510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT

I Background Information:

A 510(k) Number

K250080

B Applicant

Qiagen GmbH

C Proprietary and Established Names

QIAstat-Dx Respiratory Panel Plus; QIAstat-Dx Respiratory Panel Mini

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
QOF	Class II	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	MI - Microbiology

II Submission/Device Overview:

A Purpose for Submission:

The purpose of this submission is to modify the previously cleared QIAstat-Dx Respiratory Panel Plus (K233100) and the QIAstat-Dx Respiratory Panel Mini (K242353), to add the QIA-stat Dx Rise instrument.

B Measurand:

The QIAstat Respiratory Panel Plus detects and identifies nucleic acids from the following pathogens:

- Severe Acute Respiratory Syndrome (SARS)-Coronavirus-2 (SARS-CoV-2) [RNA-dependent-RNA-polymerase gene (RdRp) & Envelope protein gene (E)]
- Adenovirus [Hexon gene]
- Human Coronavirus 229E [Membrane protein gene (M)]
- Human Coronavirus HKU1 [Nucleocapsid protein gene (N)]
- Human Coronavirus NL63 [Nucleocapsid protein gene (N)]
- Human Coronavirus OC43 [Nucleocapsid protein gene (N)]
- Human Metapneumovirus A+B [A/B Nucleoprotein gene (N)]
- Influenza A [Matrix gene (M)]
- Influenza A H1 [Hemagglutinin gene (HA)]
- Influenza A H1N1 pdm09 [Neuraminidase gene (NA)]
- Influenza A H3 [Hemagglutinin gene (HA)]
- Influenza B [Nucleoprotein gene (M)]
- Parainfluenza virus 1 [Hemagglutinin-neuraminidase glycoprotein gene (HN)]
- Parainfluenza virus 2 [Hemagglutinin-neuraminidase glycoprotein gene (HN)]
- Parainfluenza virus 3 [Phosphoprotein gene (P)]
- Parainfluenza virus 4 [Nucleocapsid protein gene (N)]
- Respiratory Syncytial Virus A+B [Matrix protein gene (M)]
- Rhinovirus/Enterovirus* [5'-UTR region]
- *Bordetella pertussis* [Transposase Insertion Sequence (IS481)]
- *Chlamydophila pneumoniae* [Major outer membrane protein gene (ompA)]
- *Mycoplasma pneumoniae* [Cytadhesin gene (P1)]

*Both Rhinovirus and Enterovirus are detected but not differentiated.

The QIAstat Respiratory Panel Mini detects and identifies nucleic acids from the following pathogens:

- Severe Acute Respiratory Syndrome (SARS)-Coronavirus-2 (SARS-CoV-2) [RNA-dependent-RNA-polymerase gene (RdRp) & Envelope protein gene (E)]
- Influenza A [Matrix gene (M)]
- Influenza B [Nucleoprotein gene (M)]
- Respiratory Syncytial Virus A+B [Matrix protein gene (M)]
- Rhinovirus[#] [5'-UTR region]

#Both Rhinovirus and Enterovirus are detected but not differentiated.

C Type of Test:

Multiplexed real-time polymerase chain reaction (RT-PCR) nucleic acid assay for use with the QIAstat-Dx System for the qualitative detection of viral and bacterial pathogens in individuals with signs and symptoms of respiratory tract infection.

III Intended Use/Indications for Use:

A Intended Use(s):

The 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.

The 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 (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 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 Mini. 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.

B Indication(s) for Use:

See Intended Use(s).

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only
For in vitro Diagnostic Use Only

D Special Instrument Requirements:

The QIAstat-Dx Respiratory Panel Plus and the QIAstat-Dx Respiratory Panel Mini are part of the QIAstat-Dx system and work only with QIAstat-Dx Analyzer 1.0, QIAstat-Dx Analyzer 2.0, or QIAstat-Dx Rise.

IV Device/System Characteristics:

A Device Description:

QIAstat-Dx Respiratory Panel Plus and QIAstat-Dx Respiratory Panel Mini
The QIAstat-Dx Respiratory Panel Plus and the QIAstat-Dx Respiratory Panel Mini are part of the QIAstat-Dx system and work with QIAstat-Dx Analyzer 1.0, QIAstat-Dx Analyzer 2.0, or QIAstat-Dx Rise. The QIAstat-Dx Respiratory Panel Plus Cartridge and the QIAstat-Dx Respiratory Panel Mini Cartridge are single-use cartridges that include all reagents needed for nucleic acid extraction, nucleic acid amplification, and detection of bacteria and viruses (or their

subtypes), including SARS-CoV-2, that cause respiratory symptoms. Testing requires a small specimen volume and minimal hands-on time, and the results are available in approximately one hour. The QIAstat-Dx Respiratory Panel Plus and the QIAstat-Dx Respiratory Panel Mini are intended to be used with one (l) nasopharyngeal swab (NPS) eluted in Universal Transport Media (UTM), which is not provided with the QIAstat-Dx Respiratory Panel Plus or the QIAstat-Dx Respiratory Panel Mini.

The QIAstat-Dx Rise is a higher throughput platform than QIAstat-Dx Analyzer 1.0 or 2.0, incorporating up to eight QIAstat-Dx Analytical Modules (AM). 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 is used with the QIAstat-Dx Analyzer 1.0 or 2.0.

B Principle of Operation:

Diagnostic tests with the QIAstat-Dx Respiratory Panel Plus and the QIAstat-Dx Respiratory Panel Mini are performed on the QIAstat-Dx Analyzer 1.0, QIAstat-Dx Analyzer 2.0, or QIAstat-Dx Rise. All of the sample preparation and analysis steps are performed automatically by the QIAstat-Dx Analyzer 1.0, QIAstat-Dx Analyzer 2.0, or QIAstat-Dx Rise. Samples are collected and loaded manually, with a transfer pipette provided with the test kit, into the QIAstat-Dx Respiratory Panel Plus or QIAstat-Dx Respiratory Panel Mini Cartridge.

All the reagents required for the complete execution of the test are pre-loaded and self-contained in the QIAstat-Dx Respiratory Panel Plus Cartridge or QIAstat-Dx Respiratory Panel Mini 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 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 air-dried internal control and Proteinase K (ProtK) enzyme using provided buffer and mixing with the liquid sample (IC Cavity and ProtK Cavity).
- Cell lysis using mechanical (rotation) and chemical (chaotropic and isotonic) means (lysis chamber).
- Membrane based nucleic acid purification from lysate by: - Mixing lysate with binding buffer and capturing on the membrane (purification chamber).
    - First washing of membrane to remove bound proteins (purification chamber and waste chamber).
    - Second washing of membrane to leave only bound nucleic acids (purification chamber and waste chamber).
    - Rinsing of Transfer Chamber (TC) using the rinsing buffer before introduction of the eluate (TC).
    - Drying of membrane with bound nucleic acids with air flow generated by a high flow vacuum pump (purification chamber).
    - Elution of nucleic acids with elution buffer (purification chamber and TC).
- Mixing of the purified nucleic acid (eluate) with lyophilized “Master Mix” reagents (dry chemistry container and TC).

- Sequential transfer of defined aliquots of mixed eluate/Master Mix from the Transfer Chamber to each of eight Reaction Chambers containing the specified, air dried primers and probes. Note that each target specific probe contains a specific fluorescent dye that permits differentiation of target specific amplification within each Reaction Chamber).
- Within each Reaction Chamber, real-time, multiplex PCR ("rtPCR") testing is performed. Increase in fluorescence (indicative of detection of each target analyte) is detected directly within each Reaction Chamber.
- The detected signal per fluorescent marker per Reaction Chamber is then used by the system software to generate the assay result.

The QIAstat-Dx Analyzer 1.0, QIAstat-Dx Analyzer 2.0, or QIAstat-Dx Rise automatically interprets test results and displays a summary on the display screen. The results can be printed using a connected printer if needed. The detected analytes are displayed in red. All other tested but not detected analytes are listed in green. The analyzer 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").

C Instrument Description Information:

1. Instrument Name:
   QIAstat-Dx Analyzer 1.0 with software version 1.4 or 1.5
   QIAstat-Dx Analyzer 2.0 with software version 1.6 or higher
   QIAstat-Dx Rise with software version 2.4 or higher

2. Specimen Identification:
   Each instrument is a fully automated instrument that is bi-directionally interfaced and accepts orders from the LIS system. While test orders can be manually programmed through the attached instrument computer, an LIS-generated barcode can also be scanned to initiate testing.

3. Specimen Sampling and Handling:
   Nasopharyngeal swab (NPS) specimens collected in transport medium.

4. Calibration:
   Each instrument is provided factory-calibrated and does not require user calibration.

5. Quality Control:
   Please refer to the Quality Control information previously reviewed and presented in the K233100 FDA Decision Summary.

V Substantial Equivalence Information:

A Predicate Device Name(s):
QIAstat-Dx Respiratory Panel Plus, QIAstat-Dx Respiratory Panel Mini

B Predicate 510(k) Number(s):
K233100 (QIAstat-Dx Respiratory Panel Plus), K242353 (QIAstat-Dx Respiratory Panel Mini)

C Comparison with Predicate(s):

Table 1. QIAstat-Dx Respiratory Panel Plus Substantial Equivalence Comparison.

Device & Predicate Device(s):	K250080 (Subject)	K233100 (Predicate)
Device Trade Name	QIAstat-Dx Respiratory Panel Plus	QIAstat-Dx Respiratory Panel Plus
Regulation	21 CFR 866.3981	21 CFR 866.3981
Product Code	QOF	QOF
Device Class	Class II	Class II
General Device Characteristic 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, Parainfluenza Virus 4, Respiratory Syncytial Virus, Human Rhinovirus/Enterovirus (not	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 HK.Ul, Human Coronavirus NL63, Human Coronavirus OC43, Human Metapneumovirus, Influenza A, Influenza A Hl, Influenza A HlNl 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), Severe Acute Respiratory Syndrome Coronavirus (SARS-CoV-2), *Bordetella*

Device & Predicate Device(s):	K250080 (Subject)	K233100 (Predicate)
	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.	*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.

Device & Predicate Device(s):	K250080 (Subject)	K233100 (Predicate)
Specimen Type	Same	Nasopharyngeal swabs (NPS)
Assay Targets	Same	Twenty-one (21) targets
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.
General Device Characteristic 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
Cartridge loading into the QIAstat-Dx Analytical Module	QIAstat-Dx Analyzers – manual QIAstat-Dx Rise – automated	QIAstat-Dx Analyzers – manual
In-use Stability from opening cartridge package to loading cartridge into the QIAstat-Dx Instrument	QIAstat-Dx Analyzers – 120 minutes QIAstat-Dx Rise – 30 minutes	QIAstat-Dx Analyzers – 120 minutes

Table 2. QIAstat-Dx Respiratory Panel Mini Substantial Equivalence Comparison.

Device & Predicate Device(s):	K250080 (Subject)	K242353 (Predicate)
Device Trade Name	QIAstat-Dx Respiratory Panel Mini	QIAstat-Dx Respiratory Panel Mini
Regulation	21 CFR 866.3981	21 CFR 866.3981
Product Code	QOF	QOF
Device Class	Class II	Class II
General Device Characteristic 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 (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 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	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

Device & Predicate Device(s):	K250080 (Subject)	K242353 (Predicate)
	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 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.	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.
Specimen Type	Same	Nasopharyngeal swabs (NPS)
Assay Targets	Same	Five (5) targets
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

Device & Predicate Device(s):	K250080 (Subject)	K242353 (Predicate)
		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.
General Device Characteristic 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
Cartridge loading into the QIAstat-Dx Analytical Module	QIAstat-Dx Analyzers – manual QIAstat-Dx Rise – automated	QIAstat-Dx Analyzers – manual
In-use Stability from opening cartridge package to loading cartridge into the QIAstat-Dx Instrument	QIAstat-Dx Analyzers – 120 minutes QIAstat-Dx Rise – 30 minutes	QIAstat-Dx Analyzers – 120 minutes

VI Standards/Guidance Documents Referenced:

Standards

- ISO 14971 Third Edition 2019-12; Medical devices - Application of risk management to medical devices
- IEC 62304 Edition 1.1 2015-06; Medical device software - Software life cycle processes
- IEC 81001-5-1 Edition 1.0 2021-12; IEC 81001-5-1 Edition 1.0 2021-12; Health software and health IT systems safety effectiveness and security - Part 5-1: Security - Activities in the product life cycle
- IEC 61010-1 Edition 3.1 2017-01; Safety requirements for electrical equipment for measurement control and laboratory use - Part 1: General requirements [Including: Corrigendum 1 (2019)]
- IEC 60601-1-2 Edition 4.1 2020-09; Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 62366-1 Edition 1.1 2020-06; Medical devices - Part 1: Application of usability engineering to medical devices

Special Controls

- Class II Special Controls as per 21 CFR 866.3981

FDA Guidance Documents

- Highly Multiplexed Microbiological/Medical Countermeasure In Vitro Nucleic Acid Based Diagnostic Devices (August 2014)
- Class II Special Controls Guidance Document: Testing for Detection and Differentiation of Influenza A Virus Subtypes Using Multiplex Nucleic Acid Assays (October 2009)
- Content of Premarket Submissions for Device Software Functions (June 2023)

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:
   A reproducibility study of the QIAstat-Dx Respiratory Panel Plus and the automated loading in the QIAstat-Dx Rise system was conducted by operators at three sites using panels of representative combined analytes at moderate positive, low positive, and negative concentrations. Samples were prepared by spiking individual pathogens in simulated NPS matrix (**Table 3**). The testing was performed across five non-consecutive days using three operators, three instruments (one per site), and three reagent lots. Each operator performed two replicates per analyte at each sample concentration each testing day for a total of 90 datapoints per analyte and concentration (3 operators x 2 replicates x 3 sites x 5 days). The results are shown in **Table 4** and **Table 5**.

Table 3. Analyte Concentrations Used in the Reproducibility Study.

Analyte (Strain/Isolate)	Catalog #	Low Positive Concentration (1x LoD)	Moderate Positive Concentration (3x LoD)	Units
Influenza B (B/Taiwan/2/62)	ATCC VR-295	4.99E+01	1.50E+02	$TCID_{50}$/mL
Human coronavirus NL63	ZeptoMetrix 0810228CFHI	3.70E-02*	1.11E-01**	$TCID_{50}$/mL
Parainfluenza virus 3 (C-243)	ATCC VR-93	6.96E+00*	2.09E+01**	$TCID_{50}$/mL
Rhinovirus (HGP)	ATCC VR-482	8.88E+00	2.66E+01	$TCID_{50}$/mL
Adenovirus (G3)	ATCC VR-3	4.99E+03	1.5E+04	$TCID_{50}$/mL
Mycoplasma pneumoniae (PI 1428)	ATCC 29085	1.00E+00	3.00E+00	CCU/mL
SARS-CoV-2 (England/02/2020)	20/146	3.16E+02	9.48E+02	Copies/mL

* Human coronavirus NL63 and parainfluenza virus 3 was tested at or about 3x LoD.
** Human coronavirus NL63 and parainfluenza virus 3 was tested at 11x and 9x LoD, respectively.

Table 4. Agreement with the Expected Results in the Reproducibility Study (Results Applicable for the QIAstat-Dx Respiratory Panel Mini Are Reported in Blue).

Grouping Variable(s)			Agreement		Two-Sided 95% Confidence Limit	
Analyte	**Sample Type**	**Site**	**Fraction**	**Percentage**	**Lower**	**Upper**
Adenovirus	Low Positive	Site 1	30 / 30	100.00%	88.43%	100.00%
		Site 2	30 / 30	100.00%	88.43%	100.00%
		Site 3	30 / 30	100.00%	88.43%	100.00%
		Total	90 / 90	100.00%	95.98%	100.00%
	Moderate Positive	Site 1	30 / 30	100.00%	88.43%	100.00%
		Site 2	30 / 30	100.00%	88.43%	100.00%
		Site 3	30 / 30	100.00%	88.43%	100.00%
		Total	90 / 90	100.00%	95.98%	100.00%
Human coronavirus NL63	Low Positive	Site 1	30 / 30	100.00%	88.43%	100.00%
		Site 2	30 / 30	100.00%	88.43%	100.00%
		Site 3	30 / 30	100.00%	88.43%	100.00%
		Total	90 / 90	100.00%	95.98%	100.00%
	Moderate Positive	Site 1	30 / 30	100.00%	88.43%	100.00%
		Site 2	30 / 30	100.00%	88.43%	100.00%
		Site 3	30 / 30	100.00%	88.43%	100.00%
		Total	90 / 90	100.00%	95.98%	100.00%
Influenza B	Low Positive	Site 1	30 / 30	100.00%	88.43%	100.00%
		Site 2	30 / 30	100.00%	88.43%	100.00%
		Site 3	30 / 30	100.00%	88.43%	100.00%
		Total	90 / 90	100.00%	95.98%	100.00%
	Moderate Positive	Site 1	30 / 30	100.00%	88.43%	100.00%
		Site 2	30 / 30	100.00%	88.43%	100.00%
		Site 3	30 / 30	100.00%	88.43%	100.00%
		Total	90 / 90	100.00%	95.98%	100.00%
Mycoplasma pneumoniae	Low Positive	Site 1	29 / 30	96.67%	82.78%	99.92%
		Site 2	30 / 30	100.00%	88.43%	100.00%
		Site 3	30 / 30	100.00%	88.43%	100.00%
		Total	89 / 90	98.89%	93.96%	99.97%
	Moderate Positive	Site 1	30 / 30	100.00%	88.43%	100.00%
		Site 2	30 / 30	100.00%	88.43%	100.00%
		Site 3	30 / 30	100.00%	88.43%	100.00%
		Total	90 / 90	100.00%	95.98%	100.00%
Parainfluenza virus 3	Low Positive	Site 1	30 / 30	100.00%	88.43%	100.00%
		Site 2	30 / 30	100.00%	88.43%	100.00%
		Site 3	30 / 30	100.00%	88.43%	100.00%
		Total	90 / 90	100.00%	95.98%	100.00%
	Moderate Positive	Site 1	30 / 30	100.00%	88.43%	100.00%
		Site 2	30 / 30	100.00%	88.43%	100.00%
		Site 3	30 / 30	100.00%	88.43%	100.00%
		Total	90 / 90	100.00%	95.98%	100.00%
	Low Positive	Site 1	30 / 30	100.00%	88.43%	100.00%
		Site 2	30 / 30	100.00%	88.43%	100.00%

Grouping Variable(s)			Agreement		Two-Sided 95% Confidence Limit	
Analyte	Sample Type	Site	Fraction	Percentage	Lower	Upper
Human rhinovirus/ Enterovirus*		Site 3	30 / 30	100.00%	88.43%	100.00%
		Total	90 / 90	100.00%	95.98%	100.00%
	Moderate Positive	Site 1	30 / 30	100.00%	88.43%	100.00%
		Site 2	30 / 30	100.00%	88.43%	100.00%
		Site 3	30 / 30	100.00%	88.43%	100.00%
		Total	90 / 90	100.00%	95.98%	100.00%
SARS-CoV-2	Low Positive	Site 1	29 / 30	96.67%	82.78%	99.92%
		Site 2	30 / 30	100.00%	88.43%	100.00%
		Site 3	29 / 30	96.67%	82.78%	99.92%
		Total	88 / 90	97.78%	92.20%	99.73%
	Moderate Positive	Site 1	30 / 30	100.00%	88.43%	100.00%
		Site 2	30 / 30	100.00%	88.43%	100.00%
		Site 3	30 / 30	100.00%	88.43%	100.00%
		Total	90 / 90	100.00%	95.98%	100.00%
None	Negative	Site 1	30 / 30	100.00%	88.43%	100.00%
		Site 2	30 / 30	100.00%	88.43%	100.00%
		Site 3	30 / 30	100.00%	88.43%	100.00%
		Total	90 / 90	100.00%	95.98%	100.00%

*Reported as Human Rhinovirus in the QIAstat-Dx Respiratory Panel Mini.

Table 5. Precision Components in SD and CV% for Each Pathogen and Concentration, with 95% Confidence Intervals (Results Applicable for the QIAstat-Dx Respiratory Panel Mini Are Reported in Blue).

Pathogen	Sample Type	# of Amplified	# of Non-Amplified	Mean Ct	Between Site SD % CV	Between Operator Within Site SD % CV	Between Day Within Site SD % CV	Between Lot SD % CV	Residual* SD % CV	#Total** SD % CV
Adenovirus	Low	89	0	34.29	0.05 0.16%	0.00 0.00%	0.00 0.00%	0.02 0.07%	0.71 2.06%	0.71 2.07%
Human coronavirus NL63	3.7xLoD	90	0	34.06	0.12 0.36%	0.00 0.00%	0.09 0.26%	0.15 0.45%	0.44 1.30%	0.48 1.41%
Influenza B	1xLoD	90	0	33.98	0.22 0.64%	0.00 0.00%	0.00 0.00%	0.00 0.00%	0.74 2.18%	0.76 2.24%
Mycoplasma pneumoniae	1xLoD	89	1	33.72	0.08 0.25%	0.00 0.00%	0.00 0.00%	0.00 0.00%	0.73 2.16%	0.73 2.17%
Parainfluenza virus 3	3xLoD	90	0	33.35	0.17 0.50%	0.05 0.16%	0.00 0.00%	0.15 0.44%	0.51 1.53%	0.54 1.63%
Human rhinovirus/ Enterovirus***	1xLoD	90	0	34.10	0.05 0.14%	0.15 0.43%	0.00 0.00%	0.00 0.00%	0.53 1.54%	0.55 1.60%
SARS-CoV-2	1xLoD	88	2	35.33	0.00 0.00%	0.19 0.55%	0.00 0.00%	0.00 0.00%	0.50 1.41%	0.53 1.51%
Adenovirus	3xLoD	88	0	32.57	0.00 0.00%	0.00 0.00%	0.00 0.00%	0.18 0.55%	0.70 2.15%	0.72 2.20%

Pathogen	Sample Type	# of Amplified	# of Non-Amplified	Mean Ct	Between Site SD % CV	Between Operator Within Site SD % CV	Between Day Within Site SD % CV	Between Lot SD % CV	Residual* SD % CV	#Total** SD % CV
Human coronavirus NL63	11.1xLoD	90	0	32.49	0.00 0.00%	0.00 0.00%	0.00 0.00%	0.04 0.13%	0.34 1.04%	0.34 1.04%
Influenza B	3xLoD	90	0	32.20	0.00 0.00%	0.15 0.47%	0.00 0.00%	0.10 0.32%	0.56 1.74%	0.58 1.82%
Mycoplasma pneumoniae	3xLoD	90	0	32.02	0.00 0.00%	0.00 0.00%	0.00 0.00%	0.06 0.19%	0.52 1.63%	0.52 1.64%
Parainfluenza virus 3	9xLoD	88	0	31.64	0.00 0.00%	0.00 0.00%	0.00 0.00%	0.21 0.68%	0.50 1.57%	0.53 1.67%
Human rhinovirus/ Enterovirus***	3xLoD	89	0	32.78	0.12 0.37%	0.02 0.05%	0.13 0.39%	0.13 0.39%	0.46 1.40%	0.50 1.52%
SARS-CoV-2	3xLoD	89	0	34.16	0.00 0.00%	0.11 0.33%	0.11 0.31%	0.00 0.00%	0.36 1.05%	0.39 1.13%

*RESIDUAL refers to the within-run variability
**TOTAL means total variability observed across the study
***Reported as Human Rhinovirus in the QIAstat-Dx Respiratory Panel Mini

All negative, moderate positive, and low positive samples for all analytes exhibited acceptable performance. There were no significant differences observed within run, between lots, between days, between operators, or between sites (**Table 5**). Overall, Ct variability was low, and the study demonstrates assay variability within an acceptable range.

For the QIAstat-Dx Respiratory Panel Mini, the raw data generated with this study were reanalyzed using the Assay Definition File (ADF) corresponding to the QIAstat-Dx Respiratory Panel Mini. The reanalysis of the results using the QIAstat-Dx Respiratory Panel Mini Assay Definition File showed equivalent results to all the results obtained for the targets detected by both panels. Therefore, this study demonstrates the performance of the QIAstat-Dx Respiratory Panel Plus and the QIAstat-Dx Respiratory Panel Mini is reproducible for the conditions tested when used in combination with the QIAstat-Dx Rise system.

2. Linearity:
   Not applicable. The QIAstat-Dx Respiratory Panel Plus and the QIAstat-Dx Respiratory Panel Mini are qualitative assays.

3. Analytical Specificity/Interference:
   No new Analytical Specificity/Interference data were reviewed in this 510(k). The only modification to the QIAstat-Dx Respiratory Panel Plus and the QIAstat-Dx Respiratory Panel Mini in this 510(k) submission is the addition of the QIAstst-Dx Rise instrument. Refer to FDA Decision Summary K233100 for Analytical Specificity/Interference data FDA reviewed and accepted previously.

4. Assay Reportable Range:
   Not applicable. The QIAstat-Dx Respiratory Panel Plus and the QIAstat-Dx Respiratory Panel Mini are qualitative assays.

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

   a. Controls

      Refer to section IV. C. 5 above.

   b. In-Use Sample Stability

      In-use sample stability testing demonstrated that the QIAstat-Dx Respiratory Panel Plus cartridge performance is not impacted when removing the cartridge from its primary container, and loading with an NPS sample after 30 minutes at room temperature (15 – 25°C), followed by a wait time up to 300 minutes at 30ºC in the QIAstat-Dx Rise cartridge tray before running the cartridge.

      The generated in-use sample stability raw data were reanalyzed with the QIAstat-Dx Respiratory Panel Mini ADF demonstrating the same in-use sample stability claim for the QIAstat-Dx Respiratory Panel Mini.

6. Detection Limit:
   Please refer to the Detection Limit data previously reviewed and presented in the K233100 FDA Decision Summary.

7. Assay Cut-Off:
   Assay Cut-Off for SARS-CoV-2 was established in K233100 and K183597 for the other analytes. No changes were made with the addition of the QIAstat-Dx Rise as an amplification and detection instrument system. The QIAstat-Dx Rise uses the same Assay Definition File (ADF) as the QIAstat-Dx Analyzers (1.0/2.0) to run the QIAstat-Dx Respiratory Panels.

8. Accuracy (Instrument):
   Not Applicable.

9. Carry-Over:
   A Carry-Over study was previously conducted under K233100 to examine cross-contamination between consecutive runs and between cartridge chambers. Please refer to the Carry-Over study data reviewed and presented in the K233100 FDA Decision Summary. An additional Carry-Over study was performed using the QIAstat-Dx Respiratory Panel Plus to evaluate the potential for cross-contamination during automatic handling of cartridges by the robotic arm and during cartridge storage in the sample input drawer.

   A positive panel consisting of high concentrations of influenza B, parainfluenza virus 3, rhinovirus, *M. pneumoniae*, human coronavirus NL63, adenovirus, and SARS-CoV-2 were prepared in simulated NPS matrix. This positive panel was tested 22 times between runs of negative (no analyte) cartridges for a total of 8 runs and 18 cartridges/run (122 negative cartridges). No carryover between cartridges or chambers within the cartridges was observed.

   The reanalysis of the results using the QIAstat-Dx Respiratory Panel Mini Assay Definition File showed equivalent results to all the results obtained for the targets detected by both panels.

B Comparison Studies:

1. Method Comparison with Predicate Device:
   Not applicable.

2. Matrix Comparison:
   Please refer to the Matrix Comparison data previously reviewed and presented in the K233100 FDA Decision Summary.

C Clinical Studies:

1. Clinical Sensitivity:
   Please refer to the Clinical Sensitivity data previously reviewed and presented in the K233100 FDA Decision Summary.

2. Clinical Specificity:
   Please refer to the Clinical Specificity data previously reviewed and presented in the K233100 FDA Decision Summary.

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):
   Not applicable.

D Clinical Cut-Off:

Not applicable.

E Expected Values/Reference Range:

Please refer to the Expected Values data previously reviewed and presented in the K233100 FDA Decision Summary.

F Other Supportive Instrument Performance Characteristics Data:

Instrument Equivalency Study

A study was performed to assess whether the performance of the QIAstat-Dx Respiratory Panel Plus and the QIAstat-Dx Respiratory Panel Mini with the QIAstat-Dx Rise are equivalent to the performance with the QIAstat-Dx Analyzer 1.0 at low positive concentrations.

This study was initially performed for all targets included in the QIAstat-Dx Respiratory Panel Plus, except for SARS-CoV-2 (**Table 6**). Therefore, a second study was subsequently conducted that included SARS-CoV-2 and a representative panel of analytes included in the QIAstat-Dx Respiratory Panel Plus (**Table 7**). For each study, 20 replicates of co-spiked samples were tested at serial dilutions in the QIAstat-Dx Analyzer 1.0 until the lowest concentration where the target was detected ≥95% of the time was achieved. Then, the highest concentration where the target

was detected <95% of the time was also determined for each target. Then, the same concentrations were tested in the QIAstat-Dx Rise to evaluate the equivalency of both platforms. The results are summarized in **Tables 6-8**.

The reanalysis of the results using the QIAstat-Dx Respiratory Panel Mini Assay Definition File showed no discrepancies on the qualitative results (see **Table 6** and **Table 7**). The only difference between the results of the QIAstat-Dx Respiratory Panel Plus and QIAstat-Dx Respiratory Panel Mini was the masking of the influenza A subtype (see **Table 8**).

Thes studies demonstrate equivalence of the QIAstat-Dx Respiratory Panel Plus and the QIAstat-Dx Respiratory Panel Mini performed on the QIAstat-Dx Rise when compared to the QIAstat-Dx Analyzer 1.0.

Table 6. Results for the Instrument Equivalency Study for the QIAstat-Dx Respiratory Panel (Applicable Results to the QIAstat-Dx Respiratory Panel Mini Highlighted in Blue, Except for Influenza A - See Table 8).

Analyte	Concentration tested	QIAstat-Dx Analyzer 1.0		QIAstat-Dx Rise	
		Hit rate	Ct mean	Hit rate	Ct mean
Influenza B (B/Florida/4/2006) (ATCC VR- 1804)	1.08E+03 $CEID_{50}$/mL	20/20	32.7	20/20	32.3
	1.08E+02 $CEID_{50}$/mL	13/20	35.8	17/20	35.5
Human coronavirus HKU1 (Clinical sample)	4.00E+03 cop/mL	19/20	37.1	19/20	37.3
	4.00E+02 cop/mL	1/20	37.5	7/20	37.4
Parainfluenza virus 3 (ATCC VR-93)	2.32E+00 $TCID_{50}$/mL	20/20	35.8	20/20	35.0
	2.32E-01 $TCID_{50}$/mL	9/20	37.2	9/20	37.1
Rhinovirus A2 (ATCC VR- 482)	2.81E+01 $TCID_{50}$/mL	20/20	35.5	20/20	35.3
	8.88E+00 $TCID_{50}$/mL	18/20*	36.8	20/20	36.3
	2.81E+00 $TCID_{50}$/mL	10/20	37.4	15/20	37.4
Adenovirus B3 (ATCC VR-3)	4.99E+03 $TCID_{50}$/mL	19/20	34.8	20/20	35.0
	4.99E+02 $TCID_{50}$/mL	7/20	37.2	2/20	37.4
Mycoplasma pneumoniae (ATCC 29085)	1.00E+00 ccu/mL	20/20	34.0	20/20	33.7
	1.00E-01 ccu/mL	11/20	36.2	12/20	36.1
Influenza A H1N1 (New Caledonia/20/99)	1.44E+01 $TCID_{50}$/mL	19/20	35.8	20/20	35. 5

Analyte	Concentration tested	QIAstat-Dx Analyzer 1.0		QIAstat-Dx Rise	
		Hit rate	Ct mean	Hit rate	Ct mean
(ZeptoMetrix 0810036CFHI)	4.57E00 $TCID_{50}$/mL	17/20	36.2	14/20	36.7
Human coronavirus OC43 (ZeptoMetrix 0810024CFHI)	3.32E+00 U/mL	20/20	31.5	20/20	31.5
	3.32E-01 U/mL	17/20	35.3	20/20	35.3
	1.05E-01 U/mL	18/20*	35.9	20/20	35.4
	1.05E-02 U/mL	6/20	37.6	3/20	36.6
Parainfluenza virus 1 (ATCC VR-94)	1.58E+00 $TCID_{50}$/mL	19/20	36.4	19/20	36.4
	1.58E-01 $TCID_{50}$/mL	8/20	38.0	6/20	37.3
RSV A (ATCC VR-1540)	1.20E+02 PFU/mL	20/20	36.8	20/20	36.3
	1.20E+01 PFU/mL	6/20	36.9	6/20	37.4
B. pertussis (ATCC BAA- 2707)	2.70E-01 cfu/mL	20/20	35.2	19/20	35.5
	2.70E-02 cfu/mL	8/20	36.8	7/20	36.7
Influenza A H1N1 (pdm 09) (A/Virginia/ATCC1/2009) (ATCC VR-1736)	2.12E+01 PFU/mL	20/20	34.5	20/20	32.8
	6.70E+00 PFU/mL	18/20*	35.0	19/20	35.0
	6.70E-01 PFU/mL	10/20	37.3	6/20	36.3
Human coronavirus 229E (ATCC VR-740)	4.99E-01 $TCID_{50}$/ mL	19/20	36.0	20/20	35.8
	1.58E-02 $TCID_{50}$/ mL	18/20	37.0	18/20	37.0
Parainfluenza virus 4a (ATCC VR-1378)	5.06E-01 $TCID_{50}$/ mL	19/20	36.6	20/20	35.4
	5.06E-02 $TCID_{50}$/ mL+HH28:K28	8/20	36.9	14/20	36.8
Enterovirus D68 (ATCC VR-1824)	2.81E+01 $TCID_{50}$/mL	19/20	37.3	19/20	37.1
	2.81E+00 $TCID_{50}$/mL	3/20	37.0	5/20	37.1
Human metapneumovirus A1 (ZeptoMetrix 0810024CFHI)	1.51E+00 U/mL	20/20	35.3	19/20	34.5
	1.51E-01 U/mL	18/20	36.5	16/20	36.6

Analyte	Concentration tested	QIAstat-Dx Analyzer 1.0		QIAstat-Dx Rise	
		Hit rate	Ct mean	Hit rate	Ct mean
C. pneumoniae (ATCC VR- 2282)	1.42E+00 IFU/mL	20/20	33.1	20/20	33.3
	1.42E-01 IFU/mL	11/20	35.5	11/20	35.6
Human coronavirus NL63 (ZeptoMetrix 0810228CFHI)	3.70E-02 $TCID_{50}$/mL	20/20	35.8	20/20	36.1
	3.70E-03 $TCID_{50}$/mL	10/20	37.9	13/20	37.6
Parainfluenza virus 2 (ATCC VR-92)	7.33E+00 $TCID_{50}$/mL	20/20	34.2	19/20	34.9
	7.33E-01 $TCID_{50}$/mL	16/20	36.8	10/20	36.9
Influenza A H3N2 (A/Port Chalmers/1/73) (ATCC VR- 810)	4.99E+03 $CEID_{50}$/mL	20/20	31.7	20/20	31.5
	1.58E+03 $CEID_{50}$/mL	18/20*	34.6	20/20	34.2
	4.99E+02 $CEID_{50}$/mL	17/20	36.1	16/20	36.0

*For Influenza A H1N1 pdm09, influenza A H3N2, rhinovirus A and human coronavirus OC43 additional concentrations were tested. Statistical analysis confirmed there is no significant difference between either platform on the tested concentrations. Based on the obtained results, the platforms can be considered equivalent.
** Parainfluenza virus 1 did not initially show equivalency at 1.58E+00 $TCID_{50}$/mL between the QIAstat-Dx Analyzer and the QIAstat-Dx Rise. However, testing was repeated with two additional sets of 20 replicates per instrument and equivalency between instruments was demonstrated in those sets.

Table 7. Results for the Instrument Equivalency Study for the QIAstat-Dx Respiratory Panel Plus (Applicable Results to the QIAstat- Dx Respiratory Panel Mini Highlighted in Blue).

Analyte	Concentration tested	QIAstat-Dx Analyzer 1.0		QIAstat-Dx Rise	
		Hit rate	Ct Mean	Hit rate	Ct Mean
Influenza B (B/Taiwan/2/62) (ATCC, VR- 295)	4.99E+01 $TCID_{50}$/mL	19/20	35.4	20/20	35.5
	4.99E+00 $TCID_{50}$/mL	6/20	37.1	4/20	37.6
Human coronavirus NL63 (ZeptoMetrix, 0810228CFHI)	3.70E-02 $TCID_{50}$/mL	20/20	34.6	20/20	35.0
	3.70E-03 $TCID_{50}$/mL	13/20	37.8	13/20	37.5
Parainfluenza Virus 3 (ATCC, VR- 93)	6.96E+00 $TCID_{50}$/mL	20/20	34.1	20/20	34.8

Analyte	Concentration tested	QIAstat-Dx Analyzer 1.0		QIAstat-Dx Rise	
		Hit rate	Ct Mean	Hit rate	Ct Mean
	2.32E+00 $TCID_{50}$/mL	20/20	35.6	18/20*	35.9
	6.96E-01 $TCID_{50}$/mL	11/20	35.4	13/20	35.9
Human rhinovirus (ATCC, VR- 482)	8.88E+00 $TCID_{50}$/mL	19/20	36.6	19/20	36.3
	8.88E-01 $TCID_{50}$/mL	18/20	37.8	4/20	37.6
Adenovirus (ATCC, VR-3)	4.99E+03 $TCID_{50}$/mL	20/20	34.2	19/20	34.0
	4.99E+02 $TCID_{50}$/mL	10/20	36.4	11/20	36.8
Mycoplasma pneumoniae (ATCC, 29085)	1.00E+00 CCU/mL	20/20	34.1	20/20	34.2
	1.00E-01 CCU/mL	10/20	36.3	10/20	36.2
SARS-CoV-2 (England/02/2020) (NIBSC, 20-146)	1.05E+03 copies/mL	20/20	33.5	20/20	33.5
	3.16E+02 copies/mL	18/20**	35.8	19/20	36.0
	1.05E+02 copies/mL	8/20	35.1	12/20	36.2

*For Parainfluenza virus 3 a new sample with a concentration 3x the LoD obtained for the QIAstat-Dx Analyzer (6.96E+00 $TCID_{50}$/mL) was prepared and tested with both platforms, obtaining a hit rate of 100 %. Statistical analysis confirmed there is no significant difference between either platform on the tested concentrations.
** For SARS-CoV-2 additional concentrations were tested. Statistical analysis confirmed there is no significant difference between either platform on the tested concentrations despite the minor difference in detection rate. Based on the obtained results, the platforms can be considered as equivalent.

Table 8. Results for the Instrument Equivalency Study and Comparison Between QIAstat-Dx Respiratory Panel Assays and Reanalysis Results for Influenza A Strains.

Analyte	Concentration	Results QIAstat Dx-Respiratory Panel Plus*				Results QIAstat Dx-Respiratory Panel Mini			
		Analyzer 1.0		Rise		Analyzer 1.0		Rise	
		Hit rate	Ct mean	Hit rate	Ct mean	Hit rate	Ct mean	Hit rate	Ct mean
Influenza A H1N1 (New Caledonia/20/99) (ZeptoMetrix 0810036CFHI)	1.44E+01 $TCID_{50}$/mL	Flu A: 20/20 H1: 19/20	Flu A: 36.4 H1: 35.8	Flu A: 20/20 H1: 20/20	Flu A: 35.8 H1: 35.4	Flu A: 20/20	36.4	Flu A: 20/20	35.8
	4.57E+00 $TCID_{50}$/mL	Flu A: 20/20 H1: 17/20	Flu A: 36.7 H1: 36.2	Flu A: 16/20 H1: 14/20	Flu A: 36.7 H1: 36.7	Flu A: 20/20	36.7	Flu A: 16/20	36.7

Analyte	Concentration	Results QIAstat Dx-Respiratory Panel Plus*				Results QIAstat Dx-Respiratory Panel Mini			
		Analyzer 1.0		Rise		Analyzer 1.0		Rise	
		Hit rate	Ct mean	Hit rate	Ct mean	Hit rate	Ct mean	Hit rate	Ct mean
	4.57E-01 $TCID_{50}$/mL	Flu A:7/20 H1: 2/20	Flu A: 37.7 H1: 36.6	Flu A: 4/20 H1: 1/20	Flu A: 37.2 H1: 35.1	Flu A: 7/20	37.7	Flu A: 4/20	37.2
Influenza A H1N1 (A/Virginia/ATCC1/2009) (ATCC VR-1736)	2.12E+01 PFU/mL	Flu A: 20/20 H1N1: 20/20	Flu A: 34.6 H1N1: 34.5	Flu A: 20/20 H1N1: 20/20	Flu A: 33.2 H1N1: 33.1	Flu A: 20/20	34.6	Flu A: 20/20	33.2
	6.70E+00 PFU/mL	Flu A: 20/20 H1N1 pdm: 18/20	Flu A: 35.4 H1N1: 35.0	Flu A: 20/20 H1N1 pdm: 19/20	Flu A: 35.3 H1N1: 35.0	Flu A: 20/20	35.4	Flu A: 20/20	35.3
	6.70E-01 PFU/mL	Flu A: 14/20 H1N1 pdm: 10/20	Flu A: 37.6 H1N1: 37.3	Flu A: 11/20 H1N1 pdm: 6/20	Flu A: 37.1 H1N1: 36.3	Flu A: 14/20	37.6	Flu A: 11/20	37.1
Influenza A H3N2 (A/Port Chalmers/1/73) (ATCC VR-810)	4.99E+03 $CEID_{50}$/mL	Flu A: 20/20 H3: 20/20	Flu A: 33.2 H3: 31.7	Flu A: 20/20 H3: 20/20	Flu A: 32.9 H3: 31.5	Flu A: 20/20	33.2	Flu A: 20/20	32.9
	1.58E +03 $CEID_{50}$/mL	Flu A: 20/20 H3: 18/20	Flu A: 36.2 H3: 34.6	Flu A: 20/20 H3: 20/20	Flu A: 35.7 H3: 34.2	Flu A: 20/20	36.2	Flu A: 20/20	35.7
	4.99E+02 $CEID_{50}$/mL	Flu A: 17/20 H3: 17/20	Flu A: 36.9 H3: 36.1	Flu A: 17/20 H3: 16/20	Flu A: 36.9 H3: 36.0	Flu A: 17/20	36.9	Flu A: 17/20	36.9

* Influenza A results were internally collected by reanalyzing the raw data with IN2DATA tool. This target is not reported by QIAstat-Dx Respiratory Panel ADF.

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.