



January 15, 2026

Nano-Ditech Corporation
James B Chang
President
259 Prospect Plains Rd., Bldg K
Cranbury, New Jersey 08512

Re: K252283
Trade/Device Name: Nano-Check Influenza A+B Test
Regulation Number: 21 CFR 866.3328
Regulation Name: Influenza Virus Antigen Detection Test System
Regulatory Class: Class II
Product Code: PSZ
Dated: July 21, 2025
Received: July 22, 2025

Dear James B Chang:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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

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

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

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

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

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

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

Sincerely,

JOSEPH BRIGGS -S

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

Enclosure

Indications for Use

510(k) Number (if known)

K252283

Device Name

Nano-Check Influenza A+B Test

Indications for Use (Describe)

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.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Nano-Check™ Influenza A+B Test

I. Submitter

Applicant: Nano-Ditech Corporation
259 Prospect Plains Rd., Bldg. K Cranbury, NJ 08512 USA
Phone: 1-609-409-3300
Contact Person: James B Chang (jchang@nanoditech.com)
Date Prepared: December 16, 2025

II. Device

- A. Trade, Proprietary, and Established Name:** Nano-Check™ Influenza A+B Test
- B. Product Code:** PSZ
- C. Classification:** Class II
- D. Regulation Number:** 21 CFR 866.3328
- E. Device Classification Name:** Devices Detecting Influenza A, B, And C Virus Antigens
- F. Panel:** MI-Microbiology (83)
- G. Submission Purpose:** New device 510(k) clearance for Nano-Check™ Influenza A+B Test
- H. Measurand:** Influenza A Nucleoprotein Antigen, Influenza B Nucleoprotein Antigen
- I. Type of Test:** Qualitative lateral flow immunoassay

III. Predicate Device

- A. Trade Name:** BD Veritor™ System for Rapid Detection of Flu A+B CLIA Waived Kit
- B. FDA 510k Number:** K232434 (Cleared December 05, 2023)
- C. Product Code:** PSZ

IV. 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

For *In Vitro* Diagnostic Use

D. Special Instrument Requirements:

N/A

V. Device/System Characteristics:**A. Device Description :**

The Nano-Check™ Influenza A+B Test is a lateral flow immunochromatographic assay intended for in vitro rapid, simultaneous qualitative detection and differentiation of influenza A, and influenza B nucleoprotein antigens directly from anterior nasal swab specimens.

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, one negative control swab, one Instructions for Use, and one Quick Reference Instruction. An external positive control swab contains noninfectious influenza A and influenza B antigens dried onto the swab and an external negative control swab contains noninfectious blank universal viral transport media dried on the swab. The kit should be stored at 2°C - 30°C.

B. Principles of Operations :

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

The test strip enclosed in a cassette housing is comprised of the following components: sample pad, reagent pad, biotin-free pad, reaction membrane, and absorbent pad. The reagent pad contains colloidal gold conjugated with monoclonal antibodies (mAb) specific to Flu A and Flu B target proteins. The reaction membrane contains the secondary antibodies for the proteins of Flu A and Flu B. The whole strip is fixed inside a plastic cassette.

When the specimens are extracted and added to the sample well of the test device, any Flu A and/or Flu B nucleoprotein antigens present in the specimen will form complexes with the anti-Flu A/Flu B conjugate which are then 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.

VI. Comparison of Technological Characteristics with the Predicate Device

The table below compares the Nano-Check™ Influenza A+B Test to the predicate devices of BD Veritor™ System for Rapid Detection of Flu A+B CLIA Waived Kit.

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

	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.	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)	Immunochromatographic	Same
Test Result	Qualitative	Same
Differences		
Reading Time	10-15 minutes	15 -20 minutes
Specimen Type	Nasal and nasopharyngeal swabs	Anterior nasal swab
Interpretation Result	An opto-electronic reader determines the line intensity	Visual determination

VII. Performance Data

A. Analytical Performance

1. Precision/Reproducibility:

a) Precision and Repeatability

a) Within Laboratory Precision

The precision study 1 was undertaken by two operators with each operator conducting 24 test runs over a 12-day period, resulting in a total of 96 replicates per level. The study employed blind sample panels comprising true negative (TN), low positive (LP, $1 \times \text{LoD}$), and moderate positive (MP, $3 \times \text{LoD}$) samples for each analyte (influenza A and influenza B). The precision testing was conducted according to the Package Insert and the qualitative results are summarized in Table 1 below.

Table 1. Precision Study 1 -Summary Result

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 LP (1X LoD)	Flu A	48/48 (100%)	48/48 (100%)	96/96 (100%)
	Flu B	0/48 (0%)	0/48 (0%)	0/96 (0%)
Flu A MP (3X LoD)	Flu A	48/48 (100%)	48/48 (100%)	96/96 (100%)
	Flu B	0/48 (0%)	0/48 (0%)	0/96 (0%)
Flu B LP (1X LoD)	Flu A	0/48 (0%)	0/48 (0%)	0/96 (0%)
	Flu B	48/48 (100%)	48/48 (100%)	96/96 (100%)
Flu B MP (3X LoD)	Flu A	0/48 (0%)	0/48 (0%)	0/96 (0%)
	Flu B	48/48 (100%)	48/48 (100%)	96/96 (100%)

The study results demonstrated 100% agreement for all samples. These findings satisfied the acceptance criteria of the precision study.

Study 2 was specifically conducted to assess between-lot variability. The study used negative samples (TN, without virus analytes), high negative samples (HN, 0.1× LoD), low positive samples at C90, and moderate positive (MP, 3× LoD) samples for each analyte (influenza A and influenza B). Samples were blinded and tested randomized. This supplemental precision testing was conducted by three operators, with each operator conducting 12 test runs per lot over 12 days with three lots, resulting in a total of 144 replicates per level. The lot and operator stratified results from this testing are included in Table 2 below.

Table 2. Precision Study 2 -Summary Result

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	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)	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%)

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)	Flu A	42/48 (87.5%)	41/48 (85.4%)	45/48 (93.8%)	128/144 (88.9%)
	Flu B	0/48 (0%)	0/48 (0%)	0/48 (0%)	0/144 (0%)
Flu A (3X LoD)	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)	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)	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%)

The study results demonstrated that the performance was consistent across all three lots tested.

Taken together, the results of both precision assessments demonstrate a test precision and a lot-to-lot precision that are consistent with the expectations for the analyte concentrations in the samples, the test's technology, and the test's LoD. The between-lot variability does not impact low-concentrated samples equal to or above 3 X LoD of the test.

b) Reproducibility

The reproducibility study was designed to evaluate site-to-site, operator-to-operator, and level-to-level variability and demonstrate that the Nano-Check™ Influenza A+B Test can be performed consistently and correctly. This study was conducted at 4 distinct sites, each with two (2) or three (3) different operators, testing three (3) reagent lots, using a coded panel of contrived samples consisting of a true negative (TN), a high negative sample (HN, 0.1x LoD), a low positive (LP, 1.0 x LoD) and a medium positive (MP, 5.0 x LoD) sample for each analyte (influenza A and influenza B). A total of 8 untrained operators at 3 CLIA waived sites and 3 operators in the internal site each tested using 105 coded samples (TN: 15, HN-Flu A: 15, HN-Flu B: 15, LP-Flu A: 15, LP-Flu B: 15, MP-Flu A: 15, MP-Flu B: 15, respectively) over five nonconsecutive days. The summary of results is presented in Table 3 below.

Table 3. Reproducibility Study- Summary Result

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 NCM	0/30 (0%)	0/45 (0%)	0/45 (0%)	0/45 (0%)	0/165 (0%)
0.1X LoD Flu A	0/30 (0%)	0/45 (0%)	0/45 (0%)	0/45 (0%)	0/165 (0%)
0.1X LoD Flu B	0/30 (0%)	0/45 (0%)	1/45 (2.2%)	0/45 (0%)	1/165 (0.6%)
1X LoD Flu A	30/30 (100%)	45/45 (100%)	44/45 (97.8%)	45/45 (100%)	164/165 (99.4%)
1X LoD Flu B	30/30 (100%)	45/45 (100%)	45/45 (100%)	45/45 (100%)	165/165 (100%)
5X LoD Flu A	30/30 (100%)	45/45 (100%)	45/45 (100%)	45/45 (100%)	165/165 (100%)
5X LoD Flu B	30/30 (100%)	45/45 (100%)	45/45 (100%)	45/45 (100%)	165/165 (100%)

All samples tested in the reproducibility study generated no significant difference between sites.

2. Linearity: This section is not applicable as this test device is a qualitative assay.
3. Cross-reactivity (Analytical Specificity):
 - a) Cross-reactivity and Microbial Interference Study

Cross-Reactivity and Interference study of the Nano-Check™ Influenza A+B Test was conducted with 53 potential cross-reactive or interfering pathogens of bacteria (19), fungi (2), and viruses (30), and negative matrix (2). Each microorganism was tested in three (3) replicates in the absence or presence of 2x LoD concentrations of influenza A and influenza B antigens. The concentrations of potentially interfering microorganisms tested and the results from the cross-reactivity study are presented in Table 4 below.

Table 4. Results of Cross-Reactivity/Microbial Interference

Microorganism (Strain)	Concentration Tested	Positive Sample (# Positive/ # Tested)*	Negative Sample (# Positive/ # Tested)*	Cross-Reactivity/ Microbial Interference
<i>Bordetella pertussis</i>	1.0×10 ⁶ cfu/mL	3/3	0/3	No
<i>Candida albicans</i>	1.0×10 ⁶ cfu/mL	3/3	0/3	No
<i>Chlamydomphila pneumoniae</i>	1.0×10 ⁶ IFU/mL	3/3	0/3	No
<i>Corynebacterium diphtheriae</i>	1.0×10 ⁶ cfu/mL	3/3	0/3	No
<i>Escherichia coli</i>	1.0×10 ⁶ IFU/mL	3/3	0/3	No
<i>Haemophilus influenzae, B</i>	1.0×10 ⁶ cfu/mL	3/3	0/3	No
<i>Lactobacillus acidophilus</i>	1.0×10 ⁶ cfu/mL	3/3	0/3	No

Microorganism (Strain)	Concentration Tested	Positive Sample (# Positive/ # Tested)*	Negative Sample (# Positive/ # Tested)*	Cross-Reactivity/ Microbial Interference
<i>Legionella Pneumophila</i> subsp. <i>Pneumophila</i>	1.0×10 ⁶ cfu/mL	3/3	0/3	No
<i>Moraxella catarrhalis</i>	1.0×10 ⁶ cfu/mL	3/3	0/3	No
<i>Mycobacterium tuberculosis</i>	1.0×10 ⁶ cfu/mL	3/3	0/3	No
<i>Mycoplasma pneumoniae</i>	1.0×10 ⁶ cfu/mL	3/3	0/3	No
<i>Neisseria meningitidis</i>	1.0×10 ⁶ cfu/mL	3/3	0/3	No
<i>Neisseria mucosa</i>	1.0×10 ⁶ cfu/mL	3/3	0/3	No
<i>Neisseria subflava</i>	1.0×10 ⁶ cfu/mL	3/3	0/3	No
<i>Pseudomonas aeruginosa</i>	1.0×10 ⁶ cfu/mL	3/3	0/3	No
<i>Pneumocystis jirovecii</i> - <i>S. cerevisiae</i>	1.0×10 ⁶ cfu/mL	3/3	0/3	No
<i>Staphylococcus aureus</i>	1.0×10 ⁶ cfu/mL	3/3	0/3	No
<i>Staphylococcus epidermidis</i>	1.0×10 ⁶ cfu/mL	3/3	0/3	No
<i>Streptococcus pneumoniae</i>	1.0×10 ⁶ cfu/mL	3/3	0/3	No
<i>Streptococcus pyogenes</i>	1.0×10 ⁶ cfu/mL	3/3	0/3	No
<i>Streptococcus salivarius salivarius</i>	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	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	1.95×10^4 TCID ₅₀ /mL	3/3	0/3	No
SARS-CoV-2, USA/COR-22-063113/2022	1.0×10^5 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 a 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 results for both influenza A and B (i.e., 3 replicates for each).

The study results showed that none of the evaluated microorganisms demonstrated cross-reactivity or interference with the Nano-Check™ Influenza A+B Test at the tested concentrations.

b) Endogenous/Exogenous Interference

The Endogenous/Exogenous interference study of the Nano-Check™ Influenza A+B Test was conducted using medically relevant endogenous and exogenous interferents. The influenza A or influenza B were diluted in negative clinical matrix to 2x LoD separately and the potentially interfering substance was spiked to the concentration presented in Table 5 below. Three (3) replicates were tested for each sample prepared.

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 of the 3 x LoD co-spiked samples, the vaccine also resulted in false positive results for Flu A (as expected based on the composition of the vaccine) at 15% v/v. When diluted down to 1.5% v/v, the results of the unspiked samples were negative for Flu A. Hand sanitizer lotion at 15% v/v showed false negative results for Flu B, but detected all analytes at 10% v/v.

Table 5. Results of Endogenous/Exogenous Interference Study

Substances	Interferent Conc.	Interference
Nasal Spray 1	15% v/v	No
Nasal Spray 2	15% v/v	No
Nasal Spray 3	15% v/v	No
Nasal Spray 4	15% v/v	No
Budesonide Nasal Spray	15% v/v	No
Nasonex 24 hr Allergy	15% v/v	No
Nasacort Allergy 24HR	15% v/v	No

Substances	Interferent Conc.	Interference
Sore Throat (Oral Pain Reliever spray)	15% v/v	No
ZICAM® Oral mist	15% v/v	No
Sore Throat Lozenges	15% w/v	No
Zinc Cold Therapy	15% w/v	No
Homeopathic Allergy Nasal Spray	15% v/v	No
NasoGEL (Gel Spray)	15% v/v	No
NasalCrom Nasal Allergy spray	15% v/v	No
Histaminum 30C	15% w/v	No
Skin relief hand cream	1% w/v	No
Hand Soap Fresh Breeze Scent	1% w/v	No
Antibacterial liquid Hand Soap	15% w/v	No
Hand Sanitizer Gel	15% w/v	No
Hand sanitizer lotion	15% w/v	Yes
	10% w/v	No
Disinfectant Spray	1% v/v	No
Acetylsalicylic acid	$3.00 \times 10^1 \mu\text{g/mL}$	No
Dexamethasone	$1.20 \times 10^1 \mu\text{g/mL}$	No
Mometasone furoate	$4.50 \times 10^{-4} \mu\text{g/mL}$	No
Mupirocin	$1.50 \times 10^0 \mu\text{g/mL}$	No
Oseltamivir phosphate	$3.99 \times 10^{-1} \mu\text{g/mL}$	No
Tobramycin	$3.30 \times 10^1 \mu\text{g/mL}$	No
Beclomethasone dipropionate	$5.04 \mu\text{g/mL}$	No
Flunisolide	$870 \mu\text{g/mL}$	No
Molnupiravir	3.29 mg/mL	No
Remdesivir	$240 \mu\text{g/mL}$	No
Zanamivir	30 mg/mL	No
Human Neutrophils	$5 \times 10^6 \text{ cells/mL}$	No
Mucin (Bovine submaxillary Glands, Type I-S)	5 mg/mL	No
Whole Blood	2.5%	No
FluMist® (Trivalent/Live)	15% v/v*	Yes
	1.5% v/v	No
Biotin	3500 ng/mL	No

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

4. Assay Reportable Range: This section is not applicable as this test device is a qualitative assay.
5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):
 - a) Internal Quality Control

The Nano-Check™ Influenza A+B Test contains 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.

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, and the negative control swab contains blank Universal Viral Transport media.

c) External Controls Lot-to-Lot Precision

The lot-to-lot precision for the external positive and negative control swabs was evaluated using three lots of external controls. The results from the study are summarized in Table 6 below.

Table 6. External Controls Lot-to-Lot Precision Study Results

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%)
Negative External Control	1	0/10 (0%)	0/10 (0%)
	2	0/10 (0%)	0/10 (0%)
	3	0/10 (0%)	0/10 (0%)

All lots of external controls generated 100% agreement with the expected results.

d) 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 influenza A and influenza B sample at 2 x LoD in the 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, 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, as shown in Table 7 below.

Table 7. Specimen Stability Results

Specimen Storage Temperature	Tested Sample	Specimen Storage Time (No. of Positive/No. of Total Test)						
		0 hour	1 hour	2 hours	4 hours	8 hours	24 hours	48 hours
23.5°C	Influenza A	5/5	5/5	5/5	5/5	5/5	5/5	5/5
	Influenza B	5/5	5/5	5/5	5/5	5/5	5/5	5/5
	Negative	0/5	0/5	0/5	0/5	0/5	0/5	0/5
30°C	Influenza A	5/5	5/5	5/5	5/5	5/5	5/5	5/5
	Influenza B	5/5	5/5	5/5	5/5	5/5	5/5	5/5
	Negative	0/5	0/5	0/5	0/5	0/5	0/5	0/5

Specimen Storage Temperature	Tested Sample	Specimen Storage Time (No. of Positive/No. of Total Test)						
		0 hour	1 hour	2 hours	4 hours	8 hours	24 hours	48 hours
2°C to 8°C	Influenza A	5/5	5/5	5/5	5/5	5/5	5/5	5/5
	Influenza B	5/5	5/5	5/5	5/5	5/5	5/5	5/5
	Negative	0/5	0/5	0/5	0/5	0/5	0/5	0/5
-20°C	Influenza A	5/5	5/5	5/5	5/5	5/5	5/5	5/5
	Influenza B	5/5	5/5	5/5	5/5	5/5	5/5	5/5
	Negative	0/5	0/5	0/5	0/5	0/5	0/5	0/5

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. The freshly collected specimens should be processed immediately after collection.

6. Detection Limit:

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. The preliminary LoD initially determined by testing a two-fold serial dilution series of 3 replicates was confirmed by testing in 20 replicates. The results from these studies are summarized below in Table 8.

Table 8. Limit of Detection (LoD)

Virus	Strain	LoD	Positive Rate (%) (# Positive/# Tested)
Influenza A	H1N1: A/California/04/2009	2.8×10^3 TCID ₅₀ /mL (1.4×10^2 TCID ₅₀ /swab)	100%
	H3N2: A/Victoria/361/2011	1.4×10^5 CEID ₅₀ /mL (7.0×10^3 CEID ₅₀ /swab)	95%
Influenza B	Victoria: B/Hong Kong/330/2001	2.25×10^5 CEID ₅₀ /mL (1.13×10^4 CEID ₅₀ /swab)	95%
	Yamagata: B/Phuket/3073/13	1.04×10^2 TCID ₅₀ /mL (5.2×10^0 TCID ₅₀ /swab)	100%

7. Analytical Reactivity (Inclusivity):

A total of 27 strains of influenza A and 15 strains of influenza B were tested in the inclusivity study. 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 3 replicates in this study. The lowest concentration of each strain that resulted in 100% detection (3/3) is presented in Table 9 below.

Table 9. Inclusivity

Virus	Virus Strains	Concentration Tested	Units
Flu A H1N1	A/Puerto Rico/8/34	8.00E+06	CEID ₅₀ /mL
	A/Brisbane/59/2007	4.45E+06	CEID ₅₀ /mL
	A/Denver/1/57	4.00E+05	CEID ₅₀ /mL
	A/San Diego/1/2009 pdm09	2.80E+04	TCID ₅₀ /mL
	A/Tijuana/4/09	2.45E+01	TCID ₅₀ /mL
	A/Solomon Islands/3/2006	4.45E+05	CEID ₅₀ /mL
	A/NWS/33	1.23E+05	CEID ₅₀ /mL
	A/FM/1/47	4.25E+05	CEID ₅₀ /mL
	A/New Jersey/8/76	1.70E+04	CEID ₅₀ /mL
	A/New Caledonia/20/1999	4.00E+05	CEID ₅₀ /mL
	A/Victoria/4897/2022(pdm09)	1.58E+07	EID ₅₀ /mL
	A/Victoria/2570/2019 (pdm09)	9.98E+05	EID ₅₀ /mL
Flu A H1N2	A/Swine/Ohio/09SW1477/2009	2.30E+04	TCID ₅₀ /mL
Flu A H3N2	A/Hong Kong/8/1968	1.40E+05	CEID ₅₀ /mL
	A/Aichi/2/1968	4.00E+05	CEID ₅₀ /mL
	A/Wisconsin/67/2005	7.00E+05	CEID ₅₀ /mL
	A/Hong Kong/4801/2014	9.60E+05	CEID ₅₀ /mL
	A/Netherlands/22/2003	8.00E+02	TCID ₅₀ /mL
	A/Netherlands/823/1992	1.44E+01	TCID ₅₀ /mL
	A/Brisbane/10/2007	1.38E+05	CEID ₅₀ /mL
	A/Wisconsin/15/2009	5.00E+03	CEID ₅₀ /mL
	A/Sydney/5/97	4.45E+04	CEID ₅₀ /mL
	A/Port Chalmers/1/73	2.00E+05	CEID ₅₀ /mL
	A/Victoria/3/75	4.00E+05	CEID ₅₀ /mL
	A/Perth/16/2009 x A/Puerto Rico/8/19 34, NIB-64	2.80E+06	CEID ₅₀ /mL
	A/Singapore/INFIMH-16-0019 /16	2.51E+03	TCID ₅₀ /mL
Flu A H5N1	A/mallard/Wisconsin/2576/2009	5.25E+05	GE/mL
Flu B (Victoria Lineage)	B/Brisbane/60/2008	9.00E+04	CEID ₅₀ /mL
	B/Malaysia/2506/2004	1.12E+06	CEID ₅₀ /mL
	B/New York/1056/2003	3.20E+03	TCID ₅₀ /mL
Flu B (Yamagata Lineage)	B/Florida/78/2015	2.80E+04	TCID ₅₀ /mL
	B/Texas/06/2011	4.45E+08	CEID ₅₀ /mL
	B/New York/1061/2004	8.00E+02	TCID ₅₀ /mL
	B/Christchurch/33/2004	8.00E+02	TCID ₅₀ /mL
	B/Sydney/507/2006	1.60E+05	TCID ₅₀ /mL
	B/Wisconsin/1/2010	1.80E+06	CEID ₅₀ /mL
	B/Florida/4/2006	3.50E+05	CEID ₅₀ /mL
Flu B (Non-Victoria/ Yamagata)	B/Colorado/6/17	1.78E+02	TCID ₅₀ /mL
	B/Taiwan/2/1962	4.45E+03	CEID ₅₀ /mL
	B/Lee/1940	9.00E+04	CEID ₅₀ /mL

Virus	Virus Strains	Concentration Tested	Units
	B/GL/1739/54	5.00E+04	CEID ₅₀ /mL
	B/Great Lakes/1739/1954	3.20E+04	CEID ₅₀ /mL

8. High Dose Hook Effect:

High-dose hook effect study was conducted to determine if a hook effect would be observed at high concentrations of the analyte (i.e., a false negative at high concentrations of influenza A and influenza B) in a testing sample. The series of three or five concentrations with each two (2) strains of influenza A and influenza B were prepared in pooled negative nasal fluid matrix and tested in three replicates on Influenza A+B Test. The concentration of each virus in the prepared samples ranged from the maximum virus concentration possible (undiluted virus stock) to 2x LoD. All spiked samples were 100% positive, as expected, at all tested concentrations. The Nano-Check™ Influenza A+B Test showed no high-dose hook effect when subjected to 2.8×10^6 TCID₅₀/mL for influenza A (A/California/04/2009, H1N1), 2.8×10^8 CEID₅₀/mL for influenza A (A/Victoria/361/2011, H3N2), 1.8×10^7 TCID₅₀/mL for influenza B (B/Hong Kong/330/2001, Victoria) and 4.17×10^5 TCID₅₀/mL for influenza B (B/Phuket/3073/13, Yamagata).

9. Competitive Interference Study

For co-infection, influenza A at levels near LoD was tested in the presence of high levels of influenza B, and influenza B at levels near LoD was tested in the presence of high levels of influenza A. Contrived samples with both high and low titers of influenza A (H1N1 and H3N2) and influenza B were evaluated. No competitive interference was observed between influenza A and B as listed in Table 10 below.

Table 10. Competitive Inhibition

High Titer Target		Low Titer Target		Low Titer Target Percent Positivity
Virus Name	Concentration Tested	Virus Name	Concentration Tested	
Flu A (H1N1)	2.8×10^5	Flu B (Victoria)	6.75×10^5	100%
Flu A (H1N1)	2.8×10^5	Flu B (Yamagata)	3.12×10^2	100%
Flu A (H3N2)	2.8×10^6	Flu B (Victoria)	6.75×10^5	100%
Flu A (H3N2)	2.8×10^6	Flu B (Yamagata)	3.12×10^2	100%
Flu B (Victoria)	1.8×10^6	Flu A (H1N1)	8.4×10^3	100%
Flu B (Victoria)	1.8×10^6	Flu A (H3N2)	4.2×10^5	100%
Flu B (Yamagata)	4.17×10^5	Flu A (H1N1)	8.4×10^3	100%
Flu B (Yamagata)	4.17×10^5	Flu A (H3N2)	4.2×10^5	100%

9. Assay Cut-off:

Not Applicable

10. Carry-Over:

Carry-over contamination is not applicable to this test device as each sample uses an independent, new, single-use test cassette that is discarded after each run.

B. Comparison Studies:

1. Method Comparison with Predicate Device:

Not applicable. The performance of the Nano-Check™ Influenza A+B Test was evaluated in a clinical study against an FDA-cleared molecular assay.

2. Matrix Comparison:

The Nano-Check™ Influenza A+B Test is only intended for the qualitative detection of influenza A and influenza B nucleoprotein antigens in direct anterior nasal swab specimens. As no other specimen or sample type is claimed herein.

C. Clinical Study:

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 one thousand nine hundred sixty-nine (1,969) subjects were consecutively enrolled and tested by fourteen (14) operators across six (6) different clinical CLIA-waived sites. Two anterior nasal swabs were collected from each study subject during the same visit. The first AN swab specimen for the comparator method was collected by the operators from both sides of the nose. The collected AN swab specimen was stored/transported and tested at a reference laboratory with an FDA cleared RT-PCR method as per the cleared instruction for use. The second AN swab 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 an operator at the site.

There were 1,969 subjects evaluated, 21.1% were collected from patients who are 5 years or younger, 43.8% from patients aged 6-21 years, 26.3 % from patients aged 22 to 60 years, and 8.8% from patients aged 61 years or older. Among the subjects, 51.6% were from female patients, while 48.4% were from male patients. Results obtained with the Nano-Check™ Influenza A+B Test were compared to the results obtained with the RT-PCR comparator test to determine clinical sensitivity and specificity.

For influenza A detection, 480 of these specimens tested positive, and 1,489 tested negative by the FDA-cleared RT-PCR method. The comparison of Nano-Check™ Influenza A+B Test results with the comparator method results showed a PPA of 86.9% (417/480) with a 95% CI of 83.6% - 89.6%, NPA of 99.6% (1,483/1,489) with a 95% CI of 99.1% - 99.8%.

For influenza B detection, 114 of these specimens tested positive, and 1,855 tested negative by the FDA-cleared RT-PCR method. The comparison of Nano-Check™ Influenza A+B Test results with the comparator method results showed a PPA of 86.8% (99/114) with a 95% CI of 79.4% - 91.9%, NPA of 99.7% (1,850/1,855) with a 95% CI of 99.4% - 99.9%.

Table 11. Clinical Performance of Nano-Check™ Influenza A+B Test Compared to an RT-PCR Comparator

Influenza A Detection			
Nano-Check™ Influenza A+B Test	RT-PCR Comparator		Total
	Positive	Negative	
Positive	417	6	423
Negative	63	1,483	1,546
Total	480	1,489	1,969
Positive Percent Agreement (PPA) = (417/480) x 100% = 86.9% (95% CI: 83.6% - 89.6%)			
Negative Percent Agreement (NPA) = (1,483/1,489) x 100% = 99.6% (95% CI: 99.1% - 99.8%)			
Influenza B Detection			
Nano-Check™ Influenza A+B Test	RT-PCR Comparator		Total
	Positive	Negative	
Positive	99	5	104
Negative	15	1,850	1,865
Total	114	1,855	1,969
Positive Percent Agreement (PPA) = (99/114) x 100% = 86.8% (95% CI: 79.4% - 91.9%)			
Negative Percent Agreement (NPA) = (1,850/1,855) x 100% = 99.7% (95% CI: 99.4% - 99.9%)			

1. Clinical Sensitivity:

Please refer to Section VI.C (Clinical Studies) above for the clinical validation. The PPAs for each analyte in the Nano-Check™ Influenza A+B Test are presented below.

- a) Influenza A: 86.9% (417/480, 95% CI: 83.6% - 89.6%)
- b) Influenza 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 NPAs for each analyte in the Nano-Check™ Influenza A+B Test are presented below.

- a) Influenza A: 99.6% (1,483/1,489, 95% CI: 99.1% - 99.8%)
- b) Influenza B: 99.7% (1,850/1,855, 95% CI: 99.4% - 99.9%)

D. Clinical Cut-Off:

Not Applicable since there is no clinical cutoff related to the presence of influenza A and influenza B in patient samples.

E. Expected Value/Reference Range:

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

F. Other Supportive Information:

1. Flex Studies

To assess the robustness and risk for false results of the test when deviating from the IFU/QRI test steps, flex studies were conducted that assessed all major aspects of the test procedure (sample volume, reading time, other deviations from the procedure [delay in mixing, delay in addition of sample to the well, incubation time] and variability of environmental test conditions that the test may be subjected to when in use (lighting, disturbance during use, temperature and humidity stress conditions). The test was performed with contrived positive nasal swabs generated by diluting influenza A and influenza B into a negative nasal fluid matrix at 2xLoD. The results demonstrated that the test system is robust and that false results can be expected to be reasonably mitigated through labeling.

G. Conclusion

The information presented in this Premarket Notification is complete and supports a substantial equivalence decision. Based on the comparison of technological characteristics and intended use, and as a result of the non-clinical and clinical performance testing completed on Nano-Check™ Influenza A+B Test, the proposed device does not raise new questions of safety and effectiveness and supports the conclusion that the proposed device is substantially equivalent to the predicate device. The results of non-clinical and clinical testing demonstrate that the device is as safe, as effective, and performs as well as the predicate device. Therefore, the Nano-Check™ Influenza A+B Test is substantially equivalent to the predicate device.