June 2025

QIAstat-Dx® Respiratory SARS-CoV-2 Panel Summary of Safety and Performance

Σ 6

Version 1

IVD

For In Vitro Diagnostic Use

For Use with QIAstat-Dx Analyzer1.0, QIAstat-Dx Analyzer2.0, and QIAstat-Dx Rise

CE 0197

REF 691215

QIAGEN GmbH, QIAGEN Strasse 1, 40724 Hilden, GERMANY

R2

Sample to Insight

Summary of Safety and Performance

This Summary of Safety and Performance (SSP) is intended to provide public access to an up-to-date summary of the main aspects of the safety and performance of the device.

The SSP is not intended to replace the Instructions For Use as the main document to ensure the safe use of the device, nor is it intended to provide diagnostic or therapeutic suggestions to intended users.

The following information is intended for professional users.

Document revision: 02
Date issued: June 2025
Manufacturer's reference number for the SSP: HB-3413-SPR

1. Device identification and general information	
1.1 Device trade name(s)	QIAstat-Dx Respiratory SARS-CoV-2 Panel
1.2 Manufacturer's name and address	QIAGEN GmbH, QIAGEN Strasse 1, 40724 Hilden, GERMANY
1.3 Manufacturer's single	DE-MF-000004949

registration number (SRN)	
1. 4 Basic UDI-DI	4053228RRPSC2QST0000001PM
1.5 European Medical Device Nomenclature (EMDN) description / text	W0105070503 Respiratory Tract Infections - Multiplex NA Reagents
1.6 Risk Class of the device	Class C
1.7 Indication whether it is a device for near-patient testing and/or a companion diagnostic	This device is not intended for near-patient testing. This device is not a companion diagnostic.
1.8 Year when the first certificate was issued under Regulation (EU) 2017/746 covering the device	2024

1.9 Authorised representative if applicable; name and the SRN	Not applicable
1.10 Notified body and the single identification number (SIN)	TÜV Rheinland LGA Products GmbH, Tillystraße 2 90431 Nürnberg, Germany 0197
2. Intended use of the device	
2.1 Intended purpose	The QIAstat-Dx® Respiratory SARS-CoV-2 Panel is a qualitative test intended for analyzing nasopharyngeal swab (NPS) samples taken from symptomatic patients suspected of respiratory infection for the presence of viral or bacterial nucleic acids. The assay is designed for use with the QIAstat-Dx Analyzer 1.0, QIAstat-Dx Analyzer 2.0, and the QIAstat-Dx Rise for automated integrated nucleic acid extraction and multiplex real-time RT-PCR detection of nucleic acids in the sample. QIAstat-Dx Respiratory SARS-CoV-2 Panel detects and differentiates* Adenovirus, Bocavirus, Coronavirus 229E, Coronavirus OC43, Coronavirus NL63, Coronavirus HKU1, SARS-CoV-2, Human Metapneumovirus A+B, Influenza A, Influenza A H1N1/pdm09, Influenza A H1, Influenza A H3, Influenza B, Parainfluenza virus 1, Parainfluenza virus 2, Parainfluenza virus 3, Parainfluenza virus 4, Respiratory Syncytial Virus A+B, Rhinovirus/Enterovirus, *Bordetella*

	pertussis, *Chlamydophila pneumoniae*, *Legionella pneumophila*, and *Mycoplasma pneumoniae*. * Enterovirus and Rhinovirus are both detected, but not differentiated, with the QIAstat-Dx Respiratory SARS-CoV-2 Panel. The QIAstat-Dx Respiratory SARS-CoV-2 Panel is an aid in diagnosis of respiratory infections from symptomatic patients. The results from the QIAstat-Dx Respiratory SARS-CoV-2 Panel must be interpreted within the context of all relevant clinical and laboratory findings. Results from the QIAstat-Dx Respiratory SARS-CoV-2 Panel are not intended to be used as the sole basis for diagnosis, treatment, or other patient management decisions but in conjunction with other clinical, laboratory and epidemiological data. Positive results do not rule out co-infection with other organisms not included in the QIAstat-Dx Respiratory SARS-CoV-2 Panel. The agent or agents detected may not be the definite cause of the disease. Negative results do not preclude respiratory infection. Assay performance characteristics have been established only for individuals who have shown respiratory symptoms. The QIAstat-Dx Respiratory SARS-CoV-2 Panel is intended for use by trained laboratory professionals only and is not intended for self-testing or near-patient testing. For in vitro diagnostic use.
2.2 Indication(s) and target population(s)	The QIAstat-Dx Respiratory SARS-CoV-2 Panel is a qualitative real-time RT-PCR test to detect viral or bacterial nucleic acids from

	nasopharyngeal swabs (NPS) taken from symptomatic patients suspected of respiratory infection. The QIAstat-Dx Respiratory SARS-CoV-2 Panel is for in vitro diagnostic use and intended for use in hospital laboratory settings or in a laboratory environment by trained laboratory professionals only.
2.3 Limitations and/or contra-indications	• Results from the QIAstat-Dx Respiratory SARS-CoV-2 Panel are not intended to be used as the sole basis for diagnosis, treatment, or other patient management decisions. • Positive results do not rule out co-infection with organisms not included in the QIAstat-Dx Respiratory SARS-CoV-2 Panel. The agent detected may not be the definitive cause of the disease. • Negative results do not preclude infection of the upper respiratory tract. Not all agents of acute respiratory infection are detected by this assay. • A negative result with the QIAstat-Dx Respiratory SARS-CoV-2 Panel does not exclude the infectious nature of the syndrome. Negative assay results may originate from several factors and their combinations, including sample handling mistakes, variation in the nucleic acid sequences targeted by the assay, infection by organisms not included in the assay, organism levels of included organisms that are below the limit of detection for the assay and use of certain medications, therapies, or agents. • The QIAstat-Dx Respiratory SARS-CoV-2 Panel is not intended for testing of samples other than those described in these Instructions for Use. Test performance characteristics have been established with NPS samples from individuals with respiratory symptoms. • The QIAstat-Dx Respiratory SARS-CoV-2 Panel is intended to be used in conjunction with standard of care culture for organism recovery, serotyping and/or antimicrobial susceptibility testing where applicable.

	• The results from the QIAstat-Dx Respiratory SARS-CoV-2 Panel must be interpreted by a trained healthcare professional within the context of all relevant clinical, laboratory, and epidemiological findings • The QIAstat-Dx Respiratory SARS-CoV-2 Panel can be used only with the QIAstat-Dx Analyzer 1.0*, QIAstat-Dx Analyzer 2.0, and QIAstat-Dx Rise. • The QIAstat-Dx Respiratory SARS-CoV-2 Panel is a qualitative assay and does not provide a quantitative value for detected organisms. • Viral and bacterial nucleic acids may persist in vivo, even if the organism is not viable or infectious. Detection of a target marker does not imply that the corresponding organism is the causative agent of the infection or the clinical symptoms. • Detection of viral and bacterial nucleic acids depends on proper sample collection, handling, transportation, storage, and loading into the QIAstat-Dx Respiratory SARS-CoV2 Panel Cartridge. Improper operations for any of the aforementioned processes can cause incorrect results, including false-positive or false-negative results. • The assay sensitivity and specificity for the specific organisms and for all organisms combined are intrinsic performance parameters of a given assay and do not vary depending on prevalence. In contrast, both the negative and positive predictive values of a test result are dependent on the disease/organism prevalence. • The performance of this test has not been established in individuals who received influenza vaccine. Recent administration of a nasal influenza vaccine may cause false positive results for Influenza A and/or Influenza B.

	* DiagCORE Analyzer instruments running QIAstat-Dx software version 1.5 or higher can be used as an alternative to QIAstat-Dx Analyzer 1.0 instruments.
3. Device description	
3.1 Description of the device, including the conditions to use the device	**a) General description of the device, including its intended purpose and intended users** Description of the device: The QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge is a disposable plastic device that allows performance of fully automated molecular assays for the detection of respiratory pathogens. The main features of the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge include compatibility with respiratory NPS directly using dry NPS (e.g., Copan® FLOQSwabs®, cat. no. 503CS01 / 550C) and NPS in universal transport medium (UTM), hermetical containment of the pre-loaded reagents necessary for testing, and true walk-away operation. All sample preparation and assay testing steps are performed within the cartridge. All reagents required for the complete execution of a test run are pre-loaded and self-contained in the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge. The user does not need to come in contact with and/or manipulate any reagents. During the test, reagents are handled within the cartridge in the Analytical Module of the QIAstat-Dx Analyzer 1.0, QIAstat-Dx Analyzer 2.0, and QIAstat-Dx Rise by pneumatically-operated microfluidics and make no direct contact with the actuators. The QIAstat-Dx Analyzer 1.0, QIAstat-Dx Analyzer 2.0, and QIAstat-Dx Rise house air filters for both incoming and outgoing air, further

	safeguarding the environment. After testing, the cartridge stays hermetically closed at all times, greatly enhancing its safe disposal. Within the cartridge, multiple steps are automatically performed in sequence using pneumatic pressure to transfer samples and fluids via the transfer chamber to their intended destinations. This kit is intended for professional use. The product is to be used only by personnel specifically instructed and trained in molecular biology techniques and familiar with this technology. Intended purpose of the device: The QIAstat-Dx Respiratory SARS-CoV-2 Panel is a qualitative real-time RT-PCR test to detect viral or bacterial nucleic acids from nasopharyngeal swabs (NPS) taken from symptomatic patients suspected of respiratory infection. The QIAstat-Dx Respiratory SARS-CoV-2 Panel is for in vitro diagnostic use and intended for use in hospital laboratory settings or in a laboratory environment by trained laboratory professionals only. **b) Description of the principle of the assay method or principles of operation of the instrument** Diagnostic tests with the QIAstat-Dx Respiratory SARS-CoV-2 Panel are performed on the QIAstat-Dx Analyzer 1.0, QIAstat-Dx Analyzer 2.0, and 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, and QIAstat-Dx Rise. Samples are collected and

	loaded manually into the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge, depending on the processing option: either inserting the NPS into the swab port when using dry NPS or using a transfer pipette for dispensing NPS in universal transport medium (UTM) into the main port. Sample collection and cartridge loading The collection of samples and their subsequent loading into the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge should be performed by personnel trained in safe handling of biological samples. The following steps are involved and must be executed by the user: 1. A single-use nasopharyngeal swab sample is collected. The nasopharyngeal swab is placed into a single-use tube filled with universal transport medium only in the case of NPS in universal transport medium processing option. The sample information can either be manually written or a sample label affixed to the top of a QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge. In case of using QIAstat-Dx Rise, a label with the sample information must be affixed to the top of the QIAstat-Dx Respiratory SARS-CoV-2 Panel cartridge. Sample is loaded manually into the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge: ○ Dry NPS: The nasopharyngeal swab is inserted into the swab port of the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge. ○ NPS in Universal Transport medium: 300 µL of sample is transferred into the main port of the QIAstat-Dx Respiratory

	SARS-CoV-2 Panel Cartridge using one of the included transfer pipettes. The sample barcode and QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge barcode are scanned in the QIAstat-Dx Analyzer 1.0, QIAstat-Dx Analyzer 2.0, or QIAstat-Dx Rise. The QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge is introduced into the QIAstat-Dx Analyzer 1.0, QIAstat-Dx Analyzer 2.0, or QIAstat-Dx Rise. The test is started on the QIAstat-Dx Analyzer 1.0, QIAstat-Dx Analyzer 2.0, or QIAstat-Dx Rise. Sample preparation, nucleic acid amplification, and detection The extraction, amplification, and detection of nucleic acids in the sample are performed automatically by the QIAstat-Dx Analyzer 1.0, QIAstat-Dx Analyzer 2.0, and QIAstat-Dx Rise. 1. The sample is homogenized, and cells are lysed in the lysis chamber of the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge, which includes a rotor that turns at high speed. Nucleic acids are purified from the lysed sample via binding to a silica membrane in the purification chamber of the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge in the presence of chaotropic salts and alcohol. The purified nucleic acids are eluted from the membrane in the purification chamber and are mixed with the lyophilized PCR chemistry in the dried-chemistry chamber of the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge.

	The mixture of sample and PCR reagents is dispensed into the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge PCR chambers, which contains lyophilized, assay-specific primers and probes. The QIAstat-Dx Analyzer 1.0, QIAstat-Dx Analyzer 2.0, and QIAstat-Dx Rise create the optimal temperature profiles to carry out effective multiplex real-time RT-PCR and perform real-time fluorescence measurements to generate amplification curves. The QIAstat-Dx Analyzer 1.0, QIAstat-Dx Analyzer 2.0, and QIAstat-Dx Rise Software interpret the resulting data and process control and deliver a test report. **c) Rationale for qualifying the product as a device, and risk class of the device (excerpt from regulatory strategy document)** The QIAstat-Dx Respiratory SARS-CoV-2 Panel is a reagent cartridge that provides information concerning a pathological state as defined in the products' intended purpose. This qualifies the QIAstat-Dx Respiratory SARS-CoV-2 Panel cartridge and ADF software as in-vitro diagnostic medical devices as defined in clause 2(2) of IVDR 2017/746. In addition, in accordance with clause 1.9 of ANNEX VIII of IVDR 2017/746, the overall product is classified as Class C. .
3.2 In case the device is a kit, description of the components (including regulatory status of components,	The QIAstat-Dx Respiratory SARS-CoV-2 Panel kit consists of six individually packed cartridges and six individually packed transfer pipettes. The kit contents are not sold separately.

<table>
<tr><td>for example, IVDs, medical devices and any Basic UDI-DIs)</td><td colspan="4">The QIAstat-Dx Respiratory SARS-CoV-2 Panel provides information concerning a pathological state as defined in the products' intended purpose. This qualifies the QIAstat-Dx Respiratory SARS-CoV-2 Panel as in-vitro diagnostic medical devices as defined in clause 2(2) of IVDR 2017/746.</td></tr>
<tr><td rowspan="5">3.3 A reference to previous generation(s) or variants if such exists, and a description of the differences</td><td colspan="4">The difference between the subject device, QIAstat-Dx Respiratory SARS-CoV-2 Panel, and the previous versions: QIAstat-Dx Respiratory SARS-CoV-2 Panel IVDD version 1 and QIAstat-Dx Respiratory Panel, are listed in the table below.</td></tr>
<tr><td></td><td>QIAstat-Dx Respiratory SARS-CoV-2 Panel (Cat. No. 691215 and Cat. No 691214 V2 IVDD version)</td><td>QIAstat-Dx Respiratory SARS-CoV-2 Panel (691214 V1 IVDD version)</td><td>QIAstat-Dx Respiratory Panel (691211 IVDD version)</td></tr>
<tr><td>Target differentiation</td><td>This panel unmasked the Chlamydophila pneumoniae target after regulatory approval.</td><td>The panel added the SARS-CoV-2 virus to reaction chamber 8, due to the need for detection in the Global COVID-19 Pandemic. The panel has the Chlamydophila pneumoniae target masked.</td><td>The panel has the Chlamydophila pneumoniae target masked. The panel does not detect SARS-CoV-2 target.</td></tr>
<tr><td>Inclusivity</td><td>The inclusivity of some targets was upgraded to cover a wider range of genetic variability</td><td>The inclusivity of some targets was upgraded to cover a wider range of genetic variability.</td><td>The inclusivity of some targets was limited due to the smaller number of strains covered</td></tr>
<tr><td>Shelf Life</td><td>9 months</td><td>9 months</td><td>6 months</td></tr>
<tr><td>3.4 Description of accessories intended to be</td><td colspan="4">Not applicable.</td></tr>
</table>

used in combination with the device	
3.5 Description of any other devices and products which are intended to be used in combination with the device	The QIAstat-Dx Respiratory SARS-CoV-2 Panel is designed for use with the QIAstat-Dx Analyzer 1.0, QIAstat-Dx Analyzer 2.0, and QIAstat-Dx Rise. Please note Assay Definition File (ADF) for the QIAstat-Dx Respiratory SARS-CoV-2 Panel is available at **www.qiagen.com**.
4. Reference to any harmonised standards and CS applied	
4.1 Harmonised standards and Common Specifications (CS) applied	Harmonized Standards: • EN ISO 13485:2016+AC:2018+A11:2021 – Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016) • EN ISO 14971:2019+A11:2021 – Medical devices – Application of risk management to medical devices o EN ISO 15223-1:2021 – Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements • EN 62366-1:2015 + AC:2015 + AC:2016 + A1:2020 Medical devices - Application of usability engineering to medical devices

	• EN 13612:2002 Performance Evaluation of In Vitro Diagnostic Medical Devices • EN ISO 18113-1:2011 In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling) – Part 1: Terms, definitions and general requirements • EN ISO 18113-2:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling) • EN 62304:2006+A1:2015 Medical device software – Software life-cycle processes • ISO 20916:2019 In vitro diagnostic medical devices – Clinical performance studies using specimens from human subjects - Good study practice (ISO 20916) • EN ISO 23640:2015 In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents • EN 13975:2003 Sampling Procedures used for acceptance testing of in vitro diagnostic medical devices – statistical aspects (the list includes existing harmonized standards and ones listed to be harmonized)

	There are no Common Specifications established by the European Commission applicable to QIAstat-Dx Respiratory SARS-CoV-2 Panel
5. Risks and warnings	
5.1 Residual risks and undesirable effects	Risks have been mitigated as far as possible and deemed as acceptable. There are no undesirable effects.
5.2 Warnings and precautions	The QIAstat-Dx Respiratory SARS-CoV-2 Panel is to be used by laboratory professionals trained in the use of QIAstat-Dx Analyzer 1.0, QIAstat-Dx Analyzer 2.0, and the QIAstat-Dx Rise. Be aware that you may be required to consult your local regulations for reporting serious incidents that have occurred in relation to the device to the manufacturer and the regulatory authority in which the user and/or the patient is established. When working with chemicals, always wear a suitable lab coat, disposable gloves, and protective goggles. For more information, please consult the appropriate safety data sheets (SDSs). These are available online in convenient and compact PDF format at www.qiagen.com/safety, where you can find, view and print the SDS for each QIAGEN kit. Specimens and samples are potentially infectious. Follow your institution's safety procedures for handling biological samples. Discard sample and assay waste according to your local safety procedures.

	Always wear appropriate personal protective equipment, including but not limited to disposable powder-free gloves, a lab coat, and protective eyewear. Protect skin, eyes, and mucus membranes. Change gloves often when handling samples. Handle all samples, cartridges, and transfer pipettes as if they are capable of transmitting infectious agents. Always observe safety precautions as outlined in relevant guidelines, such as the Clinical and Laboratory Standards Institute® (CLSI) Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline (M29) or other appropriate documents provided by local authorities. Dispose of samples, QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridges, and transfer pipettes according to the appropriate regulations. The QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge is a closed, single-use device that contains all reagents needed for sample preparation and multiplex real-time RT-PCR within the QIAstat-Dx Analyzer 1.0, QIAstat-Dx Analyzer 2.0, and QIAstat-Dx Rise. Do not use a QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge that is past its expiration date, appears damaged, or leaks fluid. Observe standard laboratory procedures for keeping the working area clean and contamination-free. Guidelines are outlined in publications such as the European Centre for Disease Prevention and Control (**https://www.ecdc.europa.eu/en/aboutus/networks/disease-and-laboratory-networks/erlinet-biosafety**). The following hazard and precautionary statements apply to components of the QIAstat-Dx Respiratory SARS-CoV-2 Panel.

	 Contains: ethanol; guanidine hydrochloride; guanidine thiocyanate; isopropanol; proteinase K; t-Octylphenoxypolyethoxyethanol. Danger! Causes severe skin burns and eye damage. Harmful if swallowed or if inhaled. Harmful to aquatic life with long lasting effects. Highly flammable liquid and vapor. May be harmful in contact with skin. May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause drowsiness or dizziness. Contact with acids liberates very toxic gas. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Keep cool. Use only outdoors or in a well-ventilated area. Avoid release to the environment. Wear protective gloves/ protective clothing/ eye protection/ face protection. In case of inadequate ventilation wear respiratory protection. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. IF exposed or concerned: Immediately call a POISON CENTER or doctor. Rinse mouth. Do NOT induce vomiting. Remove person to fresh air and keep comfortable for breathing. Wash contaminated clothing before reuse. Store in a well-ventilated place. Keep container tightly closed. Dispose of contents/ container to an approved facility in accordance with local, regional, national and international regulations.
5.3 Other relevant aspects of safety, including a summary of any	Not applicable.

field safety corrective action (FSCA including FSN), if applicable	
6. Summary of the performance evaluation and post-market performance follow-up (PMPF)	
6.1 Summary of scientific validity of the device	Highly sensitive multiplex PCR tests allow for the simultaneous detection of multiple viral and bacterial pathogens, with greater sensitivity and specificity than traditional methods. These tests are widely adopted in the diagnostic work-up of respiratory tract infections, and they represent the State of the Art in current clinical practice. Several international guidelines recommend the use of molecular tests for the diagnosis of respiratory tract infections. Collective information gathered from systematic literature searches supports the scientific validity of the analytes (nucleic acids from SARS-CoV-2, Influenza A, Influenza A H1N1/pdm09, Influenza A H1, Influenza A H3, Influenza B, Coronavirus 229E, Coronavirus HKU1, Coronavirus NL63, Coronavirus OC43, Parainfluenza virus 1, Parainfluenza virus 2, Parainfluenza virus 3, Parainfluenza virus 4, Respiratory Syncytial virus A/B, human Metapneumovirus A/B, Adenovirus, Bocavirus, Rhinovirus/Enterovirus, *Mycoplasma pneumoniae, Chlamydophila pneumoniae, Legionella pneumophila* and *Bordetella pertussis)* with the clinical condition of respiratory infection. As such, scientific validity of the QIAstat-Dx Respiratory Panel is established
6.2 Summary of performance data from the equivalent	Not applicable.

device, if applicable	
6.3 Summary of performance data from conducted studies of the device prior to CE-marking	See Appendix 01 Analytical Performance (Analytical), Appendix 02 Clinical Performance (Clinical) - extracted from the Instructions for Use.
6.4 Summary of performance data from other sources, if applicable	Conclusion of clinical performance data obtained by literature Through a systematic literature study, 11 studies were retrieved that contained relevant information to support the clinical performance of the device under evaluation. In these studies, different comparator methods were used. Eight studies mainly focused on the analyte SARS-CoV-2. The PPA of the QIAstat-Dx Panel and the comparator device ranged from 84 – 100% and the NPA from 90.48–100%. Five studies contained information about the performance for non-SARS-CoV-2 analytes. Overall, PPA in the latter studies ranged from 78–99.5%.
6.5 An overall summary of the performance and safety	The overall performance and safety of QIAstat-Dx Respiratory SARS-CoV-2 Panel is based on the following: • Scientific validity was demonstrated based on a systematic literature review, assessment of available/retrieved/new data relevant to QIAstat-Dx Respiratory SARS-CoV-2 Panel and its intended purpose and consensus experts' opinions/positions from international guidelines, proof-of-concept studies, and clinical

	performance studies. The results demonstrate the scientific validity of the QIAstat-Dx Respiratory SARS-CoV-2 Panel for its intended purpose. • Analytical performance was demonstrated based on verification studies achieving the acceptance criteria for: o Specimen handling and collection o The applicable analytical performance characteristics ▪ Analytical sensitivity: limit of blank, limit of detection ▪ Analytical specificity: analytical reactivity, cross-reactivity, interference ▪ Precision: reproducibility and repeatability ▪ Carry-over ▪ Assay reliability ▪ Shelf-life, in-use and transport stability. o Equivalent performance of the product, used with either the QIAstat-Dx Analyzer 1.0, QIAstat-Dx Analyzer 2.0, or the QIAstat-Dx Rise system. o Performance of the QIAstat-Dx Respiratory SARS-CoV-2 Panel ADF software • Clinical performance was demonstrated based on clinical validation studies and a systematic literature review for the following clinical performance indicators: diagnostic sensitivity (addressed as Positive Percent Agreement; PPA) and diagnostic specificity (addressed as Negative Percent Agreement; NPA) with a comparator method. The clinical validation studies achieved the acceptance criteria. The literature review supported adequate clinical performance of the product. The assessment of scientific validity, analytical performance, and clinical performance allows to constitute the clinical evidence for the QIAstat-Dx Respiratory SARS-CoV-2 Panel. The clinical evidence demonstrates that the product meets the user needs and also provides valid assurance that the relevant General Safety and Performance

	Requirements (GSPR 1-9.1) are fulfilled when used as intended by the manufacturer and according to the Instructions for Use. Based on the scientific validity, analytical performance and clinical performance, the QIAstat-Dx Respiratory SARS-CoV-2 Panel achieves the clinical benefit of rapidly and accurately determining the presence or absence of the following respiratory pathogens in symptomatic patients suspected of respiratory infection: Adenovirus, Bocavirus, Coronavirus 229E, Coronavirus OC43, Coronavirus NL63, Coronavirus HKU1, SARS-CoV-2, Human Metapneumovirus A+B, Influenza A (not differentiated), Influenza A H1N1/pdm09, Influenza A H1, Influenza A H3, Influenza B, Parainfluenza virus 1, Parainfluenza virus 2, Parainfluenza virus 3, Parainfluenza virus 4, Respiratory Syncytial Virus A+B, Rhinovirus/Enterovirus (both detected but not differentiated), *Bordetella pertussis*, *Chlamydophila pneumoniae*, *Legionella pneumophila*, *Mycoplasma pneumoniae*. This helps physicians to make timely decisions regarding treatment, hospital admission, infection control, and return of the patient to work and family. It may also greatly support improved antimicrobial stewardship and other important public health initiatives. To summarize for the QIAstat-Dx Respiratory SARS-CoV-2 Panel (Cat. No. 691215): • The product conforms to General Safety and Performance Requirements set out in Annex I 1 to 8 and 9.1 of Regulation (EU) 2017/746 • Scientific validity has been demonstrated taking into account the generally acknowledged state of the art • There are adequate analytical and clinical performance data to support the required analytical/clinical performance

	parameters listed in Annex 9.1 (a) and (b) of Regulation (EU) 2017/746. • The product can be considered state of the art in medicine. • No performance and/or safety issues have been identified during this performance evaluation. • The current residual risks are acceptable. The benefits of the product outweigh potential risks and the benefit-risk profile for the product is considered positive and acceptable.
6.6 Ongoing or planned post-market performance follow-up	Based on the collected evidence, it was concluded that the QIAstat-Dx Respiratory SARS-CoV-2 Panel is safe and effective for its intended use and no unacceptable residual risks remain. An additional shelf-life study will be performed to test the upper limit (25± 2°C) of the intended room temperature storage claim (15-25°C) and to support the current shelf-life claim of 9 months.
7. Metrological traceability of assigned values	
7.1 Explanation of the unit of measurement, if applicable	Not applicable.
7.2 Identification of applied reference materials and/or reference measurement procedures of higher order	Not applicable.

used by the manufacturer for the calibration of the device	
8. Suggested profile and training for users	
8.1 Suggested profile and training for users	The QIAstat-Dx Respiratory SARS-CoV-2 Panel (cat. no. 691215) is a qualitative test intended for analyzing nasopharyngeal swab (NPS) samples taken from symptomatic patients suspected of respiratory infection for the presence of viral or bacterial nucleic acids. The assay is designed for use with the QIAstat-Dx Analyzer 1.0, QIAstat-Dx Analyzer 2.0, and the QIAstat-Dx Rise for automated integrated nucleic acid extraction and multiplex real-time RT-PCR detection of nucleic acids in the sample. The QIAstat-Dx Respiratory SARS-CoV-2 Panel is intended for use by trained laboratory professionals only and is not intended for self-testing or near-patient testing. The product is to be used only by personnel specifically instructed and trained in molecular biology techniques and familiar with this technology.

Revision History

SSP Revision Number	Date issued	Change description	Revision validated by the Notified Body
01	January 2025	1st revision	☑ Yes Validation language: English □ No (only applicable for class C (IVDR, Article 48 (7)) for which the SSP is not yet validated by the NB)
02	June 2025	Inclusion of QIAstat-Dx Analyzer 2.0 as another instrument that the panel can work with Reclassification from class D to C Removal of references to common specifications from sections 4.1 and 6.5 In section 6.6, update of temperature to be tested from 25±3 to 25±2 °C	☑ Yes Validation language: English □ No (only applicable for class C (IVDR, Article 48 (7)) for which the SSP is not yet validated by the NB)

Appendix

Appendix 01 Analytical Performance

Analytical performance

The analytical performance shown below was demonstrated using the QIAstat-Dx Analyzer 1.0. The QIAstat-Dx Analyzer 2.0 uses the same Analytical Module as QIAstat-Dx Analyzer 1.0; therefore, the performance is not impacted by the QIAstat-Dx Analyzer 2.0.

With regards to QIAstat-Dx Rise, specific studies to demonstrate the carryover and the repeatability were executed. The rest of analytical performance parameters shown below was demonstrated using the QIAstat-Dx Analyzer 1.0. The QIAstat-Dx Rise uses the same Analytical Module as QIAstat-Dx Analyzer 1.0; therefore, the performance is not impacted by QIAstat-Dx Rise.

Limit of Detection

The Analytical Sensitivity, or Limit of Detection (LoD), is defined as the lowest concentration at which ≥95% of the tested samples generate a positive call.

The LoD for each of the QIAstat-Dx Respiratory SARS-CoV-2 Panel target organisms was determined by analyzing serial dilutions of analytical samples prepared from culture isolates from commercial suppliers (e.g., ZeptoMetrix® and ATCC®), confirmed clinical isolates, or artificial samples for commercially unavailable target analytes* on the QIAstat-Dx Analyzer 1.0.

Simulated NPS samples representing both processing options were tested; NPS sample matrix (cultured human cells in Copan UTM) for NPS in UTM and simulated dry swab sample matrix (cultured human cells in artificial NPS) for dry NPS were spiked with one or more pathogens and tested in at least 20 replicates. The NPS in UTM processing option uses NPS eluted in UTM and a transfer of 300 µL to the cartridge, whereas the dry NPS workflow allows transfer of the NPS directly to the cartridge. Dry NPS mock swabs were prepared by pipetting 50 µL of each diluted virus/bacteria stock onto a swab and were left to dry for a minimum of 20 minutes. Mock swabs were tested following the Dry NPS processing option. Additional testing of NPS in UTM samples prepared using negative clinical matrix was conducted to assess equivalency. Also, the LoD was demonstrated to be equivalent when one representative pathogen strain for each of the QIAstat-Dx Respiratory SARS-CoV-2 Panel target organisms was tested on the QIAstat-Dx Rise system.

* Due to limited access to cultured virus, synthetic material (gBlock) was also used to determine LoD spiked in clinical negative matrix for the Bocavirus target.

Table 1. LoD values obtained for the different respiratory target strains in NPS in UTM and/or dry NPS (cultured human cells in artificial NPS) tested with the QIAstat-Dx Respiratory SARS-CoV-2 Panel

Pathogen	Strain	Source	Concentration*	Detection rate
Influenza A H1N1	A/New Jersey/8/76	ATCC VR-897	341.3 $CEID_{50}$/mL	Flu A: 20/20 H1: 20/20
Influenza A H1N1	A/Brisbane/59/07	ZeptoMetrix 0810244CFHI	4.0 $TCID_{50}$/mL	Flu A: 20/20 H1: 20/20
Influenza A H1N1	A/New Caledonia/20/99	ZeptoMetrix 0810036CFHI	28.7 $TCID_{50}$/mL	Flu A: 20/20 H1: 20/20
Influenza A H3N2	A/Virginia/ATCC6/2012	ATCC AV-VR-1811	0.1 PFU/mL	Flu A: 20/20 H3: 20/20
Influenza A H3N2	A/Port Chalmers/1/73	ATCC VR-810	3000 $CEID_{50}$/mL	Flu A: 20/20 H3: 20/20
Influenza A H3N2	A/Wisconsin/67/2005	ZeptoMetrix 0810252CFHI	3.8 $TCID_{50}$/mL	Flu A: 20/20 H3: 20/20
Influenza A/H1N1/pdm09	A/Virginia/ATCC1/2009	ATCC VR-1736	127 PFU/mL	Flu A: 20/20 H1N1: 20/20
Influenza A/H1N1/pdm09	A/SwineNY/03/2009	ZeptoMetrix 0810249CFHI	56.2 $TCID_{50}$/mL	Flu A: 20/20 H1N1: 20/20
Influenza B	B/Virginia/ATCC5/2012	ATCC VR-1807	0.03 PFU/mL	20/20
Influenza B	B/FL/04/06	ATCC VR-1804	2050 $CEID_{50}$/mL	19/20
Influenza B	B/Taiwan/2/62	ATCC VR-295	5000 $CEID_{50}$/mL	19/20
Coronavirus 229E	not available	ATCC VR-740	9.47 $TCID_{50}$/mL	20/20
Coronavirus 229E	not available	ZeptoMetrix 0810229CFHI	3.6 $TCID_{50}$/mL	20/20
Coronavirus OC43	not available	ATCC VR-1558	0.1 $TCID_{50}$/mL	20/20
Coronavirus OC43	not available	ZeptoMetrix 0810024CFHI	1.99 $TCID_{50}$/mL	20/20

Pathogen	Strain	Source	Concentration*	Detection rate
Coronavirus NL63	not available	ZeptoMetrix 0810228CFHI	0.702 $TCID_{50}$/mL	20/20
Coronavirus HKU1	not available	ZeptoMetrix NATRVP-IDI	3E+03 copies/mL	20/20
Coronavirus HKU1	not available	QIAGEN Barcelona (STAT-Dx) S510	2.4E+05 copies/mL	20/20
Parainfluenza Virus 1 (PIV1)	C35	ATCC VR-94	9.48 $TCID_{50}$/mL	20/20
Parainfluenza Virus 1 (PIV1)	not available	ZeptoMetrix 0810014CFHI	0.2 $TCID_{50}$/mL	19/20
Parainfluenza Virus 2 (PIV2)	Greer	ATCC VR-92	13.9 $TCID_{50}$/mL	20/20
Parainfluenza Virus 2 (PIV2)	not available	ZeptoMetrix 0810015CFHI	1.3 $TCID_{50}$/mL	19/20
Parainfluenza Virus 3 (PIV3)	C 243	ATCC VR-93	44.1 $TCID_{50}$/mL	20/20
Parainfluenza Virus 3 (PIV3)	not available	ZeptoMetrix 0810016CFHI	11.5 $TCID_{50}$/mL	20/20
Parainfluenza Virus 4a (PIV4a)	M-25	ATCC VR-1378	3.03 $TCID_{50}$/mL	20/20
Parainfluenza Virus 4b (PIV4b)	not available	ZeptoMetrix 0810060BCFHI	9.5 $TCID_{50}$/mL	20/20
Enterovirus	US/IL/14-18952 (enterovirus D68)	ATCC VR-1824	534 $TCID_{50}$/mL	20/20
Enterovirus	Echovirus 6	ATCC VR-241	0.9 $TCID_{50}$/mL	19/20
Rhinovirus	1059 (rhinovirus B14)	ATCC VR-284	8.9 $TCID_{50}$/mL	20/20
Rhinovirus	HGP (rhinovirus A2)	ATCC VR-482	169 $TCID_{50}$/mL	20/20
Rhinovirus	11757 (rhinovirus C16)	ATCC VR-283	50.0 $TCID_{50}$/mL	20/20
Rhinovirus	Type 1A	ATCC VR-1559	8.9 $TCID_{50}$/mL	20/20
Adenovirus	GB (adenovirus B3)	ATCC VR-3	94900 $TCID_{50}$/mL	20/20
Adenovirus	RI-67 (adenovirus E4)	ATCC VR-1572	15.8 $TCID_{50}$/mL	20/20
Adenovirus	Adenoid 71 (adenovirus C1)	ATCC VR-1	69.5 $TCID_{50}$/mL	20/20
Adenovirus	Adenoid 6 (adenovirus C2)	ATCC VR-846	28.1 $TCID_{50}$/mL	20/20
Adenovirus	Tonsil 99 (adenovirus C6)	ATCC VR-6	88.8 $TCID_{50}$/mL	20/20
Adenovirus	Adenoid 75 (adenovirus C5)	ATCC VR-5	7331.0 $TCID_{50}$/mL	20/20

Pathogen	Strain	Source	Concentration*	Detection rate
Respiratory Syncytial virus A (RSV A)	A2	ATCC VR-1540	720 PFU/mL	20/20
Respiratory Syncytial virus A (RSV A)	Long	ATCC VR-26	33.0 PFU/mL	20/20
Respiratory Syncytial virus B (RSV B)	18537	ATCC VR-1580	0.03 PFU/mL	20/20
Respiratory Syncytial virus B (RSV B)	CH93(18)-18	ZeptoMetrix 0810040CFHI	0.4 $TCID_{50}$/mL	19/20
Human Metapneumovirus (hMPV)	Peru6-2003 (type B2)	ZeptoMetrix 0810159CFHI	0.01 $TCID_{50}$/mL	19/20
Human Metapneumovirus (hMPV)	hMPV-16, IA10-2003 (A1)	ZeptoMetrix 0810161CFHI	2.86 $TCID_{50}$/mL	19/20
Human Metapneumovirus (hMPV)	hMPV-20, IA14-2003 (A2)	ZeptoMetrix 0810163CFHI	0.4 $TCID_{50}$/mL	19/20
Human Metapneumovirus (hMPV)	hMPV-3, Peru2-2002 (B1)	ZeptoMetrix 0810156CFHI	1479.9 $TCID_{50}$/mL	19/20
Bocavirus	not available	IDT (gBLock)	33000 copies/mL	20/20
Bocavirus	not available	Vall d'hebron hospital	5.5E+04 copies/mL	20/20
Mycoplasma pneumoniae	M129-B7 (type 1)	ATCC 29342	0.1 CCU/mL	20/20
Mycoplasma pneumoniae	PI 1428	ATCC 29085	6.01 CCU/mL	20/20
Chamydophila pneumoniae	TW183	ATCC VR-2282	85.3 IFU/mL	20/20
Chamydophila pneumoniae	CWL-029	ATCC VR-1310	120.0 IFU/mL	19/20
Legionella pneumophila	CA1	ATCC 700711	5370 copies/mL	20/20
Bordetella pertussis	I028	ATCC BAA-2707	5.13 CFU/mL	20/20
Bordetella pertussis	18323	ATCC 9797	2.6 CFU/mL	19/20
SARS-CoV-2	not available	WHO, NIBSC, 20/146	19000 copies/mL (6.8E+04 IU/mL)	112/112
SARS-CoV-2	USA-WA1-2020	ZeptoMetrix 0810587CFH	3160 copies/mL	23/24
SARS-CoV-2	not available	Vall d'Hebron hospital S1229	1.9E+04 copies/mL	20/20
SARS-CoV-2	not available	Vall d'Hebron hospital S1231	1.9E+04 copies/mL	24/24

Pathogen	Strain	Source	Concentration*	Detection rate
SARS-CoV-2	not available	STAT-Dx Lite, S.L (a QIAGEN company) 243	600 copies/mL	30/30

*The highest LoD is reported.

Assay Robustness

The verification of robust assay performance was assessed by analyzing the Internal Control performance in clinical nasopharyngeal swab samples. Fifty individual nasopharyngeal swab samples, negative for all pathogens possible to detect, were analyzed with the QIAstat-Dx SARS-CoV-2 Respiratory Panel. All samples tested showed a positive result and valid performance for the Internal Control of the QIAstat-Dx SARS-CoV-2 Respiratory Panel.

Exclusivity (Analytical Specificity)

The analytical exclusivity study was carried out by in silico analysis and in vitro testing to assess the Analytical Specificity of the QIAstat-Dx Respiratory SARS-CoV-2 Panel. On-panel organisms were tested to assess the potential for intra-panel cross-reactivity and off-panel organisms were tested to evaluate panel exclusivity. These organisms included specimens which are related to, but distinct from, respiratory panel organisms or that could be present in specimens collected from the intended test population. Selected organisms are clinically relevant (colonizing the upper respiratory tract or causing respiratory symptoms), are common skin flora or laboratory contaminants, or are microorganisms for which much of the population may have been infected. Both on-panel and off-panel organisms tested are shown in Table 2.

Samples were prepared by spiking potential cross-reactive organisms into simulated nasopharyngeal swab sample matrix at the highest concentration possible based on the organism stock, preferably 10^5 $TCID_{50}$/mL for viral targets and 10^6 CFU/mL for bacterial targets.

Table 2. List of Analytical Specificity pathogens tested

On-panel/ Off-panel	Type	Pathogen	Strain	Source
On-panel	Bacteria	*C. pneumoniae*	AR-39	ATCC 53592
			TWAR strain TW-183	ATCC VR-2282
		B. pertussis	E431	Zeptometrix 0801460
		M. pneumoniae	M129	Zeptometrix 0801579
			UTMB-10P	ATCC 49894
		L. pneumophila	Philadelphia	Zeptometrix 0801645
			Philadelphia-1	ATCC 33152
	Virus	Influenza A H1N1	A/New Jersey/8/76	ATCC VR-897
		Influenza A H3N2	A/Switzerland/971529/2013	ATCC VR-1837
			A/Virginia/ATCC6/2012	ATCC VR-1811
		Influenza A H1N1/pdm09	A/Virginia/ATCC1/2009	ATCC VR-1736
			A/California/07/2009 NYMC X-179A	ATCC VR-1884
		Influenza B	B/Florida/04/06	ATCC VR-1804
		Coronavirus 229E	Not available	Zeptometrix 0810229CF
			Not available	Zeptometrix 0810229CFHI
		Coronavirus OC43	Not available	ATCC VR-1558
			Not available	Zeptometrix 0810024CFHI
		Coronavirus NL63	Not available	Bei Resources NR-470
		Coronavirus HKU1	Not available	QIAGEN S506*
		Parainfluenza virus 1	C35	ATCC VR-94
		Parainfluenza virus 2	Greer	ATCC VR-92
		Parainfluenza virus 3	C 243	ATCC VR-93
		Parainfluenza virus 4	PIV4A	Zeptometrix 0810060CFHI

On-panel/ Off-panel	Type	Pathogen	Strain	Source
			PIV4B	Zeptometrix 0810060BCFHI
		Respiratory Syncytial virus	A2	ATCC VR-1540
		Human metapneumovirus	A1 (hMPV-16, IA10-2003)	Zeptometrix 0810161CFHI
		Adenovirus C	Adenoid 71 (Adenovirus C1)	ATCC VR-1
		Adenovirus B	Gomen (Adenovirus B7)	ATCC VR-7
		Enterovirus D68	US/IL/14-18952	ATCC VR-1824
		Rhinovirus	2060 (Type 1A)	ATCC VR-1559
		Bocavirus	Type 1	Kansas University*
		SARS-CoV-2	Not available	Hospital Clinic S243*
Off-panel	Bacteria	*Acinetobacter calcoaceticus*	Z160	Zeptometrix 0804096
		Bordetella avium	Z338	Zeptometrix 0804316
		Bordetella bronchiseptica	NRRL B-140	ATCC 4617
		Bordetella hinzii	LMG 13501	ATCC 51783
			Not available	Vircell MC089
		Bordetella holmesii	F061	Zeptometrix 0801464
			CDC F5101	ATCC 51541
		Bordetella parapertussis	A747	Zeptometrix 0801461
		Chlamydia trachomatis	BOUR	ATCC VR-348-B
		Corynebacterium diphteriae	Z116	Zeptometrix 0801882
			48255	ATCC 11913
			NCDC 819-56	ATCC 13048

On-panel/ Off-panel	Type	Pathogen	Strain	Source
		Enterobacter aerogenes (Klebsiella aerogenes)	Z052	Zeptometrix 0801518
		Escherichia coli (0157)	O157:H7; EDL933	Zeptometrix 0801622
		Haemophilus influenzae	L-378	ATCC 49766
		Klebsiella oxytoca	LBM 90.11.033	ATCC 700324
		Klebsiella pneumoniae	NCTC 9633 [NCDC 298-53, NCDC 410-68]	ATCC 13883
		Lactobacillus acidophilus	Scav [IFO 13951, M. Rogosa 210X, NCIB 8690, P.A. Hansen L 917]	ATCC 4356
		Lactobacillus plantarum	17-5	Zeptometrix 0801507
		Legionella bozemanii	CIP 103872 (ATCC 33217; CCUG 11880; NCTC 11368)	CECT 7276
		Legionella dumofii	CCUG 11881 (ATCC 33279; CCUG 11881; CIP 103876; NCTC 11370; strain NY 23)	CECT 7349
		Legionella feeleii	Ly166.96	ATCC 700514
			Not available	Vircell MC092
		Legionella longbeacheae	Long Beach 4	Zeptometrix 0801577
		Legionella micdadei	Tatlock	Zeptometrix 0801576
		Moraxella catarrhalis (Branhamella catarrhalis)	Ne 11 [CCUG 353, LMG 11192, NCTC 11020]	ATCC 25238
			N9 [P. Baumann N4]	ATCC 25240
		Mycobacterium tuberculosis	Not available	ATCC 25177DQ
		Mycoplasma genitalium	SEA-1	Zeptometrix 0804094-I
		Mycoplasma hominis	Z317	Zeptometrix 080411
			not available	ATCC 27545

On-panel/ Off-panel	Type	Pathogen	Strain	Source
		Mycoplasma orale	CH 19299 [NCTC 10112]	ATCC 23714
		Neisseria elongata	Z071	Zeptometrix 0801510
		Neisseria gonorrhoeae	Z017	Zeptometrix 0801482
		Neisseria meningitidis	FAM18	ATCC 700532DQ
			Serogroup Y	ATCC 35561
		Proteus mirabilis	LRA 08 01 73 [API SA, DSM 6674]	ATCC 35659
			Z050	Zeptometrix 0801544
		Pseudomonas aeruginosa	PRD-10 [CIP 103467, NCIB 10421, PCI 812]	ATCC 15442
		Serratia marcescens	PCI 1107	ATCC 14756
		Staphylococcus aureus	Subsp.. aureus, FDA 209	ATCC CRM-6538
		Staphylococcus epidermidis	FDA strain PCI 1200	ATCC 12228
		Stenotrophomonas maltophilia	810-2 [MDB strain BS 1640, NCIB 9203, NCPPB 1974, NCTC 10257, NRC 729, R.Y. Stanier 67, RH 1168]	ATCC 13637
		Streptococcus agalactiae	NCTC 8181 [G19]	ATCC 13813
			Z2019	Zeptometrix 0801545
		Streptococcus pneumoniae	Z022, 19F	Zeptometrix 0801439
		Streptococcus pyogenes	Lancefield's group A/C203 S	ATCC 14289
			Z018	ZeptoMetrix 0801512
		Streptococcus salivarus	Z127	Zeptometrix 0801896
			C699 [S30D]	ATCC 13419
		Ureaplasma urealyticum	T-strain 960 (CX8) [960, CIP 103755, NCTC 10177]	ATCC 27618

On-panel/ Off-panel	Type	Pathogen	Strain	Source
	Virus	Cytomegalovirus	AD-169	Zeptometrix NATCMV-0005
			Towne	Zeptometrix 0810499CFHI
		Epstein-Barr Virus	B958	ATCC VR-1492PQ
		Herpes Simplex Virus 1	ATCC-20111	ATCC VR-1778/ VR-1789
		Herpes Simplex Virus 2	ATCC-2011-2	ATCC VR-1779/ VR-734
		Measles Virus	Edmonston	ATCC VR-24
		Middle East Respiratory Syndrome (MERS) Coronavirus	England-1	Vircell MC121
			Not available	ATCC VR-3248SD
		Mumps	Enders	ATCC VR-106
		Severe Acute Respiratory Syndrome (SARS)	Not available	IDT (gBlocks)†
	Fungus	*Aspergillus flavus*	Harvard 997	Vircell MC064
			Z013	Zeptometrix 0801598
		Aspergillus fumigatus	MCV-C#10	Vircell MBC002
			Z014	Zeptometrix 0801716
		Candida albicans	3147 [CBS 6431, CCY 29-3-106, CIP 48.72, DSM 1386, IFO 1594, NCPF 3179, NCYC 1363, NIH 3147, VTT C-85161]	ATCC CRM-10231
		Cryptococcus neoformans	CBS 132 [CCRC 20528, DBVPG 6010, IFO 0608, NRRL Y- 2534]	ATCC 32045

* Clinical sample obtained in STAT-Dx Life, S.L (a QIAGEN company) (HKU1); Kansas University, US (Bocavirus); and Hospital Clinic, Barcelona (SARS-CoV-2).

† Artificial genomic fragments were used for SARS.

All on-panel pathogens resulted in specific detection, and all off-panel pathogens tested showed a negative result, and no cross-reactivity was observed in the QIAstat-Dx Respiratory SARS-CoV-2 Panel. The only exception is Bordetella species since *Bordetella holmesii* and *Bordetella bronchiseptica* cross-reacted with *Bordetella pertussis* assay. The target gene used for *Bordetella pertussis* detection (insertion element IS481) is a transposon also present in other Bordetella species, and a certain level of cross-reactivity was predicted by preliminary sequence analysis and was observed when high concentrations of *Bordetella holmesii* and some strains of *Bordetella bronchiseptica* were tested. In accordance with the CDC guidelines for assays that use the IS481 as a target region, when using QIAstat-Dx Respiratory SARS-CoV-2 Panel if the CT value for Bordetella pertussis is CT>29, a confirmatory specificity test is recommended. No cross-reactivity was observed with *Bordetella* parapertussis at high concentrations.

In silico analysis was performed for all primer/probe designs included in the QIAstat-Dx Respiratory SARS-CoV-2 Panel, proving specific amplification and detection of targets without cross-reactivity (with the only exception described above).

Inclusivity (Analytical Reactivity)

Analytical Reactivity (Inclusivity) study was performed to analyze the detection of a variety of strains that represent the genetic diversity of each respiratory panel target organism ("inclusivity strains").

A total of 139 Inclusivity strains were included in the study, representative of the species/types for the different organisms (for example, a range of Influenza A strains isolated from different geographical areas and in different calendar years were included). Based on wet testing and in silico analysis, the QIAstat-Dx Respiratory SARS-CoV-2 Panel primers and probes are specific and inclusive for clinically prevalent and relevant strains for each pathogen. Wet testing has been done with the strains listed in Table 3.

Table 3. List of Inclusivity Strains Tested

Pathogen	Subtype/ Serotype	Strain	Source	x LoD detected	QIAstat-Dx Result
Influenza A	H1N1	A/Brisbane/59/07	Zeptometrix 0810244CFHI†	1x LoD	Influenza A H1
		A/New Caledonia/20/99	Zeptometrix 0810036CFHI*	0.3x LoD	Influenza A H1
		A/New Jersey/8/76	ATCC VR-897*	1x LoD	Influenza A H1
		A/Denver/1/57	ATCC VR-546	0.1x LoD	Influenza A H1
		A/Mal/302/54	ATCC VR-98	1x LoD	Influenza A H1
		A/Weiss/43	ATCC VR-96	0.1x LoD	Influenza A H1
		A/PR/8/34	ATCC VR-1469	3x LoD	Influenza A H1
		A/Fort Monmouth/1/1947	ATCC VR-1754	0.1x LoD	Influenza A H1

Pathogen	Subtype/ Serotype	Strain	Source	x LoD detected	QIAstat-Dx Result
		A/WS/33	ATCC VR-1520	0.1x LoD	Influenza A H1
		A/Swine/Iowa/15/1930	ATCC VR-333	1x LoD	Influenza A H1
	H3N2	A/Virginia/ATCC6/2012	ATCC VR-1811*	1x LoD	Influenza A H3
		A/Port Chalmers/1/73	ATCC VR-810†	1x LoD	Influenza A H3
		A/Wisconsin/67/2005	Zeptometrix 0810252CFHI*	1x LoD	Influenza A H3
		A/Wisconsin/15/2009	ATCC VR-1882	1x LoD	Influenza A H3
		A/Victoria/3/75	ATCC VR-822	1x LoD	Influenza A H3
		A/Aichi/2/68	ATCC VR-1680	10x LoD	Influenza A H3
		A/Hong Kong/8/68	ATCC VR-1679	10x LoD	Influenza A H3
		A/Alice (recombinant, carries A/England/42/72)	ATCC VR-776	10x LoD	Influenza A H3
		MRC-2 (recombinant A/England/42/72 and A/PR/8/34 strains)	ATCC VR-777	100x LoD	Influenza A H3
		A/Switzerland/9715293/2013	ATCC VR-1837	1x LoD	Influenza A H3
	H1N1/pdm09	A/Virginia/ATCC1/2009	ATCC VR-1736†	1x LoD	Influenza A H1N1/pdm09
		A/SwineNY/03/2009	Zeptometrix 0810249CFHI*	1x LoD	Influenza A H1N1/pdm09
		A/Virginia/ATCC2/2009	ATCC VR-1737	0.1x LoD	Influenza A H1N1/pdm09
		A/Virginia/ATCC3/2009	ATCC VR-1738	100x LoD	Influenza A H1N1/pdm09

Pathogen	Subtype/ Serotype	Strain	Source	x LoD detected	QIAstat-Dx Result
		Swine NY/01/2009	Zeptometrix 0810248CFHI	0.3x LoD	Influenza A H1N1/pdm09
		Swine NY/02/2009	Zeptometrix 0810109CFNHI	10x LoD	Influenza A H1N1/pdm09
		A/California/07/2009 NYMC X-179A	ATCC VR-1884	0.1x LoD	Influenza A H1N1/pdm09
		Canada/6294/09	Zeptometrix 0810109CFJHI	3x LoD	Influenza A H1N1/pdm09
		Mexico/4108/09	Zeptometrix 0810166CFHI	0.1x LoD	Influenza A H1N1/pdm09
		Netherlands/2629/2009	BEI Resources NR-19823	0.3x LoD	Influenza A H1N1/pdm09
	H1N2‡	Recombinant Kilbourne F63, A/NWS/1934 (HA) x A/Rockefeller Institute/5/1957 (NA) (nucleic acid)	BEI Resources NR-9677	100x LoD	Influenza A H1
	H2N2‡	Japan/305/1957 (nucleic acid)	BEI Resources NR-2775	1x LoD	Influenza A
		Korea/426/1968x Puerto Rico/8/1934 (nucleic acid)	BEI Resources NR-9679	0.3x LoD	Influenza A
	H2N3‡	A/duck/Germany/1215/1973 (H2N3) (nucleic acid)	BEI Resources	Not applicable§	Influenza A
	H5N2‡	A/duck/Pennsylvania/10218/1984 (H5N2) (nucleic acid)	BEI Resources	Not applicable§	Influenza A
	H5N3‡	A/Duck/Singapore/645/1997 (nucleic acid)	BEI Resources NR-9682	1x LoD	Influenza A
	H7N7‡	A/equine/Prague/1956 (H7N7) (nucleic acid)	BEI Resources	Not applicable§	Influenza A

Pathogen	Subtype/ Serotype	Strain	Source	x LoD detected	QIAstat-Dx Result
	H10N7‡	Chicken/Germany /N/49 (nucleic acid)	BEI Resources NR-2765	10x LoD	Influenza A
Influenza B	Not available	B/Virginia/ATCC5 /2012	ATCC VR-1807†	1x LoD	Influenza B
		B/FL/04/06	ATCC VR-1804*	1x LoD	Influenza B
		B/Taiwan/2/62	ATCC VR-295*	0.3x LoD	Influenza B
		B/Allen/45	ATCC VR-102	Not detected	Negative¶
		B/Hong Kong/5/72	ATCC VR-823	Not detected	Negative¶
		B/Maryland/1/59	ATCC VR-296	0.1x LoD	Influenza B
		B/GL/1739/54	ATCC VR-103	1x LoD	Influenza B
		B/Wisconsin/1/2 010	ATCC VR-1883	0.1x LoD	Influenza B
		B/Massachusetts/2 /2012	ATCC VR-1813	3x LoD	Influenza B
		B/Florida/02/06	Zeptometrix 0810037CFHI	Impaired detectabili ty	Influenza B or negative**
		B/Brisbane/60/20 08	BEI Resources NR-42005	0.1x LoD	Influenza B
		B/Malaysia/2506 /2004	BEI Resources NR-9723	0.3x LoD	Influenza B
Coronavirus 229E	Not available	Not available	ATCC VR-740	0.3x LoD	Coronavirus 229
		Not available	Zeptometrix 0810229CFHI†	1x LoD	Coronavirus 229
Coronavirus OC43	Not available	Not available	ATCC VR-1558†	1x LoD	Coronavirus OC43
		Not available	Zeptometrix 0810024CFHI	1x LoD	Coronavirus OC43
Coronavirus NL63	Not available	Not available	Zeptometrix 0810228CFHI†	1x LoD	Coronavirus NL63
		Not available	BEI Resources NR-470	1x LoD	Coronavirus NL63

Pathogen	Subtype/ Serotype	Strain	Source	x LoD detected	QIAstat-Dx Result
Coronavirus HKU1	Not available	Not available	Zeptometrix NATRVP-IDI†	1x LoD	Coronavirus HKU1
		Not available	QIAGEN Barcelona†† S510	3x LoD	Coronavirus HKU1
		Not available	QIAGEN Barcelona†† S501	1x LoD	Coronavirus HKU1
		Not available	QIAGEN Barcelona†† S496	1x LoD	Coronavirus HKU1
Parainfluenza Virus 1	Not available	C35	ATCC VR-94*	1x LoD	Parainfluenza virus 1
		Not available	Zeptometrix 0810014CFHI†	1x LoD	Parainfluenza virus 1
		Not available	Zeptometrix NATRVP-IDI	10x LoD	Parainfluenza virus 1
Parainfluenza Virus 2	Not available	Greer	ATCC VR-92†	1x LoD	Parainfluenza virus 2
		Not available	Zeptometrix 0810015CFHI*	0.3x LoD	Parainfluenza virus 2
		Not available	Zeptometrix 0810504CFHI	0.1x LoD	Parainfluenza virus 2
Parainfluenza Virus 3	Not available	C 243	ATCC VR-93*	1x LoD	Parainfluenza virus 3
		Not available	Zeptometrix 0810016CFHI†	1x LoD	Parainfluenza virus 3
		Not available	Zeptometrix NATRVP-IDI	0.1x LoD	Parainfluenza virus 3
Parainfluenza Virus 4	A	M-25	ATCC VR-1378†	1x LoD	Parainfluenza virus 4
		Not available	Zeptometrix 0810060CFHI	0.1x LoD	Parainfluenza virus 4
	B	Not available	Zeptometrix 0810060BCFHI*	0.3x LoD	Parainfluenza virus 4
		CH 19503	ATCC VR-1377	0.3x LoD	Parainfluenza virus 4

Pathogen	Subtype/ Serotype	Strain	Source	x LoD detected	QIAstat-Dx Result
Respiratory Syncytial Virus	A	A2	ATCC VR-1540*	0.3x LoD	Respiratory Syncytial virus A+B
		Long	ATCC VR-26*	1x LoD	Respiratory Syncytial virus A+B
		Not available	Zeptometrix 0810040ACFHI	0.1x LoD	Respiratory Syncytial virus A+B
	B	18537	ATCC VR-1580†	1x LoD	Respiratory Syncytial virus A+B
		CH93(18)-18	Zeptometrix 0810040CFHI*	1x LoD	Respiratory Syncytial virus A+B
		B WV/14617/85	ATCC VR-1400	1x LoD	Respiratory Syncytial virus A+B
Human Metapneumovirus	A1	IA10-2003	Zeptometrix 0810161CFHI†	1x LoD	Human Metapneumovirus A+B
		IA3-2002	Zeptometrix 0810160CFHI	3x LoD	Human Metapneumovirus A+B
	A2	IA14-2003	Zeptometrix 0810163CFHI*	1x LoD	Human Metapneumovirus A+B
		IA27-2004	Zeptometrix 0810164CFHI	1x LoD	Human Metapneumovirus A+B
	B1	Peru2-2002	Zeptometrix 0810156CFHI*	1x LoD	Human Metapneumovirus A+B
		Peru3-2003	Zeptometrix 0810158CFHI	1x LoD	Human Metapneumovirus A+B
	B2	Peru6-2003	Zeptometrix 0810159CFHI*	1x LoD	Human Metapneumovirus A+B

Pathogen	Subtype/ Serotype	Strain	Source	x LoD detected	QIAstat-Dx Result
		IA18-2003	Zeptometrix 0810162CFHI	1x LoD	Human Metapneumovirus A+B
		Peru1-2002	Zeptometrix 0810157CFHI	10x LoD	Human Metapneumovirus A+B
Adenovirus A	12	Not available	ATCC VR-863	0.3x LoD	Adenovirus
Adenovirus B	3	GB	ATCC VR-3*	0.3x LoD	Adenovirus
	7	Not available	ATCC VR-7	0.1x LoD	Adenovirus
	11	Not available	ATCC VR-12	10x LoD	Adenovirus
	21	Not available	ATCC VR-256	0.3x LoD	Adenovirus
	34	Not available	ATCC VR-716	0.3x LoD	Adenovirus
	35	Not available	ATCC VR-718	0.3x LoD	Adenovirus
Adenovirus C	1	Adenoid 71	ATCC VR-1*	1x LoD	Adenovirus
	2	Adenoid 6	ATCC VR-846*	0.3x LoD	Adenovirus
	5	Adenoid 75	ATCC VR-5*	0.3x LoD	Adenovirus
	6	Tonsil 99	ATCC VR-6†	1x LoD	Adenovirus
Adenovirus D	8	Not available	ATCC VR-1815	0.3x LoD	Adenovirus
Adenovirus E	4	RI-67	ATCC VR-1572*	0.3x LoD	Adenovirus
Adenovirus F	40	Not available	ATCC VR-931	0.1x LoD	Adenovirus
	41	Not available	ATCC VR-930	3x LoD	Adenovirus
Enterovirus A	EV-A71	Not available	ATCC VR-1432	1x LoD	Rhinovirus/ Enterovirus
	CV-A10	Not available	ATCC VR-168	10x LoD	Rhinovirus/ Enterovirus
Enterovirus B	E-6	D-1 (Cox)	ATCC VR-241*	0.3x LoD	Rhinovirus/ Enterovirus
	E-11	Not available	ATCC VR-41	10x LoD	Rhinovirus/ Enterovirus
	E-30	Not available	ATCC VR-1660	1x LoD	Rhinovirus/ Enterovirus
	CV-A9	Not available	ATCC VR-1311	0.3x LoD	Rhinovirus/ Enterovirus

Pathogen	Subtype/ Serotype	Strain	Source	x LoD detected	QIAstat-Dx Result
	CV-B1	Not available	ATCC VR-28	0.3x LoD	Rhinovirus/ Enterovirus
	CV-B2	Not available	ATCC VR-29	3x LoD	Rhinovirus/ Enterovirus
	CV-B3	Not available	ATCC VR-30	0.3x LoD	Rhinovirus/ Enterovirus
	E-17	Not available	ATCC VR-47	10x LoD	Rhinovirus/ Enterovirus
Enterovirus C	CV-A21	Not available	ATCC VR-850	10x LoD	Rhinovirus/ Enterovirus
Enterovirus D	EV-D68	/US/IL/14-18952	ATCC VR-1824†	1x LoD	Rhinovirus/ Enterovirus
Rhinovirus A	1	2060	ATCC VR-1559*	0.1x LoD	Rhinovirus/ Enterovirus
	2	HGP	ATCC VR-482*	1x LoD	Rhinovirus/ Enterovirus
	16	11757	ATCC VR-283*	0.3x LoD	Rhinovirus/ Enterovirus
Rhinovirus B	14	1059	ATCC VR-284†	1x LoD	Rhinovirus/ Enterovirus
	3	Not available	ATCC VR-483	1x LoD	Rhinovirus/ Enterovirus
	17	Not available	ATCC VR-1663	3x LoD	Rhinovirus/ Enterovirus
Bocavirus	Not available	Not available	IDT gBlock†	1x LoD	Bocavirus
		Not available	Clinical Sample††	1x LoD	Bocavirus
		Not available	Zeptometrix 0601178NTS	1x LoD	Bocavirus
		Not available	Zeptometrix MB-004	0.3x LoD	Bocavirus
SARS-CoV-2	Not available	WHO reference material	NIBSC 20/146‡‡	1xLoD	SARS-CoV-2
M. pneumoniae	1	M129-B7	ATCC 29342*	1xLoD	*Mycoplasma pneumoniae*
	1	PI 1428	ATCC 29085†	1xLoD	*Mycoplasma pneumoniae*

Pathogen	Subtype/ Serotype	Strain	Source	x LoD detected	QIAstat-Dx Result
	2	Not available	ATCC 15531	0.1xLoD	*Mycoplasma pneumoniae*
B. pertussis	Not available	I028	ATCC BAA-2707†	1xLoD	*Bordetella pertussis*
	Not available	19323	ATCC 9797*	1xLoD	*Bordetella pertussis*
	Not available	not available	ATCC 10380	0.3xLoD	*Bordetella pertussis*
C. pneumoniae	Not available	TW183	ATCC VR-2282†	1xLoD	*Chlamydophila pneumoniae*
	Not available	CWL-029	ATCC VR-1310*	1xLoD	*Chlamydophila pneumoniae*
	Not available	not available	ATCC 53592	0.3xLoD	*Chlamydophila pneumoniae*
L. pneumophila	Not available	CA1	ATCC 700711†	1xLoD	*Legionella pneumophila*
	Not available	*Legionella pneumophila* subsp. Pneumophila/ 169-MN-H	ATCC 43703	3xLoD	*Legionella pneumophila*
	Not available	Not available	Zeptometrix MB-004	1xLoD	*Legionella pneumophila*
	Not available	subsp. Pneumophila / Philadelphia-1	ATCC 33152	1xLoD	*Legionella pneumophila*

* Strains tested in LoD study.
† Strains tested in LoD and used for calculation of sensitivity level (X times LoD).
‡ For all non-human Flu A strains, Influenza A/Brisbane/59/07 (Zeptometrix, 0810244CFHI) taken as reference strain to calculate the x-fold LoD detected.
§ Three non-human Flu A strains were not available for in vitro testing, and analysis was performed in silico.
¶ Both Flu B strains are derivative from B/Lee/40 ancestral lineage, currently not in circulation.
** Impaired detectability. In silico analysis supports detectability.
†† Clinical samples obtained in STAT-Dx Life, S.L (a QIAGEN company) Q), Spain (HKU1) and University of Kansas, USA (Bocavirus).
‡‡ SARS-CoV-2 WHO reference material was tested in laboratory as representative strain. Additional analysis was run for SARS-CoV-2 to cover all variants and lineages.

In addition, in silico analysis was done to characterize inclusivity coverage of on-panel pathogens against available genomic sequences in publicly available databases.

In case of SAR*S-CoV-2,* in silico *e*valuation included a total of 11,323,728 available genomes (since the beginning of the SARS-CoV-2 outbreak (January 1, 2020) until April 24, 2023) extracted from GISAID data base. This period includes all major SARS-CoV-2 lineages (Variants of Concern *Alpha*, *Beta*, *Gamma*, *Delta*, and *Omicron*; together with Variants of Interest *Lambda* and *Mu, plus variants Kappa, Epsilon, Eta, and B.1.617.3*). 11,046,667 (97,55%) of the analyzed sequence genomes showed no evidence of mismatches among the assay's oligonucleotides binding region. For the rest of analyzed genomes, only 35,063 (0.31%) presented any mismatch with potentially critical impact in assay performance with a prevalence of >0.2%. Laboratory validation of those mismatches was performed at LoD level using artificial genomic fragments including corresponding mutations, confirming no loss of performance. This deep analysis covering all main important lineages concluded that the QIAstat-Dx Respiratory SARS-CoV-2 Panel was inclusive for all analyzed SARS-CoV-2 genomes, including all known variants, lineages and sublineages. New sequences and variants are periodically monitored for potential impact on QIAstat-Dx Respiratory SARS-CoV-2 Panel performance.

Also, for those on-panel organisms with known biological subtype differentiation, coverage was analyzed. Inclusivity for Flu A (Table 4), Rhinovirus/Enterovirus (Table 5), and Adenovirus (Table 6) were evaluated based on sequences available in GenBank database. In all cases, the QIAstat-Dx Respiratory SARS-CoV-2 Panel was able to detect all described types or subtypes.

For all other organisms, a BLAST-based homology analysis also confirmed that all available target sequences in GenBank database are predicted to be detected. This applies to Flu B (Victoria and Yamagata lineages), Coronavirus 229E, Coronavirus OC43, Coronavirus NL63, Coronavirus HKU1, PIV1, PIV2, PIV3, PIV4 (including PIV4a and PIV4b), RSV (including RSVA and RSVB), hMPV (including hMPVA1, hMPVA2, hMPB1 and hMPVB2 subtypes),

Bocavirus (subtype 1), *Mycoplasma pneumoniae*, *Chlamydophila pneumoniae*, *Bordetella pertussis*, and *Legionella pneumophila* (all described serotypes).

Table 4. Inclusivity of General Influenza A Assay

	Detected by BLAST/Sequence alignment*								
H/N serotype combination	**N1**	**N2**	**N3**	**N4**	**N5**	**N6**	**N7**	**N8**	**N9**
H1	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
H2	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
H3	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
H4	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
H5	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
H6	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
H7	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
H8	Yes	Yes	Yes	Yes	N/A	Yes	N/A	Yes	N/A
H9	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
H10	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
H11	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
H12	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
H13	N/A	Yes	Yes	N/A	N/A	Yes	N/A	Yes	Yes
H14	N/A	Yes	Yes	Yes	Yes	Yes	Yes	Yes	N/A
H15	N/A	N/A	N/A	Yes	Yes	Yes	Yes	N/A	Yes
H16	N/A	N/A	Yes	N/A	N/A	N/A	N/A	Yes	Yes

* N/A: not applicable (no sequences available in GenBank database).

Table 5. Inclusivity of Rhinovirus/Enterovirus Assay

HRV/HEV subtype	Detected by BLAST/Sequence alignment*
Enterovirus A	• Coxsackievirus A10, A12, A14, A16, A2, A3, A4, A5, A6, A7, A8 • Enterovirus A114, A119, A120, A121, A123, A124, A125, A71, A76, A89, A90, A91, A92 • Simian Enterovirus 19
Enterovirus B	• Coxsackievirus A9, B1, B2, B3, B4, B5, B6 • Echovirus E1, E11, E12, E13, E14, E15, E16, E17, E18, E19, E2, E20, E21, E24, E25, E26, E27, E29, E3, E30, E31, E32, E33, E4, E5, E6, E7, E8, E9 • Enterovirus B100, B101, B106, B107, B110, B111, B69, B73, B74, B75, B77, B79, B80, B81, B82, B83, B84, B85, B86, B87, B88, B93, B97, B98 • Enterovirus Yanbian 96-83csf, Yanbian 96-85csf, Simian agent 5, Swine vesicular disease virus
Enterovirus C	• Coxsackievirus A1, A11, A13, A15, A17, A18, A19, A20, A21, A22, A24 • Enterovirus C102, C104, C105, C109, C113, C116, C117, C118, C95, C96, C99 • Human poliovirus 1, 2, 3
Enterovirus D	• Enterovirus D111, D68, D70, D94
Rhinovirus A	• Human rhinovirus A44, A95 • Rhinovirus A1, A10, A100, A101, A103, A105, A106, A11, A12, A13, A15, A16, A18, A19, A1B, A2, A20, A21, A22, A23, A24, A25, A28, A29, A30, A31, A32, A33, A34, A36, A38, A39, A40, A41, A43, A45, A46, A47, A49, A50, A51, A53, A54, A55, A56, A57, A58, A59, A60, A61, A62, A63, A64, A65, A66, A67, A68, A7, A71, A73, A74, A75, A76, A77, A78, A8, A80, A81, A82, A85, A88, A89, A9, A90, A94, A96, A98
Rhinovirus B	• Rhinovirus B100, B101, B102, B103, B14, B17, B26, B27, B3, B35, B37, B4, B42, B48, B5, B52, B6, B69, B70, B72, B79, B83, B84, B86, B91, B92, B93, B97, B99
Rhinovirus C	• Rhinovirus C1, C11, C13, C15, C17, C19, C2, C20, C23, C26, C27, C28, C3, C30, C31, C32, C33, C34, C35, C36, C4, C40. C41, C43, C44, C47, C5, C50, C51, C53, C54, C55, C56, C6, C7, C8, C9

* The rest of the Rhinovirus/Enterovirus strains that are not included in the table correspond to no target gene sequences available to corroborate positive detection.

Table 6. Inclusivity of Adenovirus assay

Adenovirus subtype	Detected by BLAST/Sequence alignment
Adenovirus A	• Human Adenovirus A12, A18, A31, A61
Adenovirus B	• Human Adenovirus B3, B3+11p, B3+7, B7, B11, B50, B55, B1, B2
Adenovirus C	• Human Adenovirus C1, C2, C5, C6, C57
Adenovirus D	• Human Adenovirus D15, D15/H9, D17, D19, D20, D22, D23, D24, D25, D26, D27, D28, D29, D30, D32, D33, D36, D38, D39, D42, D43, D44, D45, D46, D47, D48, D49, D51, D53, D54, D58, D60a, D62, D63, D64, D65, D67, D69, D71, D81, D10, D13, D37, D8, D9
Adenovirus E	• Human Adenovirus E4 • Simian Adenovirus 23, 24, 25, 26, 30, 36, 37, 38, 39, E22 • Chimpanzee adenovirus Y25, Gorilla gorilla adenovirus E1
Adenovirus F	• Adenovirus F40, F41
Adenovirus G	• Adenovirus G52

Based on both wet testing and in silico analysis, the QIAstat-Dx Respiratory SARS-CoV-2 Panel primers and probes are specific and inclusive for clinically prevalent and relevant strains for each pathogen.

Reproducibility

To prove reproducible performance of the QIAstat-Dx Respiratory SARS-CoV-2 Panel on the QIAstat-Dx Analyzer 1.0 and QIAstat-Dx Analyzer 2.0, a set of selected samples composed of low-concentrated analytes (3x LoD and 1x LoD) and high negative (0.1x LoD)/ negative samples was tested in NPS processed in UTM or dry NPS.

NPS samples processed in UTM were tested in replicates using different lots of QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridges and tests were executed on different QIAstat-Dx Analyzers 1.0 by different operators, different sites, and on different days. As SARS-CoV-2 was added as a target to the panel at a later stage, when reproducibility for all other targets had been confirmed, SARS-CoV-2 testing was conducted in one site to corroborate that it had the expected behaviour. Table 7 contains the list of tested pathogens.

Table 8 and Table 9 summarize the results for 3x and 1x LoD concentration where it is observed that the detection rate for 24 of the 24 targets was ≥95%. Table 10 summarizes the results for high negative/ negative concentration where it is observed that the detection rate for 24 of the 24 targets was <95% and 0%, respectively.

Table 7. List of Respiratory Pathogens tested for reproducibility in NPS in UTM

Pathogen	Strain
Influenza A H1	A/New Jersey/8/76
Influenza A H3	A/Port Chalmers/1/73
Influenza A H1N1 /2009	A/SwineNY/03/2009
Influenza B	B/Taiwan/2/62
Coronavirus 229E	Not available
Coronavirus OC43	Not available
Coronavirus NL63	Not available
Coronavirus HKU1	Not available
Parainfluenza Virus 1	Not available
Parainfluenza Virus 2	Greer
Parainfluenza Virus 3	C 243
Parainfluenza Virus 4a	M-25
Rhinovirus	HGP (rhinovirus A2)
Enterovirus	US/IL/14-18952 (enterovirus D68)
Adenovirus	GB (adenovirus B3)
RSV B	CH93(18)-18
RSV A	A2
hMPV	hMPV-16, IA10-2003 (A1)
Bocavirus	Clinical sample
Mycoplasma pneumoniae	PI 1428
Chlamydophila pneumoniae	TW183
Legionella pneumophila	CA1
Bordetella pertussis	I028
SARS-CoV-2	England/02/2020

Table 8. Summary of Agreement for reproducibility at 3x LoD in NPS in UTM

Target (3x LoD)	Specific signal	Site	Detection Rate	% Detection rate	Lower Two-Sided Exact 90%	Upper Two-Sided Exact 90%	% Agreement with expected result
			(#Positive)	(#Positive)	Confidence Limit	Confidence Limit	
Influenza A H1N1/pdm 09 (0810249CFHI)*	Influenza A	Site 1	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 2	19 / 19	100.00%	85.41%	100.00%	100.00%
		Site 3	19 / 19	100.00%	85.41%	100.00%	100.00%
		All Sites (Overall)	58 / 58	100.00%	94.97%	100.00%	100.00%
	H1N1/pdm 09	Site 1	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 2	19 / 19	100.00%	85.41%	100.00%	100.00%
		Site 3	19 / 19	100.00%	85.41%	100.00%	100.00%
		All Sites (Overall)	58 / 58	100.00%	94.97%	100.00%	100.00%
Influenza A H1 (ATCC VR-897)*	Influenza A	Site 1	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 2	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 3	20 / 20	100.00%	86.09%	100.00%	100.00%
		All Sites (Overall)	60 / 60	100.00%	95.13%	100.00%	100.00%
	H1	Site 1	19 / 20	95.00%	78.39%	99.74%	95.00%
		Site 2	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 3	20 / 20	100.00%	86.09%	100.00%	100.00%
		All Sites (Overall)	59 / 60	98.33%	92.34%	99.91%	98.33%

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Target (3x LoD)	Specific signal	Site	Detection Rate	% Detection rate	Lower Two-Sided Exact 90%	Upper Two-Sided Exact 90%	% Agreement with expected result
			(#Positive)	(#Positive)	Confidence Limit	Confidence Limit	
Influenza H3 (ATCC VR-810)*	Influenza A	Site 1	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 2	19 / 19	100.00%	85.41%	100.00%	100.00%
		Site 3	20 / 20	100.00%	86.09%	100.00%	100.00%
		All Sites (Overall)	59 / 59	100.00%	95.05%	100.00%	100.00%
	H3	Site 1	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 2	19 / 19	100.00%	85.41%	100.00%	100.00%
		Site 3	20 / 20	100.00%	86.09%	100.00%	100.00%
		All Sites (Overall)	59 / 59	100.00%	95.05%	100.00%	100.00%
Influenza B	Not available	Site 1	19 / 20	95.00%	78.39%	99.74%	95.00%
		Site 2	19 / 19	100.00%	85.41%	100.00%	100.00%
		Site 3	20 / 20	100.00%	86.09%	100.00%	100.00%
		All Sites (Overall)	58 / 59	98.31%	92.21%	99.91%	98.31%
Coronavirus 229E (ATCC VR-740)	Not available	Site 1	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 2	19 / 19	100.00%	85.41%	100.00%	100.00%
		Site 3	20 / 20	100.00%	86.09%	100.00%	100.00%
		All Sites (Overall)	59 / 59	100.00%	95.05%	100.00%	100.00%

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Target (3x LoD)	Specific signal	Site	Detection Rate	% Detection rate	Lower Two-Sided Exact 90%	Upper Two-Sided Exact 90%	% Agreement with expected result
			(#Positive)	(#Positive)	Confidence Limit	Confidence Limit	
Coronavirus OC43 (ATCC VR-1558)	Not available	Site 1	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 2	19 / 19	100.00%	85.41%	100.00%	100.00%
		Site 3	19 / 19	100.00%	85.41%	100.00%	100.00%
		All Sites (Overall)	58 / 58	100.00%	94.97%	100.00%	100.00%
Coronavirus NL63 (0810228C FHI)	Not available	Site 1	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 2	19 / 19	100.00%	85.41%	100.00%	100.00%
		Site 3	20 / 20	100.00%	86.09%	100.00%	100.00%
		All Sites (Overall)	59 / 59	100.00%	95.05%	100.00%	100.00%
Coronavirus HKU1 (NATRVP-IDI)	Not available	Site 1	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 2	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 3	20 / 20	100.00%	86.09%	100.00%	100.00%
		All Sites (Overall)	60 / 60	100.00%	95.13%	100.00%	100.00%
Parainfluenza Virus 1 (0810014C FHI)	Not available	Site 1	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 2	19 / 19	100.00%	85.41%	100.00%	100.00%
		Site 3	20 / 20	100.00%	86.09%	100.00%	100.00%
		All Sites (Overall)	59 / 59	100.00%	95.05%	100.00%	100.00%

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Target (3x LoD)	Specific signal	Site	Detection Rate	% Detection rate	Lower Two-Sided Exact 90%	Upper Two-Sided Exact 90%	% Agreement with expected result
			(#Positive)	(#Positive)	Confidence Limit	Confidence Limit	
Parainfluenza Virus 2 (ATCC VR-92)	Not available	Site 1	19 / 20	95.00%	78.39%	99.74%	95.00%
		Site 2	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 3	20 / 20	100.00%	86.09%	100.00%	100.00%
		All Sites (Overall)	59 / 60	98.33%	92.34%	99.91%	98.33%
Parainfluenza Virus 3 (ATCC VR-93)	Not available	Site 1	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 2	19 / 19	100.00%	85.41%	100.00%	100.00%
		Site 3	19 / 19	100.00%	85.41%	100.00%	100.00%
		All Sites (Overall)	58 / 58	100.00%	94.97%	100.00%	100.00%
Parainfluenza Virus 4 (ATCC VR-1378)	Not available	Site 1	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 2	19 / 19	100.00%	85.41%	100.00%	100.00%
		Site 3	20 / 20	100.00%	86.09%	100.00%	100.00%
		All Sites (Overall)	59 / 59	100.00%	95.05%	100.00%	100.00%
Rhinovirus (ATCC VR-482)	Not available	Site 1	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 2	19 / 19	100.00%	85.41%	100.00%	100.00%
		Site 3	19 / 19	100.00%	85.41%	100.00%	100.00%
		All Sites (Overall)	58 / 58	100.00%	94.97%	100.00%	100.00%

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Target (3x LoD)	Specific signal	Site	Detection Rate	% Detection rate	Lower Two-Sided Exact 90%	Upper Two-Sided Exact 90%	% Agreement with expected result
			(#Positive)	(#Positive)	Confidence Limit	Confidence Limit	
Enterovirus (ATCC VR-1824)	Not available	Site 1	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 2	19 / 19	100.00%	85.41%	100.00%	100.00%
		Site 3	20 / 20	100.00%	86.09%	100.00%	100.00%
		All Sites (Overall)	59 / 59	100.00%	95.05%	100.00%	100.00%
Adenovirus (ATCC VR-3)	Not available	Site 1	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 2	19 / 19	100.00%	85.41%	100.00%	100.00%
		Site 3	20 / 20	100.00%	86.09%	100.00%	100.00%
		All Sites (Overall)	59 / 59	100.00%	95.05%	100.00%	100.00%
Respiratory Syncytial Virus A (ATCC VR-1540)	Not available	Site 1	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 2	19 / 19	100.00%	85.41%	100.00%	100.00%
		Site 3	19 / 19	100.00%	85.41%	100.00%	100.00%
		All Sites (Overall)	58 / 58	100.00%	94.97%	100.00%	100.00%
Respiratory Syncytial Virus B (0810040CF)	Not available	Site 1	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 2	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 3	20 / 20	100.00%	86.09%	100.00%	100.00%
		All Sites (Overall)	60 / 60	100.00%	95.13%	100.00%	100.00%

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Table continued from previous page

Target (3x LoD)	Specific signal	Site	Detection Rate	% Detection rate	Lower Two-Sided Exact 90%	Upper Two-Sided Exact 90%	% Agreement with expected result
			(#Positive)	(#Positive)	Confidence Limit	Confidence Limit	
Human Metapneumovirus (0810161CF)	Not available	Site 1	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 2	19 / 19	100.00%	85.41%	100.00%	100.00%
		Site 3	20 / 20	100.00%	86.09%	100.00%	100.00%
		All Sites (Overall)	59 / 59	100.00%	95.05%	100.00%	100.00%
M. pneumoniae (ATCC 29085)	Not available	Site 1	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 2	19 / 19	100.00%	85.41%	100.00%	100.00%
		Site 3	19 / 19	100.00%	85.41%	100.00%	100.00%
		All Sites (Overall)	58 / 58	100.00%	94.97%	100.00%	100.00%
C. pneumoniae (ATCC VR-2282)	Not available	Site 1	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 2	19 / 20	95.00%	78.39%	99.74%	95.00%
		Site 3	20 / 20	100.00%	86.09%	100.00%	100.00%
		All Sites (Overall)	59 / 60	98.33%	92.34%	99.91%	98.33%
B. pertussis (ATCC BAA-2707)	Not available	Site 1	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 2	19 / 19	100.00%	85.41%	100.00%	100.00%
		Site 3	20 / 20	100.00%	86.09%	100.00%	100.00%
		All Sites (Overall)	59 / 59	100.00%	95.05%	100.00%	100.00%
SARS-CoV-2 (NIBSC)†	Not available	Site 1	92/92	100%	96.07%	100.00%	100.00%

Two signals are required (both generic Influenza A and the strain specific target) for the complete results reporting of the pathogen.

† Tested in one site.

Table 9. Summary of Agreement for reproducibility testing at 1x LoD in NPS in UTM

Target (1x LoD)	Specific signal	Site	Detection Rate	% Detection rate	Lower Two-Sided Exact 90%	Upper Two-Sided Exact 90%	% Agreement with expected result
			(#Positive)	(#Positive)	Confidence Limit	Confidence Limit	
Influenza A H1N1/pdm09 (0810249CFHI)*	Influenza A	Site 1	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 2	19 / 19	100.00%	85.41%	100.00%	100.00%
		Site 3	20 / 20	100.00%	86.09%	100.00%	100.00%
		All Sites (Overall)	59 / 59	100.00%	95.05%	100.00%	100.00%
	H1N1/pdm09	Site 1	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 2	19 / 19	100.00%	85.41%	100.00%	100.00%
		Site 3	20 / 20	100.00%	86.09%	100.00%	100.00%
		All Sites (Overall)	59 / 59	100.00%	95.05%	100.00%	100.00%
Influenza A H1 (ATCC VR-897)*	Influenza A	Site 1	19 / 20	95.00%	78.39%	99.74%	95.00%
		Site 2	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 3	20 / 20	100.00%	86.09%	100.00%	100.00%
		All Sites (Overall)	59 / 60	98.33%	92.34%	99.91%	98.33%
	H1	Site 1	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 2	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 3	19 / 20	95.00%	78.39%	99.74%	95.00%
		All Sites (Overall)	59 / 60	98.33%	92.34%	99.91%	98.33%

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Target (1x LoD)	Specific signal	Site	Detection Rate (#Positive)	% Detection rate (#Positive)	Lower Two-Sided Exact 90% Confidence Limit	Upper Two-Sided Exact 90% Confidence Limit	% Agreement with expected result
Influenza H3 (ATCC VR-810)*	Influenza A	Site 1	19 / 20	95.00%	78.39%	99.74%	95.00%
		Site 2	18 / 18	100.00%	84.67%	100.00%	100.00%
		Site 3	20 / 20	100.00%	86.09%	100.00%	100.00%
		All Sites (Overall)	57 / 58	98.28%	92.08%	99.91%	98.28%
	H3	Site 1	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 2	18 / 18	100.00%	84.67%	100.00%	100.00%
		Site 3	20 / 20	100.00%	86.09%	100.00%	100.00%
		All Sites (Overall)	58 / 58	100.00%	94.97%	100.00%	100.00%
Influenza B (ATCC VR-295)	Not available	Site 1	19 / 20	95.00%	78.39%	99.74%	95.00%
		Site 2	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 3	20 / 20	100.00%	86.09%	100.00%	100.00%
		All Sites (Overall)	59 / 60	98.33%	92.34%	99.91%	98.33%
Coronavirus 229E (ATCC VR-740)	Not available	Site 1	18 / 20	90.00%	71.74%	98.19%	90.00%
		Site 2	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 3	20 / 20	100.00%	86.09%	100.00%	100.00%
		All Sites (Overall)	58 / 60	96.67%	89.88%	99.40%	96.67%

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Target (1x LoD)	Specific signal	Site	Detection Rate (#Positive)	% Detection rate (#Positive)	Lower Two-Sided Exact 90% Confidence Limit	Upper Two-Sided Exact 90% Confidence Limit	% Agreement with expected result
Coronavirus OC43 (ATCC VR-1558)	Not available	Site 1	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 2	19 / 19	100.00%	85.41%	100.00%	100.00%
		Site 3	20 / 20	100.00%	86.09%	100.00%	100.00%
		All Sites (Overall)	59 / 59	100.00%	95.05%	100.00%	100.00%
Coronavirus NL63 (0810228CFHI)	Not available	Site 1	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 2	18 / 18	100.00%	84.67%	100.00%	100.00%
		Site 3	20 / 20	100.00%	86.09%	100.00%	100.00%
		All Sites (Overall)	58 / 58	100.00%	94.97%	100.00%	100.00%
Coronavirus HKU1 (NATRVP-IDI)	Not available	Site 1	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 2	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 3	20 / 20	100.00%	86.09%	100.00%	100.00%
		All Sites (Overall)	60 / 60	100.00%	95.13%	100.00%	100.00%
Parainfluenza Virus 1 (0810014CFHI)	Not available	Site 1	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 2	18 / 18	100.00%	84.67%	100.00%	100.00%
		Site 3	20 / 20	100.00%	86.09%	100.00%	100.00%
		All Sites (Overall)	58 / 58	100.00%	94.97%	100.00%	100.00%

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Target (1x LoD)	Specific signal	Site	Detection Rate (#Positive)	% Detection rate (#Positive)	Lower Two-Sided Exact 90% Confidence Limit	Upper Two-Sided Exact 90% Confidence Limit	% Agreement with expected result
Parainfluenza Virus 2 (ATCC VR-92)	Not available	Site 1	19 / 20	95.00%	78.39%	99.74%	95.00%
		Site 2	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 3	19 / 20	95.00%	78.39%	99.74%	95.00%
		All Sites (Overall)	58 / 60	96.67%	89.88%	99.40%	96.67%
Parainfluenza Virus 3 (ATCC VR-93)	Not available	Site 1	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 2	19 / 19	100.00%	85.41%	100.00%	100.00%
		Site 3	20 / 20	100.00%	86.09%	100.00%	100.00%
		All Sites (Overall)	59 / 59	100.00%	95.05%	100.00%	100.00%
Parainfluenza Virus 4 (ATCC VR-1378)	Not available	Site 1	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 2	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 3	20 / 20	100.00%	86.09%	100.00%	100.00%
		All Sites (Overall)	60 / 60	100.00%	95.13%	100.00%	100.00%
Rhinovirus (ATCC VR-482)	Not available	Site 1	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 2	19 / 19	100.00%	85.41%	100.00%	100.00%
		Site 3	20 / 20	100.00%	86.09%	100.00%	100.00%
		All Sites (Overall)	59 / 59	100.00%	95.05%	100.00%	100.00%

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Target (1x LoD)	Specific signal	Site	Detection Rate (#Positive)	% Detection rate (#Positive)	Lower Two-Sided Exact 90% Confidence Limit	Upper Two-Sided Exact 90% Confidence Limit	% Agreement with expected result
Enterovirus (ATCC VR-1824)	Not available	Site 1	19 / 20	95.00%	78.39%	99.74%	95.00%
		Site 2	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 3	19 / 20	95.00%	78.39%	99.74%	95.00%
		All Sites (Overall)	58 / 60	96.67%	89.88%	99.40%	96.67%
Adenovirus (ATCC VR-3)	Not available	Site 1	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 2	18 / 18	100.00%	84.67%	100.00%	100.00%
		Site 3	20 / 20	100.00%	86.09%	100.00%	100.00%
		All Sites (Overall)	58 / 58	100.00%	94.97%	100.00%	100.00%
Respiratory Syncytial Virus A (ATCC VR-1540)	Not available	Site 1	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 2	19 / 19	100.00%	85.41%	100.00%	100.00%
		Site 3	20 / 20	100.00%	86.09%	100.00%	100.00%
		All Sites (Overall)	59 / 59	100.00%	95.05%	100.00%	100.00%
Human Metapneumovirus (0810161CF)	Not available	Site 1	19 / 20	95.00%	78.39%	99.74%	95.00%
		Site 2	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 3	20 / 20	100.00%	86.09%	100.00%	100.00%
		All Sites (Overall)	59 / 60	98.33%	92.34%	99.91%	98.33%

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Target (1x LoD)	Specific signal	Site	Detection Rate (#Positive)	% Detection rate (#Positive)	Lower Two-Sided Exact 90% Confidence Limit	Upper Two-Sided Exact 90% Confidence Limit	% Agreement with expected result
M. pneumoniae (ATCC 29085)	Not available	Site 1	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 2	19 / 19	100.00%	85.41%	100.00%	100.00%
		Site 3	20 / 20	100.00%	86.09%	100.00%	100.00%
		All Sites (Overall)	59 / 59	100.00%	95.05%	100.00%	100.00%
C. pneumoniae (ATCC VR-2282)	Not available	Site 1	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 2	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 3	20 / 20	100.00%	86.09%	100.00%	100.00%
		All Sites (Overall)	60 / 60	100.00%	95.13%	100.00%	100.00%
B. pertussis (ATCC BAA-2707)	Not available	Site 1	18 / 20	90.00%	71.74%	98.19%	90.00%
		Site 2	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 3	20 / 20	100.00%	86.09%	100.00%	100.00%
		All Sites (Overall)	58 / 60	96.67%	89.88%	99.40%	96.67%
SARS-CoV-2 (NIBSC)†	Not available	Site 1	87/90	96.67%	90.57%	99.31%	96.67%

* Two signals are required (both generic Influenza A and the strain specific target) for the complete results reporting of the pathogen.

† Tested in one site.

Table 10. Summary of Agreement for reproducibility testing at 0.1x LoD in NPS in UTM

Target (0.1x LoD)	Specific signal	Site	Detection Rate (#Positive)	% Detection rate (#Positive)	Lower Two-Sided Exact 90% Confidence Limit	Upper Two-Sided Exact 90% Confidence Limit	% Agreement with expected result
Influenza A H1N1/pdm09 (0810249CFHI)*	Influenza A	Site 1	19 / 20	95.00%	78.39%	99.74%	95.00%
		Site 2	18 / 20	90.00%	71.74%	98.19%	90.00%
		Site 3	20 / 20	100.00%	86.09%	100.00%	100.00%
		All Sites (Overall)	57 / 60	95.00%	87.58%	98.62%	95.00%
	H1N1/pdm09	Site 1	14 / 20	70.00%	49.22%	86.04%	70.00%
		Site 2	16 / 20	80.00%	59.90%	92.86%	80.00%
		Site 3	15 / 20	75.00%	54.44%	89.59%	75.00%
		All Sites (Overall)	45 / 60	75.00%	64.15%	83.91%	75.00%
Influenza A H1 (ATCC VR-897)*	Influenza A	Site 1	14 / 20	70.00%	49.22%	86.04%	70.00%
		Site 2	9 / 19	47.37%	27.39%	67.99%	47.37%
		Site 3	12 / 20	60.00%	39.36%	78.29%	60.00%
		All Sites (Overall)	35 / 59	59.32%	47.78%	70.13%	59.32%
	H1	Site 1	13 / 20	65.00%	44.20%	82.27%	65.00%
		Site 2	13 / 19	68.42%	47.00%	85.25%	68.42%
		Site 3	15 / 20	75.00%	54.44%	89.59%	75.00%
		All Sites (Overall)	41 / 59	69.49%	58.19%	79.26%	69.49%

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Target (0.1x LoD)	Specific signal	Site	Detection Rate (#Positive)	% Detection rate (#Positive)	Lower Two-Sided Exact 90% Confidence Limit	Upper Two-Sided Exact 90% Confidence Limit	% Agreement with expected result
Influenza H3 (ATCC VR-810)*	Influenza A	Site 1	10 / 20	50.00%	30.20%	69.80%	50.00%
		Site 2	9 / 19	47.37%	27.39%	67.99%	47.37%
		Site 3	16 / 19	84.21%	64.06%	95.55%	84.21%
		All Sites (Overall)	35 / 58	60.34%	48.70%	71.17%	60.34%
	H3	Site 1	13 / 20	65.00%	44.20%	82.27%	65.00%
		Site 2	16 / 19	84.21%	64.06%	95.55%	84.21%
		Site 3	17 / 19	89.47%	70.42%	98.10%	89.47%
		All Sites (Overall)	46 / 58	79.31%	68.64%	87.61%	79.31%
Influenza B (ATCC VR-295)	n/a	Site 1	7 / 20	35.00%	17.73%	55.80%	35.00%
		Site 2	9 / 19	47.37%	27.39%	67.99%	47.37%
		Site 3	8 / 20	40.00%	21.71%	60.64%	40.00%
		All Sites (Overall)	24 / 59	40.68%	29.87%	52.22%	40.68%
Coronavirus 229E (ATCC VR-740)	n/a	Site 1	9 /20	45.00%	25.87%	65.31%	45.00%
		Site 2	12 / 19	63.16%	41.81%	81.25%	63.16%
		Site 3	5 / 20	25.00%	10.41%	45.56%	25.00%
		All Sites (Overall)	26 / 59	44.07%	33.01%	55.58%	44.07%

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Target (0.1x LoD)	Specific signal	Site	Detection Rate (#Positive)	% Detection rate (#Positive)	Lower Two-Sided Exact 90% Confidence Limit	Upper Two-Sided Exact 90% Confidence Limit	% Agreement with expected result
Coronavirus OC43 (ATCC VR-1558)	Not available	Site 1	13 / 20	65.00%	44.20%	82.27%	65.00%
		Site 2	15 / 20	75.00%	54.44%	89.59%	75.00%
		Site 3	15 / 20	75.00%	54.44%	89.59%	75.00%
		All Sites (Overall)	43 / 60	71.67%	60.58%	81.07%	71.67%
Coronavirus NL63 (0810228CFHI)	Not available	Site 1	13 / 20	65.00%	44.20%	82.27%	65.00%
		Site 2	12 / 19	63.16%	41.81%	81.25%	63.16%
		Site 3	14 / 19	73.68%	52.42%	89.01%	73.68%
		All Sites (Overall)	39 / 58	67.24%	55.74%	77.37%	67.24%
Coronavirus HKU1 (NATRVP-IDI)	Not available	Site 1	17 / 20	85.00%	65.63%	95.78%	85.00%
		Site 2	10 / 19	52.63%	32.01%	72.61%	52.63%
		Site 3	9 / 20	45.00%	25.87%	65.31%	45.00%
		All Sites (Overall)	36 / 59	61.02%	49.48%	71.69%	61.02%
Parainfluenza Virus 1 (0810014CFHI)	Not available	Site 1	14 / 20	70.00%	49.22%	86.04%	70.00%
		Site 2	12 / 19	63.16%	41.81%	81.25%	63.16%
		Site 3	9 / 19	47.37%	27.39%	67.99%	47.37%
		All Sites (Overall)	35 / 58	60.34%	48.70%	71.17%	60.34%

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Table continued from previous page

Target (0.1x LoD)	Specific signal	Site	Detection Rate	% Detection rate	Lower Two-Sided Exact 90%	Upper Two-Sided Exact 90%	% Agreement with expected result
			(#Positive)	(#Positive)	Confidence Limit	Confidence Limit	
Parainfluenza Virus 2 (ATCC VR-92)	Not available	Site 1	9 / 20	45.00%	25.87%	65.31%	45.00%
		Site 2	11 / 19	57.89%	36.81%	77.03%	57.89%
		Site 3	12 / 20	60.00%	39.36%	78.29%	60.00%
		All Sites (Overall)	32 / 59	54.24%	42.75%	65.39%	54.24%
Parainfluenza Virus 3 (ATCC VR-93)	Not available	Site 1	13 / 20	65.00%	44.20%	82.27%	65.00%
		Site 2	17 / 20	85.00%	65.63%	95.78%	85.00%
		Site 3	17 / 20	85.00%	65.63%	95.78%	85.00%
		All Sites (Overall)	47 / 60	78.33%	67.78%	86.68%	78.33%
Parainfluenza Virus 4 (ATCC VR-1378)	Not available	Site 1	10 / 20	50.00%	30.20%	69.80%	50.00%
		Site 2	11 / 19	57.89%	36.81%	77.03%	57.89%
		Site 3	9 / 20	45.00%	25.87%	65.31%	45.00%
		All Sites (Overall)	30 / 59	50.85%	39.46%	62.17%	50.85%
Rhinovirus (ATCC VR-482)	Not available	Site 1	15 / 20	75.00%	54.44%	89.59%	75.00%
		Site 2	15 / 20	75.00%	54.44%	89.59%	75.00%
		Site 3	18 / 20	90.00%	71.74%	98.19%	90.00%
		All Sites (Overall)	48 / 60	80.00%	69.62%	88.03%	80.00%

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Table continued from previous page

Target (0.1x LoD)	Specific signal	Site	Detection Rate (#Positive)	% Detection rate (#Positive)	Lower Two-Sided Exact 90% Confidence Limit	Upper Two-Sided Exact 90% Confidence Limit	% Agreement with expected result
Enterovirus (ATCC VR-1824)	Not available	Site 1	8 / 20	40.00%	21.71%	60.64%	40.00%
		Site 2	6 / 19	31.58%	14.75%	53.00%	31.58%
		Site 3	7 / 20	35.00%	17.73%	55.80%	35.00%
		All Sites (Overall)	21 / 59	35.59%	25.24%	47.08%	35.59%
Adenovirus (ATCC VR-3)	Not available	Site 1	10 / 20	50.00%	30.20%	69.80%	50.00%
		Site 2	9 / 19	47.37%	27.39%	67.99%	47.37%
		Site 3	10 / 19	52.63%	32.01%	72.61%	52.63%
		All Sites (Overall)	29 / 58	50.00%	38.54%	61.46%	50.00%
Respiratory Syncytial Virus A (ATCC VR-1540)	Not available	Site 1	6 / 20	30.00%	13.96%	50.78%	30.00%
		Site 2	7 / 20	35.00%	17.73%	55.80%	35.00%
		Site 3	9 / 20	45.00%	25.87%	65.31%	45.00%
		All Sites (Overall)	22 / 60	36.67%	26.29%	48.07%	36.67%
Respiratory Syncytial Virus B (0810040CF)	Not available	Site 1	14 / 20	70.00%	49.22%	86.04%	70.00%
		Site 2	15 / 19	78.95%	58.09%	92.47%	78.95%
		Site 3	10 / 20	50.00%	30.20%	69.80%	50.00%
		All Sites (Overall)	39 / 59	66.10%	54.67%	76.28%	66.10%

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Target (0.1x LoD)	Specific signal	Site	Detection Rate	% Detection rate	Lower Two-Sided Exact 90%	Upper Two-Sided Exact 90%	% Agreement with expected result
			(#Positive)	(#Positive)	Confidence Limit	Confidence Limit	
Human Metapneumovirus (0810161CF)	Not available	Site 1	6 / 20	30.00%	13.96%	50.78%	30.00%
		Site 2	9 / 19	47.37%	27.39%	67.99%	47.37%
		Site 3	9 / 20	45.00%	25.87%	65.31%	45.00%
		All Sites (Overall)	24 / 59	40.68%	29.87%	52.22%	40.68%
M. pneumoniae (ATCC 29085)	Not available	Site 1	13 / 20	65.00%	44.20%	82.27%	65.00%
		Site 2	14 / 20	70.00%	49.22%	86.04%	70.00%
		Site 3	14 / 20	70.00%	49.22%	86.04%	70.00%
		All Sites (Overall)	41 / 60	68.33%	57.08%	78.17%	68.33%
C. pneumoniae (ATCC VR-2282)	Not available	Site 1	11 /20	55.00%	34.69%	74.13%	55.00%
		Site 2	11 / 19	57.89%	36.81%	77.03%	57.89%
		Site 3	14 / 20	70.00%	49.22%	86.04%	70.00%
		All Sites (Overall)	36 / 59	61.02%	49.48%	71.69%	61.02%
B. pertussis (ATCC BAA-2707)	Not available	Site 1	9 / 20	45.00%	25.87%	65.31%	45.00%
		Site 2	7 / 19	36.84%	18.75%	58.19%	36.84%
		Site 3	9 / 20	45.00%	25.87%	65.31%	45.00%
		All Sites (Overall)	25 / 59	42.37%	31.43%	53.91%	42.37%
SARS-CoV-2 (NIBSC)†	Not available	Site 1	90/90‡	100%‡	95.98%	100.00%	100%

* Two signals are required (both generic Influenza A and the strain specific target) for the complete results reporting of the pathogen.

† Tested in one site at negative concentration.

‡ Refers to #Negative

NPS samples processed as dry NPS were also tested in replicates using different lots of QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridges and tests were executed on different QIAstat-Dx Analyzers 1.0 by different operators, different sites and on different days.

A representative pathogens panel was selected to include at least one RNA virus, one DNA virus and one bacteria covering all (8) Reaction Chambers of the QIAstat-Dx Respiratory SARS-CoV-2 Panel cartridge (Table 11).

Table 12 and Table 13 summarize the results for 3x and 1x LoD concentration where it is observed that the detection rate for 8 of the 8 targets was ≥95%. Table 14 summarizes the results for negative concentration where it is observed that the detection rate for 8 of the 8 targets was 0%.

Table 11. List of respiratory pathogens tested for reproducibility in dry NPS

Pathogen	Strain
Influenza B	B/Florida/4/2006
Coronavirus OC43	Not available
Parainfluenza Virus 3	C 243
Rhinovirus	HGP (rhinovirus A2)
Adenovirus	GB (adenovirus B3)
Mycoplasma pneumoniae	PI 1428
SARS-CoV-2	England/02/2020

Table 12. Summary of Agreement for reproducibility testing at 3x LoD in dry NPS.

Target (3x LoD)	Specific signal	Site	Detection Rate	% Detection rate	% Agreement with expected result
			(#Positive)	(#Positive)	
Influenza B (ATCC VR-295)	Not available	Site 1	30/30	100%	100%
		Site 2	30/30	100%	100%
		Site 3	30/30	100%	100%
		All Sites (Overall)	90/90	100%	100%
Coronavirus OC43 (ATCC VR-1558)	Not available	Site 1	30/30	100%	100%
		Site 2	30/30	100%	100%
		Site 3	30/30	100%	100%
		All Sites (Overall)	90/90	100%	100%
Parainfluenza Virus 3 (ATCC VR-93)	Not available	Site 1	30/30	100%	100%
		Site 2	30/30	100%	100%
		Site 3	30/30	100%	100%
		All Sites (Overall)	90/90	100%	100%
Rhinovirus (ATCC VR-482)	Not available	Site 1	30/30	100%	100%
		Site 2	30/30	100%	100%
		Site 3	30/30	100%	100%
		All Sites (Overall)	90/90	100%	100%
Adenovirus (ATCC VR-3)	Not available	Site 1	30/30	100%	100%
		Site 2	30/30	100%	100%
		Site 3	30/30	100%	100%
		All Sites (Overall)	90/90	100%	100%

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Target (3x LoD)	Specific signal	Site	Detection Rate	% Detection rate	% Agreement with expected result
			(#Positive)	(#Positive)	
M. pneumoniae (ATCC 29085)	Not available	Site 1	30/30	100%	100%
		Site 2	30/30	100%	100%
		Site 3	30/30	100%	100%
		All Sites (Overall)	90/90	100%	100%
SARS-CoV-2 (NIBSC)	Not available	Site 1	30/30	100%	100%
		Site 2	30/30	100%	100%
		Site 3	30/30	100%	100%
		All Sites (Overall)	90/90	100%	100%

Table 13. Summary of Agreement for reproducibility testing at 1xLoD in dry NPS

Target (1x LoD)	Specific signal	Site	Detection Rate	% Detection rate	% Agreement with expected result
			(#Positive)	(#Positive)	
Influenza B (ATCC VR-295)	Not available	Site 1	30/30	100%	100%
		Site 2	30/30	100%	100%
		Site 3	30/30	100%	100%
		All Sites (Overall)	90/90	100%	100%
Coronavirus OC43 (ATCC VR-1558)	Not available	Site 1	28/30	93.3%	100%
		Site 2	29/30	96.6%	100%
		Site 3	29/30	96.6%	100%
		All Sites (Overall)	86/90	95.5%	100%
Parainfluenza Virus 3 (ATCC VR-93)	Not available	Site 1	30/30	100%	93.3%
		Site 2	30/30	100%	96.6%
		Site 3	30/30	100%	96.6%

Target (1x LoD)	Specific signal	Site	Detection Rate	% Detection rate	% Agreement with expected result
		All Sites (Overall)	90/90	100%	95.6%
		Site 1	30/30	100%	100%
		Site 2	30/30	100%	100%
Rhinovirus (ATCC VR-482)	Not available	Site 3	30/30	100%	100%
		All Sites (Overall)	90/90	100%	100%
		Site 1	30/30	100%	100%
		Site 2	30/30	100%	100%
Adenovirus (ATCC VR-3)	Not available	Site 3	30/30	100%	100%
		All Sites (Overall)	90/90	100%	100%
		Site 1	30/30	100%	100%
		Site 2	30/30	100%	100%
M. pneumoniae (ATCC 29085)	Not available	Site 3	28/30	93.3%	93.3%
		All Sites (Overall)	88/90	97.8%	97.8%
		Site 1	30/30	100%	100%
		Site 2	30/30	100%	100%
SARS-CoV-2 (NIBSC)	Not available	Site 3	30/30	100%	100%
		All Sites (Overall)	90/90	100%	100%

Table 14. Summary of Agreement for reproducibility testing in negative dry NPS

Target (Negative)	Specific signal	Site	Detection Rate (#Positive)	% Detection rate (#Positive)	% Agreement with expected result
All	Not available	Site 1	690/690	100%	100%
		Site 2	690/690	100%	100%
		Site 3	690/690	100%	100%
		All Sites (Overall)	2070/2070	100%	100%

Reproducibility testing demonstrated that QIAstat-Dx Respiratory SARS-CoV-2 Panel running in the QIAstat-Dx Analyzer 1.0 provides highly reproducible results when the same samples are tested in multiple runs, on multiple days, with multiple sites, with various operators using different QIAstat-Dx Analyzers 1.0, and multiple lots of QIAstat-Dx Respiratory SARS-CoV-2 Panel cartridges.

The potential variation introduced by sites, days, replicates, cartridge lots, operators, and QIAstat-Dx Analyzers was assessed during the reproducibility study showing no significant contribution to variability (Coefficient of Variation and Standard Deviation values below 5% and 1.0, respectively) caused by any of the assessed variables.

Repeatability

A repeatability study was conducted on the QIAstat-Dx Analyzer 1.0 instruments using a representative set of NPS in UTM samples composed of low-concentrated analytes spiked into simulated matrix (3x LoD, 1x LoD and 0.1x LoD). Pathogens included in the positive samples were as per the Reproducibility study (see Table 7). Each sample was tested in triplicate per day and cartridge lot (three lots tested in total) in the course of 15 days. In total, at least 45 replicates of each sample concentration were run. High negative samples resulted in <95% detection rate, 1x LoD samples in ≥90% detection rate, and 3x LoD samples in ≥95% of

positive calls for all targets tested. This was also confirmed for Dry NPS samples for which a representative set of low-concentrated analytes (see Table 11) at 3x LoD and 1x LoD, as well as negative samples, were analysed. Samples were tested at least in triplicate per day, over 12 days and using a total of 3 different cartridge lots. In total, 60 replicates of each sample concentration were run. Samples resulted in ≥95.0% and ≥90% detection rate at 3xLoD and 1xLoD, respectively. For negative samples, 99.6% of negative calls were observed.

The potential variation introduced by days, replicates, cartridge lots, and QIAstat-Dx Analyzers was assessed during the repeatability study showing no significant contribution to variability (Coefficient of Variation and Standard Deviation values below 5% and 1.0, respectively) caused by any of the assessed variables.

Repeatability in the QIAstat-Dx Rise instrument was also evaluated in comparison with QIAstat-Dx Analyzers. The study was conducted on two QIAstat-Dx Rise instruments using a representative set of samples composed of low-concentrated analytes (3x LoD and 1x LoD) spiked into artificial NPS matrix and negative samples. Pathogens included in the positive samples were Influenza B, Coronavirus OC43, PIV3, Rhinovirus, Adenovirus, *M. pneumoniae* and SARS-CoV-2. Samples were tested in replicates using two lots of cartridges. The study included testing with two QIAstat-Dx Analyzer 1.0 for comparison. In total, 183 replicates of 1x LoD positive samples, 189 replicates of 3x LoD positive samples, and 155 replicates of negative samples were run. Overall results showed a 93.3-100.0% and 100.0% detection rate for 1x LoD and 3x LoD samples, respectively. Negative samples showed 100% of negative calls for all panel analytes. QIAstat-Dx Rise performance was shown to be equivalent to QIAstat-Dx Analyzer 1.0.

Whole system failure rate

The whole system failure rate was assessed by analysing SARS-CoV-2 samples tested at 3x LoD concentration (156 with QIAstat-Dx Analyzer 1.0 and 125 with QIAstat-Dx Rise). A 100% detection rate of these samples was demonstrated.

Carryover

A carryover study was performed to evaluate the potential occurrence of cross-contamination between consecutive runs when using the QIAstat-Dx Respiratory SARS-CoV-2 Panel on the QIAstat-Dx Analyzer 1.0 and the QIAstat-Dx Rise.

Samples of simulated NPS matrix, with alternating high-positive and negative samples, were tested on two QIAstat-Dx Analyzer 1.0 and one QIAstat-Dx Rise instrument containing eight AMs.

No carryover between samples was observed in the QIAstat-Dx Respiratory SARS-CoV-2 Panel.

Interfering Substances (Analytical Specificity)

The effect of potentially interfering substances on the detectability of the QIAstat-Dx Respiratory SARS-CoV-2 Panel organisms was evaluated. The interfering substances include endogenous as well as exogenous substances that are normally found in the nasopharynx or may be introduced into NPS specimens during specimen collection, respectively. Potentially interfering substances were added to contrived samples at a level predicted to be above the concentration of the substance likely to be found in an authentic NPS specimen. The contrived samples (also referred to as combined samples) were each comprised of a mix of organisms tested at a concentration of 3x- 5x LoD.

Endogenous substances such as whole blood, human genomic DNA and several pathogens were tested alongside exogenous substances like antibiotics, nasal sprays and different workflow contaminants.

The combined samples were tested with and without addition of an inhibitory substance allowing direct sample-to-sample comparison. Additionally, for substances that may contain genetic material (such as blood, mucin, DNA and microorganisms), negative specimens (blank artificial NPS sample matrix with no organism mix) were spiked with only the test substance to evaluate the potential for false positive results due to the test substance itself.

Combined samples not spiked with any test substance served as a positive control and blank artificial NPS sample matrix with no organism mix as negative control.

All pathogen-containing samples without spiked interferent generated positive signals for all pathogens present in the respective combined sample. Negative signals were obtained for all pathogens not present in the same sample but detected by the QIAstat-Dx Respiratory SARS-CoV-2 Panel.

None of the substances tested showed inhibition, except for the nasal influenza vaccines. In addition, nasal influenza vaccines (Fluenz Tetra and FluMist®) were predicted to be reactive with the QIAstat-Dx Respiratory SARS-CoV-2 Panel Influenza A (including subtypes) and Influenza B assays. Final dilution without observable interfering effect was 0.000001% v/v for both vaccines.

No impact on performance is expected when clinical NPS samples are examined in the presence of the substances tested.

The results of interfering substance testing are provided in Table 15 .

Table 15. Outcome of interfering substances highest concentrations tested

Substance tested	Concentration tested	Results
Endogenous substances		
Human genomic DNA 200 ng/µL	20 ng/µL	No Interference
Human blood (+NaCitrate)	1% v/v	No Interference
Mucin from bovine submaxillary	1% v/v	No Interference
Competitive microorganisms		
Staphylococcus aureus	1.00E+06 CFU/mL*	No Interference
	4.50E+08 CFU/mL*	No Interference
Neisseria meningitidis	5.00E+04 CFU/mL*	No Interference
	1.00E+03 CFU/mL*	No Interference
Corynebacterium diphtheriae	5.00E+03 CFU/mL*	No Interference
	1.00E+03 CFU/mL*	No Interference
Human Cytomegalovirus	1.00E+05 $TCID_{50}$/mL*	No Interference
	1.00E+04 TCID50/mL*	No Interference
Exogenous substances		
Tobramycin	0.6 mg/ml	No Interference
Mupirocin	2% w/v	No Interference
Saline nasal spray with preservatives	1% v/v	No Interference
Afrin®, severe congestion nasal spray (Oxymetazoline HCl)	1% v/v	No Interference
Analgesic ointment (Vicks® VapoRub®)	1% w/v	No Interference
Petroleum Jelly (Vaseline®)	1% w/v	No Interference
FluMist nasal influenza vaccine†	0.00001% v/v	Interference
	0.000001% v/v	No Interference
Fluenz Tetra nasal influenza vaccine†	0.00001% v/v	Interference
	0.000001% v/v	No Interference

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Substance tested	Concentration tested	Results
Chiroflu Influenza Vaccine (surface antigen inactivated)†	0.000001% v/v	No Interference
Disinfecting/cleaning substances		
Disinfecting wipes	½ inches²/1 ml UTM	No Interference
DNAZap	1% v/v	No Interference
RNaseOUT‡	1% v/v	No Interference
ProtectRNA™ RNase Inhibitor 500x Concentrate‡	1% v/v	No Interference
Bleach	5% v/v	No Interference
Ethanol	5% v/v	No Interference
Specimen collection materials		
Swab Copan 168C	1 swab/1 mL UTM	No Interference
Swab Copan FloQ	1 swab/1 mL UTM	No Interference
Swab Copan 175KS01	1 swab/1 mL UTM	No Interference
Swab Puritan 25-801 A 50	1 swab/1 mL UTM	No Interference
VTM Sigma Virocult	100%	No Interference
VTM Remel M4-RT	100%	No Interference
VTM Remel M4§	100%	No Interference
VTM Remel M5§	100%	No Interference
VTM Remel M6§	100%	No Interference
VTM RT§	100%	No Interference
DeltaSwab Virus§	100%	No Interference
BD Universal Viral Transport	100%	No Interference

* Microorganism concentrations tested depending on stock availability.

† Bocavirus, Legionella pneumophila and SARS-CoV-2 were tested with Chiroflu nasal influenza vaccine instead of FluMist and Fluenz Tetra nasal vaccines.

‡ Bocavirus, *Legionella pneumophila* and SARS-CoV-2 were tested with Protect RNA instead of RNAseOUT.

§ Bocavirus, *Legionella pneumophila* and SARS-CoV-2 were tested with VTM RT and Delta Swab Virus instead of VTM Remel M4, VTM Remel M5 and VTM Remel M6.

Co-infections

A co-infection study was performed to verify that multiple QIAstat-Dx Respiratory SARS-CoV-2 Panel analytes included in one nasopharyngeal swab sample can be detected.

High and low concentrations of different organisms were combined in one sample. Selection of organisms was made based on relevance, prevalence, and layout of the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge (distribution of targets in different reaction chambers).

Analytes were spiked into a simulated NPS sample matrix (cultured human cells in UTM) in high (25x-50x LoD concentration) and low concentrations (5x LoD concentration) and tested in different combinations. Table 16 shows the combination of co-infections tested in this study.

Table 16. List of co-infections combinations tested

Pathogens	Strain	Concentration
Influenza A H3N2 Adenovirus C2	A/Port Chalmers/1/73 Adenoid 6	50x LoD 5x LoD
Influenza A H3N2 Adenovirus C2	A/Port Chalmers/1/73 Adenoid 6	5x LoD 50x LoD
Parainfluenza Virus 3 Enterovirus D68	C243 US/IL/14-18952	50x LoD 5x LoD
Influenza A H3N2 Adenovirus C2	A/Port Chalmers/1/73 Adenoid 6	50x LoD 5x LoD
Influenza A H3N2 Adenovirus C2	A/Port Chalmers/1/73 Adenoid 6	5x LoD 50x LoD
Parainfluenza Virus 3 Enterovirus D68	C243 US/IL/14-18952	50x LoD 5x LoD
Parainfluenza 3 Virus Enterovirus D68	C243 US/IL/14-18952	5x LoD 50x LoD
Respiratory Syncytial Virus A Influenza B	A2 B/Virginia/ATCC5/2012	50x LoD 5x LoD
Respiratory Syncytial Virus A Influenza B	A2 B/Virginia/ATCC5/2012	5x LoD 50x LoD
Adenovirus C2 Rhinovirus A2	Adenoid 6 HGP	50x LoD 5x LoD
Adenovirus C2 Rhinovirus A2	Adenoid 6 HGP	5x LoD 50x LoD
Respiratory Syncytial Virus A Rhinovirus A2	A2 HGP	50x LoD 5x LoD
Respiratory Syncytial Virus A Rhinovirus A2	A2 HGP	5x LoD 50x LoD
Coronavirus OC43 Rhinovirus A2	OC43 HGP	50x LoD 5x LoD
Coronavirus OC43 Rhinovirus A2	OC43 HGP	5x LoD 50x LoD

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Pathogens	Strain	Concentration
Human Metapneumovirus B2	Peru6-2003	50x LoD
Parainfluenza Virus 1	C-35	5x LoD
Human Metapneumovirus B2	Peru6-2003	5x LoD
Parainfluenza Virus 1	C-35	50x LoD
Coronavirus 229E	229E	50x LoD
Respiratory Syncytial Virus A	A2	5x LoD
Coronavirus 229E	229E	5x LoD
Respiratory Syncytial Virus A	A2	50x LoD
Respiratory Syncytial Virus B	18537	50x LoD
Coronavirus NL63	Not available	5x LoD
Respiratory Syncytial Virus B	18537	5x LoD
Coronavirus NL63	Not available	50x LoD
Influenza A H1N1/pdm09	NY/03/09	25x LoD*
Influenza B	B/Virginia/ATCC5/2012	5x LoD
Influenza A H1N1/pdm09	NY/03/09	5x LoD
Influenza B	B/Virginia/ATCC5/2012	50x LoD
Coronavirus 229E	229E	50x LoD
Coronavirus OC43	OC43	5x LoD
Coronavirus 229E	229E	5x LoD
Coronavirus OC43	OC43	50x LoD
Parainfluenza 3	C-243	50x LoD
Parainfluenza Virus 4a	M-25	5x LoD
Parainfluenza 3	C-243	5x LoD
Parainfluenza Virus 4a	M-25	50x LoD
Respiratory Syncytial Virus B	18537	5x LoD*
Human Metapneumovirus A1	IA10-2003	5x LoD
Respiratory Syncytial Virus B	18537	5x LoD
Human Metapneumovirus A1	IA10-2003	50x LoD
Influenza A H3N2	A/Port Chalmers/1/73	50x LoD
Rhinovirus A2	HGP	5x LoD
Influenza A H3N2	A/Port Chalmers/1/73	5x LoD
Rhinovirus A2	HGP	50x LoD

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Pathogens	Strain	Concentration
M. pneumoniae	M129-B7	50x LoD
C. pneumoniae	TW183	5x LoD
M. pneumoniae	M129-B7	5x LoD
C. pneumoniae	TW183	50x LoD
Respiratory Syncytial Virus B	9320	50x LoD
Bocavirus	Clinical sample	5x LoD
Respiratory Syncytial Virus B	9320	5x LoD
Bocavirus	Clinical sample	50x LoD
Influenza A H3N2	A/Virginia/ATCC6/2012	50x LoD
Adenovirus C5	Adenoid 75	5x LoD
Influenza A H3N2	A/Virginia/ATCC6/2012	5x LoD
Adenovirus C5	Adenoid 75	50x LoD
Parainfluenza Virus 3	C243	50x LoD
Influenza A H1N1/pdm09	NY/03/09	5x LoD
Parainfluenza Virus 3	C243	5x LoD
Influenza A H1N1/pdm09	NY/03/09	50x LoD
Adenovirus C5	Adenoid 75	50x LoD
Rhinovirus B, Type HRV-B14	1059	5x LoD
Adenovirus C5	Adenoid 75	5x LoD
Rhinovirus B, Type HRV-B14	1059	50x LoD
Respiratory Syncytial Virus A	A2	50x LoD
Rhinovirus B, Type HRV-B14	1059	5x LoD
Respiratory Syncytial Virus A	A2	5x LoD
Rhinovirus B, Type HRV-B14	1059	50x LoD
Coronavirus OC43	OC43	50x LoD
Rhinovirus B, Type HRV-B14	1059	5x LoD
Coronavirus OC43	OC43	5x LoD
Rhinovirus B, Type HRV-B14	1059	50x LoD

*Final concentration tested that allowed detection of both pathogens in the mix.

Two combinations of pathogens: Influenza A H1N1/pdm09 with Influenza B; and RSV B with hMPV A1, did not produce a positive result for both targets in the mix at the initial concentration tested. After diluting the concentrations of these samples, both targets of the co-infections were successfully detected. Co-infections by Influenza A H1N1/pdm09 and Influenza B are very rare, and the circulation of both viruses simultaneously during the same season is unusual. Although RSV and hMPV viruses have overlapping seasonality, hMPV is more frequently detected in spring while RSV peak is in winter, decreasing the probability of co-infections. All other co-infections tested, with the exception of the aforementioned combinations, gave a positive result for the two pathogens combined at low and high concentrations. No effect in assay results are observed due to the presence of co-infections.

Appendix 02 Clinical Performance

The clinical performance was demonstrated using QIAstat-Dx Analyzer 1.0. The QIAstat-Dx Rise and the QIAstat-Dx Analyzer 2.0 use the same Analytical Modules as QIAstat-Dx Analyzer 1.0 therefore the clinical performance is not impacted by use of QIAstat-Dx Rise. The equivalency on performance between QIAstat-Dx Rise and QIAstat-Dx Analyzer 1.0 was confirmed through a repeatability study.

Since 2018, multiple studies across EU and USA sites have been conducted generating data which was subsequently used in a meta-analysis. This analysis included a total of 3746 subjects with signs and symptoms of respiratory infection.

Specimens tested in the clinical studies were collected using the Universal Transport Medium (UTM) (Copan Diagnostics [Brescia, Italy and CA, USA]), DeltaSwab Virus (DeltaLab, Spain), MicroTest™ M4®, M4RT®, M5®, M6® (Thermo Fisher Scientific®, MA, USA), BD™ Universal Viral Transport (UVT) System (Becton Dickinson, NJ, USA), Universal Transport Medium (UTM) System (HealthLink® Inc., FL, USA), Universal Transport Medium (Diagnostic Hybrids®, OH, USA), V-C-M Medium (Quest Diagnostics®, NJ, USA) and UniTranz-RT® Universal Transport Media (Puritan® Diagnostics, ME, USA) collection kits.

Clinical Sensitivity or Positive Percent Agreement (PPA) was calculated as 100% x (TP/[TP + FN]). True positive (TP) indicates that both the QIAstat-Dx Respiratory SARS-CoV-2 Panel and comparator(s) methods had a positive result for the organism, and false negative (FN) indicates that the QIAstat-Dx Respiratory SARS-CoV-2 Panel result was negative while the comparator methods results were positive.

Specificity or Negative Percent Agreement (NPA) was calculated as 100% x (TN/[TN + FP]). True negative (TN) indicates that both the QIAstat-Dx Respiratory SARS-CoV-2 Panel and the comparator method had negative results, and a false positive (FP) indicates that the QIAstat-Dx Respiratory SARS-CoV-2 Panel result was positive but the comparator methods results were negative. For the calculation of the clinical specificity of the individual pathogens, the total available results were used with the concerning true- and false-positive organism results subtracted. The exact binomial two-sided 95% confidence interval (CI) was calculated for each point estimate. Table 17 displays QIAstat-Dx Respiratory SARS-CoV-2 Panel Clinical Sensitivity (or Positive Percent Agreement) and Clinical Specificity (or Negative Percent Agreement) with 95% Confidence Intervals prior to discrepant resolution.

Table 17. Agreement Between QIAstat-Dx Respiratory SARS-CoV-2 Panel and Reference Method pre discrepant resolution

	Positive Percent Agreement			Negative Percent Agreement		
Target	TP/(TP+FN)	%	95% CI	TN/(TN+FP)	%	95% CI
			Viruses			
Adenovirus	124 / 136	91.18%	85.09%-95.36%	2610 / 2642	98.79%	98.29%-99.17%
Bocavirus*	N/A	N/A	N/A	N/A	N/A	N/A
Coronavirus 229E	38 / 42	90.48%	77.38%-97.34%	2734 / 2734	100.00%	99.87%-100.00%
Coronavirus OC43	63 / 67	94.03%	85.41%-98.35%	2704 / 2708	99.85%	99.62%-99.96%
Coronavirus NL63	86 / 98	87.76%	79.59%-93.51%	2674 / 2679	99.81%	99.56%-99.94%
Coronavirus HKU1	73 / 75	97.33%	90.70%-99.68%	2689 / 2701	99.56%	99.23%-99.77%

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	Positive Percent Agreement			Negative Percent Agreement		
Target	TP/(TP+FN)	%	95% CI	TN/(TN+FP)	%	95% CI
			Viruses			
SARS-CoV-2	396 / 417	94.96%	92.40%-96.86%	535 / 540	99.07%	97.85%-99.70%
Human Metapneumovirus A+B	139 / 150	92.67%	87.26%-96.28%	2622 / 2627	99.81%	99.56%-99.94%
Influenza A	267 / 270	98.89%	96.79%-99.77%	2407 / 2495	96.47%	95.67%-97.16%
Influenza A H1N1 pdm09	124 / 128	96.88%	92.19%-99.14%	2634 / 2645	99.58%	99.26%-99.79%
Influenza A H1	0 / 1	0.00%	0.00%-97.50%	2774 / 2774	100.00 %	99.87%-100.00%
Influenza A H3	199 / 203	98.03%	95.03%-99.46%	2558 / 2572	99.46%	99.09%-99.70%
Influenza B	175 / 184	95.11%	90.92%-97.74%	2590 / 2592	99.92%	99.72%-99.99%
Parainfluenza virus 1	58 / 59	98.31%	90.91%-99.96%	2713 / 2717	99.85%	99.62%-99.96%
Parainfluenza virus 2	8 / 10	80.00%	44.39%-97.48%	2766 / 2766	100.00 %	99.87%-100.00%
Parainfluenza virus 3	121 / 127	95.28%	90.00%-98.25%	2646 / 2652	99.77%	99.51%-99.92%
Parainfluenza virus 4	28 / 31	90.32%	74.25%-97.96%	2732 / 2745	99.53%	99.19%-99.75%
Respiratory Syncytial Virus A+B	313 / 329	95.14%	92.22%-97.20%	2438 / 2447	99.63%	99.30%-99.83%
Rhinovirus/Enterovirus	366 / 403	90.82%	87.57%-93.45%	2313 / 2375	97.39%	96.67%-97.99%
			Bacteria			
Bordetella pertussis	41 / 41	100.00%	91.40%-100.00%	2716 / 2735	99.31%	98.92%-99.58%
Chlamydophila pneumoniae	66 / 74	89.19%	79.80%-95.22%	2700 / 2702	99.93%	99.73%-99.99%

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	Positive Percent Agreement			Negative Percent Agreement		
Target	TP/(TP+FN)	%	95% CI	TN/(TN+FP)	%	95% CI
			Bacteria			
*Legionella pneumophila**	N/A	N/A	N/A	N/A	N/A	N/A
Mycoplasma pneumoniae	65 / 65	100.00%	94.48%-100.00%	2703 / 2711	99.70%	99.42%-99.87%
			Overall			
Overall	2750 / 2910	94.50%	93.61%-95.30%	53258 / 53559	99.44%	99.37%-99.50%

* Target not evaluated in clinical specimens. The assay performance was evaluated through the testing of contrived specimens only for Bocavirus and *Legionella pneumophila*. See Table 19 for details on contrived specimens test results.

Following discrepant resolution, 2889 true positive and 53289 true negative QIAstat-Dx Respiratory Panel results were found, as well as 120 false-negative and 162 false-positive results. Table 18 displays QIAstat-Dx Respiratory SARS-CoV-2 Panel Clinical Sensitivity (or Positive Percent Agreement) and Clinical Specificity (or Negative Percent Agreement) with 95% Confidence Intervals following discrepant resolution.

Table 18. Agreement between QIAstat Respiratory SARS-CoV-2 Panel and Reference Method following Discrepant Resolution

	Positive Percent Agreement			Negative Percent Agreement		
Target	TP/(TP+FN)	%	95% CI	TN/(TN+FP)	%	95% CI
			Viruses			
Adenovirus	136 / 141	96.45%	91.92%-98.84%	2617 / 2637	99.24%	98.83%-99.54%
Bocavirus*	N/A	N/A	N/A	N/A	N/A	N/A
Coronavirus 229E	38 / 41	92.68%	80.08%-98.46%	2735 / 2735	100.00%	99.87%-100.00%
Coronavirus OC43	66 / 70	94.29%	86.01%-98.42%	2704 / 2705	99.96%	99.79%-100.00%
Coronavirus NL63	88 / 97	90.72%	83.12%-95.67%	2677 / 2680	99.89%	99.67%-99.98%
Coronavirus HKU1	73 / 74	98.65%	92.70%-99.97%	2690 / 2702	99.56%	99.23%-99.77%
SARS-CoV-2	397 / 409	97.07%	94.93%-98.47%	544 / 548	99.27%	98.14%-99.80%
Human Metapneumovirus A+B	142 / 148	95.95%	91.39%-98.50%	2627 / 2629	99.92%	99.73%-99.99%
Influenza A	327 / 330	99.09%	97.37%-99.81%	2407 / 2435	98.85%	98.34%-99.23%
Influenza A H1N1 pdm09	124 / 128	96.88%	92.19%-99.14%	2634 / 2645	99.58%	99.26%-99.79%
Influenza A H1	0 / 1	0.00%	0.00%-97.50%	2774 / 2774	100.00%	99.87%-100.00%
Influenza A H3	210 / 214	98.13%	95.28%-99.49%	2558 / 2561	99.88%	99.66%-99.98%
Influenza B	177 / 185	95.68%	91.66%-98.11%	2591 / 2591	100.00%	99.86%-100.00%
Parainfluenza virus 1	62 / 63	98.41%	91.47%-99.96%	2713 / 2713	100.00%	99.86%-100.00%
Parainfluenza virus 2	8 / 8	100.00%	63.06%-100.00%	2768 / 2768	100.00%	99.87%-100.00%

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	Positive Percent Agreement			Negative Percent Agreement		
Target	TP/(TP+FN)	%	95% CI	TN/(TN+FP)	%	95% CI
			Viruses			
Parainfluenza virus 3	122 / 126	96.83%	92.07%-99.13%	2648 / 2653	99.81%	99.56%-99.94%
Parainfluenza virus 4	38 / 41	92.68%	80.08%-98.46%	2732 / 2735	99.89%	99.68%-99.98%
Respiratory Syncytial Virus A+B	319 / 331	96.37%	93.75%-98.11%	2442 / 2445	99.88%	99.64%-99.97%
Rhinovirus/Enterovirus	385 / 418	92.11%	89.09%-94.50%	2317 / 2360	98.18%	97.55%-98.68%
			Bacteria			
Bordetella pertussis	43 / 43	100.00%	91.78%-100.00%	2716 / 2733	99.38%	99.01%-99.64%
Chlamydophila pneumoniae	68 / 75	90.67%	81.71%-96.16%	2701 / 2701	100.00%	99.86%-100.00%
*Legionella pneumophila**	N/A	N/A	N/A	N/A	N/A	N/A
Mycoplasma pneumoniae	66 / 66	100.00%	94.56%-100.00%	2703 / 2710	99.74%	99.47%-99.90%
			Bacteria			
Overall	2889 / 3009	96.01%	95.25%-96.68%	53298 / 53460	99.70%	99.65%-99.74%

* Target not evaluated in clinical specimens. The assay performance was evaluated through the testing of contrived specimens only for Bocavirus and *Legionella pneumophila*. See Table 25 for details on contrived specimens test results.

Contrived specimens were used as surrogate clinical specimens to supplement and test the sensitivity and specificity of Bocavirus, *Legionella pneumophila,* Influenza A H1N1, Parainfluenza 2, Parainfluenza 4, Coronavirus 229E, and *Chlamydophila pneumoniae*. Residual negative clinical specimens were spiked with the pathogens at 2x, 5x and 10x LoD levels for Bocavirus and *Legionella pneumophila, and 3*x, 5x and 10x LoD levels for Influenza A H1N1, Parainfluenza 2, Parainfluenza 4, Coronavirus 229E, and *Chlamydophila pneumoniae*.

Results of the contrived specimen testing are provided in Table 19 and Table 20.

Table 19. QIAstat-Dx Respiratory SARS-CoV-2 Panel performance data on contriving samples for Bocavirus, *Legionella pneumophila*

				Exact Two-sided 95% Confidence Interval	
Pathogen	Sample Level	Frequency	Proportion (%)	Lower Limit (%)	Upper Limit (%)
Bocavirus	2xLoD	25 / 25	100.00%	86.28%	100.00%
	5xLoD	15 / 15	100.00%	78.20%	100.00%
	10xLoD	10 / 10	100.00%	69.15%	100.00%
Legionella pneumophila	2xLoD	25 / 25	100.00%	86.28%	100.00%
	5xLoD	15 / 15	100.00%	78.20%	100.00%
	10xLoD	10 / 10	100.00%	69.15%	100.00%

Table 20. QIAstat-Dx Respiratory SARS-CoV-2 Panel performance data on contriving samples for Influenza A H1N1, Parainfluenza 2, Parainfluenza 4, Coronavirus 229E and *Chlamydophila pneumoniae*

				Exact Two-sided 95% Confidence Interval	
Pathogen	Sample Level	Frequency	Proportion (%)	Lower Limit (%)	Upper Limit (%)
Influenza A, H1	3xLOD	24/24	100%	86.2%	100%
	5xLOD	27/27	100%	87.5%	100%
	10xLOD	24/24	100%	86.2%	100%
Coronavirus 229E	3xLOD	16/16	100%	80.6%	100%
	5xLOD	18/18	100%	82.4%	100%
	10xLOD	16/16	100%	80.6%	100%
Parainfluenza Virus 2	3xLODv	16/16	100%	80.6%	100%
	5xLOD	18/18	100%	82.4%	100%
	10xLOD	16/16	100%	80.6%	100%
Parainfluenza Virus 4	3xLOD	15/16	93.8%	71.7%	100%
	5xLOD	18/18	100%	82.4%	100%
	10xLOD	16/16	100%	80.6%	100%
Chlamydophila pneumoniae	3xLOD	16/16	100%	80.6%	100%
	5xLOD	18/18	100%	82.4%	100%
	10xLOD	16/16	100%	80.6%	100%

Conclusion

Extensive multicenter studies demonstrate the performance of the QIAstat-Dx Respiratory SARS-CoV-2 Panel assay.

The overall Clinical Sensitivity was found to be 96.01% (95% CI, 95.25–96.68%). The overall Clinical Specificity was found to be 99.70% (95% CI, 99.65–99.74%).