510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K252283

B Applicant

Nano-Ditech Corporation

C Proprietary and Established Names

Nano-Check Influenza A+B Test

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
PSZ	Class II	21 CFR 866.3328 - Influenza Virus Antigen Detection Test System	MI - Microbiology

II Submission/Device Overview:

A Purpose for Submission:

To obtain 510(k) clearance for the Nano-Check Influenza A+B Test

B Measurand:

Nucleoprotein antigens from Influenza A and B viruses

C Type of Test:

Qualitative lateral flow immunoassay

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

The Nano-Check Influenza A+B Test is a lateral flow immuno-chromatographic assay intended for the qualitative detection of influenza A and influenza B nucleoprotein antigens directly from anterior nasal swab (ANS) samples from patients with signs and symptoms of respiratory infection. The test is intended for use as an aid in the differential diagnosis of influenza A and influenza B viral infections. The test is not intended for the detection of influenza C antigens. Negative test results are presumptive and should be confirmed by viral culture or an FDA-cleared influenza A and B molecular assay. Negative test results do not preclude influenza viral infection and should not be used as the sole basis for treatment or other patient management decisions.

Performance characteristics for influenza A and B were established during the 2022-2025 influenza seasons when influenza A/H1N1pdm09, influenza A/H3N2, and influenza B/Victoria lineage were the predominant influenza viruses in circulation. When other influenza viruses are emerging, performance characteristics may vary.

If infection with a novel influenza 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 the state or local health department for testing. Virus culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

D Special Instrument Requirements:

Not Applicable (N/A)

IV Device/System Characteristics:

A Device Description:

The Nano-Check Influenza A+B Test candidate device is a lateral flow immunoassay designed for the qualitative detection of influenza A and B antigens in ANS specimens from individuals with signs and symptoms of respiratory infection.

The assay kit consists of 25 test cassette devices, 25 reagent tubes, 25 ampules containing extraction buffer, 25 anterior nasal specimen collection swabs, one positive control swab (contains noninfectious influenza A and B recombinant antigens), one negative control swab (without recombinant antigen), one Instructions for Use (IFU), and one Quick Reference Instruction (QRI).

Test strips are enclosed in a cassette housing comprised of the following components: sample pad, reagent pad, reaction membrane, and absorbent pad. The reagent pad contains colloidal gold conjugated with monoclonal antibodies (mAb) specific for influenza A and influenza B target proteins. The reaction membrane contains the secondary antibodies for the proteins of influenza

A and influenza B. The complete strip assembly is fixed inside a plastic cassette. The schematic of the test cassette device is shown in Figure 1 below.

Figure 1. Test Device of Nano-Check Influenza A+B Test Strip

B Principle of Operation:

The Nano-Check Influenza A+B Test is designed to detect the extracted nucleoprotein antigen specific to influenza A and influenza (Flu) B in ANS specimens directly collected from patients exhibiting signs or symptoms of a respiratory infection.

When the specimens are extracted and added to the sample well of the test device, if Flu A and/or Flu B nucleoprotein antigens are present in the specimen, a complex will form between the anti-Flu A/Flu B conjugate and the viral antigen and will be captured by the specific anti-Flu A/Flu B mAb coated on the test line region (A/B line). The absence of the test line (A/B line) suggests a negative result. To serve as a procedural control, a red line will always appear in the control line region (CON) indicating that proper volume of sample has been added and membrane wicking has occurred. Any result without this control line is invalid.

V Substantial Equivalence Information:

A Predicate Device Name(s):

BD Veritor System for Rapid Detection of Flu A+B CLIA Waived Kit

B Predicate 510(k) Number(s):

K232434

C Comparison with Predicate(s):

Device & Predicate Device(s):	K252283	Predicate: K232434
Device Trade Name	Nano-Check Influenza A+B Test	BD Veritor System for Rapid Detection of Flu A+B CLIA Waived Kit

General Device Characteristic Similarities		
Intended Use/Indications For Use	The Nano-Check Influenza A+B Test is a lateral flow immunochromatographic assay intended for the qualitative detection of influenza A and influenza B nucleoprotein antigens directly from anterior nasal swab (ANS) samples from patients with signs and symptoms of respiratory tract infection. The test is intended for use as an aid in the differential diagnosis of influenza A and influenza B viral infections. Test is not intended for the detection of influenza C antigens. Negative results are presumptive and should be confirmed by viral culture or an FDA-cleared influenza A and B molecular assay. Negative test results to not preclude influenza viral infection and should not be used as the sole basis for treatment or other patient management decisions. Performance characteristics for influenza A and B were established during the 2022-2025 influenza seasons when influenza A/H1N1pdm09, influenza A/H3N2, and influenza B/Victoria lineage were the predominant influenza viruses in circulation. When other influenza viruses are emerging, performance characteristics may vary. If infection with a novel influenza 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 the state or local health department for testing. Virus culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens	The BD Veritor System for Rapid Detection of Flu A+B CLIA Waived Kit is a rapid chromatographic immunoassay for the direct and qualitative detection of influenza A and B viral nucleoprotein antigens from nasal and nasopharyngeal swabs of symptomatic patients. The BD Veritor System for Rapid Detection of Flu A+B CLIA Waived Kit (also referred to as the BD Veritor System and BD Veritor System Flu A+B) is a differentiated test, such that influenza A viral antigens can be distinguished from influenza B viral antigens from a single processed sample using a single device. The test is to be used as an aid in the diagnosis of influenza A and B viral infections. A negative test is presumptive, and it is recommended that these results be confirmed by viral culture or an FDA-cleared influenza A and B molecular assay. Negative test results do not preclude influenza viral infection and should not be used as the sole basis for treatment or other patient management decisions. The test is not intended to detect influenza C antigens. Performance characteristics for influenza A and B were established during January through March of 2011 when influenza viruses A/2009 H1N1, A/H3N2, B/Victoria lineage, and B/Yamagata lineage were the predominant influenza viruses in circulation according to the Morbidity and Mortality Weekly Report from the CDC entitled "Update: Influenza Activity—United States, 2010–2011 Season, and Composition of the 2011–2012 Influenza Vaccine." Performance characteristics may vary against other emerging influenza viruses. If infection with a novel influenza 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 the state or local health department for testing. Virus culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.
Regulation Number	21 CFR 866.3328	Same
Analyte	Influenza A and B viral nucleoprotein antigens	Same
Assay Principle (Technology)	Lateral flow Immunochromatographic assay	Same
Usage	Single use cartridges	Same
Test Results	Qualitative	Same
Storage Temperature	2-30°C	Same
Patient Use Settings	For prescription use only by healthcare providers	Same
General Device Characteristic Differences		
Reading Time	15-20 minutes	10-15 minutes
Specimen Type	Anterior Nasal Swab	Anterior nasal and nasopharyngeal swabs
Result Interpretation	Visually	An opto-electronic reader determines the line intensity

VI Standards/Guidance Documents Referenced:

Document	Title	Publisher	Purpose
21 CFR 866.3328	Special Controls under 21 CFR 866.3328 (Influenza virus antigen detection test system)	FDA/CDRH	All studies
EP12-A2	User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline - Second Edition	CLSI	General Use
EP37 1st Edition	Supplemental tables for Interference Testing in Clinical Chemistry	CLSI	Interference
ISO 14971 Third Edition 2019-12	Medical Devices – Application of risk management to medical devices	ISO	Risk Management

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

a. Within-lab Precision/Single-lot Repeatability Study:
The repeatability study was conducted by two (2) operators with each operator conducting 24 test runs over a 12-day period, resulting in a total of 96 replicates per panel member. The study included blind sample panels comprising of true negative (TN), low positive (LP, 1X

LoD) and moderate positive (MP, 3X LoD) samples for each analyte (influenza A and influenza B). The study results are summarized in Table 1 below and are consistent with expected outcomes for all samples.

Table 1: Overall Results from Single-lot Repeatability Study

Sample	Test Line	No. of Positives / No. of Samples tested (%)		Total no. of positives / Total no. of samples (%)
		Operator 1	Operator 2	
True Negative (TN)	Flu A	0/48 (0%)	0/48 (0%)	0/96 (0%)
	Flu B	0/48 (0%)	0/48 (0%)	0/96 (0%)
Flu A (3X LoD) (MP)	Flu A	48/48 (100%)	48/48 (100%)	96/96 (100%)
	Flu B	0/48 (0%)	0/48 (0%)	0/96 (0%)
Flu A (1X LoD) (LP)	Flu A	48/48 (100%)	48/48 (100%)	96/96 (100%)
	Flu B	0/48 (0%)	0/48 (0%)	0/96 (0%)
Flu B (3X LoD) (MP)	Flu A	0/48 (0%)	0/48 (0%)	0/96 (0%)
	Flu B	48/48 (100%)	48/48 (100%)	96/96 (100%)
Flu B (1X LoD) (LP)	Flu A	0/48 (0%)	0/48 (0%)	0/96 (0%)
	Flu B	48/48 (100%)	48/48 (100%)	96/96 (100%)

b. Lot-to-Lot Precision Study:

A precision evaluation was conducted over a 12-day period to assess the lot-to-lot variability of test results across different production lots. A contrived sample panel was used consisting of true negative (TN), high negative (HN, 0.1X LoD), C90 (concentration corresponding to 90% detection probability), and moderate positive (MP, 3X LoD) samples for influenza A and B. Samples were blinded and randomized across for each panel member.

The study was conducted by three (3) on-site operators over 12 non-consecutive days at one site. Each operator performed two (2) runs per day (one in the morning and one in the afternoon), with 14 swab samples tested per run. Across the entire study, 1,008 swab samples were tested across all operators and device lots, corresponding to 144 independent replicates per panel member (48 replicates per operator). Results are summarized in Table 2 and demonstrate consistent performance across operators and lots.

Table 2: Summary of Lot-to-Lot Variability Study Results.

Sample	Test line	No. of Positives / No. of Samples tested (%)			Total no. of positives / Total no. of samples (%)
		Lot 1	Lot 2	Lot 3	
True Negative (TN)	Flu A	0/48 (0%)	0/48 (0%)	0/48 (0%)	0/144 (0%)
	Flu B	0/48 (0%)	0/48 (0%)	0/48 (0%)	0/144 (0%)
Flu A (0.1X LoD) (HN)	Flu A	0/48 (0%)	0/48 (0%)	0/48 (0%)	0/144 (0%)
	Flu B	0/48 (0%)	0/48 (0%)	0/48 (0%)	0/144 (0%)
	Flu A	42/48	41/48	45/48	128/144

Sample	Test line	No. of Positives / No. of Samples tested (%)			Total no. of positives / Total no. of samples (%)
		Lot 1	Lot 2	Lot 3	
Flu A (C90)		(87.5%)	(85.4%)	(93.8%)	(88.9%)
	Flu B	0/48 (0%)	0/48 (0%)	0/48 (0%)	0/144 (0%)
Flu A (3X LoD) (MP)	Flu A	48/48 (100%)	48/48 (100%)	48/48 (100%)	144/144 (100%)
	Flu B	0/48 (0%)	0/48 (0%)	0/48 (0%)	0/144 (0%)
Flu B (0.1X LoD) (HN)	Flu A	0/48 (0%)	0/48 (0%)	0/48 (0%)	0/144 (0%)
	Flu B	0/48 (0%)	0/48 (0%)	0/48 (0%)	0/144 (0%)
Flu B (C90)	Flu A	0/48 (0%)	0/48 (0%)	0/48 (0%)	0/144 (0%)
	Flu B	44/48 (91.7%)	43/48 (89.6%)	45/48 (93.8%)	132/144 (91.7%)
Flu B (3X LoD) (MP)	Flu A	0/48 (0%)	0/48 (0%)	0/48 (0%)	0/144 (0%)
	Flu B	48/48 100%	48/48 100%	48/48 100%	144/144 (100%)

c. Multi-site Reproducibility Study:

A multi-site reproducibility study was performed to assess the performance of the candidate device using a contrived sample panel comprised of TN, HN (0.1X LoD), a low positive (LP, 1X LoD) and a moderate positive (MP, 5X LoD) sample for each analyte. The study was conducted by untrained operators in CLIA waived settings for over five non-consecutive days. Contrived swab samples were prepared by spiking pooled human nasal wash solution (confirmed influenza A and influenza B negative by RT-PCR) with Influenza A (H1N1) and Influenza B (Victoria Lineage) to concentrations of 5X LoD, 1X LoD or 0.1X LoD. Each diluted sample (50 µL) was directly applied onto the sample collection swab head. True negative swab samples were prepared by applying fifty (50) µL of negative pooled human nasal wash directly onto the sample collection swab head.

The contrived sample swabs were randomized and blinded to each operator at three (3) discrete CLIA-waived sites and an in-house site. Eight (8) operators across three (3) CLIA waived sites and three (3) additional trained operators at the internal site conducted testing. Each operator tested 105 encoded samples, consisting of 15 samples each for various analyte levels.

The results in Table 3 showed high concordance among the eleven (11) operators across most sample types and across sites. Complete agreement was observed for TN samples, MP samples for both Flu A and Flu B, and LP-Flu B samples. All other observed results met the predefined acceptance criteria and were acceptable.

Table 3: Summary Results of Multi-site Reproducibility Study

Sample	No. of Positives / No. of Samples Tested (%)				Total no. of positives / Total no. of Samples (%)
	CLIA-Waived Site 1 (2 operators)	CLIA-Waived Site 2 (3 operators)	CLIA-Waived Site 3 (3 operators)	In-house Site 4 (3 operators)	
True Negative (TN)	0/30 (0%)	0/45 (0%)	0/45 (0%)	0/45 (0%)	0/165 (0%)
Flu A	0/30	0/45	0/45	0/45	0/165

Sample	No. of Positives / No. of Samples Tested (%)				Total no. of positives / Total no. of Samples (%)
	CLIA-Waived Site 1 (2 operators)	CLIA-Waived Site 2 (3 operators)	CLIA-Waived Site 3 (3 operators)	In-house Site 4 (3 operators)	
(0.1X LoD) (HN)	(0%)	(0%)	(0%)	(0%)	(0%)
Flu B (0.1X LoD) (HN)	0/30 (0%)	0/45 (0%)	1/45 (2.2%)	0/45 (0%)	1/165 (0.6%)
Flu A (1X LoD) (LP)	30/30 (100%)	45/45 (100%)	44/45 (97.8%)	45/45 (100%)	164/165 (99.4%)
Flu B (1X LoD) (LP)	30/30 (100%)	45/45 (100%)	45/45 (100%)	45/45 (100%)	165/165 (100%)
Flu A (5X LoD) (MP)	30/30 (100%)	45/45 (100%)	45/45 (100%)	45/45 (100%)	165/165 (100%)
Flu B (5X LoD) (MP)	30/30 (100%)	45/45 (100%)	45/45 (100%)	45/45 (100%)	165/165 (100%)

2. Linearity:

This is a qualitative assay and linearity is not applicable.

3. Analytical Specificity/Interference:

a. Cross-reactivity and Microbial Interference:
Cross-reactivity and microbial interference studies were conducted to determine if other respiratory pathogens/microbial flora that may be present in the nasal swab samples could cause a false positive test result or interfere with a true positive test result. A total of 53 potential cross-reactive or interfering pathogens comprising of bacteria (19), fungus (2), and viruses (30) and negative matrix (2) were tested in three (3) replicates in the absence (cross-reactivity) or presence (microbial interference) of 2X LoD concentrations of influenza (Flu) A and Flu B antigens. These organisms were diluted using pooled human nasal fluid in 1X phosphate buffered saline (PBS) to the target concentration, higher than $1x10^6$ CFU/mL or IFU/mL for bacteria and fungi, or higher than $1x10^5$ pfu/mL, $TCID_{50}$/mL, $CEID_{50}$/mL, or cp/mL for viruses. Samples were tested in a randomized and blinded manner by three (3) operators.

All samples containing potential cross-reactive or interfering organisms yielded the anticipated test results, as presented in Table 4 below. No instances of false negatives or false positives were observed during the study. Consequently, this study affirms that the Nano-Check Influenza A+B Test exhibits no reactivity with, nor interference from, the listed pathogens, high prevalence disease agents, and normal or pathogenic flora that are reasonably likely to be encountered in clinical specimens.

Table 4: Results of Cross-reactivity/Microbial Interference

Microorganism (Strain)	Concentration Tested	Positive Sample (# Positive/ # Tested)*	Negative Sample (# Positive/ # Tested)*	Cross-Reactivity/ Microbial Interference
Bordetella pertussis	1.0×10^6 CFU/mL	3/3	0/3	No
Candida albicans	1.0×10^6 CFU/mL	3/3	0/3	No
Chlamydophila pneumoniae	1.0×10^6 IFU/mL	3/3	0/3	No
Corynebacterium diphtheriae	1.0×10^6 CFU/mL	3/3	0/3	No
Escherichia coli	1.0×10^6 IFU/mL	3/3	0/3	No
Haemophilus influenzae, B	1.0×10^6 CFU/mL	3/3	0/3	No
Lactobacillus acidophilus	1.0×10^6 CFU/mL	3/3	0/3	No
Legionella Pneumophila subsp. *Pneumophila*	1.0×10^6 CFU/mL	3/3	0/3	No
Moraxella catarrhalis	1.0×10^6 CFU/mL	3/3	0/3	No
Mycobacterium tuberculosis	1.0×10^6 CFU/mL	3/3	0/3	No
Mycoplasma pneumoniae	1.0×10^6 CFU/mL	3/3	0/3	No
Neisseria meningitidis	1.0×10^6 CFU/mL	3/3	0/3	No
Neisseria mucosa	1.0×10^6 CFU/mL	3/3	0/3	No
Neisseria subflava	1.0×10^6 CFU/mL	3/3	0/3	No
Pneumocystis jirovecii – S. cerevisiae	1.0×10^6 CFU/mL	3/3	0/3	No
Pseudomonas aeruginosa	1.0×10^6 CFU/mL	3/3	0/3	No
Staphylococcus aureus	1.0×10^6 CFU/mL	3/3	0/3	No
Staphylococcus epidermidis	1.0×10^6 CFU/mL	3/3	0/3	No
Streptococcus pneumoniae	1.0×10^6 CFU/mL	3/3	0/3	No
Streptococcus pyogenes	1.0×10^6 CFU/mL	3/3	0/3	No
Streptococcus salivarius	1.0×10^6 CFU/mL	3/3	0/3	No
Epstein-Barr Virus	1.0×10^5 cp/mL	3/3	0/3	No
Enterovirus 71	1.0×10^5 $TCID_{50}$/mL	3/3	0/3	No
Enterovirus D 68	1.0×10^5 $TCID_{50}$/mL	3/3	0/3	No
Human Herpesvirus 5	8.0×10^4 $TCID_{50}$/mL	3/3	0/3	No
Human Adenovirus 1	1.0×10^5 $TCID_{50}$/mL	3/3	0/3	No
Human Adenovirus 2	1.0×10^5 $TCID_{50}$/mL	3/3	0/3	No
Human Adenovirus 7, Gomen	1.0×10^5 $TCID_{50}$/mL	3/3	0/3	No
Human Coronavirus, 229E	1.0×10^5 $TCID_{50}$/mL	3/3	0/3	No
Human Coronavirus, NL63	7.0×10^4 $TCID_{50}$/mL	3/3	0/3	No
Human Coronavirus, OC43	4.5×10^4 $TCID_{50}$/mL	3/3	0/3	No
Human Metapneumovirus 3, B1, Peru2-2002	1.95×10^4 $TCID_{50}$/mL	3/3	0/3	No
Human Metapneumovirus, TN/83-1211	1.0×10^5 $TCID_{50}$/mL	3/3	0/3	No
Human Parainfluenza Virus 1	1.0×10^5 $TCID_{50}$/mL	3/3	0/3	No
Human Parainfluenza Virus 2	1.0×10^5 $TCID_{50}$/mL	3/3	0/3	No
Human Parainfluenza Virus 3	1.0×10^5 $TCID_{50}$/mL	3/3	0/3	No
Human Parainfluenza Virus 4B	1.0×10^5 $TCID_{50}$/mL	3/3	0/3	No
Human RSV, A Long	1.0×10^5 $TCID_{50}$/mL	3/3	0/3	No
Human RSV, A 9320	1.0×10^5 $TCID_{50}$/mL	3/3	0/3	No
Human RSV, A2	1.0×10^5 $TCID_{50}$/mL	3/3	0/3	No
Human RSV, B 18537	1.0×10^5 $TCID_{50}$/mL	3/3	0/3	No
Human RSV, B WV/14617/85	1.0×10^5 $TCID_{50}$/mL	3/3	0/3	No
Human RSV, B1	1.0×10^5 $TCID_{50}$/mL	3/3	0/3	No
Human Rhinovirus 1A, 2060	1.0×10^5 PFU/mL	3/3	0/3	No
Measles Virus, Edmonston	1.7×10^4 $TCID_{50}$/mL	3/3	0/3	No
MERS-CoV, EMC/2012	1.0×10^5 $TCID_{50}$/mL	3/3	0/3	No

Microorganism (Strain)	Concentration Tested	Positive Sample (# Positive/ # Tested)*	Negative Sample (# Positive/ # Tested)*	Cross-Reactivity/ Microbial Interference
Mumps Virus, MuV/Iowa.US/2006	1.0×10^5 $TCID_{50}$/mL	3/3	0/3	No
Rhinovirus 20, 15-CV19	1.0×10^5 $TCID_{50}$/mL	3/3	0/3	No
SARS-CoV	1.0×10^5 PFU/mL	3/3	0/3	No
SARS-CoV-2, USA/MD-HP20874/ 2021	$1.95x10^4$ $TCID_{50}$/mL	3/3	0/3	No
SARS-CoV-2, USA/COR-22-063113/ 2022	$1.0x10^3$ $TCID_{50}$/mL	3/3	0/3	No
Pooled Human Nasal Wash	N/A	3/3	0/3	No
Pooled Human Nasal Fluid	N/A	3/3	0/3	No
Note: Coronavirus HKU1 was not tested for cross-reactivity due to lack of availability. 20 clinical samples containing Coronavirus HKU1 were tested, and all resulted as negative, however, the viral load/concentration of each sample is unknown.				

*Results represent positive and negative sample results for both influenza A and B (i.e., 3 replicates for each).

b. Endogenous/Exogenous Substances Interference Study:

The interference study aimed to evaluate potential endogenous and exogenous interference with the Nano-Check Influenza A+B Test. Thirty-six (36) substances, including whole blood, various over-the-counter (OTC) products, household items, and common chemicals, were assessed for cross-reactivity or interference with Flu A and Flu B detection. Each substance was spiked onto swab heads in the presence or absence of 2X LoD concentrations of each analyte. Samples were tested in randomized and blinded manner by three (3) operators.

With the exception of the FluMist trivalent live attenuated influenza vaccine, none of the substances caused a false positive result in the unspiked samples. While the presence of the FluMist vaccine at 15% v/v concentration did not interfere with the detection of true positive results (samples were tested at 3X LoD co-spiked), the vaccine also resulted in false positive results for Flu A (as expected based on the composition of the vaccine). When diluted to 1.5% v/v, the results of the unspiked samples were negative. Hand sanitizer lotion at 15% v/v showed false negative results for Flu B but detected all analytes at 10% v/v. Results for this study are listed in Table 5 below.

Table 5: Endogenous/Exogenous Interference Test Results

Endogenous/Exogenous Substance Test concentration	Concentration Tested	Spiked Virus (Concentration)	No. of Positive Results / No. of Total replicates	
			Flu A	Flu B
Nasal Spray 1 (Flonase)	15% v/v	Negative	0 / 3	0 / 3
		Influenza A (2X LoD)	3 / 3	0 / 3
		Influenza B (2X LoD)	0 / 3	3 / 3
Nasal Spray 2 (Similasan)	15% v/v	Negative	0 / 3	0 / 3
		Influenza A (2X LoD)	3 / 3	0 / 3
		Influenza B (2X LoD)	0 / 3	3 / 3
Nasal Spray 3 (CVS)	15% v/v	Negative	0 / 3	0 / 3
		Influenza A (2X LoD)	3 / 3	0 / 3
		Influenza B (2X LoD)	0 / 3	3 / 3
Nasal Spray 4 (Afrin)	15% v/v	Negative	0 / 3	0 / 3
		Influenza A (2X LoD)	3 / 3	0 / 3
		Influenza B (2X LoD)	0 / 3	3 / 3

Endogenous/Exogenous Substance Test concentration	Concentration Tested	Spiked Virus (Concentration)	No. of Positive Results / No. of Total replicates	
			Flu A	Flu B
Budesonide Nasal Spray	15% v/v	Negative	0 / 3	0 / 3
		Influenza A (2X LoD)	3 / 3	0 / 3
		Influenza B (2X LoD)	0 / 3	3 / 3
NASONEX 24 hr. Allergy	15% v/v	Negative	0 / 3	0 / 3
		Influenza A (2X LoD)	3 / 3	0 / 3
		Influenza B (2X LoD)	0 / 3	3 / 3
Nasacort Allergy 24 hr.	15% v/v	Negative	0 / 3	0 / 3
		Influenza A (2X LoD)	3 / 3	0 / 3
		Influenza B (2X LoD)	0 / 3	3 / 3
Sore Throat (Oral Pain Reliever spray)	15% v/v	Negative	0 / 3	0 / 3
		Influenza A (2X LoD)	3 / 3	0 / 3
		Influenza B (2X LoD)	0 / 3	3 / 3
ZICAM Oral mist	15% v/v	Negative	0 / 3	0 / 3
		Influenza A (2X LoD)	3 / 3	0 / 3
		Influenza B (2X LoD)	0 / 3	3 / 3
Sore Throat Lozenges (Cepacol)	15% w/v	Negative	0 / 3	0 / 3
		Influenza A (2X LoD)	3 / 3	0 / 3
		Influenza B (2X LoD)	0 / 3	3 / 3
Zinc Cold Therapy (Walgreens)	15% w/v	Negative	0 / 3	0 / 3
		Influenza A (2X LoD)	3 / 3	0 / 3
		Influenza B (2X LoD)	0 / 3	3 / 3
Homeopathic Allergy Nasal Spray (Alkalol)	15% v/v	Negative	0 / 3	0 / 3
		Influenza A (2X LoD)	3 / 3	0 / 3
		Influenza B (2X LoD)	0 / 3	3 / 3
NasoGEL (Gel Spray)	15% v/v	Negative	0 / 3	0 / 3
		Influenza A (2X LoD)	3 / 3	0 / 3
		Influenza B (2X LoD)	0 / 3	3 / 3
NasalCrom Nasal Allergy spray	15% v/v	Negative	0 / 3	0 / 3
		Influenza A (2X LoD)	3 / 3	0 / 3
		Influenza B (2X LoD)	0 / 3	3 / 3
Histaminum 30C	15% w/v	Negative	0 / 3	0 / 3
		Influenza A (2X LoD)	3 / 3	0 / 3
		Influenza B (2X LoD)	0 / 3	3 / 3
Skin relief hand cream (Aveeno)	1% w/v	Negative	0 / 3	0 / 3
		Influenza A (2X LoD)	3 / 3	0 / 3
		Influenza B (2X LoD)	0 / 3	3 / 3
Hand Soap Fresh Breeze Scent	1% w/v	Negative	0 / 3	0 / 3
		Influenza A (2X LoD)	3 / 3	0 / 3
		Influenza B (2X LoD)	0 / 3	3 / 3
Antibacterial liquid Hand Soap (Dial Complete)	1%, 5%, 10% and 15% w/v	Negative	0 / 3	0 / 3
		Influenza A (2X LoD)	3 / 3	0 / 3
		Influenza B (2X LoD)	0 / 3	3 / 3
Hand Sanitizer Gel	1%, 5%, 10% and 15% w/v	Negative	0 / 3	0 / 3
		Influenza A (2X LoD)	3 / 3	0 / 3
		Influenza B (2X LoD)	0 / 3	3 / 3

Endogenous/Exogenous Substance Test concentration	Concentration Tested	Spiked Virus (Concentration)	No. of Positive Results / No. of Total replicates	
			Flu A	Flu B
Hand Sanitizer Lotion	15% w/v	Negative	0 / 3	0 / 3
		Influenza A (2X LoD)	3 / 3	0 / 3
		Influenza B (2X LoD)	0 / 3	0 / 3
	10% w/v	Negative	0 / 3	0 / 3
		Influenza A (2X LoD)	3 / 3	0 / 3
		Influenza B (2X LoD)	0 / 3	3 / 3
Disinfectant Spray (Lysol)	1% v/v	Negative	0 / 3	0 / 3
		Influenza A (2X LoD)	3 / 3	0 / 3
		Influenza B (2X LoD)	0 / 3	3 / 3
Mucin from bovine submaxillary glands-Type I-S	5 mg/mL	Negative	0 / 3	0 / 3
		Influenza A (2X LoD)	3 / 3	0 / 3
		Influenza B (2X LoD)	0 / 3	3 / 3
Purified Human Neutrophils	5×10^{6} cells/mL	Negative	0 / 3	0 / 3
		Influenza A (2X LoD)	3 / 3	0 / 3
		Influenza B (2X LoD)	0 / 3	3 / 3
Whole Blood	2.5%	Negative	0 / 3	0 / 3
		Influenza A (2X LoD)	3 / 3	0 / 3
		Influenza B (2X LoD)	0 / 3	3 / 3
Acetylsalicylic acid	3.00×10^{1} µg/mL	Negative	0 / 3	0 / 3
		Influenza A (2X LoD)	3 / 3	0 / 3
		Influenza B (2X LoD)	0 / 3	3 / 3
Dexamethasone	1.20×10^{1} µg/mL	Negative	0 / 3	0 / 3
		Influenza A (2X LoD)	3 / 3	0 / 3
		Influenza B (2X LoD)	0 / 3	3 / 3
Mometasone furoate	4.50×10^{-4} µg/mL	Negative	0 / 3	0 / 3
		Influenza A (2X LoD)	3 / 3	0 / 3
		Influenza B (2X LoD)	0 / 3	3 / 3
Mupirocin	1.50×10^{0} µg/mL	Negative	0 / 3	0 / 3
		Influenza A (2X LoD)	3 / 3	0 / 3
		Influenza B (2X LoD)	0 / 3	3 / 3
Oseltamivir phosphate (Tamiflu)	3.99×10^{-1} µg/mL	Negative	0 / 3	0 / 3
		Influenza A (2X LoD)	3 / 3	0 / 3
		Influenza B (2X LoD)	0 / 3	3 / 3
Tobramycin	3.30×10^{1} µg/mL	Negative	0 / 3	0 / 3
		Influenza A (2X LoD)	3 / 3	0 / 3
		Influenza B (2X LoD)	0 / 3	3 / 3
Beclomethasone dipropionate	5.04 µg/mL	Negative	0 / 3	0 / 3
		Influenza A (2X LoD)	3 / 3	0 / 3
		Influenza B (2X LoD)	0 / 3	3 / 3
Flunisolide	870 µg/mL	Negative	0 / 3	0 / 3
		Influenza A (2X LoD)	3 / 3	0 / 3
		Influenza B (2X LoD)	0 / 3	3 / 3
Molnupiravir	3.29 mg/mL (10 mM)	Negative	0 / 3	0 / 3
		Influenza A (2X LoD)	3 / 3	0 / 3
		Influenza B (2X LoD)	0 / 3	3 / 3

Endogenous/Exogenous Substance Test concentration	Concentration Tested	Spiked Virus (Concentration)	No. of Positive Results / No. of Total replicates	
			Flu A	Flu B
Remdesivir	240 µg/mL	Negative	0 / 3	0 / 3
		Influenza A (2X LoD)	3 / 3	0 / 3
		Influenza B (2X LoD)	0 / 3	3 / 3
Zanamivir	30 mg/mL	Negative	0 / 3	0 / 3
		Influenza A (2X LoD)	3 / 3	0 / 3
		Influenza B (2X LoD)	0 / 3	3 / 3
Biotin	3500 ng/mL	Negative	0 / 3	0 / 3
		Influenza A (2X LoD)	3 / 3	0 / 3
		Influenza B (2X LoD)	0 / 3	3 / 3
FluMist	15% v/v*	Negative	3 / 3	0 / 3
		Influenza A (3X LoD)	3 / 3	0 / 3
		Influenza B (3X LoD)	0 / 3	3 / 3
	1.5% v/v	Negative	0 / 3	0 / 3
		Influenza A (3X LoD)	3 / 3	0 / 3
		Influenza B (3X LoD)	0 / 3	3 / 3

**False positive results were also observed at 3% and 6% v/v.

c. Biotin Interference:

The Nano-Check Influenza A+B Test does not utilize biotin-streptavidin complex.

d. Competitive Interference:

The competitive study interference was performed to assess the ability of the Nano-Check Influenza A+B Test to detect multiple analytes simultaneously without inhibiting each other's detection. Strains of influenza A (H1N1 and H3N2) and influenza B (Victoria and Yamagata lineage) were utilized. Each analyte was prepared at a high concentration (at least 10^5 $TCID_{50}$/mL or $CEID_{50}$/mL) and 3X LoD concentration as a low concentration. Table 6 below summarizes the results of the competitive interference study. For each condition tested, all replicates tested at the low target analyte condition tested positive in the presence of other target analytes at high concentrations. Thus, this indicates the capability of the Nano-Check Influenza A+B Test to detect low levels of influenza A in the presence of a high level of influenza B, as well as low levels of influenza B in the presence of a high level of influenza A.

Table 6: Competitive Interference Results

Influenza A (H1N1)		Influenza B (Victoria)	
Concentration Tested	% Agreement	Concentration Tested	% Agreement
High	100%	Low	100%
Low	100%	High	100%
Influenza A (H3N2)		**Influenza B (Victoria)**	
Concentration Tested	% Agreement	Concentration Tested	% Agreement
High	100%	Low	100%
Low	100%	High	100%
Influenza A (H1N1)		**Influenza B (Yamagata)**	

Concentration Tested	% Agreement	Concentration Tested	% Agreement
High	100%	Low	100%
Low	100%	High	100%
Influenza A (H3N2)		**Influenza B (Yamagata)**	
Concentration Tested	**% Agreement**	**Concentration Tested**	**% Agreement**
High	100%	Low	100%
Low	100%	High	100%

4. Assay Reportable Range:

Not applicable; the device is a binary qualitative assay that is visually read.

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

a. Internal Control
The Nano-Check Influenza A+B Test contains a built-in internal assay control. The appearance of the control line on the test ensures that sufficient flow of the sample occurred during the assay. Any result without the appearance of a control line is invalid.

b. External Quality Controls
The Nano-Check Influenza A+B Test contains one positive external control swab and one negative external control swab that allows for monitoring of the performance of the assay. The positive control swab contains recombinant influenza A nucleoprotein and recombinant influenza B nucleoprotein whereas the negative control swab does not contain recombinant antigen.

A precision study was conducted for multiple lots of the Nano-Check Influenza A+B Test's external control. The aim was to assess the precision and repeatability of the external control swab in a blinded manner. Ten (10) individual swabs from three (3) different lots of positive and negative external control swabs were randomized and distributed in a blinded fashion to operators within the laboratory, who tested the control swabs in accordance with the instructions for use of the test. The collected data were evaluated by calculating the percent agreement between test results and expected result.

As shown in Table 7 below, the external positive control produced positive results for both Flu A and Flu B analyte; while the external negative control produced negative results for both Flu A and B analyte for all replicates tested.

Table 7: Lot-to-lot Precision Study Results for External Controls

External Control	Lot No.	No. of Positive Results / No. of Total Replicates (%)	
		Flu A	Flu B
Positive External Control	1	10/10 (100%)	10/10 (100%)
	2	10/10 (100%)	10/10 (100%)
	3	10/10 (100%)	10/10 (100%)
	1	0/10	0/10

Negative External Control		(0%)	(0%)
	2	0/10 (0%)	0/10 (0%)
	3	0/10 (0%)	0/10 (0%)

c. Stability:

i) Specimen Stability:

Two test samples were prepared for the specimen stability study: a negative sample (consisting of pooled human nasal fluid with no analyte) and a low positive sample (containing a diluted Flu A, and Flu B sample at 2X LoD in negative pooled human nasal fluid). Swabs were spiked with 50 µL of each sample and subjected to four different temperature conditions: room temperature (23.5°C), high room temperature (30°C), 2°C to 8°C, and frozen (-20°C). The samples were stored under each condition for various time intervals including 0 hours (baseline), 1 hour, 2 hours, 4 hours, 8 hours, 24 hours, and 48 hours. Subsequently, the exposed sample swabs were tested using 5 replicates for each exposure time. The results showed that the nasal swab samples were stable for up to 48 hours under all temperature conditions, ranging from -20°C to 30°C. However, given the setting, the instructions for use will indicate that specimen swabs should be tested immediately after collection.

ii) Real Time Stability:

Three lots of Nano-Check Influenza A+B Test were stored at three different temperature conditions: 30°C, ambient room temperature (23.5°C), and 2-8°C. The study involved positive and negative external control swabs, as well as positive and negative contrived samples. Positive samples were prepared by diluting the influenza A (H1N1) and influenza B (Yamagata lineage) strains to a 3X LoD concentration into pooled human nasal fluid, while negative contrived swab samples were prepared using pooled human nasal fluid confirmed to be negative for influenza A, and influenza B by RT-PCR. Testing was performed at time 0 (baseline) and monthly thereafter up to 23 months. All study data are 100% concordant with expected results and support a shelf-life of up to 22 months when stored between 2-30°C.

iii) Transport Stability:

The transport simulation study was conducted to evaluate the robustness of the Nano-Check Influenza A+B Test kit under fluctuating transport and storage conditions. The thermal cycling protocol consisted of sequential temperature exposures: initial storage at 30°C for 1 day, followed by 23.5°C for 2 days, then 37°C for 1 day, 2-8°C for 3 days, -20°C for 2 days, 23.5°C for 1 day, 30°C for 2 days, 37°C for 1 day, and final storage at 23.5°C until testing was performed. Following the thermal stress protocol, the test kits were maintained at ambient room temperature (23.5°C) for 15 months to assess the long-term impact of the thermal fluctuations on the test kit's shelf-life and performance characteristics.

The study included positive and negative contrived swab samples, as well as positive and negative external control swabs. Positive contrived swab samples were prepared by diluting the influenza A (H1N1) and influenza B (Yamagata lineage) strains to a 3X LoD concentration into pooled human nasal fluid, while negative contrived swab samples were prepared using pooled human nasal fluid confirmed to be negative for influenza A and influenza B by RT-PCR. The study was scheduled over a 15-month period, with assessments performed on day 0 (as a reference before thermal fluctuation stress), on day 14

(after 13 days of thermal fluctuation), and every three months from month 3 to month 15. Results indicated that the Nano-Check Influenza A+B Test kit demonstrated stability and remained unaffected by fluctuating temperature exposures for up to 12 months.

iv) Open Kit Stability Study:

Open kit stability study was performed to assess the stability of the test devices after opening the sealed pouch using ten replicates of positive samples (2X LoD concentration of Influenza A and Influenza B viruses spiked individually) and 5 replicates of negative samples (pooled human fluid confirmed to be Influenza A and B negative by RT-PCR). The test devices were exposed to ambient conditions for various durations: 0 min, 30 min, 1 hr, 2 hrs, 3 hrs, and 4 hrs. The results showed that all positive samples had positive results for up to 4 hours and negative samples did not produce any false positive results meeting the acceptance criteria.

v) Short-term Stability:

The short-term reagent stability study for the Nano-Check Influenza A+B Test aimed to assess the stability of the Nano-Check Influenza A+B Test kit components when all kit components are stored at extremely low temperature (-20°C) and high temperature (45°C). The Nano-Check Influenza A+B Test kit was stable for 16 days when it was stored at low temperature (-20°C) and for 14 days at a high temperature (45°C). However, it is recommended that the test kit should be stored at 2°C - 30°C in the original sealed pouch.

6. Detection Limit:

a. Single-analyte LoD:

The limit of detection (LoD) was determined with two influenza A strains (influenza A H1N1: A/California/04 /2009, influenza A H3N2: A/Victoria/361/2011) and two influenza B strains (influenza B/Hong Kong/330/2001, influenza B/Phuket/3073/13). Contrived samples were prepared by spiking the strains into a pooled negative nasal fluid matrix. A preliminary LoD was determined by spiking 50 µL of serially diluted sample onto swab heads and tested using the Nano-Check Influenza A+B Test in replicates of 3 in two-fold serial dilutions. The preliminary LoD was confirmed by testing 20 replicates where at least 19/20 replicates were positive. The results from these studies are summarized below in Table 8.

Table 8: Confirmatory LoD Nano-Check Influenza A+B Test

Virus	Sub-type (Lineage)	Virus Strain	LoD
Influenza A	H1N1	A/California/04/2009	2.80×10^3 $TCID_{50}$/mL (1.4×10^2 $TCID_{50}$/swab)
	H3N2	A/Victoria/361/2011	1.40×10^5 $CEID_{50}$/mL (7.0×10^3 $CEID_{50}$/swab)
Influenza B	Victoria	B/Hong Kong/330/2001	2.25×10^5 $CEID_{50}$/mL (1.13×10^4 $CEID_{50}$/swab)
	Yamagata	B/Phuket/3073/13	1.04×10^2 $TCID_{50}$/mL (5.2×10^0 $TCID_{50}$/swab

7. High Dose Hook Effect Study:

A high-dose hook effect study was conducted to determine the concentration at which false negative results might occur when very high levels of the target antigen are present in a testing sample. In this study, 50µL of the highest concentration possible for live influenza A

and influenza B virus stocks were spiked onto sterile swabs and tested in triplicate, and swabs were tested on the device per IFU of the candidate device. No hook effect for Flu A and Flu B were observed up to the concentrations listed in Table 9 below.

Table 9: Summary of High Dose Hook Effect Study

Virus	Isolate/Lineage	Strain	Virus Concentration		# of Positive/# Total tested	
			$TCID_{50}$/mL or $CEID_{50}$/mL	$TCID_{50}$/swab or $CEID_{50}$/swab	Flu A	Flu B
Flu A	H1N1	A/California/04/2009	2.8×10^6	1.4×10^5	3/3	0/3
	H3N2	A/Victoria/361/2011	2.8×10^8	1.4×10^7	3/3	0/3
Flu B	Victoria	B/Hong Kong/330/2001	1.8×10^7	9×10^6	0/3	3/3
	Yamagata	B/Phuket/3073/13	4.17×10^5	2.08×10^4	0/3	3/3

8. Analytical Reactivity Study:

a. Inclusivity – Selected Strains

An inclusivity study was conducted involving three (3) operators encompassing various variants, lineages, and clades of influenza viruses. The study involved thirty (27) strains of influenza A and sixteen (15) strains of influenza B. The virus stocks were diluted at the predetermined concentration in the pooled negative nasal fluid matrix and 50 µL were pipetted onto the swabs. The swabs were tested in three (3) replicates in this study. The lowest concentration of each strain that resulted in 100% detection (3/3) is presented in Table 10 below.

Table 10: Summary of Inclusivity Results

Virus	Virus Strains	Concentration Tested	Units
Flu A H1N1	A/Puerto Rico/8/34	8.00×10^6	$CEID_{50}$/mL
	A/Brisbane/59/2007	4.45×10^6	$CEID_{50}$/mL
	A/Denver/1/57	4.00×10^5	$CEID_{50}$/mL
	A/San Diego/1/2009 pdm09	2.80×10^4	$TCID_{50}$/mL
	A/Tijuana/4/09	2.45×10^1	$TCID_{50}$/mL
	A/Solomon Islands/3/2006	4.45×10^5	$CEID_{50}$/mL
	A/NWS/33	1.23×10^5	$CEID_{50}$/mL
	A/FM/1/47	4.25×10^5	$CEID_{50}$/mL
	A/New Jersey/8/76	1.70×10^4	$CEID_{50}$/mL
	A/New Caledonia/20/1999	4.00×10^5	$CEID_{50}$/mL
	A/Victoria/4897/2022(pdm09)	1.58×10^7	EID_{50}/mL
	A/Victoria/2570/2019 (pdm09)	9.98×10^5	EID_{50}/mL
Flu A H1N2	A/Swine/Ohio/09SW1477/2009	2.30×10^4	$TCID_{50}$/mL
Flu A H3N2	A/Hong Kong/8/1968	1.40×10^5	$CEID_{50}$/mL
	A/Aichi/2/1968	4.00×10^5	$CEID_{50}$/mL
	A/Wisconsin/67/2005	7.00×10^5	$CEID_{50}$/mL
	A/Hong Kong/4801/2014	9.60×10^5	$CEID_{50}$/mL
	A/Netherlands/22/2003	8.00×10^2	$TCID_{50}$/mL

	A/Netherlands/823/1992	1.44 x 10^1	$TCID_{50}$/mL
	A/Brisbane/10/2007	1.38 x 10^5	$CEID_{50}$/mL
	A/Wisconsin/15/2009	5.00 x 10^3	$CEID_{50}$/mL
	A/Sydney/5/97	4.45 x 10^4	$CEID_{50}$/mL
	A/Port Chalmers/1/73	2.00 x 10^5	$CEID_{50}$/mL
	A/Victoria/3/75	4.00 x 10^5	$CEID_{50}$/mL
	A/Perth/16/2009 x A/Puerto Rico/8/19 34, NIB-64	2.80 x 10^6	$CEID_{50}$/mL
	A/Singapore/INFIMH-16-0019 /16	2.51 x 10^3	$TCID_{50}$/mL
Flu A H5N1	A/mallard/Wisconsin/2576/2009	5.25 x 10^5	GE/mL
Flu B (Victoria lineage)	B/Brisbane/60/2008	9.00 x 10^4	$CEID_{50}$/mL
	B/Malaysia/2506/2004	1.12 x 10^6	$CEID_{50}$/mL
	B/New York/1056/2003	3.20 x 10^3	$TCID_{50}$/mL
Flu B (Yamagata lineage)	B/Florida/78/2015	2.80 x 10^4	$TCID_{50}$/mL
	B/Texas/06/2011	4.45 x 10^8	$CEID_{50}$/mL
	B/New York/1061/2004	8.00 x 10^2	$TCID_{50}$/mL
	B/Christchurch/33/2004	8.00 x 10^2	$TCID_{50}$/mL
	B/Sydney/507/2006	1.60 x 10^5	$TCID_{50}$/mL
	B/Wisconsin/1/2010	1.80 x 10^6	$CEID_{50}$/mL
	B/Florida/4/2006	3.50 x 10^5	$CEID_{50}$/mL
Flu B (Non-Victoria/Yamagata)	B/Colorado/6/17	1.78 x 10^2	$TCID_{50}$/mL
	B/Taiwan/2/1962	4.45 x 10^3	$CEID_{50}$/mL
	B/Lee/1940	9.00 x 10^4	$CEID_{50}$/mL
	B/GL/1739/54	5.00 x 10^4	$CEID_{50}$/mL
	B/Great Lakes/1739/1954	3.20 x 10^4	$CEID_{50}$/mL

9. Assay Cut-Off:

   Not applicable as this is a qualitative visually read assay without numeric data.

B Comparison Studies:

1. Method Comparison with Predicate Device:

   Please refer to section VI.C (Clinical Studies) below for the clinical validation regarding the method comparison studies.

2. Matrix Comparison:

   The Nano-Check Influenza A+B Test is intended only for the qualitative detection of the nucleoprotein from Flu A and Flu B in direct anterior nasal swab specimens. As no other sample types are claimed herein, a matrix comparison study is not applicable.

C Clinical Studies:

The clinical performance of the Nano-Check Influenza A+B Test was evaluated in a multi-center, prospective clinical study in the U.S. between November 2022 and February 2025. The study only enrolled subjects who presented with symptoms of respiratory infection. A total of 2,223 subjects were initially enrolled however, 254 samples were excluded due not meeting inclusion criteria, invalid comparator results, or samples lost during shipment. The remaining

1,969 subjects were consecutively enrolled and tested by fourteen (14) operators who were representative of CLIA-waived users (i.e., not formally trained in a laboratory setting) across six (6) different clinical CLIA-waived sites. Two anterior nasal swabs (ANS) were collected from each study subject during the same visit. The first ANS specimen for the comparator method was collected by the operators from both sides of the nose. The comparator ANS specimens were stored in UVT media and packaged in dry ice for aero-transport, sent to a reference laboratory, and tested with an FDA cleared RT-PCR method as per the cleared instructions for use. The second ANS specimen was collected from both sides of the nose using the provided swab and was tested immediately using the Nano-Check Influenza A+B Test by each operator using the QRI only and with no training specifically with the candidate test.

The summary of demographics of the clinical subjects are shown in Table 11 below.

Table 11: Subject Demographics

Age Group	Female		Male		Total	
	No. of Sample	%	No. of Sample	%	No. of Sample	%
≤ 5 years	201	19.8	215	22.5	416	21.1
6 to 21 years	401	39.5	462	48.5	863	43.8
22 to 60 years	313	30.8	204	21.4	517	26.3
≥ 61 years	101	9.9	72	7.6	173	8.8
Total	1016	100	953	100	1969	100
	Female: 51.6% (1016/1969)		Male: 48.4% (953/1969)			

The clinical performance for the detection of influenza A and influenza B are shown in Table 12 and Table 13 respectively.

Table 12: Clinical Performance for Detection of Influenza A

Nano-Check Influenza A+B Test	RT-PCR Comparator		Total
	Positive	Negative	
Positive	417	6	423
Negative	63	1483	1546
Total	480	1489	1969
Positive Percent Agreement (PPA) = 86.9% (417/480, 95% CI: 83.6% - 89.6%)			
Negative Percent Agreement (NPA) = 99.6% (1483/1489, 95% CI: 99.1% - 99.8%)			

Table 13: Clinical Performance for Detection of Influenza B

Nano-Check Influenza A+B Test	RT-PCR Comparator		Total
	Positive	Negative	
Positive	99	5	104
Negative	15	1850	1865
Total	114	1855	1969
Positive Percent Agreement (PPA) = 86.8% (99/114, 95% CI: 79.4% - 91.9%)			

Nano-Check Influenza A+B Test	RT-PCR Comparator		Total
	Positive	Negative	
Negative Percent Agreement (NPA) = 99.7% (1850/1855, 95% CI: 99.4% - 99.9%)			

1. Clinical Sensitivity:

Please refer to Section VI.C (clinical Studies) above for the clinical validation. The PPA for the test for each analyte is as follows:

Flu A: 86.9% (417/480) – 95% CI: 83.6% - 89.6%
Flu B: 86.8% (99/114) – 95% CI: 79.4% - 91.9%

2. Clinical Specificity:

Please refer to Section VI.C (Clinical Studies) above for the clinical validation. The NPA for the test for each analyte is as follows:

Flu A: 99.6% (1483/1489) – 95% CI: 99.1% - 99.8%
Flu B: 99.7% (1850/1855) – 95% CI: 99.4% - 99.9%

D Clinical Cut-Off:

The test is a qualitative test with a binary positive/negative signal and there is no clinical cut-off for the test.

E Expected Values/Reference Range:

A patient sample is expected to be negative for influenza A and influenza B.

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.