



October 10, 2023

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

Re: K232775

Trade/Device Name: ID NOW Influenza A & B 2
Regulation Number: 21 CFR 866.3980
Regulation Name: Respiratory Viral Panel Multiplex Nucleic Acid Assay
Regulatory Class: Class II
Product Code: OCC, OZE, OOI
Dated: September 8, 2023
Received: September 11, 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 (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.

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 Branch Chief
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

Submission Number (if known)

K232775

Device Name

ID NOW™ Influenza A & B 2

Indications for Use (Describe)

The ID NOW™ Influenza A & B 2 assay performed on the ID NOW™ Instrument is a rapid molecular in vitro diagnostic test utilizing an isothermal nucleic acid amplification technology for the qualitative detection and discrimination of influenza A and B viral RNA in direct nasal or nasopharyngeal swabs and nasal or nasopharyngeal swabs eluted in viral transport media from patients with signs and symptoms of respiratory infection. It is intended for use as an aid in the differential diagnosis of influenza A and B viral infections in humans in conjunction with clinical and epidemiological risk factors. The assay is not intended to detect the presence of influenza C virus.

Negative results do not preclude influenza virus infection and should not be used as the sole basis for diagnosis, treatment or other patient management decisions.

Performance characteristics for influenza A were established during the 2016-2017 influenza season when influenza A/H3 and A/H1N1 pandemic were the predominant influenza A viruses in circulation. When other influenza A viruses are emerging, performance characteristics may vary.

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

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510(k) SUMMARY

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

The assigned 510(k) number is: K232775

SUBMITTER

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DATE PREPARED

9/8/2023

TRADE NAME

ID NOW™ Influenza A & B 2

COMMON NAME

ID NOW™ Flu 2, Alere™ i Flu 2, Alere™ i Influenza A & B 2

CLASSIFICATION NAME

Respiratory Viral Panel Multiplex Nucleic Acid System (per 21 CFR 866.3980)
Instrumentation for Clinical Multiplex Test Systems (per 21 CFR 862.2570)

CLASSIFICATION

Class II

PRODUCT CODE

OCC, OZE, OOI

PANEL

Microbiology (83)

PREDICATE DEVICE



ID NOW Influenza A & B 2, K220801

DEVICE DESCRIPTION

ID NOW Influenza A & B 2 is a rapid, instrument-based isothermal test for the qualitative detection and differentiation of influenza A and influenza B from nasal swab or nasopharyngeal swabs tested directly or after elution in viral transport media collected from patients presenting with signs and symptoms of respiratory infection.

All ID NOW™ assays utilize isothermal nucleic acid amplification technology and are 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, and
- ID NOW™ Instrument – repeat use reader

The reaction tubes in the ID NOW Influenza A & B 2 Test Base contain the reagents required for amplification of the target nucleic acid and an internal control. ID NOW Influenza A & B 2 utilizes a pair of templates (similar to primers) for the specific amplification of RNA from influenza A and B and a fluorescently labeled molecular beacon designed to specifically identify the amplified RNA targets.

ID NOW Influenza A & B 2 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 reduces 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 and the elution buffer is automatically heated by the 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 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, and the date/time the test was performed. 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

The ID NOW™ Influenza A & B 2 assay performed on the ID NOW™ Instrument is a rapid molecular *in vitro* diagnostic test utilizing an isothermal nucleic acid amplification technology for the qualitative detection and discrimination of influenza A and B viral RNA in direct nasal or nasopharyngeal swabs and nasal or nasopharyngeal swabs eluted in viral transport media from patients with signs and symptoms of respiratory infection. It is intended for use as an aid in the



differential diagnosis of influenza A and B viral infections in humans in conjunction with clinical and epidemiological risk factors. The assay is not intended to detect the presence of influenza C virus.

Negative results do not preclude influenza virus infection and should not be used as the sole basis for diagnosis, treatment or other patient management decisions.

Performance characteristics for influenza A were established during the 2016-2017 influenza season when influenza A/H3 and A/H1N1 pandemic were the predominant influenza A viruses in circulation. When other influenza A viruses are emerging, performance characteristics may vary.

If infection with a novel influenza A virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent Influenza viruses and sent to state or local health department for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.

COMPARISON TO THE PREDICATE

The purpose of this Special 510(k) submission is to bring to market a modification of the software contained on the ID NOW™ Instrument. A modification of the ID NOW Influenza A & B 2 algorithm was made, as a preventive measure, to mitigate the potential occurrence of false positive Influenza B test results during sequential workflow testing

There have been no changes made to other software components and no changes were made to the chemistry of the assay.

In addition, this Special 510(k) captures labeling updates to ID NOW Influenza A & B 2 to describe use of the optional, sequential workflow which allows a single patient sample to be used to run both ID NOW COVID-19 2.0 and ID NOW Influenza A & B 2 by reusing the ID NOW COVID-19 2.0 Sample Receiver with ID NOW Influenza A & B 2. Introduction of the optional, sequential workflow was first cleared for use in the ID NOW COVID-19 2.0 510(k) K221925, decision dated August 10, 2023

ID NOW Influenza A & B 2 incorporating the software modification was compared to the legally marketed predicate device, the 510(k) cleared ID NOW Influenza A & B 2.

Parameter	ID NOW™ Influenza A & B 2 (with software modification)	ID NOW™ Influenza A & B 2 (K220801)
FDA Product Code	OCC,OZE, OOI	Same
Assay Target	Influenza A, Influenza B	Same
Intended Use	The ID NOW™ Influenza A & B 2 assay performed on the ID NOW™ Instrument is a rapid molecular <i>in vitro</i> diagnostic test utilizing an isothermal nucleic acid amplification technology for the qualitative detection and discrimination of influenza A and B viral RNA in direct nasal or nasopharyngeal swabs and nasal or	Same



Parameter	ID NOW™ Influenza A & B 2 (with software modification)	ID NOW™ Influenza A & B 2 (K220801)
	nasopharyngeal swabs eluted in viral transport media from patients with signs and symptoms of respiratory infection. It is intended for use as an aid in the differential diagnosis of influenza A and B viral infections in humans in conjunction with clinical and epidemiological risk factors. The assay is not intended to detect the presence of influenza C virus. Negative results do not preclude influenza virus infection and should not be used as the sole basis for diagnosis, treatment or other patient management decisions. Performance characteristics for influenza A were established during the 2012-2013 and the 2014-2015 influenza seasons when influenza A/H3 and A/H1N1 pandemic were the predominant influenza A viruses in circulation. When other influenza A viruses are emerging, performance characteristics may vary. If infection with a novel influenza A virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent Influenza viruses and sent to state or local health department for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.	
Intended Environment for Use	Professional use, in a medical laboratory or point of care	Same
Instrumentation	ID NOW™ Instrument	Same
Assay Information		
Sample Type	Nasopharyngeal Swab, Nasal Swab and Nasal or Nasopharyngeal Swabs Eluted in Viral Transport Media	Same
Influenza A Viral Target	PB2 segment	Same
Influenza B Viral Target	PA segment	Same
Technology	Isothermal nucleic acid amplification	Same
Internal Control	Yes	Same
Result Interpretation	Automated	Same
Assay Result	Qualitative	Same
Time to Result	< 15 minutes	Same