October 21, 2026

Nuclein, LLC
Chelynne Lee
Associate Director Design Assurance and Regulatory Affairs
8305 Cross Park Dr.
Austin, Texas 78754

Re: K261347
Trade/Device Name: DASH Flu A/B Test
Regulation Number: 21 CFR 866.3980
Regulation Name: Respiratory viral panel multiplex nucleic acid assay
Regulatory Class: Class II
Product Code: OCC
Dated: April 23, 2026
Received: April 24, 2026

Dear Chelynne Lee:

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. Additional information about changes that

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

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

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

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

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

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

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

JOSEPH BRIGGS -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K261347

Device Name
DASH Flu A/B Test

Indications for Use *(Describe)*
The DASH Flu A/B Test is a rapid reverse transcription polymerase chain reaction (RT-PCR) assay performed on the DASH Rapid PCR Instrument and is intended for the simultaneous in vitro qualitative detection and differentiation of influenza A and influenza B virus ribonucleic acid (RNA) in anterior nasal swab specimens from patients with signs and symptoms of respiratory tract infection. The test is intended to aid in the differential diagnosis of influenza A, and influenza B in humans in conjunction with other clinical, epidemiologic and laboratory findings and is not intended to detect Influenza C.

Positive results of a specific target are indicative of the presence of that viral RNA and may not be the definite cause of disease. Positive results do not rule out co-infection with other pathogens. Negative results do not preclude influenza infection and should not be used as the sole basis for diagnosis, treatment or other patient management decisions.

Performance characteristics for Influenza A were established during the 2023-2024 influenza season when Influenza A/H3 and A/H1N1 pandemic were the predominant Influenza A viruses in circulation. When other Influenza A viruses are emerging, performance characteristics may vary.

If infection with a novel Influenza A virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent Influenza viruses and sent to state or local health department for testing. Viral culture should not be attempted in these cases unless a BSL3+ facility is available to receive and culture specimens.

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 [21 CFR 807.95]

807.92(a)(1), (2), (3)

Date Prepared: October 8, 2026

Submitter's Name: Chelynne Lee
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Device Trade Name: DASH® Flu A/B Test

Common Name: Respiratory viral panel multiplex nucleic acid assay

Review Panel: Office of In Vitro Diagnostics (OHT7); Division of Microbiology Devices (DMD)

Classification Name: Respiratory viral panel multiplex nucleic acid assay

Classification Code: **OCC**: Respiratory viral panel multiplex nucleic acid assay

Predicate Device: K213822: cobas Liat Influenza A/B & RSV Assay
Classification Code: OCC
Regulation: 866.3980

Device Description *807.92(a)(4)*:
The DASH Flu A/B Test is a reverse transcription polymerase chain reaction (RT-PCR) assay for rapid qualitative detection and differentiation of influenza A (Flu A) and influenza B (Flu B) from human anterior nasal swab (ANS) specimens. The test combines the technologies of sequence specific capture sample preparation and RT-PCR amplification. An anterior nasal swab with a 30-mm breakpoint is used to collect a specimen.

The ANS specimen is added directly to the DASH Flu A/B Test cartridge sample chamber. The DASH Flu A/B Test cartridge contains all reagents necessary to perform the test. The cartridge is capped and inserted into the DASH Instrument to initiate the test, and all subsequent test steps are performed automatically by the DASH Instrument.

Materials included with the DASH Flu A/B Test consist of the following:

- Ten individually pouched DASH Flu A/B Cartridges per kit
- Ten individually packaged anterior nares sample collection swabs (30 mm breakpoint, sterile elongated polyester flock) per kit
- DASH Flu A/B Test Quick Reference Guide (QRG)

The DASH Instrument, DASH SARS-CoV-2 & Flu A/B Positive Control Swabs Kit, and DASH Negative Control Swabs Kit are provided separately.

Intended Use *807.92(a)(5)*:
The DASH Flu A/B Test is a rapid reverse transcription polymerase chain reaction (RT-PCR) assay performed on the DASH Rapid PCR Instrument and is intended for the simultaneous in vitro qualitative detection and differentiation of influenza A and influenza B virus ribonucleic acid (RNA) in anterior nasal swab specimens from patients with signs and symptoms of respiratory tract infection. The test is intended to aid in the differential diagnosis of influenza A, and influenza B in humans in conjunction with other clinical, epidemiologic and laboratory findings and is not intended to detect influenza C.

Positive results of a specific target are indicative of the presence of that viral RNA and may not be the definite cause of disease. Positive results do not rule out co-infection with other pathogens. Negative results do not preclude influenza infection and should not be used as the sole basis for diagnosis, treatment or other patient management decisions.

Performance characteristics for influenza A were established during the 2023-2024 influenza season when influenza A/H3 and A/H1N1 pandemic were the predominant influenza A viruses in circulation. When other influenza A viruses are emerging, performance characteristics may vary.

If infection with a novel influenza A virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent influenza viruses and sent to state or local health department for testing. Viral culture should not be attempted in these cases unless a BSL3+ facility is available to receive and culture specimens.

Technological Characteristics *807.92(a)(6)*:
The DASH Flu A/B Test combines the technologies of sequence specific capture sample preparation and RT-PCR amplification. The DASH Flu A/B Test cartridge contains all reagents necessary to perform the test to detect RNA from influenza A and influenza B.

An ANS sample is collected and added directly to the DASH Flu A/B Test cartridge. The Test cartridge is capped and inserted into the DASH Instrument to initiate the test. The Test cartridge sample chamber contains lysis buffer which releases the RNA target from the virus. The target RNA molecules are isolated from specimens by use of biotinylated capture oligomers (capture oligomers) which are in turn captured by streptavidin-coated paramagnetic particles. The biotinylated capture oligomers contain sequences complementary to specific regions of the RNA target molecules.

During the hybridization step, the sequence specific regions of the capture oligomers bind to specific regions of the RNA target molecules. The capture oligomer:target complex is then concentrated by the addition of streptavidin-coated paramagnetic particles.

The paramagnetic particles, including the bound target molecules, are washed to remove residual specimen matrix that may contain amplification reaction inhibitors. After the target capture steps are completed, the target RNA is ready for RT-PCR amplification. Forty amplification cycles are performed, during which the fluorescence is measured with a four-color LED fluorometer.

Amplification of any assay targets, Flu A and Flu B, leads to fluorescent signal. An algorithm determines whether the result is positive or negative for each viral target assay.

Additionally, process controls are included in the cartridge to control for adequate processing of the target virus through the steps of sample purification, nucleic acid amplification and to monitor for the presence of inhibitors in the RT-PCR reaction. Total run time, from swab insertion into the Test cartridge to display of the test results is approximately 15 minutes.

The DASH Instrument contains firmware and software that operate the instrument and analyze the assay data. Test results are displayed on the DASH Instrument screen and can be printed (optional) after the test has been completed. The procedural control result will display “Valid” on the results screen for all samples, both negative and positive (see Table 1 below), to indicate that the test results may be reported.

Table 1. DASH Flu A/B Results Interpretation

TARGET	RESULT	INTERPRETATION
Flu A	**POSITIVE**	The target nucleic acids of Flu A are detected.
	NEGATIVE	The target nucleic acids of Flu A are not detected.
Flu B	**POSITIVE**	The target nucleic acids of Flu B are detected.
	NEGATIVE	The target nucleic acids of Flu B are not detected.
Procedural Control	**VALID**	Amplification meets acceptance criteria. Test results may be reported.
	INVALID	Presence or absence of the target nucleic acids cannot be determined. Repeat test with a new sample and a new cartridge.
ERROR		Presence or absence of the target nucleic acids cannot be determined. DASH Instrument detected an error and aborted the current test. Repeat test with a new sample and a new cartridge.

Predicate Comparison:

Device & Predicate Device(s):	K261347	K213822
Device Trade Name	DASH Flu A/B Test	cobas Liat Influenza A/B & RSV Assay
General Device Characteristic Similarities		
Regulation Number and Name	Same	21 CFR 866.3980; Respiratory virus panel nucleic acid assay system
Product Code	Same	OCC
Technological Principle	Same	RT-PCR
Intended Use/Indications For Use	The DASH Flu A/B Test is a rapid reverse transcription polymerase chain reaction (RT-PCR) assay performed on the DASH Rapid PCR Instrument and is intended for the simultaneous in vitro qualitative detection and differentiation of influenza A and influenza B virus ribonucleic acid (RNA) in anterior nasal swab specimens from patients with signs and symptoms of respiratory tract infection. The test is intended to aid in the differential diagnosis of influenza A, and influenza B in humans in conjunction with other clinical, epidemiologic and laboratory findings and is not intended to detect influenza C. Positive results of a specific target are indicative of the presence of that viral RNA and may not be the definite cause of disease. Positive results do not rule out co-infection with other pathogens. Negative results do not preclude influenza infection and should not be used as the sole basis for diagnosis, treatment or other patient management decisions.	The cobas® Influenza A/B & RSV Nucleic Acid Test for Use on the cobas® Liat System (cobas® Liat Influenza A/B & RSV) is an automated multiplex real-time RT-PCR assay for the rapid in vitro qualitative detection and discrimination of influenza A virus, influenza B virus and respiratory syncytial virus (RSV) RNA in nasopharyngeal swab specimens from patients with signs and symptoms of respiratory infection in conjunction with clinical and epidemiological risk factors. The test is intended for use as an aid in the diagnosis and differentiation of influenza A, influenza B, and RSV in humans and is not intended to detect influenza C. Negative results do not preclude influenza virus or RSV infection and should not be used as the sole basis for treatment or other patient management decisions. Conversely, positive results do not rule-out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Performance characteristics for influenza A were established during the 2013-2014 and the 2014-2015

	Performance characteristics for influenza A were established during the 2023-2024 influenza season when influenza A/H3 and A/H1N1 pandemic were the predominant influenza A viruses in circulation. When other influenza A viruses are emerging, performance characteristics may vary. If infection with a novel influenza A virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent influenza viruses and sent to state or local health department for testing. Viral culture should not be attempted in these cases unless a BSL3+ facility is available to receive and culture specimens.	influenza seasons when influenza A/H3 and A/H1N1 pandemic were the predominant influenza A viruses in circulation. When other influenza A viruses are emerging, performance characteristics may vary. If infection with a novel influenza A virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent Influenza viruses and sent to state or local health department for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.
Technological Principle	Same	RT-PCR
Automated Assay	Same	Sample preparation, amplification, and result interpretation
Assay Result	Same	Qualitative
Test Interpretation	Same	Automated test interpretation and report generation
Controls	Same	Test contains internal controls. External controls are also available.
General Device Characteristic Differences		
Analyte Targets	Influenza A Influenza B	Influenza A virus Influenza B virus Respiratory syncytial virus
Specimen Type	Anterior Nasal Swab	Nasopharyngeal swab in transport media
Instrument Systems	DASH Rapid PCR Instrument	cobas® Liat System

Summary of Non-Clinical Test Performance and Safety Testing *807.92(b)(1)*:

The DASH® Flu A/B Test, for use on the DASH Rapid PCR Instrument, has met the special controls established for product code OCC.

The DASH Flu A/B Test was evaluated for performance and found to conform with the following FDA recognized standards:

- CLSI EP12 3rd Edition, Evaluation of Qualitative, Binary Output Examination Performance
- CLSI EP12-A2, User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline - Second Edition.
- CLSI MM03-3rd Edition, Molecular Diagnostic Methods for Infectious Diseases; Approved Guideline
- CLSI EP07 3rd Edition, Interference Testing in Clinical Chemistry
- CLSI EP37 1st Edition, Supplemental Tables for Interference Testing in Clinical Chemistry
- CLSI EP25 2nd Edition, Evaluation of Stability of In Vitro Medical Laboratory Test Reagents
- CLSI EP25-A, Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline

Performance Characteristics

Analytical Performance:

Within-Laboratory Precision

Precision of the DASH Flu A/B Test was evaluated over a 12-day period, conducted by two (2) operators at a single site, and resulted in 96 replicates per concentration of the Flu A and Flu B targets.

Samples positive for both Flu A and Flu B were prepared in simulated clinical nasal matrix (SCNM) at 2x and 5x LoD concentrations, and negative (no analyte) samples were SCNM without viral targets. Results of replicate samples tested by each operator at 2x and 5x LoD achieved 100% positivity for each target. Negative samples also showed the expected result of 0% positivity for each target. A percent positive agreement of 100% was achieved between operators as well as between testing days for each target at 2x and 5x LoD. Data analysis included a statistical two-way nested ANOVA for each target across different sources of variability (e.g., operator, day, run). The following table provides a summary of results:

Summary of Precision Study Results

Viral Strain	Concentration	Results (Call Accuracy/Agreement)
Flu A H1N1 Victoria /2570/19	2x LoD	96/96 (100%)
	5x LoD	96/96 (100%)
Flu B Yamagata (Utah/09/14)	2x LoD	96/96 (100%)
	5x LoD	96/96 (100%)
Negative	N/A	96/96 (100%)

Mean, Standard Deviation (SD), and Percent Coefficient of Variation (%CV) for Cq*

Sample	Sample Type	N	Mean Cq*	Between Operator		Between Day (Within Operator)		Between Runs (Within Day)		Within Run/ Repeatability		Total	
				SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Flu A	Low Positive	96	24.0	0.4	1.5	0.3	1.3	0.0	0.0	1.2	5.2	1.3	5.5
	Moderate Positive	96	22.7	0.3	1.2	0.3	1.1	0.2	0.9	0.5	2.3	0.7	3.0
Flu B	Low Positive	96	25.9	0.0	0.0	0.0	0.0	0.0	0.0	0.9	3.6	0.9	3.6
	Moderate Positive	96	24.8	0.0	0.0	0.4	1.5	0.0	0.0	0.6	2.2	0.7	2.7

Note: SD and CV% were estimated using ANOVA variance component analysis using the R Package VCA.
*DASH software identifies the cycle at which an amplification curve meets a predefined mathematical criterion as Cq.

Reproducibility

A multi-site study was conducted to demonstrate the reproducibility of the DASH® Flu A/B Test with analyte concentrations near the detection limit of the assay, using contrived nasal swabs and a 3-member panel consisting of a true negative (no analyte), low positive (2x LoD), and a moderate positive (5x LoD) panel member. The study was conducted using three (3) lots of test cartridges by nine (9) untrained operators across three (3) sites, and performed over five (5) non-consecutive days, with two (2) runs per day and three (3) replicates per panel member, totaling 810 samples (270 replicates per panel member) tested throughout the course of the study and accounting for invalid repeat testing.

Positive samples were contrived including co-spiked cultured Flu A H1N1 Victoria/2570/19 and Flu B Utah/9/14 - Yamagata Lineage.

The DASH Flu A/B Test reported the expected positive results for panel members in 97.8%-100% of the samples and the expected negative results in 100% of samples. A summary of the results (percent (%) agreement with the expected positive or negative result) for each panel member by analyte and site are provided below:

Qualitative Results by Analyte Concentration and Site

Analyte*	Sample Concentration	% Agreement with Expected Results (n Agreement/N Tested) (95% CI)#			
		Site 1	Site 2	Site 3	Overall
Flu A	Low Positive	100.0% (90/90) (95.9% -100.0%)	97.8% (88/90) (92.3% - 99.4%)	100.0% (90/90) (95.9% -100.0%)	99.3% (268/270) (97.3% -99.8%)
	Moderate Positive	100.0% (90/90) (95.9% -100.0%)	100.0% (89/89)^ (95.9% -100.0%)	100.0% (90/90) (95.9% -100.0%)	100.0% (269/269) (98.6% -100.0%)
	Negative	100.0% (90/90) (95.9% -100.0%)	100.0% (90/90) (95.9% -100.0%)	100.0% (90/90) (95.9% -100.0%)	100.0% (270/270) (98.6% -100.0%)
Flu B	Low Positive	100.0% (90/90) (95.9% -100.0%)	97.8% (88/90) (92.3% - 99.4%)	100.0% (90/90) (95.9% -100.0%)	99.3% (268/270) (97.3% -99.8%)
	Moderate Positive	100.0% (90/90) (95.9% -100.0%)	100.0% (89/89)^ (95.9% -100.0%)	100.0% (90/90) (95.9% -100.0%)	100.0% (269/269) (98.6% -100.0%)
	Negative	100.0% (90/90) (95.9% -100.0%)	100.0% (90/90) (95.9% -100.0%)	100.0% (90/90) (95.9% -100.0%)	100.0% (270/270) (98.6% -100.0%)

*All samples were co-spiked with all analytes, so results are presented two times, including the Negative results.
A total of 15 samples generated invalid results on the first attempt; 14 samples generated valid results upon repeat and were included in the data analysis.
^One Moderate Positive sample produced an error/no result and was excluded from the analysis.

For each panel member, statistical analysis of mean Cq, standard deviation (SD), and percent coefficient of variation (%CV) was evaluated for between sites, between lot, between day, between operator, between run, and within run, as presented in the table below:

Cq Variability Analysis Results

Analyte	Sample Type	n/N	Mean Cq*	Between Site		Between Lot		Between Day		Between Operator		Between Run		Within-Run		Total	
				SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Flu A	Low Positive	268/270	24.2	0.0	0.2	0.0	0.0	0	0	0.0	0.0	0.4	1.6	2.3	9.5	2.3	9.6
	Moderate Positive	269/269	23.1	0.1	0.3	0.1	0.6	0	0	0.3	1.3	0.0	0.0	0.9	3.7	0.9	4.0
Flu B	Low Positive	268/270	26.1	0.0	0.0	0.3	1.1	0	0	0.3	1.2	0.0	0.0	2.3	8.9	2.4	9.1
	Moderate Positive	269/269	25.3	0.2	0.8	0.2	0.7	0	0	0.2	0.7	0.2	0.8	0.7	2.9	0.8	3.3

Note: SD and CV% were estimated using REML variance component analysis using the R Package VCA.
*DASH software identifies the cycle at which an amplification curve meets a predefined mathematical criterion as Cq.

Analytical Specificity (Cross-Reactivity & Microbial Interference)

Cross-Reactivity Wet Testing

Cross-Reactivity was evaluated for the DASH® Flu A/B Test on the DASH Instrument by wet testing of 65 different viruses, bacteria, and fungi that are common causes of respiratory infections. All samples were prepared in simulated clinical nasal matrix (SCNM) and tested individually, without the presence of the test viral targets. The testing concentrations for potentially interfering microorganisms noted in the table that shortly follows.

None of the evaluated organisms demonstrated cross-reactivity with the assay at the tested concentrations as shown in the table below.

Cross-Reactivity Testing Results

Microorganism	Microorganism Concentration (per swab)	Microorganism Concentration (per mL)
Adenovirus type C1	1.44E+04 $TCID_{50}$/swab	3.60E+05 $TCID_{50}$/mL
Cytomegalovirus (also known as HHV-5)	2.82E+03 $TCID_{50}$/swab	7.05E+04 $TCID_{50}$/mL
Epstein-Barr virus (also known as HHV-4)	1.51E+04 $TCID_{50}$/swab	3.78E+05 $TCID_{50}$/mL
Herpes Simplex Virus Type 1	4000 $TCID_{50}$/Swab	1.0E+05 $TCID_{50}$/mL
Human coronavirus 229E	4.00E+03 $TCID_{50}$/swab	1.00E+05 $TCID_{50}$/mL
Human coronavirus OC43	4.75E+03 $TCID_{50}$/swab	2.19E+05 $TCID_{50}$/mL
Human coronavirus HKU1	1.10E+04 Copies/swab	2.75E+05 Copies/mL
Human coronavirus NL63	4.00E+03 $TCID_{50}$/swab	1.00E+05 $TCID_{50}$/mL
Human Metapneumovirus	1.19E+04 $TCID_{50}$/swab	2.98E+05 $TCID_{50}$/mL
Measles virus	1.54E+04 $TCID_{50}$/swab	3.85E+05 $TCID_{50}$/mL
Middle East Respiratory Syndrome coronavirus (MERS-CoV)	[1]N/A	
Genomic RNA Middle East Respiratory Syndrome coronavirus (MERS-CoV)	1.35 ng RNA/swab	33.8 ng RNA/mL
Mumps virus	1.19E+04 $TCID_{50}$/swab	2.98E+05 $TCID_{50}$/mL
Parainfluenza virus 1	4.75E+03	1.19E+05

Microorganism	Microorganism Concentration (per swab)	Microorganism Concentration (per mL)
	$TCID_{50}$/swab	$TCID_{50}$/mL
Parainfluenza virus 2	4.00E+03 $TCID_{50}$/swab	1.00E+05 $TCID_{50}$/mL
Parainfluenza virus 3	1.44E+04 $TCID_{50}$/swab	3.60E+05 $TCID_{50}$/mL
Parainfluenza virus 4	2.82E+03 $TCID_{50}$/swab	7.05E+04 $TCID_{50}$/mL
Respiratory syncytial virus	2.82E+03 $TCID_{50}$/swab	7.05E+04 $TCID_{50}$/mL
Rhinovirus type 1A	2.82E+03 $TCID_{50}$/swab	7.05E+04 $TCID_{50}$/mL
Enterovirus type 68	3.40E+03 $TCID_{50}$/swab	8.50E+04 $TCID_{50}$/mL
Severe Acute Respiratory Syndrome coronavirus (2003 RNA)	9.80E+03 Copies/swab	2.45E+05 Copies/mL
SARS-CoV-2, Isolate hCoV- 19/USA/GA-EHC-2811C/2021 - Inactivated (Lineage B.1.1.529; Omicron Variant)	1.0E+07 Copies/Swab	2.5E+08 Copies/mL
SARS-Related Coronavirus 2, Isolate hCoV-19/USA/GA-EHC-2811C/2021 (Lineage B.1.1.529;Omicron Variant)	4000 $TCID_{50}$/Swab	1.0E+05 $TCID_{50}$/mL
SARS-Related Coronavirus 2, Isolate hCoV-19/USA/COR-22-063113/2022 (Lineage BA.5;Omicron Variant)	4000 $TCID_{50}$/Swab	1.0E+05 $TCID_{50}$/mL
SARS-Related Coronavirus 2, Isolate hCoV-19/USA/CA-Stanford-139_S23/2023 (Lineage XBB.1.16; Omicron Variant)	4000 $TCID_{50}$/Swab	1.0E+05 $TCID_{50}$/mL
SARS-Related Coronavirus 2, Isolate hCoV-19/USA/MD-HP47866/2023 (Lineage GJ.2; Deposited as XBB.2.3.3)	4000 $TCID_{50}$/Swab	1.0E+05 $TCID_{50}$/mL
SARS-Related Coronavirus 2, Isolate hCoV-19/USA/MD-HP47865/2023 (Lineage XBB.2.3;Omicron Variant)	4000 $TCID_{50}$/Swab	1.0E+05 $TCID_{50}$/mL
SARS-Related Coronavirus 2, Isolate hCoV-19/USA/MD-HP46933/2023 (Lineage EG.1.2;Omicron Variant)	4000 $TCID_{50}$/Swab	1.0E+05 $TCID_{50}$/mL
SARS-Related Coronavirus 2, Isolate hCoV-19/USA/MD-HP47946/2023 (Lineage EG.5.1; Omicron Variant)	4000 $TCID_{50}$/Swab	1.0E+05 $TCID_{50}$/mL
SARS-Related Coronavirus 2, Isolate hCoV-19/USA/New York/PV96109/2023 (Lineage JN.1;Omicron Variant)	4000 $TCID_{50}$/Swab	1.0E+05 $TCID_{50}$/mL
SARS-Related Coronavirus 2, Isolate hCoV-19/USA/CA-Stanford-165_S29/2023 (Lineage HK.3)	4000 $TCID_{50}$/Swab	1.0E+05 $TCID_{50}$/mL
SARS-Related Coronavirus 2, Isolate hCoV-19/USA/MD-HP50212/2023 (Lineage BA.2.86.1)	4000 $TCID_{50}$/Swab	1.0E+05 $TCID_{50}$/mL
SARS-Related Coronavirus 2, Isolate hCoV-19/USA/CA-GBW-GKISBBBB26982/2024 (Lineage KP.2)	4000 $TCID_{50}$/Swab	1.0E+05 $TCID_{50}$/mL
SARS-Related Coronavirus 2, Isolate hCoV-19/USA/NJ-GBW-GKISBBBB88291/2024 (Lineage KP.3)	4000 $TCID_{50}$/Swab	1.0E+05 $TCID_{50}$/mL
Varicella Zoster Virus, 10/2014 Isolate # 3	4000 Copies/Swab	1.0E+05 Copies/mL
Bordetella pertussis	5.00E+04 CFU/swab	1.25E+06 CFU/mL
Bordetella parapertussis	5.00E+04 CFU/swab	1.25E+06 CFU/mL
Chlamydia pneumoniae	5.00E+04 CFU/swab	1.25E+06 CFU/mL
Corynebacterium diphtheriae	5.00E+04 CFU/swab	1.25E+06 CFU/mL
Escherichia coli	5.00E+04 CFU/swab	1.25E+06 CFU/mL

Microorganism	Microorganism Concentration (per swab)	Microorganism Concentration (per mL)
Haemophilus influenzae	5.00E+04 CFU/swab	1.25E+06 CFU/mL
Fusobacterium necrophorum	5.00E+04 CFU/swab	1.25E+06 CFU/mL
Lactobacillus acidophilus	5.00E+04 CFU/swab	1.25E+06 CFU/mL
Legionella pneumophila	5.00E+04 CFU/swab	1.25E+06 CFU/mL
Moraxella catarrhalis	5.00E+04 CFU/swab	1.25E+06 CFU/mL
Mycobacterium tuberculosis (heat-inactivated)	5.00E+04 CFU/swab	1.25E+06 CFU/mL
Mycoplasma pneumoniae	5.00E+04 CFU/swab	1.25E+06 CFU/mL
Mycoplasma genitalium	5.00E+04 CFU/swab	1.25E+06 CFU/mL
Neisseria meningitidis	5.00E+04 CFU/swab	1.25E+06 CFU/mL
Neisseria elongata subsp. glycolytica	5.00E+04 CFU/swab	1.25E+06 CFU/mL
Neisseria mucosa	5.00E+04 CFU/swab	1.25E+06 CFU/mL
Nocardia asteroides	1.74E+05 CFU/swab	4.35E+06 CFU/mL
Pseudomonas aeruginosa	5.00E+04 CFU/swab	1.25E+06 CFU/mL
Staphylococcus aureus	5.00E+04 CFU/swab	1.25E+06 CFU/mL
Staphylococcus epidermidis	5.00E+04 CFU/swab	1.25E+06 CFU/mL
Streptococcus pneumoniae	5.00E+04 CFU/swab	1.25E+06 CFU/mL
Streptococcus pyogenes	5.00E+04 CFU/swab	1.25E+06 CFU/mL
Streptococcus salivarius	5.00E+04 CFU/swab	1.25E+06 CFU/mL
Streptococcus mitis	5.00E+04 CFU/swab	1.25E+06 CFU/mL
Streptococcus mutans	5.00E+04 CFU/swab	1.25E+06 CFU/mL
Aspergillus niger	5.00E+04 CFU/swab	1.25E+06 CFU/mL
Candida albicans	5.00E+04 CFU/swab	1.25E+06 CFU/mL
Cryptococcus neoformans	5.00E+04 CFU/swab	1.25E+06 CFU/mL
Pneumocystis jirovecii	5.00E+04 CFU/swab	1.25E+06 CFU/mL
Eikenella corrodens	5.00E+04 CFU/swab	1.25E+06 CFU/mL

[1]Concentration not available from vendor. Sample is qualitative non-infectious purified intact viral particles.

Microbial Interference Study

Microbial Interference was evaluated for the DASH® Flu A/B Test on the DASH Instrument by wet testing 65 different viruses, bacteria, and fungi that are common causes of respiratory infections. All samples were prepared in simulated clinical nasal matrix (SCNM) and tested with individual microorganisms or with pooled groups of up to four (4) microorganisms in the presence of the test viral targets at 3x their individual LoDs. Microbial non-

interference was determined if the target had a 100% positive call rate for all three (3) replicates tested.

None of the evaluated microorganisms demonstrated interference with the assay at the tested concentrations as shown in the table below.

Microbial Interference Testing Results

Microorganism	Microorganism Concentration (per swab)	Microorganism Concentration (per mL)
Adenovirus C1	1.44E+04 $TCID_{50}$/swab	3.60E+05 $TCID_{50}$/mL
Cytomegalovirus (also known as HHV-5)	2.48E+03 $TCID_{50}$/swab	6.20E+04 $TCID_{50}$/mL
Epstein-Barr virus (also known as HHV-4)	1.51E+04 $TCID_{50}$/swab	3.78E+05 $TCID_{50}$/mL
Human coronavirus 229E	4.00E+03 $TCID_{50}$/swab	1.00E+05 $TCID_{50}$/mL
Human coronavirus OC43	4.75E+03 $TCID_{50}$/swab	2.19E+05 $TCID_{50}$/mL
Human coronavirus HKU1	9.68E+03 Copies/swab	2.41E+05 Copies/mL
[1]Human coronavirus NL63	4.00E+03 $TCID_{50}$/swab	1.00E+05 $TCID_{50}$/mL
[1]Measles virus	1.54E+04 $TCID_{50}$/swab	3.85E+05 $TCID_{50}$/mL
Genomic RNA Middle East Respiratory Syndrome coronavirus (MERS-CoV)	1.35 ng RNA/swab	33.8 ng RNA/mL
Middle East Respiratory Syndrome coronavirus (MERS-CoV)	[2]N/A	
Mumps virus	1.19E+04 $TCID_{50}$/swab	2.98E+05 $TCID_{50}$/mL
Human Metapneumovirus	1.19E+04 $TCID_{50}$/swab	2.98E+05 $TCID_{50}$/mL
Parainfluenza virus 1	4.75E+03 $TCID_{50}$/swab	1.19E+05 $TCID_{50}$/mL
Parainfluenza virus 2	4.00E+03 $TCID_{50}$/swab	1.00E+05 $TCID_{50}$/mL
Parainfluenza virus 3	1.44E+04 $TCID_{50}$/swab	3.60E+05 $TCID_{50}$/mL
Parainfluenza virus 4	2.48E+03 $TCID_{50}$/swab	6.20E+04 $TCID_{50}$/mL
Respiratory syncytial virus	2.48E+03 $TCID_{50}$/swab	6.20E+04 $TCID_{50}$/mL
Rhinovirus type 1A	2.48E+03 $TCID_{50}$/swab	6.20E+04 $TCID_{50}$/mL
Enterovirus type 68	2.99E+03 $TCID_{50}$/swab	7.48E+04 $TCID_{50}$/mL
Severe Acute Respiratory Syndrome coronavirus (SARS-CoV)	8.62E+03 Copies/swab	2.16E+05 Copies/mL
[3]SARS-CoV-2, Isolate hCoV- 19/USA/GA-EHC-2811C/2021 (Lineage B.1.1.529; Omicron Variant)	5.65E+04 Copies/swab	1.41E+06 Copies/mL
[3]SARS-Related Coronavirus 2, Isolate hCoV-19/USA/GA-EHC-2811C/2021 (Lineage B.1.1.529;Omicron Variant)	44 $TCID_{50}$/swab	1.1E+03 $TCID_{50}$/mL
[3]SARS-Related Coronavirus 2, Isolate hCoV-19/USA/COR-22-063113/2022 (Lineage BA.5;Omicron Variant)	4 $TCID_{50}$/swab	1.0E+02 $TCID_{50}$/mL
[3]SARS-Related Coronavirus 2, Isolate hCoV-19/USA/CA-Stanford-139_S23/2023 (Lineage XBB.1.16; Omicron Variant)	40 $TCID_{50}$/swab	1.0E+03 $TCID_{50}$/mL
[3]SARS-Related Coronavirus 2, Isolate hCoV-19/USA/MD-HP47866/2023 (Lineage GJ.2; Deposited as XBB.2.3.3)	40 $TCID_{50}$/swab	1.0E+03 $TCID_{50}$/mL

Microorganism	Microorganism Concentration (per swab)	Microorganism Concentration (per mL)
[3]SARS-Related Coronavirus 2, Isolate hCoV-19/USA/MD-HP47865/2023 (Lineage XBB.2.3;Omicron Variant)	40 $TCID_{50}$/swab	1.0E+03 $TCID_{50}$/mL
[3]SARS-Related Coronavirus 2, Isolate hCoV-19/USA/MD-HP46933/2023 (Lineage EG.1.2;Omicron Variant)	40 $TCID_{50}$/swab	1.0E+03 $TCID_{50}$/mL
[3]SARS-Related Coronavirus 2, Isolate hCoV-19/USA/MD-HP47946/2023 (Lineage EG.5.1;Omicron Variant)	40 $TCID_{50}$/swab	1.0E+03 $TCID_{50}$/mL
[3]SARS-Related Coronavirus 2, Isolate hCoV-19/USA/New York/PV96109/2023 (Lineage JN.1;Omicron Variant)	400 $TCID_{50}$/swab	1.0E+04 $TCID_{50}$/mL
[3]SARS-Related Coronavirus 2, Isolate hCoV-19/USA/CA-Stanford-165_S29/2023 (Lineage HK.3)	400 $TCID_{50}$/swab	1.0E+04 $TCID_{50}$/mL
[3]SARS-Related Coronavirus 2, Isolate hCoV-19/USA/MD-HP50212/2023 (Lineage BA.2.86.1)	400 $TCID_{50}$/swab	1.0E+04 $TCID_{50}$/mL
SARS-Related Coronavirus 2, Isolate hCoV-19/USA/CA-GBW-GKISBBBB26982/2024 (Lineage KP.2)	4000 $TCID_{50}$/swab	1.0E+05 $TCID_{50}$/mL
[3]SARS-Related Coronavirus 2, Isolate hCoV-19/USA/NJ-GBW-GKISBBBB88291/2024 (Lineage KP.3)	40 $TCID_{50}$/swab	1.0E+03 $TCID_{50}$/mL
Varicella Zoster Virus, 10/2014 Isolate # 3	4000 Copies/Swab	1.0E+05 Copies/mL
Herpes Simplex Virus Type 1	4000 $TCID_{50}$/Swab	1.0E+05 $TCID_{50}$/mL
Bordetella pertussis	5.00E+04 CFU/swab	1.25E+06 CFU/mL
Bordetella parapertussis	5.00E+04 CFU/swab	1.25E+06 CFU/mL
Candida albicans	5.00E+04 CFU/swab	1.25E+06 CFU/mL
Chlamydia pneumoniae	5.00E+04 CFU/swab	1.25E+06 CFU/mL
Corynebacterium diphtheriae	5.00E+04 CFU/swab	1.25E+06 CFU/mL
Escherichia coli	5.00E+04 CFU/swab	1.25E+06 CFU/mL
Haemophilus influenzae	5.00E+04 CFU/swab	1.25E+06 CFU/mL
Fusobacterium necrophorum	5.00E+04 CFU/swab	1.25E+06 CFU/mL
Lactobacillus acidophilus	5.00E+04 CFU/swab	1.25E+06 CFU/mL
Legionella pneumophila	5.00E+04 CFU/swab	1.25E+06 CFU/mL
Moraxella catarrhalis	5.00E+04 CFU/swab	1.25E+06 CFU/mL
Mycobacterium tuberculosis (heat-inactivated)	5.00E+04 CFU/swab	1.25E+06 CFU/mL
Mycoplasma pneumoniae	5.00E+04 CFU/swab	1.25E+06 CFU/mL
Mycoplasma genitalium	5.00E+04 CFU/swab	1.25E+06 CFU/mL
Neisseria meningitidis	5.00E+04 CFU/swab	1.25E+06 CFU/mL
Neisseria elongata subsp. glycolytica	5.00E+04 CFU/swab	1.25E+06 CFU/mL
Pseudomonas aeruginosa	5.00E+04 CFU/swab	1.25E+06 CFU/mL
Staphylococcus aureus	5.00E+04 CFU/swab	1.25E+06 CFU/mL
Staphylococcus epidermidis	5.00E+04	1.25E+06

Microorganism	Microorganism Concentration (per swab)	Microorganism Concentration (per mL)
	CFU/swab	CFU/mL
Streptococcus pneumoniae	5.00E+04 CFU/swab	1.25E+06 CFU/mL
Streptococcus pyogenes	5.00E+04 CFU/swab	1.25E+06 CFU/mL
Streptococcus salivarius	5.00E+04 CFU/swab	1.25E+06 CFU/mL
Aspergillus niger	5.00E+04 CFU/swab	1.25E+06 CFU/mL
Cryptococcus neoformans	5.00E+04 CFU/swab	1.25E+06 CFU/mL
Pneumocystis jirovecii	5.00E+04 CFU/swab	1.25E+06 CFU/mL
Eikenella corrodens	5.00E+04 CFU/swab	1.25E+06 CFU/mL
Neisseria mucosa	5.00E+04 CFU/swab	1.25E+06 CFU/mL
Streptococcus mitis	5.00E+04 CFU/swab	1.25E+06 CFU/mL
Streptococcus mutans	5.00E+04 CFU/swab	1.25E+06 CFU/mL
Nocardia asteroides	1.74E+05 CFU/swab	4.35E+06 CFU/mL

Note: Thicker outer border indicates groups of pooled microorganisms that were tested.
[1]Tested individually as interference was observed when tested as a group.
[2]Concentration not available from vendor. Sample is qualitative non-infectious purified intact viral particles.
[3] Interference was observed at concentrations higher than the listed concentration.

Nuclein

Competitive Interference Study

The impact of competitive interference, caused by co-infections with on-target analytes, was evaluated for the DASH Flu A/B Test on the DASH Instrument by testing contrived samples consisting of individual Flu A or Flu B strains at high concentrations in the presence of the other target strain at 3x LoD. For this study, competitive interference was assessed using one strain each of influenza A and influenza B. Testing for each target strain (at 3x LoD concentration) and the potential competitive strain (at high concentration) was performed in triplicate. No competitive interference was observed if all replicates for the low concentration (3x LoD) target yielded positive results.

The study showed that Flu A at concentration of >1.38E+06 $TCID_{50}$/mL inhibited detection of Flu B at 3x LoD. In addition, Flu B at concentrations >1.01E+03 $TCID_{50}$/mL inhibited detection of Flu A at 3x LoD. The highest coinfection concentration of the competing virus, where the remaining targets are detected for three replicates at 3x LoD, are reported in the table below.

Competitive Interference Study Results

Competing Virus	Concentration at which All Targets are Positive	
	Flu A	**Flu B**
Flu A	5.52E+04 $TCID_{50}$/swab 1.38E+06 $TCID_{50}$/mL ~3405x LoD	3x LoD
Flu B	3x LoD	40.40 $TCID_{50}$/swab 1.01E+03 $TCID_{50}$/mL ~60x LoD

Exogenous/Endogenous Interfering Substances

Medically relevant substances found within clinical respiratory specimens (known as endogenous materials) and substances not commonly found in clinical respiratory specimens (exogenous substances) were evaluated for their potential impact on the DASH Flu A/B Test, and its ability to detect Flu A and Flu B.

All samples were prepared in simulated clinical nasal matrix (SCNM). Each positive sample was composed of a single exogenous or endogenous interfering substance and combined with a contrived co-spiked sample of Flu A, and Flu B at 3X LoD concentrations. Negative (no analyte) samples were prepared with simulated clinical nasal matrix (SCNM). Each interferent was tested in triplicate.

No interference was observed for any of the substances tested at the concentrations noted in the table below.

Exogenous/Endogenous Interfering Substances Study Results Summary

Interfering Substance	Concentration
Afrin® Original Nasal Spray	15% v/v
Chloroseptic® Sore Throat spray	20% v/v
Flonase®	5% v/v
Relenza®	0.3 mg/ml
Tobramycin	4 µg/mL
Mupirocin	10 mg/mL
Mucin	0.1% w/v
Blood	2% v/v
Biotin	4.58 µg/mL
Viral Transport Medium	50% v/v
Neo-Synephrine® Nasal Spray	15% v/v
Walgreens Saline Nasal Spray	15% v/v
Beclomethasone Dipropionate, USP (Micronized)	0.068 mg/mL
Flunisolide Nasal Solution, USP 0.025%	0.04 mg/mL
Nasacort® Nasal Spray	0.04 mg/mL
Walgreens 24 Hour Budesonide Nasal Spray	0.051 mg/mL
Nasonex	0.04 mg/mL
Zicam® Allergy Relief Nasal Spray	20% v/v
Snuff	0.1% (w/v)
Latex glove powder	1% (w/v)
Mucinex® Insta Sooth Kickstart Sore Throat	1.7 mg/mL
Zinc gluconate hydrate	0.1 µg/mL

Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

External Controls
The DASH SARS-CoV-2 & Flu A/B Positive Control and DASH Negative Control swabs are available separately for use as external controls. A study was conducted to evaluate these external controls with DASH Flu A/B Test. A total of 45 DASH SARS-CoV-2 & Flu A/B Positive Control and 45 DASH Negative Control swabs were tested daily by nine untrained operators at three CLIA-Waived sites across five testing days. Three lots of external controls were distributed evenly across all the three sites. All 45 external positive controls and all 45 external negative controls yielded accurate results.

Sample Stability
A study was conducted to determine the specimen stability on the swab after collection and prior to testing with the DASH Flu A/B Test on the DASH Instrument. Specimens included Flu A and Flu B, co-spiked in pooled negative nasal matrix at a concentration of 2x LoD. Twenty replicates of the positive samples were tested fresh (T0) and after storage at multiple time points (5, 10, 25, 30 and 40 minutes) at room temperature. Negative samples were also included and were tested in three replicates for each storage condition. Results indicated that positive samples remained stable, and all targets were detected up to twenty-five minutes after collection and storage at room temperature. Negative samples tested correctly for each timepoint.

Per test labeling, patient samples should be tested immediately after collection for optimal test performance.

Matrix Equivalency
The objective of this study was to establish equivalent performance of the DASH Flu A/B Test on the DASH Instrument between the two matrices used in the analytical studies: clinical pooled nasal matrix (PNM) and simulated clinical

nasal matrix (SCNM). SCNM was formulated in phosphate-buffered saline (PBS) with glycerol and mucin, added to mimic the nasal cavity fluid. For this study, Flu A (A/Victoria/2570/2019) and Flu B (B/Utah/9/2014) were co-spiked in both matrices at 2x and 5x LoD. Aliquots of negative matrices were also included in the evaluation. For both matrices, ten replicates of the negative samples, 40 replicates of the samples prepared at 2x LoD and ten replicates of the samples prepared at 5x LoD were tested. The acceptance criteria to demonstrate equivalency was ≥95% detection for samples at 2x LoD, 100% detection for the samples at 5x LoD for each target, and 0% detection of the negative samples. The results obtained in this study are summarized below. The data demonstrated equivalent performance of the test with both the matrices.

Matrix Equivalency Study Results

Viral Strain	Concentration	Matrix	n/N[1]	Detection Rate (% Positive)
Flu A	2x LoD	PNM	40/40	100
		SCNM	40/40	100
	5x LoD	PNM	10/10	100
		SCNM	10/10	100
Flu B	2x LoD	PNM	39/40	98
		SCNM	40/40	100
	5x LoD	PNM	10/10	100
		SCNM	10/10	100
Negative Matrix	N/A	PNM	10/10	0
		SCNM	10/10	0

[1]n is number of tests with expected results. N is the total number of valid tests

Analytical Sensitivity (Detection Limit)

Limit of detection (LoD) of the DASH Flu A/B Test on the DASH Rapid PCR Instrument was determined utilizing four viral strains representing the test targets. All samples were prepared in pooled negative nasal matrix. Initially, three-fold serial dilutions of each strain in pooled negative nasal matrix were prepared and tested in replicates of four to find the lowest level detectable by the DASH Flu A/B Test. The final LoD, a concentration producing 95% positivity, was confirmed by testing twenty replicates of each of the strains at the selected preliminary LoD. The final LoD results are summarized in the table below.

Limit of Detection Study Results

Viral Target	Strain	Source/ Product Type	LoD ($TCID_{50}$/swab)	LoD ($TCID_{50}$/mL)
Flu A	H1N1 Victoria/2570/19	Zeptometrics/ Culture Fluid	1.35 $TCID_{50}$/swab	33.75 $TCID_{50}$/mL
	H3N2 Darwin/9/21	Zeptometrics/ Culture Fluid	0.225 $TCID_{50}$/swab	5.63 $TCID_{50}$/mL
Flu B	Washington/02/19 - Victoria Lineage	Zeptometrics/ Culture Fluid	0.1 $TCID_{50}$/swab	2.50 $TCID_{50}$/mL
	Utah/9/14 - Yamagata Lineage	Zeptometrics/ Culture Fluid	0.675 $TCID_{50}$/swab	16.88 $TCID_{50}$/mL

Inclusivity (Analytical Reactivity):

Inclusivity was evaluated for the DASH® Flu A/B Test on the DASH Instrument through wet testing. Wet testing was performed by evaluating 21 strains of Flu A and 10 strains of Flu B. Each strain was evaluated at concentrations near LoD, prepared in pooled nasal matrix (PNM), and tested individually, with three (3) replicates evaluated per strain. Testing was executed in a blinded fashion with random negatives. Inclusivity was determined if the target had a

100% positive call rate for all three (3) replicates tested. The table that follows summarizes the wet tested analytical reactivity results:

Inclusivity Wet Test Results Summary

Test Target Variant/Subtype	Virus Concentration *(per swab)*	Virus Concentration *(per mL)*
Influenza A H1N1 (New Cal/20/99)	4.05 $TCID_{50}$/swab	101.25 $TCID_{50}$/mL
Influenza A H1N1 (PR/8/34)	4.05 $TCID_{50}$/swab	101.25 $TCID_{50}$/mL
Influenza A H1N1 (Brisbane/59/07)	4.05 $TCID_{50}$/swab	101.25 $TCID_{50}$/mL
Influenza A H1N1 (Taiwan/42/06)	4.05 $TCID_{50}$/swab	101.25 $TCID_{50}$/mL
[2]Influenza A H1N1 (Singapore/63/04)	4.05 $TCID_{50}$/swab	101.25 $TCID_{50}$/mL
Influenza A H1N1pdm (California/07/09)	4.05 $TCID_{50}$/swab	101.25 $TCID_{50}$/mL
Influenza A H1N1pdm (New York/18/09)	4.05 $TCID_{50}$/swab	101.25 $TCID_{50}$/mL
Influenza A H1N1pdm Virus (Strain: Guangdong-Maonan/SWL 1536/19)	4.05 $TCID_{50}$/swab	101.25 $TCID_{50}$/mL
Influenza A H1N1pdm (Mexico/4108/09)	4.05 $TCID_{50}$/swab	101.25 $TCID_{50}$/mL
Influenza A H1N1pdm (Victoria/2570/19)	4.05 $TCID_{50}$/swab	101.25 $TCID_{50}$/mL
Influenza A H3N2 (Wisconsin/67/05)	4.05 $TCID_{50}$/swab	101.25 $TCID_{50}$/mL
[1]Influenza A H3N2 Virus (Strain: Hong Kong/2671/19)	8.1 $TCID_{50}$/swab	202.50 $TCID_{50}$/mL
Influenza A H3N2 (Stockholm/6/14)	4.05 $TCID_{50}$/swab	101.25 $TCID_{50}$/mL
Influenza A H3N2 (HK/8/68)	4.05 $TCID_{50}$/swab	101.25 $TCID_{50}$/mL
Influenza A H3N2 (Texas/50/12)	4.05 $TCID_{50}$/swab	101.25 $TCID_{50}$/mL
[1]Influenza A H3N2 (Strain: Kansas/14/17)	8.1 $TCID_{50}$/swab	202.50 $TCID_{50}$/mL
Influenza A H3N2 (California/7/04)	4.05 $TCID_{50}$/swab	101.25 $TCID_{50}$/mL
Influenza A H3N2 (Norway/466/14)	4.05 $TCID_{50}$/swab	101.25 $TCID_{50}$/mL
Influenza A H3N2 (Kumamoto/102/02)	4.05 $TCID_{50}$/swab	101.25 $TCID_{50}$/mL
[1]Influenza A H3N2 (Brisbane/10/07)	8.1 $TCID_{50}$/swab	202.5 $TCID_{50}$/mL
Influenza A H5N3 [Genomic RNA from Kilbourne F3: A/duck/Singapore/645/1997 (H5N3) Mutant, High (Hy) Yield Influenza A Virus]	1.76E+03 ng RNA/swab	4.40E+04 ng RNA/mL
Influenza B (Lee/40)	4.05 $TCID_{50}$/swab	101.25 $TCID_{50}$/mL
Influenza B (Massachusetts/2/12)	2.025 $TCID_{50}$/swab	50.63 $TCID_{50}$/mL
Influenza B Victoria Lineage (Austria/1359417/21)	2.025 $TCID_{50}$/swab	50.63 $TCID_{50}$/mL
Influenza B Victoria Lineage (Victoria/2/87)	2.025 $TCID_{50}$/swab	50.63 $TCID_{50}$/mL
Influenza B Victoria Lineage (Alabama/2/17)	2.025 $TCID_{50}$/swab	50.63 $TCID_{50}$/mL
Influenza B Yamagata Lineage (Panama/45/90)	2.025 $TCID_{50}$/swab	50.63 $TCID_{50}$/mL
Influenza B Yamagata Lineage (Florida/04/06)	2.025 $TCID_{50}$/swab	50.63 $TCID_{50}$/mL
Influenza B Yamagata Lineage (Brisbane/9/14)	2.025 $TCID_{50}$/swab	50.63 $TCID_{50}$/mL

[1]Testing at a lower concentration (i.e., 3x LoD) failed to yield 100% detection. The lowest concentration that yielded 100% detection was 6x LoD.
[2]Influenza A H1N1 (Singapore/63/04) was detected in 2/3 replicates at 3x LoD. The strain was reprepared at 3x LoD and tested in 7 replicates for 100% detection.

Assay Cut-Off:

The DASH Rapid PCR Instrument has four fluorescence detectors also known as channels and an algorithm that is utilized for detection of the targets. The DASH Flu A/B Test does not have a simple Ct or Cq threshold below which the target is 'Detected', and above which 'Not Detected'. The Cq threshold for the test is 40, same as the total number of PCR cycles. If Cq is >40, then the target is always 'Not Detected'.

Carry-Over:

A study was conducted to evaluate the risk of contamination from one test run to another by alternating the testing of a series of single high titer (≥1x10^5 copies/mL or ≥1x10^5 $TCID_{50}$/mL) viral target (either Flu A or Flu B) samples with negative samples, when run consecutively on the same instrument. Contrived samples of single viral targets of either Flu A or Flu B were spiked into simulated clinical nasal matrix (SCNM) and applied to a sample swab. A

total of six (6) viral targets were used, including 3 strains each for Flu A and Flu B. Negative samples were composed only of SCNM. To demonstrate robustness of the DASH Flu A/B Test when run on the DASH Instrument, each viral target was evaluated in replicates of five (5) and run on five (5) DASH Rapid PCR Instruments.

No false positive calls were observed among the negative samples run immediately after high titer positive runs. Likewise, no erroneous results were issued from the positive samples. The data show that 100% call accuracy was attained for both the positive target samples (30/30 positive calls) and the negative samples (30/30 negative calls); and no carry-over or cross contamination occurred when using the DASH® Flu A/B Test on the DASH Rapid PCR Instrument.

Flex Studies

Flex studies were performed to evaluate the robustness of the DASH Flu A/B Test. Variations in workflow and operating environment that may reasonably be expected to occur with untrained operators in the intended use CLIA waived setting were evaluated. Results of the flex studies conducted demonstrate robust performance of the DASH Flu A/B Test under conditions of stress.

Clinical Studies *807.92(b)(2)**:***

Clinical Performance:

The clinical performance characteristics of the DASH Flu A/B Test on the DASH Instrument was established in a multi-center study conducted with anterior nasal swab (ANS) specimens collected from individuals with signs and symptoms of respiratory infection. Specimens were prospectively collected (i.e., all comers between two time points that met the clinical study inclusion criteria) from January and March 2024. Seven geographically diverse CLIA-waived testing sites within the United States participated in the study. Informed consent was obtained for all patients prior to testing. AN swabs for comparator testing were collected by the healthcare provider from both sides of the nose and placed into transport media for comparator testing. For testing with the DASH Flu A/B Test, AN swabs from both sides of the nose were either healthcare provider-collected or adult-collected from individuals below 14 years, or self-collected from individuals aged 14 years or older. The order of swab collection was alternated between the comparator swab and the DASH Flu A/B Test. Performance of the DASH Flu A/B Test was assessed by a comparison of results with an FDA-cleared test for Flu A and Flu B (expressed as positive percent agreement (PPA) and negative percent agreement (NPA)). All discordant results between the DASH Flu A/B Test and the comparator were investigated using a second highly sensitive FDA cleared test and are footnoted under the Performance table that shortly follows.

The clinical performance of the DASH Flu A/B Test is summarized in the table below.

Clinical Performance of DASH Flu A/B Test

Test Targets	Positive Percent Agreement		Negative Percent Agreement	
	TP/(TP+FN)	***PPA (95% CI)***	***TN/(TN+FP)***	***NPA (95% CI)***
[1]Flu A	50/53	94.3% (84.6% - 98.1%)	725/739	98.1% (96.8% - 98.9%)
[2]Flu B	36/37	97.3% (86.2% - 99.9%)	749/755	99.2% (98.3% - 99.6%)

TP-true positive; FN-false negative; TN-true negative; FP-false positive

[1]Flu A PPA: Two (2) samples were negative by another FDA cleared test, agreeing with the DASH.
Flu A NPA: 13 samples were positive by another FDA cleared test, agreeing with the DASH.

[2]Flu B PPA: One (1) sample was negative by another FDA cleared test, agreeing with the DASH.
Flu B NPA: Four (4) samples were positive by another FDA cleared test, agreeing with the DASH.

Of the 833 samples tested on DASH Flu A/B Test, including 16 repeat samples, there were 24 instances of invalid results (2.9%; 95% CI: 1.9% - 4.3%).

A total of 819 subjects were enrolled in the study from the seven clinical sites. Of these, two subjects were later found ineligible for enrollment. Of the remaining 817 enrolled subjects, 22 were excluded due to protocol deviations (e.g., specimen shipping issues, comparator sample being unable to be tested within the stability window of the test IFU, etc.), leaving 792 evaluable specimens to be included in the calculations of estimates of assay performance for Flu A and Flu B. The table below provides a summary of the subject demographics associated with the specimens collected within the study:

Summary of Subject Demographics

Subject Demographics	Overall (N=792)
Age: Mean (SD)	37.3 (18.3)
Age: Median [Min, Max]	36 [2, 87]
Age Group	
<5 years of age	15 (1.9%)
5 - <14 years of age	73 (9.2%)
14 - 24 years of age	113 (14.3%)
>24 - 64 years of age	527 (66.5%)
≥65 years of age	64 (8.1%)
Sex at Birth	
Female	464 (58.6%)
Male	328 (41.4%)
Ethnicity	
Hispanic/Latino	300 (37.9%)
Not Hispanic/Latino	492 (62.1%)
Race	
American Indian or Alaskan Native	3 (0.4%)
Asian	4 (0.5%)
Black or African American	111 (14.0%)
Native Hawaiian/Pacific Islander	4 (0.5%)
White	658 (83.1%)
Unknown/Prefer not to answer	6 (0.8%)
Other (Mixed race/biracial)	6 (0.8%)
Total	792 (100%)

Conclusion 807.92(b)(3)**:**

The intended use and fundamental scientific technology of the DASH Flu A/B Test using the DASH Instrument is substantially equivalent to the predicate device. The results of the analytical and clinical performance studies summarized above demonstrate that the DASH Flu A/B Test is substantially equivalent to the predicate device.