDER Instrument (Model 100-000082) with integrated touchscreen user interface. | FINDER Instrument (Model 100-000054) with Tablet user interface. |

## 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

## VII Performance Characteristics (if/when applicable):

### A Analytical Performance:

1. Precision/Reproducibility:
   Precision and reproducibility of the FINDER Flu A&B/SARS-CoV-2 Test was evaluated in the original 510(k) Premarket Notification (K252269). No additional testing was conducted.

2. Linearity:
   Not applicable

3. Analytical Specificity/Interference:
   Inclusivity, microbial interference, cross-reactivity, competitive interference and potential interfering substance of the FINDER Flu A&B/SARS-CoV-2 Test was evaluated in the original 510(k) Premarket Notification (K252269). No additional testing was conducted.

4. Detection Limit:
   Limit of detection for the FINDER Flu A&B/SARS-CoV-2 Test was evaluated in the original 510(k) Premarket Notification (K252269). No additional testing was conducted.

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):
   No modifications were made to the FINDER Flu A&B/SARS-CoV-2 Test. Please refer to the published decision summary for the original 510(k) submission for additional information (K252269).

6. Assay Cut-Off:
   Assay cutoff values were not modified for analyte detection, please refer to the published decision summary for the original 510(k) submission for additional information (K252269).

### 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:
   Clinical performance of the FINDER Flu A&B/SARS-CoV-2 Test was evaluated in the original 510(k) Premarket Notification (K252269). No additional testing was conducted.

2. Clinical Specificity:
   See Clinical Sensitivity above.

3. Clinical Cut-Off
   Not applicable

## D Expected Values/Reference Range:

Refer to the published decision summary for the original clearance in K252269.

## E Other Supportive Instrument Performance Characteristics Data:

1. Carryover
   Refer to the published decision summary for the original clearance in K252269.

2. Electrical safety and electromagnetic compatibility (EMC) testing were performed, and the system was found to be acceptable.

3. Software and cybersecurity documentation was reviewed and found to be acceptable.

## 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.