November 14, 2025

Princeton BioMeditech Corp.
Young-A Kim
Director, RA/QA
4242 US Hwy1
Monmouth Junction, New Jersey 08852

Re: K251538
Trade/Device Name: Status COVID-19/Flu A&B
Regulation Number: 21 CFR 866.3987
Regulation Name: Multi-Analyte Respiratory Virus Antigen Detection Test
Regulatory Class: Class II
Product Code: SCA
Dated: May 19, 2025
Received: May 19, 2025

Dear Young-A Kim:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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)*
K251538

Device Name
Status COVID-19/Flu A&B

Indications for Use *(Describe)*

The *Status* COVID-19/Flu A&B test is a lateral flow immunoassay intended for the qualitative detection and differentiation of influenza A and influenza B nucleoprotein antigens and SARS-CoV-2 nucleocapsid antigen directly from nasopharyngeal (NP) or anterior nasal swab (ANS) specimens from individuals with signs and symptoms of respiratory tract infection. Clinical signs and symptoms of respiratory viral infection due to SARS-Co V-2 and influenza can be similar.

All negative results are presumptive and should be confirmed with a molecular assay, if necessary, for patient management. Negative results do not rule out infection with influenza or SARS-CoV-2 and should not be used as the sole basis for treatment or patient management decisions.

Positive results do not rule out bacterial infection or co-infection with other viruses.

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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510(k) Summary

In accordance with 21 CFR 807.87(h) and 21 CFR 807.92, the following 510(k) Summary for ***Status*™ COVID-19/Flu A&B** test is provided.

Applicant Information

Applicant:	Princeton BioMeditech Corporation 4242 US Hwy 1, Monmouth Junction, NJ 08852 Phone: 732-274-1000 Fax: 732-274-1010
Contact Person:	Young-A Kim, Ph.D., yakim@pbmc.com
Alternate Contact Person:	Jemo Kang, Ph.D., j.kang@pbmc.com
Date Prepared:	May 19, 2025

Device Information

Proprietary Name/Tade Name:	*Status*™ COVID-19/Flu A&B
Common Name:	Multi-analyte respiratory virus antigen detection test
Classification Name:	Multi-analyte respiratory virus antigen detection test
Device Class	Class II
Regulation Number:	21 CFR 866.3987
Product Code:	SCA

Predicate Device

Trade Name:	Healgen Rapid Check COVID-19/Flu A&B Antigen Test (DEN 240029)

Intended Use

The ***Status*™ COVID-19/Flu A&B** test is a lateral flow immunoassay intended for the qualitative detection and differentiation of influenza A and influenza B nucleoprotein antigens and SARS-CoV-2 nucleocapsid antigen directly from nasopharyngeal (NP) or anterior nasal swab (ANS) specimens from individuals with signs and symptoms of respiratory tract infection. Clinical signs and symptoms of respiratory viral infection due to SARS-CoV-2 and influenza can be similar.

All negative results are presumptive and should be confirmed with a molecular assay, if necessary, for patient management. Negative results do not rule out infection with influenza or SARS-CoV-2 and should not be used as the sole basis for treatment or patient management decisions.

Positive results do not rule out bacterial infection or co-infection with other viruses.

Principle of Procedure

The ***Status*™ COVID-19/Flu A&B** test is a lateral flow immuno-chromatographic assay which utilizes the chemical extraction of viral antigens followed by solid-phase immunoassay technology. The ***Status*™ COVID-19/Flu A&B** test is designed to detect antigens from SARS-CoV-2, influenza A, and /or influenza B in nasopharyngeal or anterior nasal swab specimens from individuals with signs and symptoms of respiratory infection. It is intended to aid in the rapid differential diagnosis of SARS-CoV-2, influenza A, and /or influenza B viral infections. The ***Status*™ COVID-19/Flu A&B** test is validated for use with direct specimens without transport media.

In the test procedure, a nasopharyngeal or anterior nasal swab specimen is collected and placed into extraction reagent in the Extraction Well of the test device for one minute. During this time, the antigen is extracted from disrupted virus particles. The test device is then raised, tapped, and laid back down onto a level surface. Through this simple action, the solution of extracted specimen flows onto the test strip and migrates through the pads and membrane of the test strip. The pads contain detector antibodies conjugated to gold dye and the membrane contains immobilized capture antibodies. If SARS- CoV-2, influenza A, and/or influenza B antigens are present in the specimen, they will react with anti-SARS-CoV-2 antibody coupled to gold dye particles and/or anti-influenza antibody coupled to gold dye particles, migrate through the membrane as antigen-antibody-dye complexes, bind to the immobilized capture antibody line(s) on the membrane, and generate a colored line in the specific test line position. The rest of the sample and unbound/bound dye complexes continue to migrate to the Control line position (Ctrl), where immobilized antibodies to the anti-SARS-CoV-2 and anti-influenza antibodies capture the dye complexes and form the Control line. Formation of the Control line serves as an internal control to demonstrate that test reagents are functional, antibody-dye conjugates in the dye pad have been hydrated and released and that sufficient sample has been applied to allow for migration through the Test and Control lines. If the Control line does not appear within the designated incubation time, the result is invalid, and the test should be repeated using a new test device and specimen.

***Status*™ COVID-19/Flu A&B** test has three Test lines, one for SARS-CoV-2 (CoV19), one for influenza A (Flu A), and one for influenza B (Flu B). The three Test lines allow for the differential

identification of SARS-CoV-2, influenza A, and/or B from a single specimen. If any Test line appears in the test result window, together with the Control line, the test result is positive for SARS-CoV-2 and/or influenza. The test detects, but does not differentiate, between the SARS-CoV and SARS-CoV-2 viruses.

Substantial Equivalence

The *Status*™ COVID-19/Flu A&B test is substantially equivalent to the Healgen Rapid Check COVID-19/Flu A&B Antigen Test. Both tests qualitatively detect SARS-CoV-2, Influenza A, and Influenza B antigens using the same immunochromatographic lateral flow technology. While the *Status*™ COVID-19/Flu A&B test is intended for use by healthcare professionals in CLIA- waived settings and is validated for both nasopharyngeal and anterior nasal swabs, these differences do not affect the core functionality or intended use. A detailed comparison to the predicate device is provided in the table below.

Table 1. Comparison with Predicate Device

Features	Candidate Device	Predicate Device
Device Name	*Status*™ COVID-19/Flu A&B	Healgen Rapid Check COVID-19/Flu A&B Antigen Test DEN240029
Indications for Use	The *Status*™ COVID-19/Flu A&B test is a lateral flow immunoassay intended for the qualitative detection and differentiation of influenza A and influenza B nucleoprotein antigens and SARS-CoV-2 nucleocapsid antigen directly from nasopharyngeal (NP) or anterior nasal swab (ANS) specimens from individuals with signs and symptoms of respiratory tract infection. Clinical signs and symptoms of respiratory viral infection due to SARS-CoV-2 and influenza can be similar. All negative results are presumptive and should be confirmed with a molecular assay, if necessary, for patient management. Negative results do not rule out infection with influenza or SARS-CoV-2 and	The Healgen Rapid Check COVID-19/Flu A&B Antigen Test is a lateral flow immunochromatographic assay intended for the qualitative detection and differentiation of influenza A, and influenza B nucleoprotein antigens and SARS-CoV-2 nucleocapsid antigen directly in anterior nasal swab samples from individuals with signs and symptoms of respiratory tract infection. Symptoms of respiratory infections due to SARS-CoV-2 and influenza can be similar. This test is for non-prescription home use by individuals aged 14 years or older testing themselves, or adults testing individuals aged 2 years or older. All negative results are presumptive and should be confirmed with an FDA-cleared

	should not be used as the sole basis for treatment or patient management decisions. Positive results do not rule out bacterial infection or co-infection with other viruses.	molecular assay when determined to be appropriate by a healthcare provider. Negative results do not rule out infection with influenza, SARS-CoV-2 or other pathogens. Individuals who test negative and experience continued or worsening respiratory symptoms, such as fever, cough and/or shortness of breath, should therefore seek follow-up care from their healthcare provider. Positive results do not rule out co-infection with other respiratory pathogens and therefore do not substitute for a visit to a healthcare provider or appropriate follow-up.
Intended Users	For Prescription Use Only	For Over-the-Counter Use (OTC)
User Environment	Moderate to high complexity and CLIA- waived settings	Home or similar environment
Assay Principle	Lateral flow immunoassay	Lateral flow immunoassay
Assay Type	Qualitative	Qualitative
Sample Type	• Nasopharyngeal swab specimen • Anterior nasal swab specimen	Anterior nasal swab specimens
Measurand	Influenza type A and type B nucleoprotein and SARS-CoV-2 nucleocapsid antigens	Influenza type A and type B nucleoprotein and SARS-CoV-2 nucleocapsid antigens
Controls	Internal control	Internal control
Interpretation	Visually read	Visually read
Time to Results	15-20 minutes	15-20 minutes

Performance Testing Summary

Limit of Detection (LoD)

The LoD of *Status*™ COVID-19/Flu A&B test was determined as the lowest detectable concentration of SARS-CoV-2, influenza A, and influenza B at which at least 95 % of all true positive replicates tested positive. The LoD was assessed for each analyte in two parts, preliminary and confirmatory LoD studies.

In the preliminary LoD study, serial 10-fold dilutions of heat-inactivated SARS-CoV-2, and live influenza A and B virus stocks were prepared in a pooled negative clinical matrix (NCM). Each dilution was tested in 3 replicates using 3 independent device lots. For each replicate, 50 µL of

sample was carefully dispensed onto the swab by slowly moving the pipette tip up and down the swab tip and then tested as described in the IFU. The preliminary LoD confirmation was then evaluated in a confirmatory study by testing 20 replicates.

The acceptance criterion for confirming the LoD was at least 95 % of replicates (≥ 19/20) test positive. When the preliminary LoD concentration yielded 100 % positive results, a lower concentration was subsequently tested with 20 replicates until < 95 % positivity is obtained. The results of LoD confirmation testing are summarized in Table 2.

Table 2. Confirmatory LoD

Analyte	Stock Concentration $TCID_{50}$/mL	LoD		# Positive/ # Total	Percent Detected (%)
		$TCID_{50}$/mL	$TCID_{50}$/Swab		
SARS-CoV-2, USA-WA1/2020	3.39×10^7	3.39×10^4	1.70×10^3	58/60	96.7
SARS-CoV-2 Lineage BA.5; Omicron Variant, USA/COR-22-063113/2022	2.53×10^6	2.81×10^3	1.41×10^2	57/60	95.0
Influenza A, H1N1, Victoria/2570/19	4.68×10^4	1.56×10^1	0.78	59/60	98.3
Influenza A, H3N2, Darwin/9/21	3.74×10^4	1.25×10^1	0.63	57/60	95.0
Influenza A, H1N1, Victoria/4897/22	3.89×10^4	3.89×10^1	1.95	59/60	98.3
Influenza B, Victoria, Austria/1359417/21	2.82×10^6	9.40×10^2	4.70×10^1	58/60	96.7
Influenza B, Yamagata, Phuket/3073/13	3.89×10^4	1.30×10^1	0.65	60/60	100.0

NIBSC 21/368- WHO International Standard

The LoD of *Status*™ COVID-19/Flu A&B test was determined using the 1st WHO International standard for SARS-CoV-2 Antigen (NIBSC 21/368). A preliminary LoD was established by testing two-fold dilutions of 20,000 IU/mL stock WHO International Standard for SARS-CoV-2 antigen spiked into an NCM. The lowest concentration at which all 3 replicates tested positive was defined as the preliminary LoD (250 IU/mL). To confirm this, at least 20 replicates were tested at the

preliminary LoD, as well as at concentrations above (2xLoD) and below (0.3xLoD). The final LoD was defined as the lowest concentration yielding ≥95 % positive results (≥19/20) across two device lots. LoD confirmation results are summarized in Table 3.

Table 3. LoD with the first WHO International Standard for SARS-CoV-2 antigen

Analyte	LoD		# Positive/ # Total	Percent Detected (%)
	IU/mL	IU/Swab		
The First WHO International Standard for SARS-CoV-2 Antigen (NIBSC 21/368)	250	12.5	40/40	100

Co-spiked (Multiplexed) LoD

After the single analyte LoDs were established for the device, co-spiked LoD equivalency testing was performed to evaluate the device's performance with samples containing all three analytes at low concentrations. All analytes that were successfully detected under the device when co-spiked at their single analyte LoD, were co-spiked into positive samples used in the precision and reproducibility studies. Based on the established 1xLoD for each analyte, co-spiked samples were prepared by combining one strain each of SARS-CoV-2, influenza A, and influenza B. These samples, containing all three viruses at their individual 1xLoD concentrations in the negative nasal specimen were tested using the device in 20 replicates. Results are provided in Table 4.

Table 4. Co-spiked LoD

Analyte	LoD	LoD		# Positive/ # Total	Percent Detected (%)
		$TCID_{50}$/mL	$TCID_{50}$/Swab		
SARS-CoV-2 Lineage BA.5; Omicron Variant, USA/COR-22-063113/2022	1xLoD	2.81×10^3	1.41×10^2	20/20	100.0
Influenza A, H3N2, Darwin/9/21	1xLoD	1.25×10^1	0.63	20/20	100.0
Influenza B, Yamagata, Phuket/3073/13	1xLoD	1.30×10^1	0.65	20/20	100.0

Inclusivity (Analytical Reactivity)

Inclusivity testing was conducted using a panel of inactivated SARS-CoV-2, and live influenza A and B virus strains, selected to represent temporal and geographical diversity. Contrived samples were prepared by spiking whole virus into NCM. Each virus underwent 10-fold and 3-fold serial dilutions to assess assay reactivity, with 3 replicates per level. The lowest concentration yielding all 3 positives across 10-fold dilutions was identified, then refined using 3-fold dilutions. The minimum reactive concentration was determined as the last dilution at which all three replicates produced positive results.

Table 5. Inclusivity

Analyte	Subtype/ Lineage	Strain/Isolate	Lowest concentration with 100 % detection
SARS-CoV-2 (Omicron)	B.1.1.529	USA/MD-HP20874/2021	5.01×10^2 $TCID_{50}$/mL
	BA.2.3	USA/MD-HP245560	8.16×10^2 $TCID_{50}$/mL
	JN.1	USA/New York/PV96109/2023	3.49×10^1 $TCID_{50}$/mL
Influenza A (H1N1)	H1N1	A/Brisbane/02/18	4.41×10^2 $TCID_{50}$/mL
	H1N1	A/Baltimore/JH-22377/2022	5.33×10^6 $TCID_{50}$/mL
	H1N1	A/Guangdong-Maonan/SWL 1536/19	3.16×10^3 $TCID_{50}$/mL
	H1N1	A/Michigan/45/15	2.70×10^2 $TCID_{50}$/mL
	H1N1	A/Wisconsin/588/19	4.20×10^3 $TCID_{50}$/mL
	H1N1	A/Wisconsin/67/22	1.40×10^3 $TCID_{50}$/mL
	H1N1	A/California/07/09	2.43×10^4 $TCID_{50}$/mL
	H1N1	A/Virginia/ATCC3/2009	6.00×10^4 PFU/mL
	H1N1	A/Connecticut/11/2023	2.80×10^4 $TCID_{50}$/mL
Influenza A (H3N2)	H3N2	A/Kansas/14/17	5.03×10^4 $TCID_{50}$/mL
	H3N2	A/Baltimore/JH-0440/2022	9.33×10^4 $TCID_{50}$/mL
	H3N2	A/Hong Kong/2671/19	1.05×10^3 $TCID_{50}$/mL
	H3N2	A/Singapore/INFIMH-16-0019/16	3.16×10^3 $TCID_{50}$/mL
	H3N2	A/Norway/466/14	4.63×10^2 $TCID_{50}$/mL
	H3N2	A/Switzerland/9715293/13	1.52×10^3 $TCID_{50}$/mL
	H3N2	A/Texas/50/12	1.26×10^3 $TCID_{50}$/mL
	H3N2	A/Tasmania/503/20	4.70×10^3 $TCID_{50}$/mL
	H3N2	A/Cambodia/E0826360/20	3.90×10^2 $TCID_{50}$/mL
	H3N2	A/Michigan/173/20	3.50×10^3 $TCID_{50}$/mL
Influenza A (H5N1)	H5N1[1)]	A/bovine/Ohio/B24OSU-439/2024	3.88×10^4 $TCID_{50}$/mL
	H5N1[2)]	A/bovine/Ohio/B24OSU-439-2024	3.1×10^3 $TCID_{50}$/mL
Influenza B (Victoria)	Victoria	B/Alabama/2/17	3.90×10^1 $TCID_{50}$/mL
	Victoria	B/Victoria/705/18 Wild-Type	1.40×10^3 $TCID_{50}$/mL

	Victoria	B/Texas/2/13	1.67×10^1 $TCID_{50}$/mL
	Victoria	B/Michigan/01/21	1.17×10^4 $TCID_{50}$/mL
	Victoria	B/Washington/02/19	6.27×10^2 $TCID_{50}$/mL
	Victoria	B/Hong Kong/574/19 Wild Type	1.39×10^2 $TCID_{50}$/mL
	Victoria	B/Brisbane/35/18	1.15×10^3 $TCID_{50}$/mL
Influenza B (Yamagata)	Yamagata	B/Victoria/504/00	5.20×10^0 $TCID_{50}$/mL
	Yamagata	B/Utah/9/14	1.39×10^2 $TCID_{50}$/mL
	Yamagata	B/Texas/6/11	3.80×10^2 $TCID_{50}$/mL
	Yamagata	B/Florida/04/06	1.17×10^2 $TCID_{50}$/mL
	Yamagata	B/Massachusetts/2/12	4.20×10^2 $TCID_{50}$/mL

1) Live influenza A (H5N1) was tested for US 2024 H5N1 HPAI (Highly pathogenic avian influenza) inclusivity by ACME POCT at Emory University in September 2024.
2) Gamma-irradiated influenza A (H5N1) was tested in-house.

Competitive Interference

For competitive interference testing, 9 sample combinations were prepared, with each sample containing one analyte at high concentration (either 1000xLoD or concentration exceeding 10^5 $TCID_{50}$/mL) and one or more of the remaining analytes at low concentration (3xLoD), spiked into NCM. Each sample was tested in triplicate. Results demonstrated no competitive interference among SARS-CoV-2(heat inactivated, SARS-CoV-2, 2019 Novel Coronavirus, isolated USA-WA1/2020), live Influenza A (H3N2, Darwin/9/21) and live Influenza B (Yamagata, Phuket/3073/13) viruses.

Table 6. Competitive Interference

Combination #	Analyte concentration added to sample			Results
	Influenza A	Influenza B	SARS-CoV-2	
1	1000xLoD	3xLoD	Negative	No Interference
2	1000xLoD	Negative	3xLoD	No Interference
3	1000xLoD	3xLoD	3xLoD	No Interference
4	3xLoD	1000xLoD	Negative	No Interference
5	Negative	1000xLoD	3xLoD	No Interference
6	3xLoD	1000xLoD	3xLoD	No Interference
7	3xLoD	Negative	300xLoD	No Interference
8	Negative	3xLoD	300xLoD	No Interference
9	3xLoD	3xLoD	300xLoD	No Interference

Hook Effect

A high-dose hook effect study was conducted to evaluate whether excessively high concentrations of analytes could result in false-negative results. Inactivated SARS-CoV-2 and live Influenza A and B virus samples were tested in triplicate. No high-dose hook effect was observed at the concentrations listed in Table 7.

Table 7. High-dose Hook Effect

SARS-CoV-2 and Influenza A&B virus	Concentration ($TCID_{50}$/mL)
SARS-CoV-2, USA-WA1/2020	3.39×10^7
SARS-CoV-2 Lineage BA.5; Omicron Variant, USA/COR-22-063113/2022	2.53×10^6
Influenza A, H1N1, A/Baltimore/JH-22377/2022	1.6×10^9
Influenza A, H3N2, A/Baltimore/JH-0440/2022	2.8×10^7
Influenza A, H1N1, Victoria/2570/19	4.68×10^4
Influenza A, H3N2, Darwin/9/21	3.74×10^4
Influenza B, Victoria, Austria/1359417/21	2.82×10^6
Influenza B, Yamagata, Texas/6/11	3.80×10^6
Influenza B, Yamagata, Phuket/3073/13	3.89×10^4

Exogenous and Endogenous Interference

Interference testing was performed using 35 common interfering endogenous and exogenous substances. These substances were evaluated for their potential impact on the test's ability to detect SARS-CoV-2, Influenza A, and Influenza B. For this testing, each interfering substance was evaluated in triplicate. The evaluation was performed by preparing samples containing each substance and testing them either in the absence of any virus or in the presence of a single target virus (SARS-CoV-2, Influenza A, or Influenza B). When virus was included, heat-inactivated SARS-CoV-2 or live Influenza A or Influenza B were used at a concentration of 3xLoD. All interference samples were prepared in NCM. No interference was observed at the tested concentrations for evaluated substances, except for FluMist, live attenuated intranasal influenza vaccine. FluMist at 15% v/v did not interfere with the detection of SARS-CoV-2. For influenza targets, expected negative results (no interference) were observed at 0.15 % v/v for influenza A and 1.5 % v/v for influenza B.

Table 8. Interfering Substances

Interfering substance	Tested Concentration
Human Whole Blood	4 % v/v
Mucin	5.0 mg/mL
Leukocytes	$5x10^6$ cells/mL

Oral Anesthetic (Benzocaine)	3.0 mg/mL
Oral Anesthetic (Menthol)	3.0 mg/mL
Sore Throat Phenol Spray	15 % v/v
Nasal Spray (Phenylephrine)	15 % v/v
Nasal Spray (Cromolyn)	15 % v/v
Nasal Spray (Oxymetazoline)	15 % v/v
Nasal Spray (Sodium chloride with preservatives)	15 % v/v
Normal Saline Solution (Sodium chloride)	15 % v/v
Beclomethasone Dipropionate	15 % v/v
Dexamethasone	15 % v/v
Flunisolide	15 % v/v
Nasal corticosteroids (Triamcinolone acetonide)	15 % v/v
Nasal corticosteroids (Budesonide)	15 % v/v
Nasal corticosteroids (Mometasone furoate)	15 % v/v
Nasal corticosteroids (Fluticasone Propionate)	15 % v/v
Zicam Nasal Spray (Luffa opperculata, Galphimia glauca, Histaminum hydrochloricum)	15 % v/v
Throat spray (Zinc, Sulphur)	15 % v/v
Nasal Gel	5 % w/v
Homeophatic nasal wash (Alkalol)	15 % v/v
Oseltamivir Phosphate	5 mg/mL
Remdesivir	10 mg/mL
Molnupiravir	5 mg/mL
Zanamivir	5 mg/mL
Nirmatrelvir (Paxlovid)	10 mg/mL
Ritonavir (Paxlovid)	10 mg/mL
Mupirocin	10 mg/mL
Tobramycin	15 % v/v
Body & Hand Lotion	0.5 % w/v
Hand Lotion	5 % w/v
Hand Sanitizer, 70 % ethanol	15 % w/v
Hand soap liquid gel	10 % w/v
FluMist	SARS-CoV-2: 15 % v/v
	Flu A: ≤ 0.15 % v/v
	Flu B: ≤ 1.5 % v/v

Cross-reactivity and Microbial Interference

Cross-reactivity and microbial interference studies were conducted to assess whether other respiratory pathogens or commensal flora that could be present in a direct nasal swab sample would cause a false-positive test result or interfere with a true positive result. A total of 46 microorganisms were tested at high, clinically relevant concentrations. These concentrations were defined as

follows: ≥1.0×10⁶ CFU/mL or IFU/mL for bacteria and fungi, and ≥1.0×10⁵ $TCID_{50}$/mL or cp/mL for viruses. Each microorganism was evaluated in triplicate. The evaluation was performed by preparing samples containing each microorganism and testing them either in the absence of or in the presence of a single target virus (SARS-CoV-2, Influenza A, or Influenza B). When virus was included, heat-inactivated SARS-CoV-2 or live Influenza A or Influenza B were used at a concentration of 3xLoD. No cross-reactivity or microbial interference was observed under the conditions tested.

Table 9. Cross-Reactivity

Cross-reactant	Tested Concentration
Human Coronavirus 229E	7.05×10^4 $TCID_{50}$/mL [1)]
Human Coronavirus OC43	1.43×10^5 $TCID_{50}$/mL
Human Coronavirus NL64	1.43×10^5 $TCID_{50}$/mL
Human Coronavirus HKU1	N/A [2)]
MERS-coronavirus	N/A [3)]
SARS-coronavirus	N/A [3)]
Adenovirus 1	1.43×10^5 $TCID_{50}$/mL
Adenovirus 7A	1.43×10^5 $TCID_{50}$/mL
Human Metapneumovirus 3 Type B1	5.85×10^4 $TCID_{50}$/mL [1)]
Parainfluenza Virus 1	1.43×10^5 $TCID_{50}$/mL
Parainfluenza Virus 2	1.43×10^5 $TCID_{50}$/mL
Parainfluenza Virus 3	1.43×10^5 $TCID_{50}$/mL
Parainfluenza Virus 4B	7.05×10^4 $TCID_{50}$/mL [1)]
Influenza A, H1N1	1.43×10^5 $TCID_{50}$/mL
Influenza A, H3N2	1.43×10^5 $TCID_{50}$/mL
Influenza B, Victoria	1.43×10^5 $TCID_{50}$/mL
Influenza B, Yamagata	1.43×10^5 $TCID_{50}$/mL
Enterovirus 68	1.43×10^5 $TCID_{50}$/mL
Respiratory Syncytial Virus A	1.43×10^5 $TCID_{50}$/mL
Respiratory Syncytial Virus B	1.43×10^5 $TCID_{50}$/mL
Rhinovirus 1A	1.43×10^5 $TCID_{50}$/mL
Haemophilus influenzae B	1.00×10^6 CFU/mL
Streptococcus pneumoniae	1.00×10^6 CFU/mL
Streptococcus pyogenes	1.00×10^6 CFU/mL
Candida albicans	1.00×10^6 CFU/mL
Pooled human nasal fluid	N/A
Bordetella pertussis	1.00×10^6 CFU/mL
Mycoplasma pneumoniae	1.00×10^6 CFU/mL
Chlamydophila pneumoniae	1.00×10^6 IFU/mL
Legionella pneumophila	1.00×10^6 CFU/mL
Staphylococcus aureus	1.00×10^6CFU/mL
Staphylococcus epidermidis	1.00×10^6 CFU/mL

Moraxella catarrhalis	1.00×10^6 CFU/mL
Neisseria meningitidis	1.00×10^6 CFU/mL
Neisseria subflava biovar flava	1.00×10^6 CFU/mL
Corynebacterium diphtheriae	1.00×10^6 CFU/mL
Escherichia coli	1.00×10^6 CFU/mL
Mycobacterium tuberculosis	1.00×10^6 CFU/mL
Lactobacillus acidophilus	1.00×10^6 CFU/mL
Pneumocystis jiroveci-S. cerevisiae (Recombinant)	1.00×10^6 CFU/mL
Pseudomonas aeruginosa	1.00×10^6 CFU/mL
Streptococcus salivarius	1.00×10^6 CFU/mL
Cytomegalovirus	1.43×10^5 $TCID_{50}$/mL
Epstein-Barr Virus	1.43×10^5 cp/mL
Measles Virus	1.43×10^5 $TCID_{50}$/mL
Mumps Virus	1.43×10^5 $TCID_{50}$/mL
Coxsackievirus A16	1.43×10^5 $TCID_{50}$/mL
Human Herpes Virus 6B	1.43×10^5 cp/mL
Klebsiella pneumoniae	1.43×10^5 CFU/mL

1) Recommended testing concentrations were not achievable due to the low vial concentrations.
2) Five (5) Human Coronavirus HKU1 (HCoV-HKU1) clinical samples and one (1) HKU1 and SARS-CoV-2 double positive clinical sample were tested in the presence and absence of SARS-CoV-2.
3) For MERS and SARS-CoV viruses only In silico analysis was conducted therefore cross reactivity cannot be ruled out.

Precision

A multi-lot precision study was conducted to evaluate lot-to-lot variability of the *Status*™ COVID-19/Flu A&B test using SARS-CoV-2 (BA.5, Omicron Variant, USA/COR-22-063113/2022), Influenza A (H3N2, Darwin/9/21), and Influenza B (Yamagata, Phuket/3073/13) in two different studies.

Both studies were performed in-house by 2 trained operators for testing and one (1) operator responsible for sample preparation. For study 1, blinded and randomized test panels containing single-, dual-, and triple-analyte samples at Negative, 1xLoD, and 3xLoD concentrations. A total of 40 panels were prepared, each operator tested a total of 20 panel, 2 runs per day, 3 different lots over 10 non-consecutive days. For each of the lot, this study generated 80 replicate test results for each analyte and concentration, i.e., a total of 240. The sample panels used in study 2 were comprised of single-, dual-, and triple-analyte samples at Negative, 0.7xLoD, 1xLoD, and 3xLoD concentrations. A total of 72 replicates, based on 2 operators, 6 sessions each over 3 days, using 3 different lots, and 2 replicates per lot. The data below is presented combining data from both studies. The results demonstrate consistent precision across analytes and concentrations, with no false positives.

Table 10. Lot-to Lot Precision

Sample	Analyte	No of Positive/No of total tested (% Agreement)			Total sample count (% positive rate)
		Lot 1	Lot 2	Lot 3	Total
Negative	Influenza A	0/104 (0 %)	0/104 (0 %)	0/104 (0 %)	0/312 (0 %)
	Influenza B	0/104 (0 %)	0/104 (0 %)	0/104 (0 %)	0/312 (0 %)
	SARS-CoV-2	0/104 (0 %)	0/104 (0 %)	0/104 (0 %)	0/312 (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 %)	309/312 (99.0 %)
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 %)

Reproducibility

A multi-site reproducibility study was conducted to evaluate the performance of the *Status*™ COVID-19/Flu A&B test using contrived nasal swab samples, with a focus on weakly reactive specimens near the assay cutoff. Testing was performed at 3 CLIA-waived sites by 9 untrained operators and at one (1) in-house laboratory by trained personnel, using 3 independent device lots. The sample panel included weak positive (1xLoD), strong positive (3xLoD), high negative (C5 level, 95 % negative expected), and true negative (100 % negative expected) samples. Each operator completed 10 randomized panels over 5 days, 2 panels per day, totaling 8,640 data points across all sites. The study demonstrated high reproducibility, with positive agreement rates ≥98.8 % for 1xLoD samples and 100 % for 3xLoD samples. Negative agreement was ≥98.9 % for high negative samples and 100 % for true negatives. The reproducibility study demonstrated consistent and accurate performance across all test sites, operators, and device lots.

Table 11. Reproducibility by Site and Sample Type

Sample		No of Positive Result/No of Total Tested (% Positive Rate)				Total sample count (% positive rate)
		Site 1 3 operators	Site 2 3 operators	Site 3 3 operators	Lab 1 3 operators	Total 12 operators
True Negative	Influenza A	0/180 (0 %)	0/180 (0 %)	0/180 (0 %)	0/180 (0 %)	0/720 (0 %)
	Influenza B	0/180 (0 %)	0/180 (0 %)	0/180 (0 %)	0/180 (0 %)	0/720 (0 %)
	SARS-CoV-2	0/180 (0 %)	0/180 (0 %)	0/180 (0 %)	0/180 (0 %)	0/720 (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 %)
1xLoD	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 %)
3xLoD	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 %)

Stability

- Real-time Stability

The real-time stability studies have been conducted with three lots of devices testing negative and positive samples in 5 replicates per condition. The results demonstrate that the *Status*™ COVID-19/Flu A&B test is stable for 29 months when stored at 2-30 °C.

- Specimen Stability

A specimen stability study was conducted to evaluate the performance of the *Status*™ COVID-19/Flu A&B test using samples collected on Puritan HydraFlock® swabs stored under various conditions, room temperature (15 °C–30 °C), refrigerated (2 °C–8 °C), and frozen (below -20 °C), with contrived heat-inactivated SARS-CoV-2 and live Influenza A and Influenza B specimens. Positive samples spiked at 3xLoD and confirmed negative controls were tested at multiple time points. Results demonstrated that swab samples are stable for up to 4 hours at room temperature, 8 hours under refrigerated conditions, and 7 days under frozen conditions without compromising test performance. The samples are recommended to be tested immediately after collection.

Flex Studies

Flex studies were then performed to evaluate test robustness and the risk of false results under deviations from the IFU or QRI. The conducted studies were summarized in Table 12.

Table 12. Flex Studies

Potential Risk	Flex Studies
Environmental Factors	Extreme temperature and humidity
	Non-level surfaces
	Lighting flex
Operator Errors	Sample volume
	Sample elution
	Reading time
	Disturbance during analysis
	Device Tapping
Device Stability	Open pouch
	Transport Stability

Testing utilized NCM and low-positive samples spiked with SARS-CoV-2, Influenza A, and Influenza B at 2xLoD. Results demonstrated that the test is robust under varied conditions, and potential false results can be mitigated through proper labeling and user guidance.

Clinical Evaluation

A prospective clinical study was conducted at 6 CLIA-waived sites in US from September 2023 to October 2024 to evaluate the performance of the *Status*™ COVID-19/Flu A&B test using nasopharyngeal (NP) and anterior nasal (ANS) swab specimens. Patients presenting within 5 days of onset of respiratory symptoms consistent with SARS-CoV-2, influenza A, or influenza B were enrolled. Specimen collection and testing were performed by 31 untrained healthcare professionals following the QRI. All testing was performed in blinded fashion. For each enrolled subject, one NP swab was tested using an FDA authorized highly sensitive RT-PCR assay as the comparator method, and the other swab (NP or ANS) was tested with *Status*™ COVID-19/Flu A&B test. A total of 1,005 specimens were collected during the study period, consisting of 550 NP and 455 ANS swab specimens.

Nasopharyngeal Swab Specimens

NP swabs were collected from 550 subjects aged 2 years and older from 6 CLIA-waived US sites were used for evaluation after excluding 13 patients due to symptoms duration exceeding 5 days. Demographic characteristics of the study population from whom NP 537 specimens were obtained are summarized in Table 13.

Table 13. Subject Demographics of Nasopharyngeal Swab Specimens

Characteristics of the study population		N=537	Percent (%)
Gender	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 Islander	2	0.4
	Other (Mixed race)	4	0.7
	Prefer not to say	15	2.8

Performance of NP swab specimens tested with the *Status*™ COVID-19/Flu A&B test was assessed by comparison to NP swab specimens tested with a highly sensitive RT-PCR test as comparator. The results are presented in Tables 14-17.

Table 14. *Status*™ COVID-19/Flu A&B performance compared to reference PCR: SARS-CoV-2

		Comparator RT-PCR: SARS-CoV-2		
		Positive	Negative	Total
***Status*™ COVID-19 /Flu A&B**	SARS-CoV-2 Positive	171	1	172
	SARS-CoV-2 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 %)			

SARS-CoV-2 results were further stratified by days since symptom onset. Stratified performance data are provided in Table 15.

Table 15. Specimen Positivity Breakdown Based on Days Post-Symptom Onset

Days Post Symptom Onset	**Specimens Tested**	***Status*™ COVID/Flu A&B Positive**	**Comparator (PCR)**	**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 [1)]	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 [1)]	179	95.5 % (91.4 %-97.7 %)

1) False positive results on the *Status*™ COVID-19/Flu A&B device were excluded from the analysis.

Table 16. *Status*™ COVID-19/Flu A&B performance compared to reference PCR: Influenza A

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

Table 17. *Status*™ COVID-19/Flu A&B performance compared to reference PCR: Influenza B

		Comparator RT-PCR: Influenza B		
		Positive	Negative	Total
***Status*™ COVID-19 /Flu A&B**	Influenza B Positive	51	0	51
	Influenza B 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 %)			

Anterior Nasal Swab Specimens

ANS swabs were collected from 455 subjects of all ages from 6 CLIA-waived US sites were used for evaluation after excluding 9 specimens due to symptom duration exceeding 5 days. Demographic characteristics of the study population from whom ANS 446 specimens were obtained are summarized in Table 18.

Table 18. Patient Demographics of Anterior Nasal Swab Specimens

Characteristics of the study population		**N=446**	**Percent (%)**
Gender	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
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

Performance of ANS swab specimens tested with the *Status*™ COVID-19/Flu A&B test was assessed by comparison to NP swab specimens tested with a highly sensitive RT-PCR test as comparator. The results are presented in Tables 19-22.

Table 19. *Status*™ COVID-19/Flu A&B performance compared to reference PCR: SARS-CoV-2

		Comparator RT-PCR: SARS-CoV-2		
		Positive	Negative	Total
***Status*™ COVID-19 /Flu A&B**	SARS-CoV-2 Positive	114	0	114
	SARS-CoV-2 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 %)			

SARS-CoV-2 results were further stratified by days since symptom onset. Stratified performance data are provided in Table 20.

Table 20. Specimen Positivity Breakdown Based on Days Post Symptom Onset

Days Post Symptom Onset	Specimens Tested	*Status*™ COVID/Flu A&B Positive	Comparator (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 21. *Status*™ COVID-19/Flu A&B performance compared to reference PCR: Influenza A

		Comparator RT-PCR: Influenza A		
		Positive	Negative	Total
***Status*™ COVID-19 /Flu A&B**	Influenza A Positive	43	2	45
	Influenza A 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 22. *Status*™ COVID-19/Flu A&B performance compared to reference PCR: Influenza B

		Comparator RT-PCR: Influenza B		
		Positive	Negative	Total
***Status*™ COVID-19 /Flu A&B**	Influenza B Positive	37	1	38
	Influenza B 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: 98.9 % to 100.0 %)			

Clinical Sensitivity

Refer to Clinical Evaluation section for the clinical validation. The PPA for the test for each analyte and swab type is as follows.

Table 23. Clinical Sensitivity

	NP Swab	ANS Swab
SARS-CoV-2	95.5 % (95 % CI: 91.4 % to 97.7 %)	97.4 % (95 % CI: 92.7 % to 99.1 %)
Influenza A	94.1 % (95 % CI: 84.1 % to 98.0 %)	91.5 % (95 % CI: 80.1 % to 96.6 %)
Influenza B	92.7 % (95 % CI: 82.7 % to 97.1 %)	90.2 % (9 5% CI: 77.5 % to 96.1 %)

Clinical Specificity

Refer to Clinical Evaluation section for the clinical validation. The NPA for the test for each analyte and swab type is as follows.

Table 24. Clinical Specificity

	NP Swab	ANS Swab
SARS-CoV-2	99.7 % (95 % CI: 98.4 % to 99.9 %)	100.0 % (95 % CI: 98.9 % to 100.0 %)
Influenza A	99.4 % (95 % CI: 98.2% to 99.8 %)	99.5 % (95 % CI: 98.2 % to 99.9 %)
Influenza B	100.0 % (95 % CI: 99.2 % to 100.0 %)	99.8 % (95 % CI: 98.9 % to 100.0 %)

Conclusion

The information provided in this premarket notification supports a determination of substantial equivalence. A comparison of the technological characteristics and intended use, along with the results from analytical and clinical performance evaluations, demonstrates that *Status*™ COVID-19/Flu A&B is as safe, as effective, and performs as well as the predicate device. Accordingly, *Status*™ COVID-19/Flu A&B is determined to be substantially equivalent to the predicate device.