June 17, 2025

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

Re: K243561
Trade/Device Name: Nano-Check Influenza+COVID-19 Dual Test
Regulation Number: 21 CFR 866.3987
Regulation Name: Multi-Analyte Respiratory Virus Antigen Detection Test
Regulatory Class: Class II
Product Code: SCA
Dated: November 15, 2024
Received: November 18, 2024

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K243561

Device Name
Nano-Check Influenza+COVID-19 Dual Test

Indications for Use *(Describe)*

The Nano-Check Influenza+COVID-19 Dual Test is a lateral flow immunochromatographic assay intended for the qualitative detection and differentiation of influenza A, and influenza B nucleoprotein antigens and SARS-CoV-2 nucleocapsid antigen directly in anterior nasal swab (ANS) samples from individuals with signs and symptoms of respiratory tract infection. Clinical signs and symptoms of respiratory viral infection due to SARS-CoV-2 and influenza can be similar.

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

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

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+COVID-19 Dual Test

I. Submitter

Nano-Ditech Corporation
259 Prospect Plains Rd., Bldg. K Cranbury,
NJ 08512 USA

Contact Person: James Chang (jchang@nanoditech.com)
Phone:1-609-409-3300
Date Prepared: March 19, 2025

II. Device

A. **Trade, Proprietary, and Established Name**: Nano-Check™ Influenza+COVID-19 Dual Test

B. **Product Code:** SCA - Multi-analyte respiratory virus antigen detection test

C. **Classification:** Class II

D. **Regulation Number:** 21 CFR 866.3987

E. **Classification Name:** Multi-analyte respiratory virus antigen detection test

F. **Panel:** MI-Microbiology

G. **Purpose for Submission:** New device 510(k) clearance for the Nano-Check™ Influenza+COVID-19 Dual Test

H. **Measurand:** Nucleoprotein of influenza A and influenza B, nucleocapsid of SARS-CoV-2

I. **Type of Test:** Qualitative lateral flow immunoassay

III. Predicate Device

A. **Trade Name**: Healgen Rapid Check® COVID-19/Flu A&B Antigen Test

B. **FDA 510k Number:** DEN240029 (Cleared October 07, 2024)

C. **Product Code:** SCA

IV. Indications for Use

A. **Intended Use(s)**:
See Indications for Use below

B. Indication(s) for Use:

The Nano-Check™ Influenza+COVID-19 Dual Test is a lateral flow immunochromatographic assay intended for the qualitative detection and differentiation of influenza A, and influenza B nucleoprotein antigens and SARS-CoV-2 nucleocapsid antigen directly in anterior nasal swab (ANS) samples from individuals with signs and symptoms of respiratory tract infection. Clinical signs and symptoms of respiratory viral infection due to SARS-CoV-2 and influenza can be similar.

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

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

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+COVID-19 Dual 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 and SARS-CoV-2 nucleocapsid antigen 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, influenza B, and SARS-CoV-2 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+COVID-19 Dual Test is designed to detect the extracted nucleoprotein antigen specific to influenza A, and influenza B and the extracted nucleocapsid antigen specific to SARS-CoV-2 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 pad, reaction membrane, and absorbent pad. The reagent pad contains colloidal gold conjugated with monoclonal antibodies (mAb) specific for SARS-CoV-2, influenza A, and influenza B target proteins. The biotin pad contains biotin conjugated with mAb specific for SARS-CoV-2. The reaction membrane contains the secondary antibodies for the proteins of Flu A and Flu B, and streptavidin for the biotinylated SARS-CoV-2 antibody. The whole strip is fixed inside a plastic cassette.

When the specimens are extracted and added to the sample well of the test device, Flu A, Flu B nucleoproteins and/or SARS-CoV-2 nucleocapsid antigen is present in the specimen, a complex form between the anti-Flu A/Flu B/ SARS-CoV-2 conjugate and the viral antigen will be captured by the streptavidin or specific anti-Flu A/Flu B mAb coated on the test line region (C/A/B line). The absence of the test line (C/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+COVID-19 Dual Test to the predicate devices of Healgen Rapid Check® COVID-19/Flu A&B Antigen Test.

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

	determined to be appropriate by a healthcare provider. Negative results do not rule out infection with influenza, SARS-CoV-2 or other pathogens. Individuals who test negative and experience continued or worsening respiratory symptoms, such as fever, cough and/or shortness of breath, should seek follow-up care from their healthcare provider. Positive results do not rule out co-infection with other respiratory pathogens, and therefore do not substitute for a visit to a healthcare provider or appropriate follow-up.	Positive results do not rule out bacterial infection or co-infection with other viruses.
Regulation number	21 CFR 866.3987	Same
Disease	Multi-respiratory infections such as influenza and SARS-CoV-2	Same
Intended Use Population	Individuals with symptoms of multi-respiratory tract infections such as influenza and SARS-CoV-2	Same
Usage	Single use test	Same
Assay Principle (Technology)	Immunochromatographic	Same
Analyte	Influenza A, and influenza B nucleoprotein antigens and SARS-CoV-2 nucleocapsid antigen	Same
Test Result	Qualitative	Same
Reading Time	15 minutes	Same
Result Interpretation	Visually read	Same
Specimen Type	Anterior nasal swab specimens	Same
Differences		
Patient Use	Over the counter use/self-testing	For prescription use only and can be used in CLIA-waived settings

VII. Performance Data

A. Analytical Performance

1. Precision/Reproducibility:

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), high negative (HN, 0.1× LoD), low positive (LP, 1× LoD), and moderate positive (MP, 3× LoD) samples for each analyte (SARS-CoV-2, 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

SARS-CoV-2								
Run	True Negative		High Negative		Low Positive		Moderate Positive	
	1	2	1	2	1	2	1	2
Run 1	24 / 24	24 / 24	24 / 24	24 / 24	24 / 24	24 / 24	24 / 24	24 / 24
Run 2	24 / 24	24 / 24	24 / 24	24 / 24	24 / 24	24 / 24	24 / 24	24 / 24
Total	48 / 48	48 / 48	48 / 48	48 / 48	48 / 48	48 / 48	48 / 48	48 / 48
% Agreement	100%	100%	100%	100%	100%	100%	100%	100%
95% CI	92.6 - 100%	92.6 - 100%	92.6 - 100%	92.6 - 100%	92.6 - 100%	92.6 - 100%	92.6 - 100%	92.6 - 100%
Influenza A								
Run	True Negative		High Negative		Low Positive		Moderate Positive	
	1	2	1	2	1	2	1	2
Run 1	24 / 24	24 / 24	24 / 24	24 / 24	24 / 24	24 / 24	24 / 24	24 / 24
Run 2	24 / 24	24 / 24	24 / 24	24 / 24	24 / 24	24 / 24	24 / 24	24 / 24
Total	48 / 48	48 / 48	48 / 48	48 / 48	48 / 48	48 / 48	48 / 48	48 / 48
% Agreement	100%	100%	100%	100%	100%	100%	100%	100%
95% CI	92.6 - 100%	92.6 - 100%	92.6 - 100%	92.6 - 100%	92.6 - 100%	92.6 - 100%	92.6 - 100%	92.6 - 100%
Influenza B								
Run	True Negative		High Negative		Low Positive		Moderate Positive	
	1	2	1	2	1	2	1	2
Run 1	24 / 24	24 / 24	24 / 24	24 / 24	24 / 24	24 / 24	24 / 24	24 / 24
Run 2	24 / 24	24 / 24	24 / 24	24 / 24	24 / 24	24 / 24	24 / 24	24 / 24
Total	48 / 48	48 / 48	48 / 48	48 / 48	48 / 48	48 / 48	48 / 48	48 / 48
% Agreement	100%	100%	100%	100%	100%	100%	100%	100%
95% CI	92.6 - 100%	92.6 - 100%	92.6 - 100%	92.6 - 100%	92.6 - 100%	92.6 - 100%	92.6 - 100%	92.6 - 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 (without virus analytes), low positive samples at C90, and moderate positive (3× LoD) samples for each analyte (SARS-CoV-2, influenza A, and influenza B). Samples were blinded and tested randomized. This supplemental precision testing was conducted by two operators, with each operator conducting 12 test runs per lot over 12 days with three lots, resulting in a total of 72 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

Between lot							
Analyte	Test line	Lot 1		Lot 2		Lot 3	
		Positive	Agree	Positive	Agree	Positive	Agree
Negative	COVID-19	0/24	100%	0/24	100%	0/24	100%
	Flu A	0/24	100%	0/24	100%	0/24	100%
	Flu B	0/24	100%	0/24	100%	0/24	100%
C90 COVID-19	COVID-19	20/24	83.3%	23/24	95.8%	21/24	87.5%
	Flu A	0/24	100%	0/24	100%	0/24	100%
	Flu B	0/24	100%	0/24	100%	0/24	100%
C90, Flu A	COVID-19	0/24	100%	0/24	100%	0/24	100%
	Flu A	20/24	83.3%	21/24	87.5%	23/24	95.8%
	Flu B	0/24	100%	0/24	100%	0/24	100%
C90, Flu B	COVID-19	0/24	100%	0/24	100%	0/24	100%
	Flu A	0/24	100%	0/24	100%	0/24	100%
	Flu B	22/24	91.7%	21/24	87.5%	24/24	100%
3X LOD COVID-19	COVID-19	24/24	100%	24/24	100%	24/24	100%
	Flu A	0/24	100%	0/24	100%	0/24	100%
	Flu B	0/24	100%	0/24	100%	0/24	100%
3X LOD Flu A	COVID-19	0/24	100%	0/24	100%	0/24	100%
	Flu A	24/24	100%	24/24	100%	24/24	100%
	Flu B	0/24	100%	0/24	100%	0/24	100%
3X LOD Flu B	COVID-19	0/24	100%	0/24	100%	0/24	100%
	Flu A	0/24	100%	0/24	100%	0/24	100%
	Flu B	24/24	100%	24/24	100%	24/24	100%

Between operator					
Analyte	Test line	Operator 1		Operator 2	
		Positive	Agree	Positive	Agree
Negative	COVID-19	0/36	100%	0/36	100%
	Flu A	0/36	100%	0/36	100%
	Flu B	0/36	100%	0/36	100%
C90 COVID-19	COVID-19	31/36	86.1%	33/36	91.7%
	Flu A	0/36	100%	0/36	100%
	Flu B	0/36	100%	0/36	100%
C90, Flu A	COVID-19	0/36	100%	0/36	100%
	Flu A	32/36	88.9%	32/36	88.9%
	Flu B	0/36	100%	0/36	100%
C90, Flu B	COVID-19	0/36	100%	0/36	100%
	Flu A	0/36	100%	0/36	100%
	Flu B	33/36	88.9%	34/36	94.4%
3X LOD COVID-19	COVID-19	36/36	100%	36/36	100%
	Flu A	0/36	100%	0/36	100%
	Flu B	0/36	100%	0/36	100%

3X LOD Flu A	COVID-19	0/36	100%	0/36	100%
	Flu A	36/36	100%	36/36	100%
	Flu B	0/36	100%	0/36	100%
3X LOD Flu B	COVID-19	0/36	100%	0/36	100%
	Flu A	0/36	100%	0/36	100%
	Flu B	36/36	100%	36/36	100%

Precision estimates for samples negative samples, low positive samples (C90), and moderate positive (3× LoD), are expected to be low due to the random errors of the testing procedure across different days and runs, paired with an operator's ability to read the line intensity for samples with very low analyte concentration.

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 +COVID-19 Dual 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 (SARS-CoV-2, 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 150 coded samples (TN: 15, HN COVID: 15, HN-Flu A: 15, HN-Flu B: 15, LP-COVID: 15, LP-Flu A: 15, LP-Flu B: 15, MP-COVID: 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 Positive Result/No of Total Tested (% Positive Rate)				Agreement	
	Site 1 (2Operators)	Site 2 (3Operators)	Site 3 (3Operators)	Site 4 (3Operators)	Total	95% CI
TN	0/30 (0%)	0/45 (0%)	0/45 (0%)	0/45 (0%)	165/165 (100%)	97.7-100.0
HN COVID	0/30 (0%)	0/45 (0%)	0/45 (0%)	0/45 (0%)	165/165 (100%)	97.7-100.0
HN Flu A	0/30 (0%)	0/45 (0%)	0/45 (0%)	0/45 (0%)	165/165 (100%)	97.7-100.0
HN Flu B	0/30 (0%)	0/45 (0%)	1/45 (2.2%)	0/45 (0%)	164/165 (99.4%)	96.7-99.9

LP COVID	30/30 (100%)	45/45 (100%)	45/45 (100%)	45/45 (100%)	165/165 (100%)	97.7-100.0
LP Flu A	30/30 (100%)	45/45 (100%)	44/45 (97.8%)	45/45 (100%)	164/165 (99.4%)	96.7-99.9
LP Flu B	30/30 (100%)	45/45 (100%)	45/45 (100%)	45/45 (100%)	165/165 (100%)	97.7-100.0
MP COVID	30/30 (100%)	45/45 (100%)	45/45 (100%)	45/45 (100%)	165/165 (100%)	97.7-100.0
MP Flu A	30/30 (100%)	45/45 (100%)	45/45 (100%)	45/45 (100%)	165/165 (100%)	97.7-100.0
MP Flu B	30/30 (100%)	45/45 (100%)	45/45 (100%)	45/45 (100%)	165/165 (100%)	97.7-100.0

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+COVID-19 Dual Test was conducted with 50 potential cross-reactive or interfering pathogens of bacteria (19), fungus (1), and viruses (28) and negative matrix (2). Each microorganism was tested in three (3) replicates in the absence or presence of 2x LoD concentrations of SARS-CoV-2, 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
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
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 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	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
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
Pooled Human Nasal Wash	N/A	3/3	0/3	No
Pooled Human Nasal Fluid	N/A	3/3	0/3	No
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.				

The study results showed that none of the evaluated microorganisms demonstrated cross-reactivity or interference with the Nano-Check™ Influenza+COVID-19 Dual Test at the tested concentrations.

b) Endogenous/Exogenous Interference

The Endogenous/Exogenous interference study of the Nano-Check™ Influenza+COVID-19 Dual Test was conducted using medically relevant endogenous and exogenous interferents. The SARS-CoV-2, 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.

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
Sore Throat (Oral Pain Reliever spay)	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*	10% w/v	No
Disinfectant Spray	1% v/v	No
Acetylsalicylic acid	3.00×10^{1} µg/mL	No
Dexamethasone	1.20×10^{1} µg/mL	No
Mometasone furoate	4.50×10^{-4} µg/mL	No
Mupirocin	1.50×10^{0} µg/mL	No
Oseltamivir phosphate	3.99×10^{-1} µg/mL	No
Tobramycin	3.30×10^{1} µg/mL	No
Beclomethasone dipropionate	5.04 µg/mL	No
Flunisolide	870 µg/mL	No

Molnupiravir	3.29 mg/mL	No
Remdesivir	240 µg/mL	No
Zanamivir	30 mg/mL	No
Human Neutrophils	5×10^6 cells/mL	No
Mucin (Bovine submaxillary Glands, Type I-S)	5 mg/mL	No
Whole Blood	2.50%	No
Biotin	3500 ng/mL	No

**Hand sanitizer lotion tested at 15% w/v concentration resulted in false negative Influenza B results.*

The study results showed no interference of these substances with the Nano-Check ™ Influenza+ COVID-19 Dual Test at the concentrations tested.

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+COVID-19 Dual 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+COVID-19 Dual 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 SARS-CoV-2 nucleocapsid, 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 Result / No. of Total Test			
		COVID-19	Flu A	Flu B	Agreement with Expected Results
Positive External Control	0804-DN-3K24-P	10 / 10	10 / 10	10 / 10	100%
	0804-DN-3K27-P	10 / 10	10 / 10	10 / 10	100%
	0804-DN-3K30-P	10 / 10	10 / 10	10 / 10	100%

Negative External Control	0804-DN-3K24-N	0 / 10	0 / 10	0 / 10	100%
	0804-DN-3K27-N	0 / 10	0 / 10	0 / 10	100%
	0804-DN-3K30-N	0 / 10	0 / 10	0 / 10	100%

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 SARS-CoV-2, 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	SARS-CoV-2	5/5	5/5	5/5	5/5	5/5	5/5	5/5
	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	SARS-CoV-2	5/5	5/5	5/5	5/5	5/5	5/5	5/5
	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
2°C to 8°C	SARS-CoV-2	5/5	5/5	5/5	5/5	5/5	5/5	5/5
	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	SARS-CoV-2	5/5	5/5	5/5	5/5	5/5	5/5	5/5
	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 48 hours under all temperature conditions, ranging from -20°C to 30°C. Therefore, freshly collected specimen swabs are recommended to be processed no later than one hour after specimen collection when kept at room temperature (15°C - 30°C) or within 24 hours when stored at 2°C to 8°C.

6. Detection Limit:

The Limit of Detection (LoD) was determined with two SARS-CoV-2 Omicron variant strains (USA/MD-HP20874/2021, USA/COR-22-0631 13/2022), 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+COVID-19 Dual 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
SARS-CoV-2	USA/MD-HP20874/2021, Heat Inactivated	1.95×10^2 $TCID_{50}$/mL (9.75×10^0 $TCID_{50}$/swab)	95%
	USA/COR-22-063113/2022, Heat Inactivated	1.27×10^4 $TCID_{50}$/mL (6.35×10^2 $TCID_{50}$/swab)	100%
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%

Furthermore, the LoD was established using the 1st WHO International Standard for SARS-CoV-2 Antigen (NIBSC 21/368) in real clinical matrix of nasal fluid. Initially, a preliminary LoD test was performed by spiking 50 µL of each diluted sample onto the sample collection swab head in three replicates. Following this, a confirmatory LoD test with 17 additional replicates was conducted at the preliminary LoD concentration, a total of 20 replications. To determine LoD concentration, additional dilutions were investigated bracketing the confirmed LoD concentration, with each dilution level undergoing 20 replications. It was determined that the LoD of the 1st WHO International Standard for SARS-CoV-2 Antigen (NIBSC 21/368) in the nasal fluid matrix was confirmed to be 667 IU/mL (33.5 IU/swab).

7. Analytical Reactivity (Inclusivity):

A total of 14 strains of SARS-CoV-2, 31 strains of influenza A, and 16 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	Units
SARS-CoV-2 (B.1.1.7, Alpha)	USA/CA/CDC/5574/2020[1)]	6.77E+06	GE /mL
	USA/CA/CDC/5574/2020[2)]	2.39E+04	$TCID_{50}$/mL
	England/204820464/2020	7.19E+03	$TCID_{50}$/mL
SARS-CoV-2 (B.1.351, Beta)	USA/MD-HP01542/2021[3)]	7.20E+04	GC/mL
	USA/MD-HP01542/2021[4)]	3.80E+06	GC/mL
	South Africa/KRISP-K0053 25/2020	1.90E+04	$TCID_{50}$/mL
SARS-CoV-2 (B.1.617.2, Delta)	USA/MD-HP05285/2021[5)]	7.20E+07	GC/mL
	USA/MD-HP05285/2021[6)]	5.00E+06	GC/mL
	USA/PHC658/2021	5.21E+02	$TCID_{50}$/mL
SARS-CoV-2 (P.1, Gamma)	Japan/TY7-503/2021	1.58E+04	$TCID_{50}$/mL
	USA/NY-Wadsworth-21033 899-01/ 2021	7.85E+03	$TCID_{50}$/mL
SARS-CoV-2 (B.1.617.1, Kappa)	USA/CA-Stanford-15_S02/ 2021	8.48E+04	$TCID_{50}$/mL
SARS-CoV-2 (B.1.1.529, Omicron)	USA/GA-EHC-2811C/2021	2.11E+07	GC/mL
SARS-CoV-2 (JN.1, Omicron)	USA/New York/PV96109/20 23	3.14E+03	$TCID_{50}$/mL
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/Hawaii/66/2019	1.28	HA
	A/Hawaii/66/2019 X-345A	1.28	HA
	A/Guangdong-Maonan/1536/ 2019	1.28	HA
	A/Guangdong-Maonan/1536/ 2019 CNIC-1909	0.64	HA
	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
	B/Washington/02/2019	1.28	HA
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
	B/GL/1739/54	5.00E+04	$CEID_{50}$/mL
	B/Great Lakes/1739/1954	3.20E+04	$CEID_{50}$/mL

1) Source: Bei Resources (Cat. #: NR-55245, Lot#:70043111), 2) Source: ZeptoMetrix (Cat. #: 0810612CFHI, Lot#:328055), 3) Source: Bei Resources (Cat. #: NR-553651, Lot#:70045299), 4) Source: Bei Resources (Cat. #: NR-55350, Lot#:70045608), 5) Source: Bei Resources (Cat. #: NR-56128, Lot#:70048021), 6) Source: ATCC (Cat. #: VR-3342HK, Lot#:70048932

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 SARS-CoV-2, influenza A, and influenza B) in a testing sample. The series of three or five concentrations with each two (2) strains of SARS-CoV-2, influenza A, and influenza B were prepared in pooled negative nasal fluid matrix and tested in three replicates on Influenza+COVID-19 Dual 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+COVID-19 Dual Test showed no high-dose hook effect when subjected to 3.89×10^4 $TCID_{50}$/mL for SARS-CoV-2, USA/MD-HP20874/2021 (B.1.1.529, Omicron Variant), 2.53×10^6 $TCID_{50}$/mL for SARS-CoV-2, USA/COR-22-063113/2022 (BA.5, Omicron Variant), 2.8×10^6 $TCID_{50}$/mL for influenza A (A/California/04/2009, H1N1), 2.8×10^8 $CEID_{50}$/mL for influenza A (A/Victoria/361/2011, H3N2), 1.8×10^7 $TCID_{50}$/mL for

influenza B (B/Hong Kong/330/2001, Victoria) and 4.17×10^5 $TCID_{50}$/mL for influenza B (B/Phuket/3073/13, Yamagata).

9. Competitive Interference Study

For co-infection, SARS-CoV-2 at levels near LoD was tested in the presence of high levels of influenza A or influenza B and near LoD influenza A and influenza B in the presence of high levels of SARS-CoV-2. Additionally, the performance of Nano-Check™ Influenza+COVID-19 Dual Test was evaluated in the presence of high levels of influenza A and influenza B. Contrived high and low titer influenza A (H1N1 and H3N2) and B positive samples were. No competitive interference was observed between SARS-CoV-2 and 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	Virus Name	Concentration	
Flu A (H1N1)	2.8×10^5	SARS-CoV-2	3.81×10^4	100%
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	SARS-CoV-2	3.81×10^4	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	SARS-CoV-2	3.81×10^4	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	SARS-CoV-2	3.81×10^4	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%
SARS-CoV-2	2.53×10^5	Flu A (H1N1)	8.4×10^3	100%
SARS-CoV-2	2.53×10^5	Flu A (H3N2)	4.2×10^5	100%
SARS-CoV-2	2.53×10^5	Flu B (Victoria)	6.75×10^5	100%
SARS-CoV-2	2.53×10^5	Flu B (Yamagata)	3.12×10^2	100%
Flu A (H1N1)	2.8×10^5	Flu B (Yamagata)	3.12×10^2	100%
		SARS-CoV-2	3.81×10^4	100%
Flu A (H1N1)	2.8×10^5	Flu B (Victoria)	6.75×10^5	100%
		SARS-CoV-2	3.81×10^4	100%
Flu A (H3N2)	2.8×10^6	Flu B (Yamagata)	3.12×10^2	100%
		SARS-CoV-2	3.81×10^4	100%
Flu A (H3N2)	2.8×10^6	Flu B (Victoria)	6.75×10^5	100%
		SARS-CoV-2	3.81×10^4	100%
Flu B (Victoria)	1.8×10^6	Flu A (H1N1)	8.4×10^3	100%
		SARS-CoV-2	3.81×10^4	100%
Flu B (Victoria)	1.8×10^6	Flu A (H3N2)	4.2×10^5	100%

		SARS-CoV-2	3.81×10^4	100%
Flu B (Yamagata)	4.17×10^5	Flu A (H1N1)	8.4×10^3	100%
		SARS-CoV-2	3.81×10^4	100%
Flu B (Yamagata)	4.17×10^5	Flu A (H3N2)	4.2×10^5	100%
		SARS-CoV-2	3.81×10^4	100%
SARS-CoV-2	2.53×10^5	Flu A (H1N1)	8.4×10^3	100%
		Flu B (Victoria)	6.75×10^5	100%
SARS-CoV-2	2.53×10^5	Flu A (H1N1)	8.4×10^3	100%
		Flu B (Yamagata)	3.12×10^2	100%
SARS-CoV-2	2.53×10^5	Flu A (H3N2)	4.2×10^5	100%
		Flu B (Victoria)	6.75×10^5	100%
SARS-CoV-2	2.53×10^5	Flu A (H3N2)	4.2×10^5	100%
		Flu B (Yamagata)	3.12×10^2	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+COVID-19 Dual Test was evaluated in a clinical study against an FDA-cleared molecular assay.

2. Matrix Comparison:

The Nano-Check™ Influenza+COVID-19 Dual Test is only intended for the qualitative detection of influenza A, and influenza B nucleoprotein antigens and SARS-CoV-2 nucleocapsid antigen 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+COVID-19 Dual 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+COVID-19 Dual 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+COVID-19 Dual Test were compared to the results obtained with the RT-PCR comparator test to determine clinical sensitivity and specificity.

For SARS-CoV-2 detection, 265 of these specimens tested positive, and 1,704 tested negative by the FDA-cleared RT-PCR method. The comparison of Nano-Check™ Influenza+COVID-19 Dual Test results with the comparator method results showed a PPA of 87.6% (232/265) with a 95% CI of 83.0% - 91.0%, NPA of 99.8% (1,701/1,704) with a 95% CI of 99.5% - 99.9%.

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+COVID-19 Dual 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+COVID-19 Dual 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+COVID-19 Dual Test Compared to an RT-PCR Comparator

SARS-CoV-2 Detection			
Nano-Check™ Influenza+COVID-19 Dual Test	RT-PCR Comparator		Total
	Positive	Negative	
Positive	232	3	235
Negative	33	1,701	1,734
Total	265	1,704	1,969
Positive Percent Agreement (PPA) = (232/265) x 100% = 87.6% (95% CI: 83.0% - 91.0%)			
Negative Percent Agreement (NPA) = (1,701/1,704) x 100% = 99.8% (95% CI: 99.5% - 99.9%)			
Positivity in Study Cohort = 13.46% (265/1,969; 95% CI: 12.0 - 15.0%)			

Influenza A Detection			
Nano-Check™ Influenza+COVID-19 Dual 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) = (1483/1,489) x 100% = 99.6% (95% CI: 99.1% - 99.8%)			
Positivity in Study Cohort = 24.4% (480/1,969; 95% CI: 22.5 – 26.3%)			
Influenza B Detection			
Nano-Check™ Influenza+COVID-19 Dual 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%)			
Positivity in Study Cohort = 5.8% (114/1,969; 95% CI: 4.8 – 6.9%)			

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+COVID-19 Dual Test are presented below.

a) SARS-CoV-2: 87.6% (232/265, 95% CI: 83.0% - 91.0%)
b) Influenza A: 86.9% (417/480, 95% CI: 83.6% - 89.6%)
c) 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+COVID-19 Dual Test are presented below.

a) SARS-CoV-2: 99.8% (1,701/1,704, 95% CI: 99.5% - 99.9%)
b) Influenza A: 99.6% (1,483/1,489, 95% CI: 99.1% - 99.8%)
c) 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 SARS-CoV-2, influenza A, and influenza B in patient samples.

E. Expected Value/Reference Range:

The rate of positivity as determined by the Nano-Check™ Influenza+COVID-19 Dual Test during the 2022-2025 clinical study was 21.5% for influenza A (423/1,969), 5.3% for influenza B (104/1,969), and 11.9% for SARS-CoV-2 (235/1,969).

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 SARS-CoV-2 virus, 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.

VIII. 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+COVID-19 Dual 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+COVID-19 Dual Test is substantially equivalent to the predicate device.