August 27, 2025

Qiagen GmbH
℅ Melissa Mahall
Senior Director, Regulatory Affairs
Qiagen
19300 Germantown Road
Germantown, Maryland 20874

Re: K250080
Trade/Device Name: QIAstat-Dx Respiratory Panel Plus; QIAstat-Dx Respiratory Panel Mini
Regulation Number: 21 CFR 866.3981
Regulation Name: Device To Detect And Identify Nucleic Acid Targets In Respiratory Specimens From Microbial Agents That Cause The SARS-CoV-2 Respiratory Infection And Other Microbial Agents When In A Multi-Target Test
Regulatory Class: Class II
Product Code: QOF
Dated: February 14, 2025
Received: February 14, 2025

Dear Melissa Mahall:

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,

ANNA M. MIELECH -S

Anna Mielech, PhD.
Deputy Branch Chief (Acting)
Viral Respiratory and HPV Branch
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

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K250080

Device Name
QIAstat-Dx Respiratory Panel Plus
QIAstat-Dx Respiratory Panel Mini

Indications for Use *(Describe)*

QIAstat-Dx Respiratory Panel Plus:
The QIAstat-Dx Respiratory Panel Plus is a multiplexed nucleic acid test intended for use with the QIAstat-Dx system for the simultaneous in vitro qualitative detection and identification of multiple respiratory viral and bacterial nucleic acids in nasopharyngeal swabs (NPS) obtained from individuals with clinical signs and symptoms of respiratory tract infections, including Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2).

The following organism types and subtypes are identified using the QIAstat-Dx Respiratory Panel Plus: Adenovirus, Human Coronavirus 229E, Human Coronavirus HKU1, Human Coronavirus NL63, Human Coronavirus OC43, Human Metapneumovirus, Influenza A, Influenza A H1, Influenza A H1N1 pdm09, Influenza A H3, Influenza B, Parainfluenza Virus 1, Parainfluenza Virus 2, Parainfluenza Virus 3, Parainfluenza Virus 4, Respiratory Syncytial Virus, Human Rhinovirus/Enterovirus (not differentiated), SARS-CoV-2, Bordetella pertussis, Chlamydophila pneumoniae, and Mycoplasma pneumoniae.

Nucleic acids from viral and bacterial organisms identified by this test are generally detectable in NPS specimens during the acute phase of infection. Detecting and identifying specific viral and bacterial nucleic acids from individuals presenting with signs and symptoms of a respiratory infection aids in the diagnosis of respiratory infection, if used in conjunction with other clinical, epidemiological and laboratory findings. The results of this test should not be used as the sole basis for diagnosis, treatment or other patient management decisions.

Negative results in the presence of a respiratory illness may be due to infection with pathogens that are not detected by the test, or due to lower respiratory tract infection that is not detected by a NPS specimen.

Conversely, positive results are indicative of the presence of the identified microorganism, but do not rule out co-infection with other pathogens not detected by the QIAstat-Dx Respiratory Panel Plus. The agent(s) detected by the QIAstat-Dx Respiratory Panel Plus may not be the definite cause of disease.

The use of additional laboratory testing (e.g., bacterial and viral culture, immunofluorescence, and radiography) may be necessary when evaluating a patient with possible respiratory tract infection.

QIAstat-Dx Respiratory Panel Mini:
The QIAstat-Dx Respiratory Panel Mini is a multiplexed nucleic acid test intended for use with the QIAstat-Dx system for the simultaneous in vitro qualitative detection and identification of multiple respiratory viral nucleic acids in nasopharyngeal swabs (NPS) obtained from individuals with clinical signs and symptoms of respiratory tract infections, including Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2).

The following viruses are identified using the QIAstat-Dx Respiratory Panel Mini: Influenza A, Influenza B, Respiratory Syncytial Virus, Human Rhinovirus, and SARS-CoV-2.

Nucleic acids from viral organisms identified by this test are generally detectable in NPS specimens during the acute phase of infection. Detecting and identifying specific viral nucleic acids from individuals presenting with signs and symptoms of a respiratory infection aids in the diagnosis of respiratory infection, if used in conjunction with other clinical, epidemiological and laboratory findings. The results of this test should not be used as the sole basis for diagnosis,

treatment or other patient management decisions.

Negative results in the presence of a respiratory illness may be due to infection with pathogens that are not detected by the test or due to lower respiratory tract infection that is not detected by a NPS specimen.

Conversely, positive results are indicative of the presence of the identified microorganism, but do not rule out co-infection with other pathogens not detected by the QIAstat-Dx Respiratory Panel Mini. The agent(s) detected by the QIAstat-Dx Respiratory Panel Mini may not be the definite cause of disease.

The use of additional laboratory testing (e.g., bacterial and viral culture, immunofluorescence, and radiography) may be necessary when evaluating a patient with possible respiratory tract infection.

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

General Information

Submitted by: QIAGEN GmbH
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Date Prepared: August 26, 2025

Device Name: QIAstat-Dx Respiratory Panel Plus
QIAstat-Dx Respiratory Panel Mini

Classification: 21 CFR 866.3981 - Device To Detect And Identify Nucleic Acid Targets In Respiratory Specimens From Microbial Agents That Cause The SARS-CoV-2 Respiratory Infection And Other Microbial Agents When In A Multi-Target Test

Product Code: QOF

Predicate Device: QIAstat-Dx Respiratory Panel Plus, K233100
QIAstat-Dx Respiratory Panel Mini, K242353

Device Description

The QIAstat-Dx Respiratory Panel Plus and the QIAstat-Dx Respiratory Panel Mini are multiplexed nucleic acid tests which are designed for use with the QIAstat-Dx system (currently QIAstat-Dx Analyzer 1.0 and QIAstat-Dx Analyzer 2.0). The device modification is to add the QIAstat-Dx Rise as an additional instrument for use with the QIAstat-Dx Respiratory Panel Plus and the QIAstat-Dx Respiratory Panel Mini ("QIAstat-Dx Respiratory Panels"). The QIAstat-Dx Rise is a higher throughput platform, incorporating up to eight QIAstat-Dx Analytical Modules (AM) on a small footprint. The instrument allows queuing up to 18 cartridges, which are scheduled for processing and delivered to the appropriate AM by an integrated robotic handler. The AM used with the QIAstat-Dx Rise is the same AM that can be used with the QIAstat-Dx Analyzer 1.0 or 2.0.

The modified QIAstat-Dx Respiratory Panel Plus and QIAstat-Dx Respiratory Panel Mini are identical to the QIAstat-Dx Respiratory Panel Plus (K233100) and the QIAstat-Dx Respiratory Panel Mini (K242353), respectively, with the exception of the Instructions for Use which were updated to include the assay-specific procedure for the QIAstat-Dx Rise.

The QIAstat-Dx Respiratory Panels are intended to be used with one nasopharyngeal swab (NPS) eluted in Universal Transport Media (UTM), which is not provided with the QIAstat-Dx Respiratory Panels.

All the reagents required for the complete execution of the test are pre-loaded and self-contained in a QIAstat-Dx Respiratory Panel cartridge. The user does not need to manipulate any reagents. During the test, reagents are handled by pneumatically-operated microfluidics without any direct contact with the user or the analyzer actuators.

Within the cartridge, multiple steps are automatically performed in sequence by using pneumatic pressure and a multiport valve to transfer the sample and fluids via the Transfer Chamber (TC) to their intended destinations. Following the introduction of the sample from a disposable transfer pipette, the following assay steps occur automatically and sequentially:

- Resuspension of Internal Control
- Cell lysis using mechanical and/or chemical means
- Membrane-based nucleic acid purification
- Mixing of the purified nucleic acid with lyophilized master mix reagents
- Transfer of defined aliquots of eluate/master mix to different reaction chambers
- Performance of multiplex real-time RT-PCR testing within each reaction chamber

The QIAstat-Dx Respiratory Panel Assay Definition File (ADF) automatically interprets test results and displays a summary on the instrument display screen. The detected analytes are displayed in red. All other tested but not detected analytes are listed in green. The instrument will report if an error occurs during processing, in which case the test will fail and no results will be provided (screen will show "FAIL").

Intended Use

QIAstat-Dx Respiratory Panel Plus

The QIAstat-Dx Respiratory Panel Plus is a multiplexed nucleic acid test intended for use with the QIAstat-Dx system for the simultaneous in vitro qualitative detection and identification of multiple respiratory viral and bacterial nucleic acids in nasopharyngeal swabs (NPS) obtained from individuals with clinical signs and symptoms of respiratory tract infections, including Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2).

The following organism types and subtypes are identified using the QIAstat-Dx Respiratory Panel Plus: Adenovirus, Human Coronavirus 229E, Human Coronavirus HKU1, Human Coronavirus NL63, Human Coronavirus OC43, Human Metapneumovirus, Influenza A, Influenza A H1, Influenza A H1N1 pdm09, Influenza A H3, Influenza B, Parainfluenza Virus 1, Parainfluenza Virus 2, Parainfluenza Virus 3, Parainfluenza Virus 4, Respiratory Syncytial Virus, Human Rhinovirus/Enterovirus (not differentiated), SARS-CoV-2, *Bordetella pertussis*, *Chlamydophila pneumoniae*, and *Mycoplasma pneumoniae*.

Nucleic acids from viral and bacterial organisms identified by this test are generally detectable in NPS specimens during the acute phase of infection. Detecting and identifying specific viral and bacterial nucleic acids from individuals presenting with signs and symptoms of a respiratory infection aids in the diagnosis of respiratory infection, if used in conjunction with other clinical, epidemiological and laboratory findings. The results of this test should not be used as the sole basis for diagnosis, treatment or other patient management decisions.

Negative results in the presence of a respiratory illness may be due to infection with pathogens that are not detected by the test, or due to lower respiratory tract infection that is not detected by a NPS specimen.

Conversely, positive results are indicative of the presence of the identified microorganism, but do not rule out co-infection with other pathogens not detected by the QIAstat-Dx Respiratory Panel Plus. The agent(s) detected by the QIAstat-Dx Respiratory Panel Plus may not be the definite cause of disease.

The use of additional laboratory testing (e.g., bacterial and viral culture, immunofluorescence, and radiography) may be necessary when evaluating a patient with possible respiratory tract infection.

QIAstat-Dx Respiratory Panel Mini

The QIAstat-Dx Respiratory Panel Mini is a multiplexed nucleic acid test intended for use with the QIAstat-Dx system for the simultaneous in vitro qualitative detection and identification of multiple respiratory viral nucleic acids in nasopharyngeal swabs (NPS) obtained from individuals with clinical signs and symptoms of respiratory tract infections, including Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2).

The following viruses are identified using the QIAstat-Dx Respiratory Panel Mini: Influenza A, Influenza B, Respiratory Syncytial Virus, Human Rhinovirus, and SARS-CoV-2.

Nucleic acids from viral organisms identified by this test are generally detectable in NPS specimens during the acute phase of infection. Detecting and identifying specific viral nucleic acids from individuals presenting with signs and symptoms of a respiratory infection aids in the diagnosis of respiratory infection, if used in conjunction with other clinical, epidemiological and laboratory findings. The results of this test should not be used as the sole basis for diagnosis, treatment or other patient management decisions.

Negative results in the presence of a respiratory illness may be due to infection with pathogens that are not detected by the test or due to lower respiratory tract infection that is not detected by a NPS specimen.

Conversely, positive results are indicative of the presence of the identified microorganism, but do not rule out co-infection with other pathogens not detected by the QIAstat-Dx Respiratory Panel Mini. The agent(s) detected by the QIAstat-Dx Respiratory Panel Mini may not be the definite cause of disease.

The use of additional laboratory testing (e.g., bacterial and viral culture, immunofluorescence, and radiography) may be necessary when evaluating a patient with possible respiratory tract infection.

Comparison of the QIAstat-Dx Respiratory Panels with QIAstat-Dx Rise and the Predicate Devices

Similarities and differences between the QIAstat-Dx Respiratory Panel Plus with QIAstat-Dx Rise and QIAstat-Dx Respiratory Panel Mini with QIAstat-Dx Rise and the predicate devices are shown in Table 1 and Table 2, respectively.

Table 1: Comparison of the QIAstat-Dx Respiratory Panel Plus with QIAstat-Dx Rise with the predicate device

Characteristic	Subject Device	Predicate
Name	QIAstat-Dx Respiratory Panel Plus	QIAstat-Dx Respiratory Panel Plus
510(k) No.	K250080	K233100
Regulation	21 CFR 866.3981	21 CFR 866.3981
Product Code	QOF	QOF
Device Class	Class II	Class II
Similarities		
Intended Use/Indications for Use	The QIAstat-Dx Respiratory Panel Plus is a multiplexed nucleic acid test intended for use with the QIAstat-Dx system for the simultaneous in vitro qualitative detection and identification of multiple respiratory viral and bacterial nucleic acids in nasopharyngeal swabs (NPS) obtained from individuals with clinical signs and symptoms of respiratory tract infections, including Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2). The following organism types and subtypes are identified using the QIAstat-Dx Respiratory Panel Plus: Adenovirus, Human Coronavirus 229E, Human Coronavirus HKU1, Human Coronavirus NL63, Human Coronavirus OC43, Human Metapneumovirus, Influenza A, Influenza A H1, Influenza A H1N1 pdm09, Influenza A H3, Influenza B, Parainfluenza Virus 1, Parainfluenza Virus 2, Parainfluenza Virus 3,	The QIAstat-Dx Respiratory Panel Plus is a multiplexed nucleic acid test intended for use with the QIAstat-Dx system for the simultaneous in vitro qualitative detection and identification of multiple respiratory viral and bacterial nucleic acids in nasopharyngeal swabs (NPS) obtained from individuals with clinical signs and symptoms of respiratory tract infection, including SARS-CoV-2. The following organism types and subtypes are identified using the QIAstat-Dx Respiratory Panel Plus: Adenovirus, Human Coronavirus 229E, Human Coronavirus HKU1, Human Coronavirus NL63, Human Coronavirus OC43, Human Metapneumovirus, Influenza A, Influenza A H1, Influenza A H1N1 pdm09, Influenza A H3, Influenza B, Parainfluenza virus 1, Parainfluenza virus 2, Parainfluenza virus 3, Parainfluenza virus 4, Respiratory Syncytial Virus, Human

Characteristic	Subject Device	Predicate
	Parainfluenza Virus 4, Respiratory Syncytial Virus, Human Rhinovirus/Enterovirus (not differentiated), SARS-CoV-2, *Bordetella pertussis*, *Chlamydophila pneumoniae*, and *Mycoplasma pneumoniae*. Nucleic acids from viral and bacterial organisms identified by this test are generally detectable in NPS specimens during the acute phase of infection. Detecting and identifying specific viral and bacterial nucleic acids from individuals presenting with signs and symptoms of a respiratory infection aids in the diagnosis of respiratory infection, if used in conjunction with other clinical, epidemiological and laboratory findings. The results of this test should not be used as the sole basis for diagnosis, treatment or other patient management decisions. Negative results in the presence of a respiratory illness may be due to infection with pathogens that are not detected by the test, or due to lower respiratory tract infection that is not detected by a NPS specimen. Conversely, positive results are indicative of the presence of the identified microorganism, but do not rule out co-infection with other pathogens not detected by the QIAstat-Dx Respiratory Panel Plus. The agent(s) detected by the QIAstat-Dx Respiratory Panel Plus may not be the definite cause of disease.	Rhinovirus/Enterovirus (not differentiated), Severe Acute Respiratory Syndrome Coronavirus (SARS-CoV-2), *Bordetella pertussis*, *Chlamydophila pneumoniae* and *Mycoplasma pneumoniae*. Nucleic acids from viral and bacterial organisms identified by this test are generally detectable in NPS specimens during the acute phase of infection. Detecting and identifying specific viral and bacterial nucleic acids from individuals presenting with signs and symptoms of a respiratory infection aids in the diagnosis of respiratory infection, if used in conjunction with other clinical, epidemiological and laboratory findings. The results of this test should not be used as the sole basis for diagnosis, treatment or other patient management decisions. Negative results in the presence of a respiratory illness may be due to infection with pathogens that are not detected by the test or due to lower respiratory tract infection that is not detected by a NPS specimen. Conversely, positive results are indicative of the presence of the identified microorganism, but do not rule out co-infection with other pathogens not detected by the QIAstat-Dx Respiratory Panel Plus. The agent(s) detected by the QIAstat-Dx Respiratory Panel Plus may not be the definite cause of disease.

Characteristic	Subject Device	Predicate
	The use of additional laboratory testing (e.g., bacterial and viral culture, immunofluorescence, and radiography) may be necessary when evaluating a patient with possible respiratory tract infection.	The use of additional laboratory testing (e.g., bacterial and viral culture, immunofluorescence and radiography) may be necessary when evaluating a patient with possible respiratory tract infection.
Specimen Type	Same	Nasopharyngeal swabs (NPS)
Amplification and Detection Technology	Same	PCR
Assay Controls	Same	One internal control in each cartridge to control for sample processing that is subjected to all nucleic acid extraction and amplification steps similar to patient samples. Instructions for Use indicates quality control requirements should be performed in conformance with local, state, and/or federal regulations or accreditation requirements and the laboratory's standard quality control procedures.
Nucleic Acid Extraction	Same	Extraction of nucleic acids using spin columns
Technology	Same	Detection of amplified targets uses an increase in fluorescence to generate the assay results.
Operational	Same	The sample is loaded straight into the cartridge.
Assay Targets	Same	Twenty-one (21) targets
Differences		
Amplification and Detection Instrument System	QIAstat-Dx Analyzer 1.0, QIAstat-Dx Analyzer 2.0, and QIAstat-Dx Rise	QIAstat-Dx Analyzer 1.0 and QIAstat-Dx Analyzer 2.0

Table 2: Comparison of the QIAstat-Dx Respiratory Panel Mini with QIAstat-Dx Rise with the predicate device

Characteristic	Subject Device	Predicate
Name	QIAstat-Dx Respiratory Panel Mini	QIAstat-Dx Respiratory Panel Mini
510(k) No.	K250080	K242353
Regulation	21 CFR 866.3981	21 CFR 866.3981
Product Code	QOF	QOF

Characteristic	Subject Device	Predicate
Device Class	Class II	Class II
Similarities		
Intended Use/Indications for Use	The QIAstat-Dx Respiratory Panel Mini is a multiplexed nucleic acid test intended for use with the QIAstat-Dx system for the simultaneous in vitro qualitative detection and identification of multiple respiratory viral nucleic acids in nasopharyngeal swabs (NPS) obtained from individuals with clinical signs and symptoms of respiratory tract infections, including Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2). The following viruses are identified using the QIAstat-Dx Respiratory Panel Mini: Influenza A, Influenza B, Respiratory Syncytial Virus, Human Rhinovirus, and SARS-CoV-2. Nucleic acids from viral organisms identified by this test are generally detectable in NPS specimens during the acute phase of infection. Detecting and identifying specific viral nucleic acids from individuals presenting with signs and symptoms of a respiratory infection aids in the diagnosis of respiratory infection, if used in conjunction with other clinical, epidemiological and laboratory findings. The results of this test should not be used as the sole basis for diagnosis, treatment or other patient management decisions. Negative results in the presence of a respiratory illness may be due to infection with pathogens that are not detected by the test or due to	The QIAstat-Dx Respiratory Panel Mini is a multiplexed nucleic acid test intended for use with the QIAstat-Dx system for the simultaneous in vitro qualitative detection and identification of multiple respiratory viral nucleic acids in nasopharyngeal swabs (NPS) obtained from individuals with clinical signs and symptoms of respiratory tract infections, including Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2). The following viruses are identified using the QIAstat-Dx Respiratory Panel Mini: Influenza A, Influenza B, Respiratory Syncytial Virus, Human Rhinovirus, and SARS-CoV-2. Nucleic acids from viral organisms identified by this test are generally detectable in NPS specimens during the acute phase of infection. Detecting and identifying specific viral nucleic acids from individuals presenting with signs and symptoms of a respiratory infection aids in the diagnosis of respiratory infection, if used in conjunction with other clinical, epidemiological and laboratory findings. The results of this test should not be used as the sole basis for diagnosis, treatment or other patient management decisions. Negative results in the presence of a respiratory illness may be due to infection with pathogens that are not detected by the test or due to

Characteristic	Subject Device	Predicate
	lower respiratory tract infection that is not detected by a NPS specimen. Conversely, positive results are indicative of the presence of the identified microorganism, but do not rule out co-infection with other pathogens not detected by the QIAstat-Dx Respiratory Panel Mini. The agent(s) detected by the QIAstat-Dx Respiratory Panel Mini may not be the definite cause of disease. The use of additional laboratory testing (e.g., bacterial and viral culture, immunofluorescence, and radiography) may be necessary when evaluating a patient with possible respiratory tract infection.	lower respiratory tract infection that is not detected by a NPS specimen. Conversely, positive results are indicative of the presence of the identified microorganism, but do not rule out co-infection with other pathogens not detected by the QIAstat-Dx Respiratory Panel Mini. The agent(s) detected by the QIAstat-Dx Respiratory Panel Mini may not be the definite cause of disease. The use of additional laboratory testing (e.g., bacterial and viral culture, immunofluorescence, and radiography) may be necessary when evaluating a patient with possible respiratory tract infection.
Specimen Type	Same	Nasopharyngeal swabs (NPS)
Amplification and Detection Technology	Same	PCR
Assay Controls	Same	One internal control in each cartridge to control for sample processing that is subjected to all nucleic acid extraction and amplification steps similar to patient samples. Instructions for Use indicates quality control requirements should be performed in conformance with local, state, and/or federal regulations or accreditation requirements and the laboratory's standard quality control procedures.
Nucleic Acid Extraction	Same	Extraction of nucleic acids using spin columns
Technology	Same	Detection of amplified targets uses an increase in fluorescence to generate the assay results.
Operational	Same	The sample is loaded straight into the cartridge.

Characteristic	Subject Device	Predicate
Assay Targets	Same	Five (5) targets
Differences		
Amplification and Detection Instrument System	QIAstat-Dx Analyzer 1.0, QIAstat-Dx Analyzer 2.0, and QIAstat-Dx Rise	QIAstat-Dx Analyzer 1.0 and QIAstat-Dx Analyzer 2.0

Summary of Performance Data:

The performance for the QIAstat-Dx Respiratory Panel Plus and the QIAstat-Dx Respiratory Panel Mini with QIAstat-Dx Rise is equivalent to the performance for the QIAstat-Dx Respiratory Panel Plus (K233100) and the QIAstat-Dx Respiratory Panel Mini (K242353).

The following analytical studies were performed on the QIAstat-Dx Rise and successfully demonstrated the equivalent performance of the QIAstat-Dx Respiratory Panel Plus and the QIAstat-Dx Respiratory Panel Mini:

- Equivalence at Low Analyte Concentration
- Carryover
- Reproducibility

Conclusions

The technological characteristics and the indications for use of the QIAstat-Dx Respiratory Panel Plus and the QIAstat-Dx Respiratory Panel Mini remain the same. Validation data and information submitted in this premarket notification to add QIAstat-Dx Rise demonstrate that the modified QIAstat-Dx Respiratory Panel Plus and QIAstat-Dx Respiratory Panel Mini are substantially equivalent to the predicate devices.