CLIA Waiver by Application Approval Determination
Decision Summary

I. Document Number

CW250005

II. Parent Document Number

K251538

III. CLIA Waiver Type

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

IV. Applicant

Princeton BioMeditech Corp.

V. Proprietary and Established Names

Status COVID-19/Flu A&B

VI. Measurand (analyte)

Influenza A and B nucleoprotein antigens and SARS-CoV-2 nucleocapsid protein antigens

VII. Sample Type(s)

Anterior nasal (ANS) swab and nasopharyngeal (NP) swab specimens

VIII. Type of Test

Qualitative lateral flow immunoassay.

IX. Test System Description

A Overview

The *Status* COVID-19/Flu A&B test is a lateral flow immunochromatographic assay that utilizes chemical extraction of viral antigens followed by solid-phase immunoassay technology for the qualitative detection of SARS-CoV-2, influenza A, and influenza B antigens. This test is intended to be used with nasopharyngeal or anterior nasal swab specimens collected from individuals presenting with signs and symptoms of respiratory infection when collected and tested by individuals who work in a CLIA Waived setting. The assay is intended to aid healthcare

providers in the rapid differential diagnosis of SARS-CoV-2, influenza A, and influenza B viral infections in CLIA-waived laboratory settings.

Principle

The *Status* COVID-19/Flu A&B test procedure begins with collection of a nasopharyngeal or anterior nasal swab specimen, which is then placed into the extraction reagent within the extraction well of the test device for one minute to allow for antigen extraction from disrupted virus particles. Following this extraction period, the test device is raised, tapped, and laid back down onto a level surface, causing the extracted specimen solution to flow onto the test strip and migrate through the pads and membrane components. The test strip contains detector antibodies conjugated to gold dye particles within the pads and immobilized capture antibodies on the membrane surface. When SARS-CoV-2, influenza A, and/or influenza B antigens are present in the specimen, they react with their respective anti-viral antibodies coupled to gold dye particles, migrate through the membrane as antigen-antibody-dye complexes, and bind to the corresponding immobilized capture antibody lines on the membrane, generating colored lines at specific test line positions. The remaining sample and unbound/bound dye complexes continue migrating to the control line position, where immobilized antibodies capture the dye complexes to form the control line, which serves as an internal control confirming that test reagents are functional, antibody-dye conjugates have been properly hydrated and released, and sufficient sample volume has been applied for proper migration. The *Status* COVID-19/Flu A&B test features three distinct test lines - one for SARS-CoV-2 (CoV19), one for influenza A (Flu A), and one for influenza B (Flu B) - enabling separate and differential identification of these respiratory pathogens from a single specimen. Test results are read in 15-20 minutes.

External positive and negative control swabs are provided in each kit of *Status* COVID-19/Flu A&B and should be processed according to the instructions for use upon receiving a new lot of test kits or for each untrained operator. The control swabs are intended to be used as quality control samples representative of positive and negative test samples to demonstrate that the reagents are functional, and the assay procedure is performed correctly.

B Test System Components

Status COVID-19/Flu A&B kit contains enough reagents and materials for 25 tests. The following components are included in a kit.

- *Status* COVID-19/Flu A&B test devices (25): The test strip in each device contains mouse monoclonal antibodies to nucleoprotein of influenza A, influenza B and nucleocapsid protein of SARS-CoV-2. The device is individually pouched.
- Extraction Reagent in vials (25): For use with swab specimens; 300 µL of phosphate buffer with detergents and preservative
- Sterile Swabs (25): For swab specimen collection
- Positive Control Swab (1): Influenza A, B, and SARS-CoV-2 antigen (non-infective recombinant nucleocapsid protein)
- Negative Control Swab (1): Inactivated Group B Streptococcus antigen (non-infective)
- Package Insert /Instructions for use (IFU) (1)
- Quick Reference Instructions (QRI) (1)

X. Specific Contents for CLIA Waiver

A Demonstrating "Simple":

The *Status* COVID-19/Flu A&B test is designed to be simple and easy to use incorporating the following key features:

- The test is self-contained.
- The test uses unprocessed anterior nasal and nasopharyngeal swab specimens directly.
- The test needs only basic, non-technique-dependent specimen manipulation and reagent handling.
- The supplied reagents are premeasured and provided in single-use vials.
- The test does not require any operator intervention during the analysis step.
- The test does not require technical or specialized training for troubleshooting or interpretation of multiple or complex error codes.
- The test does not require any electronic or mechanical maintenance beyond simple tasks.
- The test produces results that do not require operator calibration, interpretation, or calculation.
- The test produces easily determinable results, such as 'positive' or 'negative'.

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

1. Risk Analysis:

   A comprehensive risk analysis was conducted in accordance with ISO14971 which included identification and addressing of potential risks or error sources, analyzing potential causes, effects and the existing measures or mitigation factors related to the *Status* COVID-19/Flu A&B test. The elements considered included operator error, environmental factors, specimen and reagent handling, storage, and external controls.

   Potential sources of errors that could adversely affect system performance were identified and mitigated first through system design verification and validation studies and then through additional precautions and warnings in the labeling. The identified risks which could result in erroneous test results were evaluated in flex studies that stressed the functional limits of the test system (see Item 3 below).

2. Fail-Safe and Failure Alert Mechanisms:

   The *Status* COVID-19/Flu A&B test was designed to include numerous features and fail-safe mechanisms built into the system to prevent erroneous results.

   Design Features

   - Each *Status* COVID-19/Flu A&B test device is individually packaged in a foil pouch containing desiccant to maintain the integrity of the test device and reagents.
   - The kit is printed with the assay name/type, lot number, and expiration date to ensure clarity and appropriate use.
   - Each test cassette features distinct position marks within the results window to facilitate clear and accurate result interpretation. The control line is denoted as "Ctrl", SARS-CoV-2 antigen line is denoted as "CoV19", influenza A antigen line is denoted as "Flu A", and influenza B antigen line is denoted as "Flu B".

- The instructions for use/quick instructions for use clearly define the intended user, environment and indications for use for test device.

Fail-safe Features

- Internal Quality Control – Each *Status* COVID-19/Flu A&B test device has a built-in procedural control. The internal procedural control "Ctrl" line is designed to control for the flow of reagents, adequate sample migration, and integrity of the assay. A distinct reddish-purple control line should always appear if the test has been performed correctly. If the control line does not appear, the test result is invalid, and a new test should be performed.
- External Quality Control – two external control swabs are provided with the test device to ensure that the reagents and test cassette are functioning properly, and to demonstrate proper use and performance by the operator:
    - The Positive Control Swab contains influenza A, B, and SARS-CoV-2 antigen (non-infective recombinant protein).
    - The Negative Control Swab contains Inactivated Group B Streptococcus antigen (non-infective)

  The manufacturer recommends that external control testing be performed with each new operator and before using a new lot or shipment of *Status* COVID-19/Flu A&B kits to confirm the expected Q.C. results, using the external controls provided in the kit. Users are instructed to follow laboratory's standard Q.C. procedures and local, state, and federation regulations regarding quality control procedures and frequency to use. If the controls do not perform as expected, users are instructed to not report the test results.

  External control swabs are extracted and processed according to the test instructions for use. When the positive control is tested, reddish purple lines appear at the Ctrl as well as Flu A, Flu B, and CoV19 positions. When the negative control is tested, a reddish-purple line appears at the Ctrl position only. Each control swab is individually packaged in a foil pouch and the pouch is printed with information such as control swab type and the expiration date. Users are instructed not to use expired external controls. Upon confirmation of the expected results, the kit is ready for use with patient specimens. If external controls do not perform as expected, users are instructed to not use the test results and to repeat the tests or to contact the manufacturer.

3. Flex Studies:

To assess the robustness and risk for false results of the test when deviating from the IFU/QRI test steps, flex studies were conducted that assessed all critical aspects of the test procedure. Each flex condition was tested by three (3) operators who each tested a panel comprised of five (5) negative samples (PNSM only) and five (5) low positive (2x LoD) individually spiked samples for each analyte. Samples were blinded and randomized for testing. The strains used for testing and their respective concentrations are presented in Table 1 and the summary of results are presented in Table 2 below.

Table 1. Strains and Concentrations of Viruses used in Flex Studies

Virus Strains	SARS-CoV-2 (Omicron lineage BA.5)	Influenza A (H3N2/Darwin/9/21)	Influenza B (Yamagata/Phuket/3073/13)
Stock Conc.	$2.53x10^6$ $TCID_{50}$/mL	$3.74x10^4$ $TCID_{50}$/mL	$3.89x10^4$ $TCID_{50}$/mL
2x LoD Conc.	$5.6x10^3$ $TCID_{50}$/mL	$2.5x10^1$ $TCID_{50}$/mL	$2.6x10^1$ $TCID_{50}$/mL

Table 2. Summary Results of Flex Studies

Condition		Sample	Positive Replicates / Total Replicates		
			SARS-CoV-2	Flu A	Flu B
Effect of varying temperatures and humidity on storage up to 1 hour and testing operation	Control: 15 ± 15°C; 40 ± 20% RH	SARS-CoV-2 Positive	15/15	0/15	0/15
		Influenza A Positive	0/15	15/15	0/15
		Influenza B Positive	0/15	0/15	15/15
		Negative	0/15	0/15	0/15
	45 ±5ºC; 85 ± 15% RH	SARS-CoV-2 Positive	15/15	0/15	0/15
		Influenza A Positive	0/15	15/15	0/15
		Influenza B Positive	0/15	0/15	15/15
		Negative	0/15	0/15	0/15
	45 ±5ºC; 5 ± 15% RH	SARS-CoV-2 Positive	15/15	0/15	0/15
		Influenza A Positive	0/15	15/15	0/15
		Influenza B Positive	0/15	0/15	15/15
		Negative	0/15	0/15	0/15
	5 ±5ºC; 85 ± 15% RH	SARS-CoV-2 Positive	15/15	0/15	0/15
		Influenza A Positive	0/15	15/15	0/15
		Influenza B Positive	0/15	0/15	15/15
		Negative	0/15	0/15	0/15
	12 ±3ºC; 12 ± 5% RH	SARS-CoV-2 Positive	15/15	0/15	0/15
		Influenza A Positive	0/15	15/15	0/15
		Influenza B Positive	0/15	0/15	15/15
		Negative	0/15	0/15	0/15
Non-level Surface study	Control – 0° (Surface level, device facing up)	SARS-CoV-2 Positive	15/15	0/15	0/15
		Influenza A Positive	0/15	15/15	0/15
		Influenza B Positive	0/15	0/15	15/15
		Negative	0/15	0/15	0/15
	30° (Device facing up)	SARS-CoV-2 Positive	15/15	0/15	0/15
		Influenza A Positive	0/15	15/15	0/15
		Influenza B Positive	0/15	0/15	15/15

Condition		Sample	Positive Replicates / Total Replicates		
			SARS-CoV-2	Flu A	Flu B
		Negative	0/15	0/15	0/15
	60° (Device facing up)	SARS-CoV-2 Positive	15/15	0/15	0/15
		Influenza A Positive	0/15	15/15	0/15
		Influenza B Positive	0/15	0/15	15/15
		Negative	0/15	0/15	0/15
	90° (Device facing up)	SARS-CoV-2 Positive	15/15	0/15	0/15
		Influenza A Positive	0/15	15/15	0/15
		Influenza B Positive	0/15	0/15	15/15
		Negative	0/15	0/15	0/15
	0° (Device facing down)	SARS-CoV-2 Positive	15/15	0/15	0/15
		Influenza A Positive	0/15	15/15	0/15
		Influenza B Positive	0/15	0/15	15/15
		Negative	0/15	0/15	0/15
	30° (Device facing down)	SARS-CoV-2 Positive	15/15	0/15	0/15
		Influenza A Positive	0/15	15/15	0/15
		Influenza B Positive	0/15	0/15	15/15
		Negative	0/15	0/15	0/15
	60° (Device facing down)	SARS-CoV-2 Positive	15/15	0/15	0/15
		Influenza A Positive	0/15	15/15	0/15
		Influenza B Positive	0/15	0/15	15/15
		Negative	0/15	0/15	0/15
	90° (Device facing down)	SARS-CoV-2 Positive	15/15	0/15	0/15
		Influenza A Positive	0/15	15/15	0/15
		Influenza B Positive	0/15	0/15	15/15
		Negative	0/15	0/15	0/15
Impact of reading light source	1204 lux	SARS-CoV-2 Positive	15/15	0/15	0/15
		Influenza A Positive	0/15	15/15	0/15
		Influenza B Positive	0/15	0/15	15/15

Condition		Sample	Positive Replicates / Total Replicates		
			SARS-CoV-2	Flu A	Flu B
		Negative	0/15	0/15	0/15
	1195 lux	SARS-CoV-2 Positive	15/15	0/15	0/15
		Influenza A Positive	0/15	15/15	0/15
		Influenza B Positive	0/15	0/15	15/15
		Negative	0/15	0/15	0/15
	515 lux	SARS-CoV-2 Positive	15/15	0/15	0/15
		Influenza A Positive	0/15	15/15	0/15
		Influenza B Positive	0/15	0/15	15/15
		Negative	0/15	0/15	0/15
	126 lux	SARS-CoV-2 Positive	15/15	0/15	0/15
		Influenza A Positive	0/15	15/15	0/15
		Influenza B Positive	0/15	0/15	15/15
		Negative	0/15	0/15	0/15
Buffer Volume Variability	25% volume dispensed (75µL)	SARS-CoV-2 Positive	8/15 (7/15 I*)	0/15 (7/15 I*)	0/15 (7 I/15*)
		Influenza A Positive	0/15 (8/15 I*)	7/15 (8/15 I*)	0/15 (8 /15I*)
		Influenza B Positive	0/15 (8 /15I*)	0/15 (8/15 I*)	7/715(8 /15I*)
		Negative	0/15 (8/15 I*)	0/15 (8/15 I*)	0/15 (8/15 I*)
	50% volume dispensed (150µL)	SARS-CoV-2 Positive	15/15	0/15	0/15
		Influenza A Positive	0/15	15/15	0/15
		Influenza B Positive	0/15	0/15	15/15
		Negative	0/15	0/15	0/15
	100% volume dispensed (300µL)	SARS-CoV-2 Positive	15/15	0/15	0/15
		Influenza A Positive	0/15	15/15	0/15
		Influenza B Positive	0/15	0/15	15/15
		Negative	0/15	0/15	0/15
		SARS-CoV-2 Positive	15/15	0/15	0/15

Condition		Sample	Positive Replicates / Total Replicates		
			SARS-CoV-2	Flu A	Flu B
Effect of swab rotation variability	Control – rotate swab 3 times, 1 minute incubation, rotate swab again 3 times	Influenza A Positive	0/15	15/15	0/15
		Influenza B Positive	0/15	0/15	15/15
		Negative	0/15	0/15	0/15
	0 rotation	SARS-CoV-2 Positive	15/15	0/15	0/15
		Influenza A Positive	0/15	15/15	0/15
		Influenza B Positive	0/15	0/15	15/15
		Negative	0/15	0/15	0/15
	Rotate swab 3 times, 1 minute incubation	SARS-CoV-2 Positive	15/15	0/15	0/15
		Influenza A Positive	0/15	15/15	0/15
		Influenza B Positive	0/15	0/15	15/15
		Negative	0/15	0/15	0/15
	1-minute incubation, rotate swab 3 times	SARS-CoV-2 Positive	15/15	0/15	0/15
		Influenza A Positive	0/15	15/15	0/15
		Influenza B Positive	0/15	0/15	15/15
		Negative	0/15	0/15	0/15
	Rotate swab 6 times, 1 minute incubation	SARS-CoV-2 Positive	15/15	0/15	0/15
		Influenza A Positive	0/15	15/15	0/15
		Influenza B Positive	0/15	0/15	15/15
		Negative	0/15	0/15	0/15
	Rotate swab 6 times, 1 minute incubation, rotate swab again 6 times	SARS-CoV-2 Positive	15/15	0/15	0/15
		Influenza A Positive	0/15	15/15	0/15
		Influenza B Positive	0/15	0/15	15/15
		Negative	0/15	0/15	0/15
	rotate swab 3 times, and rotate swab again 3 times, no incubation	SARS-CoV-2 Positive	15/15	0/15	0/15
		Influenza A Positive	0/15	15/15	0/15
		Influenza B Positive	0/15	0/15	15/15
		Negative	0/15	0/15	0/15
		SARS-CoV-2 Positive	15/15	0/15	0/15

Condition		Sample	Positive Replicates / Total Replicates		
			SARS-CoV-2	Flu A	Flu B
Device standing and tapping	Control – raise device upright, let stand 1-2 seconds, gently tap the device, lay the device back down	Influenza A Positive	0/15	15/15	0/15
		Influenza B Positive	0/15	0/15	15/15
		Negative	0/15	0/15	0/15
	Raise device upright, let stand 1-2 seconds, lay the device back down, no tapping	SARS-CoV-2 Positive	15/15	0/15	0/15
		Influenza A Positive	0/15	15/15	0/15
		Influenza B Positive	0/15	0/15	15/15
		Negative	0/15	0/15	0/15
	No raising or tapping	SARS-CoV-2 Positive	15/15	0/15	0/15
		Influenza A Positive	0/15	15/15	0/15
		Influenza B Positive	0/15	0/15	15/15
		Negative	0/15	0/15	0/15
Physical Impact of test device	Control (No impact)	SARS-CoV-2 Positive	15/15	0/15	0/15
		Influenza A Positive	0/15	15/15	0/15
		Influenza B Positive	0/15	0/15	15/15
		Negative	0/15	0/15	0/15
	Premature handling of device by picking up for reading after 5 minutes	SARS-CoV-2 Positive	15/15	0/15	0/15
		Influenza A Positive	0/15	15/15	0/15
		Influenza B Positive	0/15	0/15	15/15
		Negative	0/15	0/15	0/15
	Dropping device from 1 meter after 5 minutes	SARS-CoV-2 Positive	15/15	0/15	0/15
		Influenza A Positive	0/15	15/15	0/15
		Influenza B Positive	0/15	0/15	15/15
		Negative	0/15	0/15	0/15
Dry swab and swab in extraction buffer sample stability	Sample Stability – delay in inserting swab to the sample port – 15 min	SARS-CoV-2 Positive	15/15	0/15	0/15
		Influenza A Positive	0/15	15/15	0/15
		Influenza B Positive	0/15	0/15	15/15
		Negative	0/15	0/15	0/15
		SARS-CoV-2 Positive	15/15	0/15	0/15

Condition		Sample	Positive Replicates / Total Replicates		
			SARS-CoV-2	Flu A	Flu B
	Sample Stability – delay in inserting swab to the sample port –30 min	Influenza A Positive	0/15	15/15	0/15
		Influenza B Positive	0/15	0/15	15/15
		Negative	0/15	0/15	0/15
	Sample Stability – delay in inserting swab to the sample port –60 min	SARS-CoV-2 Positive	15/15	0/15	0/15
		Influenza A Positive	0/15	15/15	0/15
		Influenza B Positive	0/15	0/15	15/15
		Negative	0/15	0/15	0/15
	Sample Stability – Swab is inserted, then the subsequent rotation step is intentionally delayed-15 min	SARS-CoV-2 Positive	15/15	0/15	0/15
		Influenza A Positive	0/15	15/15	0/15
		Influenza B Positive	0/15	0/15	15/15
		Negative	0/15	0/15	0/15
	Sample Stability – Swab is inserted, then the subsequent rotation step is intentionally delayed-30 min	SARS-CoV-2 Positive	15/15	0/15	0/15
		Influenza A Positive	0/15	15/15	0/15
		Influenza B Positive	0/15	0/15	15/15
		Negative	0/15	0/15	0/15
	Sample Stability – Swab is inserted, then the subsequent rotation step is intentionally delayed-60 min	SARS-CoV-2 Positive	15/15	0/15	0/15
		Influenza A Positive	0/15	15/15	0/15
		Influenza B Positive	0/15	0/15	15/15
		Negative	0/15	0/15	0/15
Reading Time	5 min**	SARS-CoV-2 Positive	6/15	0/15	0/15
		Influenza A Positive	0/15	5/15	0/15
		Influenza B Positive	0/15	0/15	5/15
		Negative	0/15	0/15	0/15
	10 min	SARS-CoV-2 Positive	15/15	0/15	0/15
		Influenza A Positive	0/15	15/15	0/15
		Influenza B Positive	0/15	0/15	15/15
		Negative	0/15	0/15	0/15
	Control - 15 min	SARS-CoV-2 Positive	15/15	0/15	0/15

Condition		Sample	Positive Replicates / Total Replicates		
			SARS-CoV-2	Flu A	Flu B
		Influenza A Positive	0/15	15/15	0/15
		Influenza B Positive	0/15	0/15	15/15
		Negative	0/15	0/15	0/15
	20 min	SARS-CoV-2 Positive	15/15	0/15	0/15
		Influenza A Positive	0/15	15/15	0/15
		Influenza B Positive	0/15	0/15	15/15
		Negative	0/15	0/15	0/15
	25 min	SARS-CoV-2 Positive	15/15	0/15	0/15
		Influenza A Positive	0/15	15/15	0/15
		Influenza B Positive	0/15	0/15	15/15
		Negative	0/15	0/15	0/15
	30 min	SARS-CoV-2 Positive	15/15	0/15	0/15
		Influenza A Positive	0/15	15/15	0/15
		Influenza B Positive	0/15	0/15	15/15
		Negative	0/15	0/15	0/15
	60 min	SARS-CoV-2 Positive	15/15	0/15	0/15
		Influenza A Positive	0/15	15/15	0/15
		Influenza B Positive	0/15	0/15	15/15
		Negative	0/15	0/15	0/15
Open Pouch Stability at room temperature	**Control - 0 min**	SARS-CoV-2 Positive	15/15	0/15	0/15
		Influenza A Positive	0/15	15/15	0/15
		Influenza B Positive	0/15	0/15	15/15
		Negative	0/15	0/15	0/15
	1 hr	SARS-CoV-2 Positive	15/15	0/15	0/15
		Influenza A Positive	0/15	15/15	0/15
		Influenza B Positive	0/15	0/15	15/15
		Negative	0/15	0/15	0/15
	2 hrs	SARS-CoV-2 Positive	15/15	0/15	0/15

Condition		Sample	Positive Replicates / Total Replicates		
			SARS-CoV-2	Flu A	Flu B
		Influenza A Positive	0/15	15/15	0/15
		Influenza B Positive	0/15	0/15	15/15
		Negative	0/15	0/15	0/15
	4 hrs	SARS-CoV-2 Positive	15/15	0/15	0/15
		Influenza A Positive	0/15	15/15	0/15
		Influenza B Positive	0/15	0/15	15/15
		Negative	0/15	0/15	0/15
	8 hrs	SARS-CoV-2 Positive	15/15	0/15	0/15
		Influenza A Positive	0/15	15/15	0/15
		Influenza B Positive	0/15	0/15	15/15
		Negative	0/15	0/15	0/15

* "I" = invalid; adding only 0.25x of the required buffer volume resulted in invalid test results.
** False negative results were observed when interpreted at 5 minutes.

The flex studies demonstrate that the test is robust in the claimed intended use condition with an insignificant risk of erroneous results.

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

1. Comparison study:

a) Anterior Nasal (AN) Swab Specimen:

A clinical study was conducted to evaluate the performance of the *Status* COVID-19/Flu A&B test using AN swab specimens. A total of four hundred fifty-five (455) AN swab specimens were prospectively collected from six (6) CLIA-waived clinical sites between September 2023 and October 2024. Data from nine (9) patients were excluded from the analysis because they did not meet inclusion criteria. Therefore, the final performance evaluation was based on four hundred forty-six (446) AN swab specimens. Results from the candidate device were compared to NP swab specimen results when tested with an FDA cleared RT-PCR assay for both SARS-CoV-2 and influenza A and B to demonstrate performance.

Patient Demographics

Demographic information was collected for all four hundred forty-six (446) patients included in the study.

Table 3. Patient Demographic: AN Swab Specimen

Characteristics of the study population		N=446	Percent (%)
Sex	Male	160	35.9%
	Female	284	63.7%

	Prefer not to say	2	0.4%
Age	<2	3	0.7%
	2-4	6	1.3%
	5-7	18	4.0%
	8-10	19	4.3%
	11-13	24	5.4%
	14-17	23	5.2%
	18-25	92	20.6%
	26-35	89	20.0%
	36-65	142	31.8%
	>65	30	6.7%
	Prefer not to say	0	0.0%
Ethnicity	Hispanic or Latino	60	13.5%
	Not Hispanic or Latino	361	80.9%
	Prefer not to say	25	5.6%
Race	Asian	7	1.6%
	Black or African American	27	6.1%
	White or Caucasian	376	84.3%
	Native Hawaiian or Other Pacific Islander	3	0.7%
	American Indian or Alaska Native	2	0.4%
	Other (Mixed race)	11	2.5%
	Prefer not to say	20	4.5%

Table 4. SARS-CoV-2 Performance of the *Status* COVID-19/Flu A&B Test with AN Swab Specimens Compared to RT-PCR

SARS-CoV-2		**Comparator test**		
		Positive	**Negative**	**Total**
***Status* COVID-19 /Flu A&B**	**Positive**	114	0	114
	Negative	3	329	332
	Total	117	329	446
	Positive Percent Agreement (PPA) = 97.4% (95% CI: 92.7% to 99.1%)			
	Negative Percent Agreement (NPA) = 100.0% (95% CI: 98.9% to 100.0%)			

Table 5. SARS-CoV-2 Test Performance by Days Post-Symptom Onset (DPSO) – AN Swab Specimens

DPSO	**Specimens tested**	***Status* positive**	**RT-PCR positive**	**PPA (95% CI)**
Day 0	14	5	6	83.3% (43.7%-97.0%)

Day 1	109	32	32	100.0% (89.3%-100.0%)
Day 2	165	45	46	97.8% (88.7%-99.6%)
Day 3	92	20	21	95.2% (77.3%-99.2%)
Day 4	50	11	11	100.0% (74.1%-100.0%)
Day 5	16	1	1	100.0% (20.7%-100.0%)
Total	446	114	117	97.4% (92.7%-99.1%)

Table 6. Influenza A Performance of the *Status* COVID-19/Flu A&B Test with AN Swab Specimens Compared to RT-PCR

Influenza A		**Comparator test**		
		Positive	**Negative**	**Total**
***Status* COVID-19 /Flu A&B**	**Positive**	43	2	45
	Negative	4	397	401
	Total	47	399	446
	Positive Percent Agreement (PPA) = 91.5% (95% CI: 80.1% to 96.6%)			
	Negative Percent Agreement (NPA) = 99.5% (95% CI: 98.2% to 99.9%)			

Table 7. Influenza B Performance of the *Status* COVID-19/Flu A&B Test with AN Swab Specimens Compared to RT-PCR

Influenza B		**Comparator test**		
		Positive	**Negative**	**Total**
***Status* COVID-19 /Flu A&B**	**Positive**	37	1	38
	Negative	4	404	408
	Total	41	405	446
	Positive Percent Agreement (PPA) = 90.2% (95% CI: 77.5% to 96.1%)			
	Negative Percent Agreement (NPA) = 99.8% (95% CI: 98.6% to 100.0%)			

b) <u>Nasopharyngeal (NP) Swab Specimen:</u>

In the clinical study, NP swab specimens were also collected and tested using the *Status* COVID-19/Flu A&B assay. A total of five hundred fifty (550) NP specimens were obtained from six (6) CLIA Waived clinical sites between September 2023 and October 2024. Thirteen (13) specimens were excluded from the final analysis because they did not meet inclusion criteria. Accordingly, the performance evaluation of the *Status* COVID-19/Flu A&B assay was conducted using five hundred thirty-seven (537) prospectively collected NP swab specimens. Results from the candidate device were compared to NP swab specimen results when tested with an FDA cleared RT-PCR assay for both SARS-CoV-2 and influenza A and B to demonstrate performance.

Patient Demographics

Patient demographic data were available for all five hundred thirty-seven (537) patients included in the NP swab specimen study population.

Table 8. Patient Demographics –NP Swab Specimens

Characteristics of the study population		N=537	Percent (%)
Sex	Male	191	35.6%
	Female	346	64.4%
	Prefer not to say	0	0.0%
Age	<2	0	0.0%
	2-4	3	0.6%
	5-7	11	2.0%
	8-10	16	3.0%
	11-13	21	3.9%
	14-17	33	6.1%
	18-25	106	19.7%
	26-35	108	20.1%
	36-65	198	36.9%
	>65	41	7.6%
	Prefer not to say	0	0.0%
Ethnicity	Hispanic or Latino	22	4.1%
	Not Hispanic or Latino	494	92.0%
	Prefer not to say	21	3.9%
Race	Asian	3	0.6%
	Black or African American	13	2.4%
	White or Caucasian	500	93.1%
	Native Hawaiian or Other Pacific	2	0.4%
	Other (Mixed race)	4	0.7%
	Prefer not to say	15	2.8%

The performance of the *Status* COVID-19/Flu A&B test using NP swab specimens was compared to those from the RT-PCR assay.

Table 9. SARS-CoV-2 Performance of the *Status* COVID-19/Flu A&B Test with NP Swab Specimens Compared to RT-PCR

SARS-CoV-2		Comparator test		
		Positive	**Negative**	**Total**
***Status* COVID-19 /Flu A&B**	**Positive**	171	1	172
	Negative	8	357	365
	Total	179	358	537

	Positive Percent Agreement (PPA) = 95.5% (95% CI: 91.4% to 97.7%)
	Negative Percent Agreement (NPA) = 99.7% (95% CI: 98.4% to 99.9%)

Table 10. SARS-CoV-2 Test Performance by DPSO – NP Swab Specimens

DPSO	Specimens tested	*Status* positive	PCR positive	PPA (95% CI)
Day 0	15	7	7	100.0% (64.6%-100.0%)
Day 1	163	63	64	98.4% (91.7%-99.7%)
Day 2	197	61	64	95.3% (87.1%-98.4%)
Day 3	106	25*	28	89.3% (72.8%-96.3%)
Day 4	40	9	10	90.0% (59.6%-98.2%)
Day 5	16	6	6	100.0% (61.0%-100.0%)
Total	537	171*	179	95.5% (91.4%-97.7%)

* One false positive result was excluded from the analysis. Total includes only true positives based on PCR comparator.

Table 11. Influenza A Performance of the *Status* COVID-19/Flu A&B Test with NP Swab Specimens Compared to RT-PCR

Influenza A		Comparator test		
		Positive	**Negative**	**Total**
***Status* COVID-19 /Flu A&B**	**Positive**	48	3	51
	Negative	3	483	486
	Total	51	486	537
	Positive Percent Agreement (PPA) = 94.1% (95% CI: 84.1%-98.0%)			
	Negative Percent Agreement (NPA) = 99.4% (95% CI: 98.2%-99.8%)			

Table 12. Influenza B Performance of the *Status* COVID-19/Flu A&B Test with NP Swab Specimens Compared to RT-PCR

Influenza B		Comparator test		
		Positive	**Negative**	**Total**
***Status* COVID-19 /Flu A&B**	**Positive**	51	0	51
	Negative	4	482	486
	Total	55	482	537
	Positive Percent Agreement (PPA) = 92.7% (95% CI: 82.7% to 97.1%)			
	Negative Percent Agreement (NPA) = 100.0% (95% CI: 99.2% to 100.0%)			

2. Device Performance with Analyte Concentrations Near the Cutoff:

The precision and reproducibility studies were conducted separately.

a. Multi-Lot Precision:

Two precision studies were conducted to evaluate the lot-to-lot variability of the *Status* COVID-19/Flu A&B using contrived samples containing heat-inactivated SARS-CoV-2: omicron variant, live influenza (Flu) A: H3N2/Darwin/9/21, and live Flu B: Yamagata/Phuket/3073/13. Both studies were conducted at a single internal site and are described below separately, and results are summarized in Table 1.

Study 1 assessed test performance using test samples prepared as follows:

i. Negative sample (without any analyte)
ii. Low positive: each analyte at 1x LoD
iii. Moderate positive: each analyte at 3x LoD

Fifty (50) µL of each coded sample was applied to dry nasal swab and processed per the IFU. Blinded and randomized samples were tested using three (3) device lots by two (2) operators over ten (10) non-consecutive days (2 runs/day, 2 replicates/run), generating 240 total results per analyte.

Study 2 specifically evaluated lot-to-lot variability using the same viral strains at the following concentrations:

i. Negative sample (without any analyte)
ii. Very low positive: each analyte at 0.7x LoD
iii. Low positive: each analyte at 1x LoD
iv. Moderate positive: each analyte at 3x LoD

Two (2) operators tested three (3) different lots of the *Status* COVID-19/Flu A&B over three (3) non-consecutive days (2 runs/day, 2 replicates/run), generating 72 results per analyte.

The results from studies 1 and 2 demonstrated that all negative samples and those prepared at 3x LoD exhibited 100% agreement with expected results across the operators, lots, days, and runs. Samples prepared at 1x LoD, demonstrated greater than 95% agreement with the expected result across all test conditions, indicating consistent performance at the limit of detection. As expected, samples prepared at 0.7x LoD exhibited slightly lower precision (<95%), consistent with inherent variability at below the LoD level. However, the performance was consistent across all three lots tested. The results from study 1 and study 2 are summarized below.

Table 13. Lot-to-Lot Precision Study Results

Sample	Analyte	# of positive result/# of total tested (% positive rate)			Total sample count (% positive rate)
		Lot 1	Lot 2	Lot 3	
Negative	Influenza A	0/104 (0.0%)	0/104 (0.0%)	0/104 (0.0%)	312/312 (0.0%)
	Influenza B	0/104 (0.0%)	0/104 (0.0%)	0/104 (0.0%)	312/312 (0.0%)
	SARS-CoV-2	0/104 (0.0%)	0/104 (0.0%)	0/104 (0.0%)	312/312 (0.0%)

0.7xLoD	Influenza A	9/24 (37.5%)	11/24 (45.8%)	12/24 (50.0%)	32/72 (44.4%)
	Influenza B	22/24 (91.7%)	22/24 (91.7%)	20/24 (83.3%)	64/72 (88.9%)
	SARS-CoV-2	15/24 (62.5%)	14/24 (58.3%)	16/24 (66.7%)	45/72 (62.5%)
1xLoD	Influenza A	102/104 (98.1%)	103/104 (99.0%)	102/104 (98.1%)	307/312 (98.4%)
	Influenza B	101/104 (97.1%)	102/104 (98.1%)	104/104 (100.0%)	307/312 (98.4%)
	SARS-CoV-2	104/104 (100.0%)	102/104 (98.1%)	103/104 (99.0%)	310/312 (99.4%)
3xLoD	Influenza A	104/104 (100.0%)	104/104 (100.0%)	104/104 (100.0%)	312/312 (100.0%)
	Influenza B	104/104 (100.0%)	104/104 (100.0%)	104/104 (100.0%)	312/312 (100.0%)
	SARS-CoV-2	104/104 (100.0%)	104/104 (100.0%)	104/104 (100.0%)	312/312 (100.0%)

b. Multi-Site Reproducibility Study:

A multi-site reproducibility study was performed to assess the performance of the candidate device using a contrived sample panel comprised of a true negative, a high negative sample (C5, 95% expected to be negative), a low positive (1x LoD), and a moderate positive (3x LoD) sample for each analyte. The study was conducted by untrained operators in CLIA waived settings over five non-consecutive days.

Contrived swab samples were prepared by spiking pooled human nasal wash using the same panel of SARS-CoV-2, Influenza A, and Influenza B strains as described above in the precision study. Each diluted sample (50 µL) was directly applied onto the sample collection swab head. True negative swab samples were prepared by applying fifty (50) µL of negative pooled human nasal wash directly onto the sample collection swab head.

The contrived sample swabs were randomized and blinded to each operator at three (3) CLIA-waived sites and one in-house site. Nine (9) untrained operators at the CLIA waived sites and three (3) trained operators at the internal site conducted testing. A total 10 panels were prepared, where each panel consisted of 4 samples at different concentration of each analyte. Each operator tested 10 panels in replicates of 2, 2 runs per day, and on 3 lots of devices for over 5 days.

The results are shown below in Table 2 below. These outcomes all met the predefined acceptance criteria and generated no significant difference between sites.

Table 14. Summary of Multi-Site Reproducibility Study

Sample		**# of positive result/# of total tested (% positive rate)**				**Total sample count (% positive rate)**
		Site 1	**Site 2**	**Site 3**	**Lab 1**	
True Negative	Influenza A	0/180 (0.0%)	0/180 (0.0%)	0/180 (0.0%)	0/180 (0.0%)	0/720 (0.0%)
	Influenza B	0/180 (0.0%)	0/180 (0.0%)	0/180 (0.0%)	0/180 (0.0%)	0/720 (0.0%)

	SARS-CoV-2	0/180 (0.0%)	0/180 (0.0%)	0/180 (0.0%)	0/180 (0.0%)	0/720 (0.0%)
High Negative	Influenza A	2/180 (1.1%)	2/180 (1.1%)	1/180 (0.6%)	2/180 (1.1%)	7/720 (0.9%)
	Influenza B	3/180 (1.7%)	1/180 (0.6%)	2/180 (0.6%)	2/180 (1.1%)	8/720 (1.1%)
	SARS-CoV-2	1/180 (0.6%)	2/180 (1.1%)	1/180 (0.6%)	1/180 (0.6%)	5/720 (0.7%)
1x LoD	Influenza A	178/180 (98.9%)	177/180 (98.3%)	178/180 (98.9%)	179/180 (99.4%)	712/720 (98.9%)
	Influenza B	177/180 (98.3%)	178/180 (98.9%)	177/180 (98.3%)	179/180 (99.4%)	711/720 (98.8%)
	SARS-CoV-2	179/180 (99.4%)	179/180 (99.4%)	178/180 (98.9%)	180/180 (100%)	716/720 (99.4%)
3x LoD	Influenza A	180/180 (100%)	180/180 (100%)	180/180 (100%)	180/180 (100%)	720/720 (100%)
	Influenza B	180/180 (100%)	180/180 (100%)	180/180 (100%)	180/180 (100%)	720/720 (100%)
	SARS-CoV-2	180/180 (100%)	180/180 (100%)	180/180 (100%)	180/180 (100%)	720/720 (100%)

3. Operator questionnaire:

A total of thirty-one (31) untrained operators participated in a usability assessment to evaluate comprehension of the product labeling, test procedure, and result interpretation. Each participant was provided with the Quick Reference Instructions (QRI) and test materials and instructed to perform the test without prior training. The questionnaire included 7 questions, and the questions along with the operators' responses are provided in the Table below. The questionnaire employed a five-point scale (Strongly Agree, Agree, Neutral, Disagree, Strongly Disagree) to capture the level of agreement with statements.

Table 15. Operator's Questionnaire and Response

Question	Response selected				
	Strongly agree	**Agree**	**Neutral**	**Disagree**	**Strongly disagree**
The Quick Reference Guide was easy to read and understand	30/31 (96.8%)	1/31 (3.2%)	0/31 (0%)	0/31 (0%)	0/31 (0%)
It was easy to prepare the sample for testing.	30/31 (96.8%)	1/31 (3.2%)	0/31 (0%)	0/31 (0%)	0/31 (0%)
The *Status* COVID-19/Flu A&B Test was easy to perform.	30/31 (96.8%)	1/31 (3.2%)	0/31 (0%)	0/31 (0%)	0/31 (0%)
The control line was easy to see	31/31 (100%)	0/31 (0%)	0/31 (0%)	0/31 (0%)	0/31 (0%)
The test lines were easy to see.	29/31 (93.5%)	2/31 (6.5%)	0/31 (0%)	0/31 (0%)	0/31 (0%)
I understand how to interpret results for the test.	29/31	2/31	0/31	0/31	0/31

	(93.5%)	(6.5%)	(0%)	(0%)	(0%)
I did not need help to perform the test or read the results.	31/31 (100%)	0/31 (0%)	0/31 (0%)	0/31 (0%)	0/31 (0%)

Based on the operators' feedback, the overall *Status* COVID-19/Flu A&B test was found to be easy to use in the hands of untrained users.

D Labeling for Waived Devices

The labeling submitted for the *Status* COVID-19/Flu A&B consists of:

1. Quick Reference Instructions (QRI)
2. Instructions for Use (IFU)
3. Package Labeling – kit box labels

The following elements are appropriately present:

- The QRI and the IFU identify the test as CLIA waived.
- The IFU contains a statement that a Certificate of Waiver is required to perform the test in a waived setting.
- A statement clearly states the specimen type.
- A statement that laboratories with a Certificate of Waiver must follow the manufacturer's instructions for performing the test.
- The IFU contains a statement that any modification to the test or the manufacturer's instructions will result in the test being classified as high complexity. Step-by-step instructions for all control procedures, including frequencies and action to be taken if control results are out of range or invalid, or if other failure alert or fail-safe mechanisms are activated.
- The IFU and QRI provide instructions for conducting quality control procedures.
- A warning addressing color blindness when waived tests use color-coded reagents and/or endpoints.
- Telephone number to contact manufacturer for technical assistance or troubleshooting the test system which directs the user to call for assistance when the device or the control materials do not work as specified by the manufacturer.
- 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.