



August 31, 2026

Abbott Diagnostics Scarborough, Inc.
Stephanie Rose
Senior Specialist Regulatory Affairs
10 Southgate Rd.
Scarborough, Maine 04074

Re: K262747

Trade/Device Name: ID NOW Influenza A & B 2; ID NOW RSV; ID NOW Strep A 2; ID NOW
COVID-19 2.0

Regulation Number: 21 CFR 866.3980

Regulation Name: Respiratory viral panel multiplex nucleic acid assay

Regulatory Class: Class II

Product Code: OCC, OOI, OZE, PGX, QWR

Dated: August 1, 2026

Received: August 3, 2026

Dear Stephanie Rose:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

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

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

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

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

Sincerely,

JOSEPH BRIGGS -S

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

Enclosure

Indications for Use

510(k) Number (if known)

K262747

Device Name

ID NOW Influenza A & B 2; ID NOW RSV; ID NOW Strep A 2; ID NOW COVID-19 2.0

Indications for Use (Describe)

ID NOW Influenza A & B 2

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.

ID NOW RSV

The ID NOW RSV 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 of respiratory syncytial virus (RSV) viral RNA in direct nasopharyngeal swabs and 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 diagnosis of RSV in children <18 years and adults ≥60 years in conjunction with clinical and epidemiological risk factors.

ID NOW Strep A 2

ID NOW Strep A 2 is a rapid, instrument-based, molecular in vitro diagnostic test utilizing isothermal nucleic acid amplification technology for the qualitative detection of *Streptococcus pyogenes*, Group A *Streptococcus* bacterial nucleic acid in throat swab specimens obtained from patients with signs and symptoms of pharyngitis. It is intended to aid in the rapid diagnosis of Group A *Streptococcus* bacterial infections.

ID NOW COVID-19 2.0

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 coinfection 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.

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

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K262747 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: K262747

SUBMITTER

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Establishment Registration Number: 1221359

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DATE PREPARED

24 August 2026

TRADE NAME

ID NOW Influenza A & B 2
ID NOW Strep A 2
ID NOW RSV
ID NOW COVID-19 2.0

COMMON NAME

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

ID NOW™ Strep 2, Alere™ i Strep A 2

Alere™ i RSV

ID NOW™ COVID, ID NOW™ COVID-19

CLASSIFICATION NAME

Respiratory Viral Pan Multiplex Nucleic Acid System (per 21 CFR 866.3980)

Streptococcus spp Nucleic Acid-Based Assay (per 21 CFR 866.2680)

Instrumentation for Clinical Multiplex Test Systems (per 21 CFR 862.2570)

Respiratory Virus Panel Nucleic Acid System (per 21 CFR 866.3980)

Simple Point-Of-Care Device to Detect Sar-Cov-2 Nucleic Acid Targets from Clinical Specimens In Near-Patient Settings (per 21 CRR 866.3982)

CLASSIFICATION

Class II

PRODUCT CODE

OCC, OZE, OOI

PGX, OOI

OCC, OOI

QWR

PANEL

Microbiology (83)

PREDICATE DEVICE

ID NOW Influenza A & B 2, K232775

ID NOW Strep A 2, K220801

ID NOW RSV, K173932

ID NOW COVID-19 2.0, K221925

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.

ID NOW Strep A 2 is a rapid, instrument-based, molecular *in vitro* diagnostic test utilizing isothermal nucleic acid amplification technology for the qualitative detection of *Streptococcus pyogenes*, Group A *Streptococcus* bacterial nucleic acid in throat swab specimens obtained from patients with signs and symptoms of pharyngitis. It is intended to aid in the rapid diagnosis of Group A *Streptococcus* bacterial infections.

ID NOW RSV is a rapid molecular *in vitro* diagnostic test utilizing an isothermal nucleic acid amplification technology for the qualitative detection of respiratory syncytial virus (RSV) viral RNA in direct nasopharyngeal swabs and 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 diagnosis of RSV in children <18 years and adults ≥60 years in conjunction with clinical and epidemiological risk factors.

ID NOW COVID-19 2.0 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. A negative test result is presumptive, and it is recommended these results be confirmed by another molecular SARS-CoV-2 assay.

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.

The reaction tubes in the ID NOW Strep A 2 Test Base contain the reagents required for Group A Strep bacterial lysis and the subsequent amplification of the target nucleic acid and an internal control. ID NOW Strep A 2 utilizes a pair of templates (similar to primers) for the specific amplification of DNA from Group A Strep and a fluorescently labeled molecular beacon designed to specifically identify the amplified nucleic acid target.

The reaction tubes in the ID NOW RSV Test Base contain the reagents required for amplification of the target nucleic acid and an internal control. ID NOW RSV 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.

The reaction tubes in the ID NOW COVID-19 2.0 Test Base contain the reagents required for amplification of the target nucleic acid and an internal control. ID NOW COVID-19 2.0 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.

All ID NOW assays are 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 initiating bacterial lysis (for ID NOW™ Strep A 2) 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

ID NOW Influenza A & B 2

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.

ID NOW Strep A 2

ID NOW Strep A 2 is a rapid, instrument-based, molecular *in vitro* diagnostic test utilizing isothermal nucleic acid amplification technology for the qualitative detection of *Streptococcus pyogenes*, Group A *Streptococcus* bacterial nucleic acid in throat swab specimens obtained from patients with signs and symptoms of pharyngitis. It is intended to aid in the rapid diagnosis of Group A *Streptococcus* bacterial infections.

ID NOW RSV

The ID NOW RSV 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 of respiratory syncytial virus (RSV) viral RNA in direct nasopharyngeal swabs and 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 diagnosis of RSV in children <18 years and adults ≥60 years in conjunction with clinical and epidemiological risk factors

ID NOW COVID-19 2.0

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.

COMPARISON TO THE PREDICATE

The purpose of this Special 510(k) submission is to bring to market a modification of the operating system contained on the ID NOW Instrument. The Operating System was updated as the previous Operating System is nearing end of life. This is an operating system update only, there have been no changes made to the chemistry of the assays.

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 new operating system)	ID NOW Influenza A & B 2 (K232775)
FDA Product Code	OCC, OZE, OOI	Same
Assay Target	Influenza A, Influenza B	Same

Parameter	ID NOW Influenza A & B 2 (with new operating system)	ID NOW Influenza A & B 2 (K232775)
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 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. 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.	Same
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	Same

Parameter	ID NOW Influenza A & B 2 (with new operating system)	ID NOW Influenza A & B 2 (K232775)
	Nasopharyngeal Swabs Eluted in Viral Transport Media	
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

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

Parameter	ID NOW Strep A 2 (with new operating system)	ID NOW Strep A 2 (K220801)
FDA Product Code	PGX, OOI	Same
Assay Target	<i>Streptococcus pyogenes</i>	Same
Intended Use	ID NOW Strep A 2 is a rapid, instrument-based, molecular <i>in vitro</i> diagnostic test utilizing isothermal nucleic acid amplification technology for the qualitative detection of <i>Streptococcus pyogenes</i> , Group A <i>Streptococcus</i> bacterial nucleic acid in throat swab specimens obtained from patients with signs and symptoms of pharyngitis. It is intended to aid in the rapid diagnosis of Group A <i>Streptococcus</i> bacterial infections.	Same
Intended Environment for Use	Professional use, in a medical laboratory or point of care	Same
Instrumentation	ID NOW Instrument	Same
Assay Information		
Sample Type	Throat Swab	Same
Target Analyte	Group A <i>Streptococcus</i> (<i>Streptococcus pyogenes</i>)	Same
Technology	Isothermal nucleic acid amplification	Same

Parameter	ID NOW Strep A 2 (with new operating system)	ID NOW Strep A 2 (K220801)
Internal Control	Yes	Same
Result Interpretation	Automated	Same
Assay Result	Qualitative	Same
Time to Result	< 8 minutes	Same

ID NOW RSV incorporating the software modification was compared to the legally marketed predicate device, the 510(k) cleared ID NOW RSV.

Parameter	ID NOW RSV (with new operating system)	ID NOW RSV (K173932)
FDA Product Code	OCC, OOI	Same
Assay Target	RSV	Same
Intended Use	The ID NOW RSV 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 of respiratory syncytial virus (RSV) viral RNA in direct nasopharyngeal swabs and 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 diagnosis of RSV in children <18 years and adults ≥60 years in conjunction with clinical and epidemiological risk factors.	Same
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
Target Analyte	NS2 gene and nucleocapsid gene N	Same
Technology	Isothermal nucleic acid amplification	Same
Internal Control	Yes	Same
Result Interpretation	Automated	Same
Assay Result	Qualitative	Same

Parameter	ID NOW RSV (with new operating system)	ID NOW RSV (K173932)
Time to Result	<15 minutes	Same

ID NOW COVID-19 2.0 incorporating the software modification was compared to the legally marketed predicate device, the 510(k) cleared ID NOW COVID-19 2.0.

Parameter	ID NOW COVID-19 2.0 (with new operating system)	ID NOW COVID-19 2.0 (K221925)
FDA Product Code	QWR	Same
Assay Target	SARS-CoV-2 viral RNA	Same
Intended Use	ID NOW COVID-19 2.0 performed on the ID NOW Instrument is a rapid molecular <i>in vitro</i> 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	Same

Parameter	ID NOW COVID-19 2.0 (with new operating system)	ID NOW COVID-19 2.0 (K221925)
	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.	
Intended Environment for Use	Professional use, in a medical laboratory or point of care	Same
Instrumentation	ID NOW Instrument	Same
Assay Information		
Sample Type	Direct anterior nasal or nasopharyngeal swabs	Same
Target Analyte	RdRp gene	Same
Technology	Isothermal nucleic acid amplification	Same
Internal Control	Yes	Same
Result Interpretation	Automated	Same
Assay Result	Qualitative	Same
Time to Result	≤12 minutes	Same