Abbott Diagnostics Scarborough, Inc.
Jessica Stahle
Regulatory Affairs Manager
10 Southgate Road
Scarborough, Maine 04074

Re: K221925
Trade/Device Name: ID NOW COVID-19 2.0
Regulation Number: 21 CFR 866.3982
Regulation Name: Simple Point-Of-Care Device To Directly Detect SARS-CoV-2 Viral Targets From Clinical Specimens In Near-Patient Settings
Regulatory Class: Class II
Product Code: QWR
Dated: April 29, 2023
Received: May 1, 2023

August 10, 2023

Dear Jessica Stahle:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Kristian M. Roth -S

For: Himani Bisht, Ph.D.
Assistant Director
Viral Respiratory and HPV Branch
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Products 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)*
K221925

Device Name
ID NOW COVID-19 2.0

Indications for Use *(Describe)*
ID NOW COVID-19 2.0 performed on the ID NOW Instrument is a rapid molecular in vitro diagnostic test utilizing an isothermal nucleic acid amplification technology (NAAT) intended for the qualitative detection of nucleic acid from SARS-CoV-2 in direct anterior nasal (nasal) or nasopharyngeal swabs from individuals with signs and symptoms of respiratory tract infection. ID NOW COVID-19 2.0 performed on the ID NOW Instrument is intended for use as an aid in the diagnosis of COVID-19 if used in conjunction with other clinical, epidemiologic, and laboratory findings. SARS-CoV-2 RNA is generally detectable in nasal and nasopharyngeal swab specimens during the acute phase of infection.

Positive results are indicative of the presence of SARS-CoV-2 RNA. Positive results do not preclude co-infection with bacteria or other viruses and should not be used as the sole basis for diagnosis, treatment, or other patient management decisions.

A negative test result is presumptive, and it is recommended these results be confirmed by another molecular SARS-CoV-2 assay. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for diagnosis, treatment, or other patient management decisions. This test is intended for prescription use only and can be used in Point-of-Care settings.

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.

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: **K221925**

SUBMITTER
Abbott Diagnostics Scarborough, Inc.
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Scarborough, Maine 04074 USA
Establishment Registration Number: 1221359

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DATE PREPARED
June 30, 2022

TRADE NAME
ID NOW COVID-19 2.0

COMMON NAME
ID NOW COVID, ID NOW COVID-19

CLASSIFICATION NAME
21 CFR 866.3982
Simple Point-Of-Care Device To Directly Detect SARS-CoV-2 Viral Targets From Clinical Specimens In Near-Patient Settings

CLASSIFICATION
Class II

PRODUCT CODE
QWR

PANEL
Microbiology (83)

PREDICATE DEVICE
Sofia 2 SARS Antigen+ FIA, DEN220039

DEVICE DESCRIPTION
ID NOW COVID-19 2.0 is a rapid, instrument-based isothermal test for the qualitative detection of nucleic acid from SARS-CoV-2 viral RNA in direct nasal or nasopharyngeal swabs. The ID NOW COVID-19 2.0 System utilizes isothermal nucleic acid amplification technology and is comprised of:

- Sample Receiver – single use, disposable containing the elution buffer
- Test Base – single use, disposable comprising two sealed reaction tubes, each containing a lyophilized pellet
- Transfer Cartridge – single use, disposable for transfer of the eluted sample to the Test Base
- Patient Swabs – sterile anterior nasal swabs (foam) for anterior nasal swab collection and for use as a Negative Control Swab
- Positive Control Swab – single use, to ensure that test reagents are working properly and that the test is correctly performed, and
- ID NOW Instrument

The reaction tubes in the Test Base contain lyophilized reagents required for amplification of the target nucleic acid and an internal control. ID NOW COVID-19 2.0utilizes a pair of templates (similar to primers) for the specific amplification of RNA from SARS-CoV-2 and a fluorescently labeled molecular beacon designed to specifically identify the amplified nucleic acid targets. ID NOW COVID-19 2.0 is performed within the confinement of the Test Base, and no other part of the ID NOW Instrument has contact with the sample during the amplification process. This minimizes the risk of instrument contamination and sample carry-over between measurements.

To perform the assay, the Sample Receiver and Test Base are inserted into the ID NOW Instrument. The sample is added to the Sample Receiver and transferred via the Transfer Cartridge to the Test Base, resuspending the lyophilized pellets contained within the Test Base and initiating viral lysis and target amplification. Heating, mixing and detection by fluorescence is provided by the instrument, with results automatically reported.

Results are displayed by the ID NOW Instrument and are also stored in an on-board archive and are assigned to a sample ID that has been entered into the ID NOW Instrument by the operator either manually or using barcode scanner . Data can be retrieved and downloaded by the operator at any time after testing. An external Universal Printer can be attached via USB to the ID NOW Instrument to print test results.

INTENDED USE
ID NOW COVID-19 2.0 performed on the ID NOW Instrument is a rapid molecular *in vitro* diagnostic test utilizing an isothermal nucleic acid amplification technology (NAAT) intended for the qualitative detection of nucleic acid from SARS-CoV-2 in direct anterior nasal (nasal) or nasopharyngeal swabs from individuals with signs and symptoms of respiratory tract infection. ID NOW COVID-19 2.0 performed on the ID NOW Instrument is intended for use as an aid in the diagnosis of COVID-19 if used in conjunction with other clinical, epidemiologic, and laboratory findings. SARS-CoV-2 RNA is generally detectable in nasal and nasopharyngeal swab specimens during the acute phase of infection.

Positive results are indicative of the presence of SARS-CoV-2 RNA. Positive results do not preclude co-infection with bacteria or other viruses and should not be used as the sole basis for diagnosis, treatment, or other patient management decisions.

A negative test result is presumptive, and it is recommended these results be confirmed by another molecular SARS-CoV-2 assay. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for diagnosis, treatment, or other patient management decisions. This test is intended for prescription use only and can be used in Point-of-Care settings.

TECHNOLOGICAL CHARACTERISTICS

ID NOW COVID-19 2.0 and the predicate device, Sofia 2 SARS Antigen+ FIA, have the same intended use and indications for use. They are both assays for the qualitative detection of SARS-CoV-2 in point of care patient settings.

DEVICE COMPARISON

ID NOW COVID-19 2.0 was compared to the legally marketed predicate device, the Sofia 2 SARS Antigen+ FIA assay.

Parameter	ID NOW COVID-19 2.0	Sofia 2 SARS Antigen+ FIA (DEN220039)
FDA Product Code	QWR	QVF
Regulation Number/Name	21 CFR 866.3982 - Simple Point-Of-Care Device To Directly Detect SARS-CoV-2 Viral Targets From Clinical Specimens In Near-Patient Settings	Same
Assay Target	SARS-CoV-2 viral RNA	SARS-CoV-2 nucleocapsid protein
Intended Use	ID NOW COVID-19 2.0 performed on the ID NOW Instrument is a rapid molecular *in vitro* diagnostic test utilizing an isothermal nucleic acid amplification technology (NAAT) intended for the qualitative detection of nucleic acid from SARS-CoV-2 in direct anterior nasal (nasal) or nasopharyngeal swabs from individuals with signs and symptoms of respiratory tract infection. ID NOW COVID-19 2.0 performed on the ID NOW Instrument is intended for use as an aid in the diagnosis of COVID-19 if used in conjunction with other clinical, epidemiologic, and laboratory findings. SARS-CoV-2 RNA is generally detectable in nasal and nasopharyngeal swab specimens during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 RNA. Positive results do not preclude co-infection with bacteria or other viruses and should not be used as the sole basis for diagnosis,	The Sofia 2 SARS Antigen+ FIA is a lateral flow immunofluorescent sandwich assay that is used with the Sofia 2 instrument for the rapid, qualitative detection of SARS-CoV-2 nucleocapsid protein antigens directly in anterior nasal swab specimens from individuals with signs and symptoms of upper respiratory infection (i.e., symptomatic) when testing is started within 6 days of symptom onset. The test is intended for use as an aid in the diagnosis of SARS-CoV-2 infections (COVID-19) in symptomatic individuals when tested at least twice over three days with at least 48 hours between tests. The test does not differentiate between SARS-CoV and SARS-CoV-2. A negative test result is presumptive, and it is recommended these results be confirmed by a molecular SARS-CoV-2 assay.

Parameter	ID NOW COVID-19 2.0	Sofia 2 SARS Antigen+ FIA (DEN220039)
	treatment, or other patient management decisions. A negative test result is presumptive, and it is recommended these results be confirmed by another molecular SARS-CoV-2 assay. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for diagnosis, treatment, or other patient management decisions. This test is intended for prescription use only and can be used in Point-of-Care settings.	Negative results do not preclude SARS-CoV-2 infections and should not be used as the sole basis for treatment or other patient management decisions. Positive results do not rule out co-infection with other respiratory pathogens. Performance characteristics for SARS-CoV-2 were established during the 2021-2022 SARS-CoV-2 pandemic when SARS-CoV-2 Omicron was the predominant SARS-CoV-2 variant in circulation. When other SARS-CoV-2 virus variant are emerging, performance characteristics may vary. This test is intended for prescription use only and can be used in Point-of-Care settings.
Intended Environment for Use	Professional use, in a medical laboratory or point-of-care	Same
Instrumentation	ID NOW Instrument	Sofia Q, Sofia 2, Sofia
Automated Assay	Yes, Sample preparation, amplification, detection and result interpretation	Automated test interpretation and report generation
Assay Information		
Sample Type	Direct anterior nasal or nasopharyngeal swabs	Direct anterior nasal swabs
SARS-CoV-2 Target	RdRp gene	Nucleocapsid Protein Antigen
Technology	Isothermal nucleic acid amplification for detecting the presence/absence of viral RNA in clinical specimens	lateral flow immunofluorescent sandwich assay for detecting the presence/absence of the nucleocapsid protein antigen in clinical specimens
Internal Control	Yes	Same
Result Interpretation	Automated	Same
Assay Result	Qualitative	Same
Time to Result	≤ 12 minutes	About 15 minutes

PERFORMANCE SUMMARY

CLINICAL STUDY

The clinical performance of ID NOW COVID-19 2.0 was established in a multi-center, prospective clinical study conducted at twenty-one (21) US sites in 2020/2021. A total of 60 different operators, across the sites tested subjects with ID NOW COVID-19 2.0. The study sites and the test operators used in this clinical study were representative of the CLIA waived setting.

To be enrolled in the study at the participating study centers, patients had to be presenting at the participating study centers showing signs and symptoms of upper respiratory infection. Two nasal or nasopharyngeal swabs were collected from each patient and tested using ID NOW COVID-19 2.0 at all study sites. Three (3) FDA

Emergency Use Authorized real-time Polymerase Chain Reaction (RT-PCR) assays for the detection of SARS-CoV-2 were utilized in a composite comparator method. At all sites, one nasal or nasopharyngeal swab was tested directly in ID NOW COVID-19 2.0 according to product instructions and the other swab was eluted in Universal Transport Media (UTM). All sites shipped the UTM sample to a central testing laboratory for RT-PCR testing with the composite comparator.

The performance of ID NOW COVID-19 2.0 was established with 914 specimens, including 460 anterior nasal swabs and 454 nasopharyngeal swabs collected from individuals showing signs and symptoms of upper respiratory infection.

ID NOW COVID-19 2.0 performance, including 95% confidence intervals (Wilson score), against the composite comparator is provided below.

ID NOW COVID-19 2.0 Performance against Composite Comparator (Nasal and Nasopharyngeal Swabs Combined)

ID NOW COVID-19 2.0	Composite Comparator Result		
	Positive	Negative	Total
Positive	254	10	264
Negative	23	627	650
Total	277	637	914
Positive Agreement: 254/277	91.7% (95% CI: 87.8% - 94.4%)		
Negative Agreement: 627/637	98.4% (95% CI: 97.1% - 99.1%)		

ANALYTICAL STUDIES

Analytical Sensitivity (Limit of Detection)

ID NOW COVID-19 2.0 limit of detection (LoD) in natural nasal swab matrix was determined by evaluating different concentrations of inactivated SARS-CoV-2 virus (USA-WA1/2020).

Presumed negative natural nasal swab specimens were eluted in Universal Transport Media. Swab eluates were combined and mixed thoroughly to create a clinical matrix pool to be used as the diluent. SARS-CoV-2 virus was diluted in this natural nasal matrix pool to generate virus dilutions for testing.

A point estimate was determined using Probit analysis and the LoD was confirmed as the lowest concentration that was detected ≥95% of the time.

The confirmed LoD in natural nasal swab matrix is presented in the table below. Equivalent performance was also verified in natural nasopharyngeal swab matrix.

Limit of Detection (LoD) Study Results

Virus	Swab Matrix	Claimed LoD	
		copies/swab	copies/reaction
SARS-CoV-2 RNA	Nasal Swab	500	20
	Nasopharyngeal Swab	500	20

Analytical Reactivity (Inclusivity)

Wet Testing

An Analytical Reactivity (inclusivity) study was performed to determine whether ID NOW COVID-19 2.0 is able to detect a variety of SARS-CoV-2 strains.

Vendor provided stocks of SARS-CoV-2 strains were diluted in natural nasal swab matrix to approximately 1 – 3 times the limit of detection. Contrived swab samples were prepared by coating 50 microliters of virus dilution onto each swab.

A concentration level was considered "reactive/positive" in this study if all five replicates generated a positive result. If 5/5 COVID-19 positive results were not obtained across all three device lots at the concentration tested, the isolate was tested at increasing concentrations until 5/5 positive results were obtained.

ID NOW COVID-19 2.0 detected all strains tested at the concentrations indicated in the table below:

Analytical Reactivity Study Results

SARS-CoV-2 Strain	Detected Concentration (copies/reaction)	Detected Concentration (copies/swab)
Hong Kong/VM200001061/2020	60	1,500
Italy-INMI1	60	1,500
SARS-CoV-2-USA- WA1/2020	58.3	1,457.5
P.2 (Zeta)	26	650
P.1 (Gamma)	61.1	1,527.5
B.1.1.7 (Alpha)	45.9	1,147.5
B.1.429 (Epsilon)	18.7	467.5
B.1.1.318	28.8	720
Wa1-wt	41	1,025
B.1.351 (Beta)	23	575
B.1.1.7 (Alpha)	100.2	2,505
B.1.617.1 (Kappa)	19	475
B.1.617.1 (Kappa)	40.5	1,012.5
B.1.617.2 (Delta)	22.4	560
B.1.617.2 (Delta)	20.7	517.5
B.1.1.529 (Omicron)	60	1,500
BA.2.12.1 (Omicron)	60	1,500
BA.4.6 (Omicron)	60	1,500
BA.5.1 (Omicron)	60	1,500

BA.5.2 (Omicron)	80	2,000
BE.1 (Omicron)	60	1,500
BF.5 (Omicron)	100	2,500
BF.7 (Omicron)	80	2,000
BA.4.1 (Omicron)	60	1,500
BQ.1 (Omicron)	60	1,500
BQ.1.1 (Omicron)	60	1,500
XBB.1 (Omicron)	80	2,000
XBB.6 (Omicron)	60	1,500

In-Silico Analysis

An alignment was performed with the oligonucleotide primer and probe sequences of the ID NOW COVID-19 2.0 with all publicly available SARS-CoV-2 genomic sequences submitted to NCBI Genbank and GISAID databases between December 1, 2019 and December 3-4, 2021. A total of 431,147 high quality SARS-CoV-2 sequences (<1% Ns, unknown or unidentified nucleotides) plus a reference genome were available from NCBI GenBank, and 4,252,920 from GISAID databases. Both datasets contained sequences obtained from human hosts only. 217,267 sequences were present in both databases. To avoid redundancy only the GISAID copies of the duplicated sequences were retained for analysis bringing the total number of high quality human SARS-CoV-2 sequences available from both databases to 4,466,800. Of the total number of sequences analyzed, 3,274 sequences contained at least 1 ambiguous or unidentified nucleotide within the target region, bringing the total number of isolates suitable for inclusivity analysis down to 4,463,526. From this analysis 99.58% of the sequences provided 100% homology to the ID NOW COVID-19 2.0 primer and probe sequences.

An additional alignment was performed with the oligonucleotide primer and probe sequences of the ID NOW COVID-19 2.0 with all publicly available SARS-CoV-2 genomic sequences collected within the United States and submitted to the GISAID database between October 17, 2022 and April 17, 2023. The dataset contained sequences obtained from human hosts only and totaled 382,309 sequences. ID NOW COVID-19 2.0 provided 100% sequence homology across 99.51% of the sequences.

Analytical Specificity (Cross Reactivity)

To determine the analytical specificity of ID NOW COVID-19 2.0, 38 commensal and pathogenic microorganisms (24 viruses, 12 bacteria, and 2 yeasts) that may be present in the nasal cavity or nasopharynx were tested. All of the following microorganisms were negative when tested at concentrations ranging from 10^6 to 10^7 cells/mL, IFU/mL, or CFU/mL (bacteria), 10^5 to 10^8 $TCID_{50}$/mL, copies/mL, GE/mL or IU/mL (viruses), and 10^6 to 10^7 cells/mL or CFU/mL (yeast).

Viruses	**Bacteria**	**Yeast**
Human Adenovirus 1	*Bordetella pertussis*	*Candida albicans*
Human Adenovirus 7	*Chlamydia pneumoniae*	*Pneumocystis jirovecii* (PJP)
Human Coronavirus 229E	*Haemophilus influenzae*	
Human Coronavirus HKU1	*Legionella pneumophila*	
Human Coronavirus OC43	*Mycobacterium tuberculosis avirulent*	
Human Coronavirus NL63	*Mycoplasma pneumoniae*	
MERS-coronavirus	*Pseudomonas aeruginosa*	

Viruses	**Bacteria**	**Yeast**
Enterovirus 70	*Staphylococcus aureus*	
Human Echovirus 7	*Staphylococcus epidermidis*	
Human Metapneumovirus (hMPV)	*Streptococcus salivarius*	
Human Parainfluenza virus 1	*Streptococcus pneumoniae*	
Human Parainfluenza virus 2	*Streptococcus pyogenes*	
Human Parainfluenza virus 3		
Human Parainfluenza virus 4a		
Human Influenza A/California/7/2009		
Human Influenza A/Texas/50/2012		
Human Influenza B/Wisconsin/1/2010		
Human Influenza B/Malaysia/2506/04		
Mumps virus		
Respiratory Syncytial Virus (RSV) A		
Respiratory Syncytial Virus (RSV) B		
Rhinovirus 1		
Rhinovirus 2		
SARS-Coronavirus		

In addition, *in silico* analysis was performed to determine whether there is any significant overlap between ID NOW COVID-19 2.0 target nucleic acid sequence and the genomes of the following upper respiratory tract microorganisms. Based on this analysis, none of the evaluated microorganisms are predicted/expected to cross-react with the ID NOW COVID-19 2.0.

Viruses	**Bacteria**	**Yeast**
Human coronavirus 229E	*Bordetella pertussis*	*Candida Albicans*
Human coronavirus OC43	*Bordetella bronchiseptica*	*Pneumocystis jirovecii (PJP)*
Human coronavirus HKU1	*Chlamydia pneumoniae*	
Human coronavirus NL63	*Chlamydia trachomatis*	
SARS-coronavirus	*Corynebacterium diphtheriae*	
MERS-coronavirus	*Escherichia coli*	
Human adenovirus 1	*Haemophilus influenzae*	
Human adenovirus 2	*Klebsiella pneumoniae*	
Human adenovirus 3	*Lactobacillus plantarum*	
Human adenovirus 4	*Legionella pneumophila*	
Human adenovirus 5	*Moraxella catarrhalis*	
Human adenovirus 7	*Mycobacterium tuberculosis*	
Human adenovirus 11	*Mycoplasma pneumoniae*	
Human adenovirus 14	*Neisseria gonorrhoeae*	
Human adenovirus 31	*Neisseria meningitidis*	
Cytomegalovirus	*Neisseria mucosa*	
Echovirus E6		
Echovirus E7	*Proteus mirabilis*	

Viruses	Bacteria	Yeast
Echovirus E9	*Proteus vulgaris*	
Echovirus E11	*Pseudomonas aeruginosa*	
Epstein Barr virus	*Staphylococcus aureus*	
Human Metapneumovirus (hMPV)	*Staphylococcus epidermidis*	
Influenza A	*Streptococcus pneumoniae*	
Influenza B	*Streptococcus pyogenes*	
Measles virus	*Streptococcus salivarius*	
Mumps virus		
Parainfluenza Type 1		
Parainfluenza Type 2		
Parainfluenza Type 3		
Parainfluenza Type 4a and 4b		
RSV A		
RSV B		
Rhinovirus:		
Coxsackievirus B4		
Human rhinovirus B35		
Enterovirus 70 (VR-836)		
Other rhinoviruses		

Microbial Interference

ID NOW COVID-19 2.0 test performance in the presence of non-SARS-CoV-2 respiratory pathogens was evaluated. Vendor provided stocks of SARS-CoV-2 virus were diluted in clinical matrix to 1.74 times the limit of detection and tested in the presence of RSV A, RSV B, Flu A/California, Flu A/Texas, Flu B/Wisconsin, and Flu B/Malaysia at concentrations shown below; all others were tested with SARS-CoV-2 virus diluted in clinical matrix to 3 times the limit of detection. Contrived SARS-CoV-2 positive swab specimens were prepared by coating 50 microliters of virus dilution onto each swab. The following panel of non-SARS-CoV-2 viruses, bacteria, and yeast were tested at the concentration provided in the table below and were found not to affect test performance.

Panel Viruses	Concentration
Human Adenovirus 1	1.0×10^5 $TCID_{50}$/mL
Human Adenovirus 7	1.0×10^5 $TCID_{50}$/mL
Human Coronavirus 229E	1.0×10^5 $TCID_{50}$/mL
Human Coronavirus NL63	1.17×10^5 $TCID_{50}$/mL
Human Coronavirus OC43	1.0×10^5 $TCID_{50}$/mL
Human Coronavirus HKU1	1.0×10^8 copies/mL
MERS-Coronavirus	1.0×10^5 GE/mL
SARS-Coronavirus	2.0×10^5 copies/mL
Enterovirus 70	1.0×10^5 $TCID_{50}$/mL
Human Echovirus 7	1.0×10^5 $TCID_{50}$/mL
Human Metapneumovirus (hMPV)	1.0×10^5 U/mL
Human Parainfluenza Virus 1	2.0×10^5 $TCID_{50}$/mL
Human Parainfluenza Virus 2	1.0×10^5 $TCID_{50}$/mL
Human Parainfluenza Virus 3	1.0×10^5 $TCID_{50}$/mL

Human Parainfluenza Virus 4a	1.0 x 10^5 $TCID_{50}$/mL
Human Influenza A/California/7/2009	1.0 x 10^5 IU/mL
Human Influenza A/Texas/50/2012	1.0 x 10^5 IU/mL
Human Influenza B/Wisconsin/1/2010	1.0 x 10^5 IU/mL
Human Influenza B/Malaysia/2506/04	1.0 x 10^5 IU/mL
Mumps virus	1.0 x 10^5 $TCID_{50}$/mL
Respiratory Syncytial Virus (RSV) A	1.0 x 10^5 IU/mL
Respiratory Syncytial Virus (RSV) B	1.0 x 10^5 IU/mL
Rhinovirus 1	1.0 x 10^5 $TCID_{50}$/mL
Rhinovirus 2	1.0 x 10^5 $TCID_{50}$/mL
Bacteria	
Bordetella pertussis	1.0 x 10^6 CFU/mL
Chlamydia pneumoniae	1.0 x 10^6 IFU/mL
Haemophilus influenzae	1.0 x 10^6 CFU/mL
Legionella pneumophila	1.0 x 10^6 cells/mL
Mycobacterium tuberculosis	1.0 x 10^6 CFU/mL
Mycoplasma pneumoniae	1.0 x 10^6 CFU/mL
Pseudomonas aeruginosa	1.0 x 10^6 CFU/mL
Staphylococcus aureus	1.0 x 10^6 CFU/mL
Staphylococcus epidermidis	1.0 x 10^6 CFU/mL
Streptococcus salivarius	1.0 x 10^6 CFU/mL
Streptococcus pneumoniae	1.0 x 10^6 CFU/mL
Streptococcus pyogenes	1.0 x 10^6 CFU/mL
Yeast	
Candida albicans	1.0 x 10^6 cells/mL
Pneumocystis jirovecii (PJP)	1.0 x 10^6 CFU/mL

Interfering Substances

The following substances, naturally present in respiratory specimens or that may be artificially introduced into the nasal cavity or nasopharynx, were evaluated with ID NOW COVID-19 2.0 at the concentrations listed below in a negative sample and in a positive sample with SARS-CoV-2 concentrations at 3 times the limit of detection and were found not to affect test performance.

Substance	**Concentration**
Mucin[1]	1% w/v
Whole Blood	1% v/v
Post nasal lavage discharge	1% v/v
Phenylephrine	20% v/v
Oxymetazoline	20% v/v
Sodium chloride with preservatives	20% v/v
Cromolyn sodium	20% v/v
Alkalol	20% v/v
Phenol	20% v/v
Zincum gluconium, Zincum aceticum[2]	10% w/v
Galphimia glauca, Histaminum hydrochloricum, Luffa opperculata, Sulfur	20% v/v
Beclomethasone	0.068 mg/mL
Fluticasone propionate	20% v/v
Dexamethasone	0.48 mg/mL
Flunisolide	0.04 mg/mL
Triamcinolone	0.04 mg/mL
Budesonide	0.051 mg/mL
Mometasone	0.04 mg/mL
Zanamivir (Relenza)	0.284 mg/mL
Mupirocin	4.3 mg/mL

Tobramycin	1.44 mg/mL
Remdesivir (Brand Name: Veklury)	0.12 mg/mL
Throat Lozenge (Benzocaine, Methol)	0.63 mg/mL
Toothpaste (Fluoride)	1% w/v
Tobacco	0.1% w/v
Nicotine	0.1% w/v
Oral Rinse	10% v/v
Leukocytes	1.1 x 10^6 cells/mL
Fluticasone furoate	20% v/v

[1]Mucin at 2% w/v in the absence of SARS-CoV-2 yielded 1/5 invalid result and therefore was tested at a lower concentration.
[2]When Zincum gluconium, Zincum aceticum was tested at 20% w/v in the presence of SARS-CoV-2, 1/5 invalid result was generated and therefore was tested at a lower concentration.

Reproducibility/Near the Cut Off

A reproducibility/near the cut off study of ID NOW COVID-19 2.0 was conducted by nine operators at three sites over five different days using panels of four samples contrived in clinical matrix. The percent agreement relative to the expected results for the moderate positive samples was 98.1% (263/268). The percent agreement relative to the expected results for the low positive samples was 96.3% (260/270). The percent agreement relative to the expected results for the high negative samples was 89.6% (240/268) and the true negative samples were 99.6% (267/268).

The Reproducibility Study site-to-site qualitative results (agreements relative to the expected results) are presented in the table below:

Sample Category		Site			Overall Agreement and 95% CI	
		Site 1	Site 2	Site 3		
1.16x LoD	Percent Agreement	97.8%	94.4%	96.7%	96.3% (260/270)	93.3%, 98.0%
	Count	88/90	85/90	87/90		
1.74xLoD	Percent Agreement	98.9%	96.6%	98.9%	98.1% (263/268)	95.7%, 99.2%
	Count	89/90	86/89[2]	88/89[2]		
0.0235x LoD (High Negative)	Percent Agreement	87.8%	90.9%	90.0%	89.6% (240/268)	85.3%, 92.7%
	Count	79/90	80/88[2]	81/90		
Virus Free Negative[1]	Percent Agreement	100.0%	100.0%	98.9%	99.6% (267/268)	97.9%, 99.9%
	Count	90/90	89/89[2]	88/89[2]		
Positive Control	Percent Agreement	100%	100%	100%	100% (137/137)	97.3% - 100%
	Count	45/45	46/46	46/46		
Negative Control	Percent Agreement	100%	100%	100%	100% (137/137)	97.3% - 100%
	Count	45/45	46/46	46/46		

[1]Percent Agreement correlates to the percent of negative results.
[2]Sample(s) excluded due to protocol deviation

Conclusion Drawn from Analytical and Clinical Studies

The results presented in this 510(k) premarket notification demonstrate that the subject device (ID NOW COVID-19 2.0) performance is substantially equivalent to the predicate device (Sofia 2 SARS Antigen+ FIA, DEN220039).

The similarities and differences between the subject device and the predicate device are presented in the Device Comparison Table. Differences between the subject device and the predicate device shown in the table do not affect the demonstration of substantial equivalence.