



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

I Background Information:

A 510(k) Number

K261336

B Applicant

Cepheid

C Proprietary and Established Names

Xpert Respiratory Panel

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
QOF	Class II	21 CFR 866.3981 - Device To Detect And Identify Nucleic Acid Targets In Respiratory Specimens From Microbial Agents That Cause The Sars-Cov-2 Respiratory Infection And Other Microbial Agents When In A Multi-Target Test	MI - Microbiology

II Submission/Device Overview:

A Purpose for Submission:

To demonstrate that the Xpert Respiratory Panel is substantially equivalent to the QIAstat-Dx Respiratory Panel Plus (K233100) on the GeneXpert Instrument Systems and to obtain clearance for the Xpert Respiratory Panel.

B Measurand:

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

- Adenovirus (A-E)
- Coronavirus (HKU1, NL63, 229E, OC43)
- Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2)
- Human Metapneumovirus
- Rhinovirus/Enterovirus
- Parainfluenza (1-4)
- Influenza A
- Influenza B
- Respiratory Syncytial Virus (A and B)
- *Bordetella pertussis*
- *Bordetella parapertussis*
- *Mycoplasma pneumoniae*
- *Chlamydia pneumoniae*

C Type of Test:

Qualitative reverse transcriptase polymerase chain reaction (RT-PCR) and polymerase chain reaction (PCR)

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

The Xpert Respiratory Panel test, performed on the GeneXpert Instrument Systems, is a qualitative multiplexed *in vitro* diagnostic test for the simultaneous detection and identification of DNA and RNA from multiple bacteria and/or viruses in nasopharyngeal swab (NPS) specimens obtained from individuals with clinical signs and symptoms of respiratory tract infection.

The following organism types and subtypes are detected and identified using the Xpert Respiratory Panel test:

- Adenovirus (A-E)
- Coronavirus (HKU1, NL63, 229E, OC43)
- SARS-CoV-2
- Human Metapneumovirus
- Rhinovirus/Enterovirus
- Parainfluenza (1-4)
- Influenza A
- Influenza B
- Respiratory Syncytial Virus (A and B)
- *Bordetella pertussis*
- *Bordetella parapertussis*
- *Mycoplasma pneumoniae*
- *Chlamydia pneumoniae*

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

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

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

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

C Special Conditions for Use Statement(s):

Rx – For Prescription Use Only

For In Vitro Diagnostic Use Only

D Special Instrument Requirements:

For use with the GeneXpert Instrument Systems (GeneXpert Dx System, GeneXpert Infinity System and GeneXpert System with Touchscreen), equipped with GeneXpert 10-color modules running Dx software version 6.6 and higher, Xpertise software version 7.2 or higher, and Cepheid OS software 2.3 or higher, respectively

IV Device/System Characteristics:

A Device Description:

The Xpert Respiratory Panel test is performed on GeneXpert Instrument Systems (GeneXpert Dx System, GeneXpert Infinity System and GeneXpert System with Touchscreen), equipped with GeneXpert 10-color modules running Dx software version 6.6 and higher, Xpertise software version 7.2 or higher, and Cepheid OS software 2.3 or higher, respectively.

The GeneXpert Instrument Systems automate and integrate sample preparation, nucleic acid extraction and amplification, and detection of multiple bacterial/viral target sequences in simple or complex samples using real-time reverse transcription (RT)-polymerase chain reaction (PCR) for RNA targets and PCR for DNA targets. Depending on the instrument, the GeneXpert Instrument Systems can have from 1 and up to 80 randomly accessible modules, each capable of performing separate sample preparation and real-time RT-PCR and PCR tests. Each module

contains a syringe drive for dispensing fluids (*i.e.*, the syringe drive activates the plunger that works in concert with the rotary valve in the cartridge to move fluids between chambers), an ultrasonic horn for lysing cells or spores, and a proprietary I-CORE thermocycler for performing real-time RT-PCR and PCR as well as detection. The systems require the use of single-use disposable cartridges that hold the RT-PCR reagents and host sample purification, nucleic acid amplification, and detection of the target sequences. Because the cartridges are self-contained, cross-contamination between samples is minimized.

The Xpert Respiratory Panel test includes reagents for the detection of DNA and RNA from Adenovirus, Coronavirus, SARS-CoV-2, Human Metapneumovirus, Rhinovirus/Enterovirus, Parainfluenza, Influenza A, Influenza B, RSV, *Bordetella pertussis*, *Bordetella parapertussis*, *Chlamydia pneumoniae* and *Mycoplasma pneumoniae* from nasopharyngeal swab (NPS) specimens. The primers and probes in the Xpert Respiratory Panel test are designed to amplify and detect unique genetic sequences for each on-panel analyte.

B Principle of Operation:

The Xpert Respiratory Panel test, performed on Cepheid GeneXpert Instrument Systems, is an automated *in vitro* diagnostic test for qualitative detection and differentiation of multiple bacteria and/or viruses in nasopharyngeal swab (NPS) specimens collected from individuals suspected of having respiratory tract infection (RTI).

C Instrument Description Information:

1. Instrument Name:

GeneXpert Instrument Systems (GeneXpert Dx System, GeneXpert Infinity System and GeneXpert System with Touchscreen), equipped with GeneXpert 10-color modules running Dx software version 6.6 and higher, Xpertise software version 7.2 or higher, and Cepheid OS software 2.3 or higher, respectively.

2. Specimen Sampling and Handling:

The ancillary specimen collection kits, swabs and transport media validated for use with the Xpert Respiratory Panel test included:

Nasopharyngeal Sample Collection Kit

- Copan UTM 3C057N (Flexible Minitip Flocked Swab with UTM Medium)
- Copan eNAT Molecular Collection and Preservation Medium P/N 6U074S01
- BD™ Becton Dickinson Specimen Collection and Transport System P/N 220531 (Flexible Minitip Flocked Swab with UVT Medium)

Alternatively, swabs and transport media can be obtained separately:

- Nylon flocked swab (Copan P/N 503CS01)
- Viral transport medium (Copan P/N 3C047N, Remel MicroTest M4RT, M5 and M6 Transport Medium, PrimeStore Molecular Transport Medium)

3. Calibration:

Not applicable.

4. Quality Control:

Internal Controls

The assay uses Sample Processing Control (SPC) to control for adequate processing of the sample and to monitor for the presence of potential inhibitor(s) in the RT-PCR reaction. The SPC also ensures that the RT-PCR reaction conditions (temperature and time) are appropriate for the amplification reaction and that the RT-PCR reagents are functional. In addition, SPC also functions as a control for the melt curve analysis. The assay uses a Probe Check Control (PCC) to verify reagent rehydration, PCR tube filling, and confirms that all reaction components are present in the cartridge including monitoring for probe integrity and dye stability.

External Controls

External controls are not provided with the Xpert Respiratory Panel. External controls in the form of inactivated bacteria and viruses are available from ZeptoMetrix (Buffalo, NY) for optional use with the Xpert Respiratory Panel test.

- External Positive Control – NATtrol Respiratory Positive Control; Cat # NATRSPPOS-8C-IVD
- External Negative Control – NATtrol Respiratory Negative Control; Cat # NATRSPNEG-8C-IVD

The following information on external control testing is included in the Instructions for Use, “*Quality control requirements must be performed in conformance with local, state, and/or federal regulations or accreditation requirements and your laboratory’s standard quality control procedures.*”

V Substantial Equivalence Information:

A Predicate Device Name(s):

QIAstat-Dx Respiratory Panel Plus

B Predicate 510(k) Number(s):

K233100

C Comparison with Predicate(s):

Device & Predicate Device(s):	<u>K261336</u>	<u>K233100</u>
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Device Trade Name	Xpert Respiratory Panel	QIAstat-Dx Respiratory Panel Plus
General Device Characteristic Similarities		
Technology/Detection	Qualitative multiplex reverse transcription polymerase chain reaction (RT-PCR) with both amplification and melt detected targets	Nucleic acid extraction, nucleic acid amplification, and detection of amplified targets that use an increase in fluorescence to generate the assay results
Intended Use / Indications for Use	The Xpert Respiratory Panel test, performed on the GeneXpert Instrument Systems, is a qualitative multiplexed <i>in vitro</i> diagnostic test for the simultaneous detection and identification of DNA and RNA from multiple bacteria and/or viruses in nasopharyngeal swab (NPS) specimens obtained from individuals with clinical signs and symptoms of respiratory tract infection. The following organism types and subtypes are detected and identified using the Xpert Respiratory Panel test: • Adenovirus (A-E) • Coronavirus (HKU1, NL63, 229E, OC43) • SARS-CoV-2 • Human Metapneumovirus • Rhinovirus/Enterovirus • Parainfluenza (1-4)	The QIAstat-Dx Respiratory Panel Plus is a multiplexed nucleic acid test intended for use with the QIAstat-Dx system for the simultaneous <i>in vitro</i> qualitative detection and identification of multiple respiratory viral and bacterial nucleic acids in nasopharyngeal swabs (NPS) obtained from individuals with clinical signs and symptoms of respiratory tract infection, including SARS-CoV-2. The following organism types and subtypes are identified using the QIAstat-Dx Respiratory Panel Plus: Adenovirus, Human Coronavirus 229E, Human Coronavirus HKU1, Human Coronavirus NL63,

	• Influenza A • Influenza B • Respiratory Syncytial Virus (A and B) • <i>Bordetella pertussis</i> • <i>Bordetella parapertussis</i> • <i>Mycoplasma pneumoniae</i> • <i>Chlamydia pneumoniae</i> Nucleic acids from viral and bacterial organisms identified by this test are generally detectable in NPS specimens during the acute phase of infection. Detecting and identifying specific viral and bacterial nucleic acids from individuals presenting with signs and symptoms of a respiratory infection aids in the diagnosis of respiratory infection, if used in conjunction with other clinical, epidemiological and laboratory findings. The results of this test should not be used as the sole basis for diagnosis, treatment or other patient management decisions. Negative results in the presence of a respiratory illness may be due to infection with pathogens that are not detected by the test, or due to lower respiratory	Human Coronavirus OC43, Human Metapneumovirus, Influenza A, Influenza A H1, Influenza A H1N1 pdm09, Influenza A H3, Influenza B, Parainfluenza virus 1, Parainfluenza virus 2, Parainfluenza virus 3, Parainfluenza virus 4, Respiratory Syncytial Virus, Human Rhinovirus/Enterovirus (not differentiated), Severe Acute Respiratory Syndrome Coronavirus (SARS-CoV-2), <i>Bordetella pertussis</i>, <i>Chlamydia pneumoniae</i>, <i>Mycoplasma pneumoniae</i> Nucleic acids from viral and bacterial organisms identified by this test are generally detectable in NPS specimens during the acute phase of infection. Detecting and identifying specific viral and bacterial nucleic acids from
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	tract infection that is not detected by a NPS specimen. Conversely, positive results are indicative of the presence of the identified microorganism, but do not rule out co-infection with other pathogens not detected by the Xpert Respiratory Panel. The agent(s) detected by the Xpert Respiratory Panel may not be the definite cause of disease. The use of additional laboratory testing (e.g., bacterial and viral culture, immunofluorescence, and radiography) may be necessary when evaluating a patient with possible respiratory tract infection.	individuals presenting with signs and symptoms of a respiratory infection aids in the diagnosis of respiratory infection, if used in conjunction with other clinical, epidemiological and laboratory findings. The results of this test should not be used as the sole basis for diagnosis, treatment or other patient management decisions. Negative results in the presence of a respiratory illness may be due to infection with pathogens that are not detected by the test or due to lower respiratory tract infection that is not detected by a NPS specimen. Conversely, positive results are indicative of the presence of the identified microorganism, but do not rule out co-infection with other pathogens not detected by the QIAstat-Dx Respiratory Panel Plus. The agent(s) detected by the QIAstat-Dx Respiratory Panel Plus may not be the definite cause of disease. The use of additional
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		laboratory testing (e.g., bacterial and viral culture, immunofluorescence and radiography) may be necessary when evaluating a patient with possible respiratory tract infection.
Intended User / Environment	The Xpert Respiratory Panel test is intended to be performed by laboratory and healthcare professionals trained on the use of the test. This test is for use in a laboratory environment.	The QIAstat-Dx Respiratory Panel Plus is to be used by laboratory professionals trained in the use of the QIAstat-Dx Analyzer 1.0, QIAstat-Dx Analyzer 2.0, or QIAstat-Dx Rise.
Specimen Type	Same	Nasopharyngeal swab (NPS)
Transport Media	- Universal Transport Medium (UTM)/ Viral Transport Medium (VTM) - eNAT	Universal Transport Medium (UTM)
Test Automation	Same	Automated Nucleic Acid Extraction, Detection and Results Interpretation
Test Format	Same	Single Use
Internal Controls	- Sample Processing Control (SPC) - Probe Check Control (PCC)	Titered MS2 bacteriophage that provides verification that all steps of the analysis process
Assay Targets	- Adenovirus (A-E) - Coronavirus (HKU1, NL63, 229E, OC43) - SARS-CoV-2 - Human Metapneumovirus - Rhinovirus/Enterovirus - Parainfluenza (1-4)	- Adenovirus - Human Coronavirus 229E, Human Coronavirus HKU1, Human Coronavirus NL63, Human Coronavirus OC43, - Human Metapneumovirus - Influenza A

	• Influenza A • Influenza B • Respiratory Syncytial Virus (A and B) • <i>Bordetella pertussis</i> • <i>Bordetella parapertussis</i> • <i>Mycoplasma pneumoniae</i> • <i>Chlamydia pneumoniae</i>	○ Influenza A H1 ○ Influenza A H1N1 pdm09 ○ Influenza A H3 • Influenza B • Parainfluenza virus 1, Parainfluenza virus 2, Parainfluenza virus 3, Parainfluenza virus 4, • Respiratory Syncytial Virus, • Human Rhinovirus/Enterovirus (not differentiated) • Severe Acute Respiratory Syndrome Coronavirus (SARS-CoV-2) • <i>Bordetella pertussis</i> • <i>Chlamydophila pneumoniae</i> <i>Mycoplasma pneumoniae</i>
Assay Results	Same	Qualitative
Test Access	Same	Prescription Use Only
Time to Result	~56 minutes	~60 minutes
Instrument Systems	GeneXpert Instrument Systems: • GeneXpert Dx System • GeneXpert Infinity Systems (48s and 80) GeneXpert System with Touchscreen	• QIAstat-Dx Analyzer 1.0 • QIAstat-Dx Analyzer 2.0 • QIAstat-Dx Rise
Systems Software for Instrument Family	• GeneXpert Dx software version 6.6 or higher • GeneXpert Xpertise software 7.2 or higher	• For QIAstat-Dx Analyzer 1.0, use software version 1.4 or 1.5 • For QIAstat-Dx Analyzer 2.0, use

	Cepheid OS software version 2.3 or higher	software version 1.6 or later For QIAstat-Dx Rise, use software version 2.4 or later
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D Standards/Guidance Documents Referenced:

- 21 CFR 866.3981 – Device to detect and identify nucleic acid targets in respiratory specimens from microbial agents that cause the SARS-CoV-2 respiratory infection and other microbial agents when in a multi-target test.
- FDA Class II Special Controls Guidance: Respiratory Viral Panel Multiplex Nucleic Acid Assay – Class II Special Controls Guidance for Industry and FDA Staff (DEN200031).
- ANSI/AAMI/ISO 14971:2019. Medical devices – Application of risk management to medical devices. (FDA Recognized Standard 5-125)
- CLSI EP12-A2. User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline – Second Edition. (FDA Recognized Standard 7-152)
- CLSI EP17-A2. Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline – Second Edition. (FDA Recognized Standard 7-233)
- CLSI EP24-A2. Assessment of the Diagnostic Accuracy of Laboratory Tests Using Receiver Operating Characteristic Curves; Approved Guideline – Second Edition. (FDA Recognized Standard 7-234)
- CLSI EP25-A. Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline. (FDA Recognized Standard 7-235)
- CLSI EP05-A3. Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline – Third Edition. (Reaffirmed: September 2019) (FDA Recognized Standard 7-251)
- CLSI MM03, 3rd Edition. Molecular Diagnostic Methods for Infectious Diseases; Approved Guideline. (FDA Recognized Standard 7-260)
- CLSI EP07, 3rd Edition. Interference Testing in Clinical Chemistry. (FDA Recognized Standard 7-275)
- CLSI MM17, 2nd Edition. Verification and Validation of Multiplex Nucleic Acid Assays. (FDA Recognized Standard 7-289)
- CLSI MM13, 2nd Edition. Collection Transport Preparation and Storage of Specimens for Molecular Methods. (FDA Recognized Standard 7-300)
- ANSI/AAMI IEC 62304:2006/A1:2016. Medical device software – Software life cycle processes [Including Amendment 1 (2016)]. (FDA Recognized Standard 13-79)
- ANSI/AAMI IEC 60601-1-2:2014 [Including AMD 1:2021]. Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests. (FDA Recognized Standard 19-36)
- IEC 61326-1, Edition 3.0 2020-10. Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 1: General requirements. (FDA Recognized Standard 19-42)

- IEC 61326-2-6, Edition 3.0 2020-10. Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 2-6: Particular requirements – In vitro diagnostic (IVD) medical equipment. (FDA Recognized Standard 19-43)

VI Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

Reproducibility

The reproducibility of the Xpert Respiratory Panel test was established at 3 sites (1 internal, 2 external) using 7-member panels, each panel includes 1 negative sample, 3 low positive and 3 moderate positive samples. Collectively, the 3 positive panel members at each level included one strain per on-panel analyte for a total of 14 analytes detected by the Xpert Respiratory Panel. Positive panel members consisted of 5 – 6 different analytes, contrived in simulated NPS matrix to a low (~1x LoD) or moderate (~3x LoD) level. The negative sample consisted of simulated NPS matrix only. Testing was performed across 6 non-consecutive days, using 3 lots of cartridges. Each site had 2 operators who tested 2 runs of 2 replicates per testing day to yield a total of 144 observations per panel member (3 Sites × 2 Operators × 3 Lots × 2 Days /Lot × 2 Run × 2 Replicates = 144 test results/panel member).

Table 1 presents the qualitative summary of the reproducibility testing. The nested ANOVA analysis of the internal continuous response in the Xpert Respiratory Panel test (either Ct values or melt curve measurements) are presented by analyte in **Table 2**. The results of the study demonstrate acceptable assay precision and reproducibility.

Table 1: Summary of Reproducibility Results - Percent Agreement

Analyte	Level	Site 01			Site 02			Site 03			Total Agreement with 95% CI
		Op 1	Op 2	Subtotal	Op 1	Op 2	Subtotal	Op 1	Op 2	Subtotal	
PIV	Low Pos (~1x LoD)	95.8% 23/24	95.8% 23/24	95.8% 46/48	100% 24/24	100% 23/23	100% 47/47	100% 24/24	95.8% 23/24	97.9% 47/48	97.9% (140/143) 94.0-99.3%
	Mod Pos	100% 24/24	100% 24/24	100% 48/48	100% 24/24	100% 24/24	100% 48/48	100% 24/24	100% 24/24	100% 48/48	100% (144/144) 97.4-100%
CoV	Low Pos (~1x LoD)	100% 24/24	100% 24/24	100% 48/48	100% 24/24	100% 23/23	100% 47/47	100% 24/24	100% 24/24	100% 48/48	100% (143/143) 97.4-100%
	Mod Pos	100% 24/24	100% 24/24	100% 48/48	100% 24/24	100% 24/24	100% 48/48	100% 24/24	100% 24/24	100% 48/48	100% (144/144) 97.4-100%
<i>B. paraptussis</i>	Low Pos (~1x LoD)	100% 24/24	100% 24/24	100% 48/48	100% 24/24	100% 23/23	100% 47/47	100% 24/24	100% 24/24	100% 48/48	100% (143/143) 97.4-100%
	Mod Pos	100% 24/24	100% 24/24	100% 48/48	100% 24/24	100% 24/24	100% 48/48	100% 24/24	100% 24/24	100% 48/48	100% (144/144) 97.4-100%
Flu A	Low Pos	95.8%	100%	97.9%	100%	100%	100%	95.8%	100%	97.9%	98.6%

Analyte	Level	Site 01			Site 02			Site 03			Total Agreement with 95% CI
		Op 1	Op 2	Subtotal	Op 1	Op 2	Subtotal	Op 1	Op 2	Subtotal	
	(~1x LoD)	23/24	24/24	47/48	24/24	23/23	47/47	23/24	24/24	47/48	(141/143) 95.0-99.6%
	Mod Pos	100% 24/24	100% 24/24	100% 48/48	100% 24/24	100% 24/24	100% 48/48	100% 24/24	100% 24/24	100% 48/48	100% (144/144) 97.4-100%
RSV	Low Pos (~1x LoD)	100% 24/24	100% 24/24	100% 48/48	100% 24/24	100% 23/23	100% 47/47	100% 24/24	100% 24/24	100% 48/48	100% (143/143) 97.4-100%
	Mod Pos	100% 24/24	100% 24/24	100% 48/48	100% 24/24	100% 24/24	100% 48/48	100% 24/24	100% 24/24	100% 48/48	100% (144/144) 97.4-100%
<i>C. pneumoniae</i>	Low Pos (~1x LoD)	91.7% 22/24	100% 24/24	95.8% 46/48	87.5% 21/24	95.8% 23/24	91.7% 44/48	95.8% 23/24	100% 24/24	97.9% 47/48	95.1% (137/144) 90.3-97.6%
	Mod Pos	100% 24/24	100% 24/24	100% 48/48	95.8% 23/24	100% 24/24	97.9% 47/48	100% 24/24	100% 24/24	100% 48/48	99.3% (143/144) 96.2-99.9%
Flu A H1N1-09	Low Pos (~1x LoD)	100% 24/24	100% 24/24	100% 48/48	95.8% 23/24	95.8% 23/24	95.8% 46/48	100% 24/24	100% 24/24	100% 48/48	98.6% (142/144) 95.1-99.6%
	Mod Pos	100% 24/24	100% 24/24	100% 48/48	100% 24/24	100% 24/24	100% 48/48	100% 24/24	100% 24/24	100% 48/48	100% (144/144) 97.4-100%
hMPV	Low Pos (~1x LoD)	100% 24/24	100% 24/24	100% 48/48	100% 24/24	100% 24/24	100% 48/48	100% 24/24	100% 24/24	100% 48/48	100% (144/144) 97.4-100%
	Mod Pos (~3x LoD)	100% 24/24	100% 24/24	100% 48/48	100% 24/24	100% 24/24	100% 48/48	100% 24/24	100% 24/24	100% 48/48	100% (144/144) 97.4-100%
AdV	Low Pos (~1x LoD)	95.8% 23/24	95.8% 23/24	95.8% 46/48	91.7% 22/24	95.8% 23/24	93.8% 45/48	100% 24/24	95.8% 23/24	97.9% 47/48	95.8% (138/144) 91.2-98.1%
	Mod Pos (~3x LoD)	100% 24/24	100% 24/24	100% 48/48	100% 24/24	100% 24/24	100% 48/48	100% 24/24	100% 24/24	100% 48/48	100% (144/144) 97.4-100%
RV/EV	Low Pos (~1x LoD)	100% 24/24	100% 24/24	100% 48/48	100% 24/24	100% 24/24	100% 48/48	100% 24/24	100% 24/24	100% 48/48	100% (144/144) 97.4-100%
	Mod Pos (~3x LoD)	100% 24/24	100% 24/24	100% 48/48	100% 24/24	100% 24/24	100% 48/48	100% 24/24	100% 24/24	100% 48/48	100% (144/144) 97.4-100%
Flu B	Low Pos (~1x LoD)	100% 24/24	100% 24/24	100% 48/48	100% 24/24	100% 24/24	100% 48/48	100% 24/24	100% 24/24	100% 48/48	100% (144/144) 97.4-100%
	Mod Pos (~3x LoD)	100% 24/24	100% 24/24	100% 48/48	100% 24/24	100% 24/24	100% 48/48	100% 24/24	100% 24/24	100% 48/48	100% (144/144) 97.4-100%
<i>B. pertussis</i>	Low Pos (~1x LoD)	100% 24/24	100% 24/24	100% 48/48	95.8% 23/24	95.8% 23/24	95.8% 46/48	100% 24/24	100% 24/24	100% 48/48	98.6% (142/144) 95.1-99.6%
	Mod Pos (~3x LoD)	100% 24/24	100% 24/24	100% 48/48	100% 24/24	95.8% 23/24	97.9% 47/48	100% 24/24	100% 24/24	100% 48/48	99.3% (143/144) 96.2-99.9%
<i>M. pneumoniae</i>	Low Pos (~1x LoD)	100% 24/24	100% 24/24	100% 48/48	100% 24/24	100% 24/24	100% 48/48	100% 24/24	100% 24/24	100% 48/48	100% (144/144) 97.4-100%
	Mod Pos (~3x LoD)	100% 24/24	100% 24/24	100% 48/48	100% 24/24	95.8% 23/24	97.9% 47/48	100% 24/24	100% 24/24	100% 48/48	99.3% (143/144) 96.2-99.9%

Analyte	Level	Site 01			Site 02			Site 03			Total Agreement with 95% CI
		Op 1	Op 2	Subtotal	Op 1	Op 2	Subtotal	Op 1	Op 2	Subtotal	
SARS-CoV-2	Low Pos (~1x LoD)	100% 24/24	100% 24/24	100% 48/48	100% 24/24	100% 24/24	100% 48/48	100% 24/24	100% 24/24	100% 48/48	100% (144/144) 97.4-100%
	Mod Pos (~3x LoD)	100% 24/24	100% 24/24	100% 48/48	100% 24/24	100% 24/24	100% 48/48	100% 24/24	100% 24/24	100% 48/48	100% (144/144) 97.4-100%
Negative	N/A	100% 24/24	95.8% 23/24	97.9% 47/48	95.8% 23/24	100% 23/23	97.9% 46/47	100% 24/24	100% 24/24	100% 48/48	98.6% (141/143) 95.0-99.6%

Table 2: Summary of Nested ANOVA by Coefficient of Variation

Analyte (Level)	Response	N	Mean	Variance Source													
				Site		OP		Lot		Day		Run		Within-Run		Total	
				SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)
PIV (Low Pos)	Ct	140 ^{ab}	39.2	0.2	0.6	0.0	0.0	0.7	1.7	0.2	0.4	0.0	0.0	1.2	3.1	1.4	3.7
PIV (Mod Pos)	Ct	144	38.5	0.0	0.0	0.0	0.0	0.6	1.5	0.0	0.0	0.5	1.2	1.2	3.0	1.4	3.6
CoV (Low Pos)	Ct	143 ^a	39	0.0	0.0	0.0	0.0	0.4	1.1	0.2	0.6	0.0	0.0	0.8	2.2	1.0	2.5
CoV (Mod Pos)	Ct	144	38.2	0.1	0.4	0.0	0.0	0.5	1.4	0.2	0.5	0.0	0.0	0.7	1.8	0.9	2.3
<i>B. paraptussis</i> (Low Pos)	MP	143 ^a	15.9	0.7	4.3	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	2.9	18.0	2.9	18.5
	MV	143 ^a	14	0.7	4.7	0.0	0.0	0.0	0.0	0.0	0.0	0.5	3.4	2.5	18.0	2.6	18.9
<i>B. paraptussis</i> (Mod Pos)	MP	144	16.9	1.3	7.6	0.0	0.0	0.3	2.0	0.0	0.0	0.9	5.2	2.7	15.7	3.1	18.4
	MV	144	15	1.2	8.0	0.1	0.7	0.3	1.8	0.0	0.0	1.0	6.6	2.4	16.1	2.9	19.2
Flu A (Low Pos)	Ct	142 ^{ab}	37	0.1	0.4	0.0	0.0	0.5	1.5	0.1	0.3	0.0	0.0	0.9	2.4	1.0	2.8
Flu A (Mod Pos)	Ct	144	36.4	0.0	0.0	0.0	0.0	0.3	0.9	0.0	0.0	0.1	0.4	5.3	14.5	0.6	1.8
RSV (Low Pos)	Ct	143 ^a	35.9	0.2	0.7	0.0	0.0	0.0	0.0	0.5	1.3	0.1	0.4	1.3	3.5	1.4	3.8
RSV (Mod Pos)	Ct	144	35.4	0.1	0.3	0.0	0.0	0.5	1.4	0.0	0.0	0.0	0.0	1.0	2.8	1.1	3.1
<i>C. pneumoniae</i> (Low Pos)	MP	137 ^c	9.1	0.0	0.0	0.0	0.0	0.5	6.0	0.1	1.1	0.5	5.2	1.0	11.4	1.3	13.9
	MV	137 ^c	4.6	0.0	0.0	0.0	0.0	0.5	11.7	0.0	0.0	0.5	11.7	0.8	18.1	1.1	24.5
<i>C. pneumoniae</i> (Mod Pos)	MP	143 ^c	9.7	0.0	0.0	0.0	0.0	0.4	4.3	0.0	0.0	0.2	2.3	1.2	11.9	1.2	12.8
	MV	143 ^c	5.1	0.0	0.0	0.0	0.0	0.5	9.4	0.0	0.0	0.2	3.9	1.0	18.9	1.1	21.4
hMPV (Low Pos)	MP	144	7	1.4	19.6	0.0	0.0	0.3	4.0	0.0	0.0	0.0	0.0	2.0	28.4	2.4	34.8
	MV	144	6.7	1.3	19.1	0.0	0.0	0.3	4.5	0.0	0.0	0.0	0.0	2.0	29.5	2.4	35.4
hMPV (Mod Pos)	MP	144	8.1	1.4	17.8	0.1	1.2	0.0	0.0	0.1	1.7	0.9	10.6	1.6	20.1	2.3	29.0
	MV	144	7.8	1.4	17.3	0.2	2.6	0.0	0.0	0.0	0.0	0.9	11.4	1.5	19.5	2.2	28.6
AdV (Low Pos)	Ct	138 ^b	39.8	0.3	0.7	0.0	0.0	0.0	0.0	0.0	0.0	0.2	0.5	1.1	2.9	1.2	3.0
AdV (Mod Pos)	Ct	144	39.2	0.4	0.9	0.0	0.0	0.0	0.0	0.0	0.0	0.4	1.0	1.1	2.9	1.3	3.2
RV/EV (Low Pos)	Ct	144	36.4	0.1	0.3	0.0	0.0	0.3	0.7	0.0	0.0	0.1	0.4	0.4	1.0	0.5	1.3

Analyte (Level)	Response	N	Mean	Variance Source													
				Site		OP		Lot		Day		Run		Within-Run		Total	
				SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)
RV/EV (Mod Pos)	Ct	144	35.8	0.0	0.0	0.0	0.0	0.3	0.9	0.1	0.4	0.0	0.0	0.3	0.9	0.5	1.4
Flu B (Low Pos)	Ct	144	37.2	0.0	0.0	0.0	0.0	0.7	1.8	0.0	0.0	0.0	0.0	0.4	1.2	0.8	2.2
Flu B (Mod Pos)	Ct	144	36.5	0.0	0.0	0.0	0.0	0.7	1.8	0.0	0.0	0.1	0.3	0.3	0.8	0.7	2.0
<i>B. pertussis</i> (Low Pos)	MP	142 ^c	14.1	0.9	6.3	0.0	0.0	0.8	5.5	0.2	1.6	0.0	0.0	2.2	15.7	0.8	5.6
	MV	142 ^c	11.6	0.7	6.3	0.0	0.0	0.7	6.0	0.1	1.2	0.0	0.0	1.8	15.6	2.1	18.0
<i>B. pertussis</i> (Mod Pos)	MP	143 ^c	14.4	1.2	8.1	0.0	0.0	1.1	7.6	0.0	0.0	0.0	0.0	2.3	15.6	2.8	19.2
	MV	143 ^c	11.9	1.0	8.1	0.0	0.0	1.0	8.3	0.3	2.4	0.0	0.0	1.9	15.7	2.3	19.7
<i>M. pneumoniae</i> (Low Pos)	MP	144	16.3	0.8	50.6	0.9	5.7	0.1	0.9	0.7	4.2	1.6	9.7	3.8	23.4	4.4	26.7
	MV	144	18.6	0.8	4.6	0.8	4.5	1.2	6.6	0.8	4.5	2.0	10.9	4.3	23.2	5.1	27.6
<i>M. pneumoniae</i> (Mod Pos)	MP	143 ^c	19.5	0.4	2.3	0.0	0.0	1.1	5.7	0.0	0.0	1.5	7.5	3.6	18.7	4.1	21.1
	MV	143 ^c	22.6	0.7	2.9	0.0	0.0	1.6	6.9	0.0	0.0	1.6	6.9	4.2	18.5	4.8	21.1
SARS-CoV-2 (Low Pos)	Ct	144	35.9	0.1	0.4	0.0	0.0	0.5	1.5	0.2	0.5	0.2	0.7	0.9	2.5	1.1	3.1
SARS-CoV-2 (Mod Pos)	Ct	144	35.1	0.2	0.6	0.0	0.0	0.5	1.4	0.0	0.0	0.0	0.0	0.9	2.6	1.0	3.0

Abbreviations: Ct, cycle threshold; CV, coefficient of variation; Low Pos, low positive ~1xLoD; MP, melt peak; Mod Pos, moderate positive ~3xLoD; MV, melt valley; SD, standard deviation

^a Sample excluded due to an ND result.

^b Sample excluded due to 0 Ct value.

^c Sample excluded due to missing melt peak and melt valley values.

2. Linearity:

Not applicable. This is a qualitative assay.

3. Analytical Specificity/Interference:

Analytical Reactivity (Inclusivity)

Wet-Testing

The inclusivity of the Xpert Respiratory Panel test was evaluated through testing of multiple strains of each target analyte. A total of 169 strains were initially tested at near LoD concentrations: 14 Adenovirus strains, 11 Coronavirus strains, 14 SARS-CoV-2 strains, 9 hMPV strains, 46 RV and EV strains, 11 PIV strains, 31 Influenza A virus strains, 7 Influenza B virus strains, 5 RSV strains, 4 *Bordetella parapertussis* strains, 8 *Bordetella pertussis* strains, 3 *Chlamydia pneumoniae* strains, and 6 *Mycoplasma pneumoniae* strains. Each analyte was individually spiked into negative simulated NPS matrix and five (5) replicates were tested for each strain. If less than 100% reactivity was observed during testing, the strain was prepared at a higher concentration and tested until 100% reactivity was achieved. **Table 3** presents the lowest concentration of the viral or bacterial strain/isolate at which all 5 replicates reported positive

results.

Table 4: Analytical Reactivity (Inclusivity) of the Xpert Respiratory Panel Test

Adenovirus	Type/ Strain	Vendor	Part Number	Lowest Concentration With 100% Positivity (N=5)
A	12	ATCC	VR-863	544 Copies/mL
	18	ATCC	VR-19	272 Copies/mL
	31	ZeptoMetrix	0810073CF	544 Copies/mL
B	3	ZeptoMetrix	0810062CF	1,719 Copies/mL ^a
	7A	ZeptoMetrix	0810021CF	91 Copies/mL
	16	ATCC	VR-17	27.2 Copies/mL
	34	ATCC	VR-716	11,625 Copies/mL ^a
	35	ATCC	VR-718	3,913 Copies/mL ^a
C	2	ATCC	VR-846	272 Copies/mL
	5	ZeptoMetrix	0810020CF	897 Copies/mL
	6	ATCC	VR-6	30 Copies/mL
D	8	ZeptoMetrix	0810069CF	272 Copies/mL
	20	ZeptoMetrix	0810115CF	272 Copies/mL
	37	ZeptoMetrix	0810119CF	544 Copies/mL
Coronavirus	Type/ Strain	Vendor	Part Number	Lowest Concentration With 100% Positivity (N=5)
229E	229E	ATCC	VR-740	0.2 TCID ₅₀ /mL
	229E	ZeptoMetrix	0810229CF	0.001 TCID ₅₀ /mL
	229E	Clinical Specimen	NA	991 Copies/mL
HKU1	HKU1	Clinical specimen	NA	50 Copies/mL
	HKU1	Clinical Specimen	NA	100 Copies/mL
NL63	NL63/Amsterdam/2003	BEI	NR-470	0.0006 TCID ₅₀ /mL
	NL63	ZeptoMetrix	0810228CF	0.002 TCID ₅₀ /mL
	NL63	Clinical Specimen	NA	248 Copies/mL
OC43	OC43	ATCC	VR-1558	0.03 TCID ₅₀ /mL
	OC43	ZeptoMetrix	0810024CF	0.5 TCID ₅₀ /mL
	OC43	Clinical Specimen	NA	495 Copies/mL
SARS-CoV-2	Type/ Strain	Vendor	Part Number	Lowest Concentration With 100% Positivity (N=5)
SARS-CoV-2	Italy-INMI1	ZeptoMetrix	0810589CFHI	12 TCID ₅₀ /mL
	USA-WA1/2020	ZeptoMetrix	0810587CFHI	0.6 TCID ₅₀ /mL
	Alpha	ZeptoMetrix	0810614CFHI	0.09 TCID ₅₀ /mL
	Beta	ZeptoMetrix	0810613CFHI	0.9 TCID ₅₀ /mL
	Delta	ZeptoMetrix	0810624CFHI	0.1 TCID ₅₀ /mL
	Gamma	ZeptoMetrix	0810616CFHI	0.2 TCID ₅₀ /mL
	Iota	ZeptoMetrix	0810620CFHI	0.7 TCID ₅₀ /mL
	Kappa	ZeptoMetrix	0810623CFHI	12 TCID ₅₀ /mL
	Zeta	ZeptoMetrix	0810618CFHI	0.3 TCID ₅₀ /mL

	SARS-CoV-2, Omicron- hCoV-19/USA/New York/ PV96109/2023	BEI	NR-59693	0.6 TCID ₅₀ /mL
	SARS-CoV-2, Omicron hCoV-19/USA/ CA-Stanford -165 S29/ 2023	BEI	NR-59709	0.2 TCID ₅₀ /mL
	SARS-CoV-2, Omicron hCoV-19/USA/MD-HP49152/2023	BEI	NR-59703	0.03 TCID ₅₀ /mL
	SARS-CoV-2, Omicron hCoV-19/USA/MD-HP47946/2023	BEI	NR-59503	0.6 TCID ₅₀ /mL
	SARS-CoV-2, Omicron	ZeptoMetrix	0810682CFHI	0.1 TCID ₅₀ /mL
Human Metapneumovirus	Type/ Strain	Vendor	Part Number	Lowest Concentration With 100% Positivity (N=5)
A	A1, Strain 9	ZeptoMetrix	0810161CF	20 Copies/mL
	A1, Strain 16	ZeptoMetrix	0810160CF	39 Copies/mL
	A2, Strain 20	ZeptoMetrix	0810163CF	78 Copies/mL
	A2, Strain 27	ZeptoMetrix	0810164CF	20 Copies/mL
B	B1, Strain 3	ZeptoMetrix	0810156CF	78 Copies/mL
	B1, Strain 5	ZeptoMetrix	0810158CF	39 Copies/mL
	B1, PP947667 (Synthetic ssDNA)	IDT	NA	1,510 Copies/mL ^b
	B2, Strain 4	ZeptoMetrix	0810157CF	78.4 Copies/mL
	B2, Strain 8	ZeptoMetrix	0810159CF	78.4 Copies/mL
Rhinovirus/ Enterovirus	Type/ Strain	Vendor	Part Number	Lowest Concentration With 100% Positivity (N=5)
Rhinovirus A	A1	ZeptoMetrix	0810012CFN	130 Copies/mL
	A2	ATCC	VR-482	130 Copies/mL
	A7	ATCC	VR-1601	130 Copies/mL
	A16	ATCC	VR-283	260 Copies/mL
	A57	ATCC	VR-1600	13,023 Copies/mL
	A63 OK649395 Synthetic ssDNA	IDT	NA	39,070 Copies/mL
	A77	ATCC	VR-1187	260 Copies/mL
Rhinovirus B	B14	ATCC	VR-284	203 Copies/mL
	B17	ATCC	VR-1663	33 Copies/mL
	B27	ATCC	VR-1137	130 Copies/mL
	B42	ATCC	VR-1950	65 Copies/mL
	B83	ATCC	VR3341	43 Copies/mL
	B85	ATCC	VR-1195	65 Copies/mL
Rhinovirus C	Clinical sample PC4S1GES50113	NA	NA	1,390 Copies/mL ^c

	Clinical sample PC4S1GES50210	NA	NA	10,000 Copies/mL ^c
	Clinical Sample PC4S1GES50258	NA	NA	1,000 Copies/mL ^c
	Clinical Sample PC4S1GES50332	NA	NA	861 Copies/mL ^c
	C7 OM001438 Synthetic ssDNA	IDT	NA	1,628 Copies/mL
	C20 MZ427502 Synthetic ssDNA	IDT	NA	1,736,000 Copies/mL ^d
	C36 PP158746 Synthetic ssDNA	IDT	NA	407 Copies/mL
Coxsackievirus	A1	ZeptoMetrix	0810140CF	1,884 Copies/mL
	A9	ZeptoMetrix	0810017CF	3,768 Copies/mL
	A15, strain 'G-19'	ZeptoMetrix	0810144CF	55,000 Copies/mL
	A21	ATCC	VR-850	3,768Copies/mL
	CoxA4 ON730810 Synthetic ssDNA	IDT	NA	5,652 Copies/mL
	CoxA10 PP078948 Synthetic ssDNA	IDT	NA	1,884 Copies/mL
	CoxB5 OQ408283 Synthetic ssDNA	IDT	NA	1,884 Copies/mL
Echovirus	Type 6	ZeptoMetrix	0810076CF	1,884 Copies/mL
	Type 9	ZeptoMetrix	0810077CF	3,768 Copies/mL
	Type 11	ZeptoMetrix	0810023CF	5,652 Copies/mL
	Type 13, H06368-226	ZeptoMetrix	0810607CF	628 Copies/mL
	Type 14, H08330539	ZeptoMetrix	0810502CF	3,768 Copies/mL
	Type 18, H07218-472	ZeptoMetrix	0810608CF	314 Copies/mL
	Type 30	ZeptoMetrix	0810078CF	1,884 Copies/mL
Enterovirus	A71	ZeptoMetrix	0810236CF	628 Copies/mL
	A71 OR791510 Synthetic ssDNA	IDT	NA	1,884 Copies/mL
	D68 Major Group, 9/ 2014 Isolate 3	ZeptoMetrix	0810303CF	1,884 Copies/mL
	HEV-D68/ Fermon	BEI	NR-51430	30,094 Copies/mL ^e
	D68/US/MO/14- 18949	BEI	NR-49130	1,884 Copies/mL
	D68/US/IL/14-18952	BEI	NR-49131	940 Copies/mL
	D68/USA/2018- 23089	BEI	NR-51998	3,762 Copies/mL
	D68/US/KY/14- 18953	BEI	NR-49132	5,966 Copies/mL
	Sabin monovalent Polio vaccine type 1 (1st International Standard)	NIBSC	Code 16/196	188,390 Copies/mL ^f
	Poliovirus OPV reference mOPV 3	NIBSC	Code 16/202	56,517 Copies/mL ^f
	Poliovirus OP410429 Synthetic ssDNA	IDT	NA	31,398 Copies/mL ^f
	Poliovirus PV557050 Synthetic ssDNA	IDT	NA	NA ^f
Parainfluenza Virus	Type/ Strain	Vendor	Part Number	Lowest Concentration

				With 100% Positivity (N=5)
PIV1	Type 1	ZeptoMetrix	0810014CF	275 Copies/mL
	Type 1, strain FRA/29221106/2009	BEI	NR-48680	1,240 Copies/mL
PIV2	Type 2	ZeptoMetrix	0810015CF	35 TCID ₅₀ /mL
	Type 2, strain Greer	BEI	NR-5994	0.04 TCID ₅₀ /mL
PIV3	Type 3	ZeptoMetrix	0810016CF	248 Copies/mL
	Type 3, NIH Wash/47885/57	BEI	NR-3233	6,614 Copies/mL
PIV4	Type 4A	ATCC	VR-1378	69 Copies/mL
	Type 4A, strain M-25	BEI	NR-3237	207 Copies/mL
	Type 4B CH19503	ATCC	VR-1377	69 Copies/mL
	Type 4B	ZeptoMetrix	0810060BCF	28 Copies/mL
	PV224554 Synthetic ssDNA	IDT	NA	411 Copies/mL
Influenza A	Type/ Strain	Vendor	Part Number	Lowest Concentration With 100% Positivity (N=5)
H3N2	A/New York/21/2020	IRR	FR-1761	4 FFU/mL
	A/Tasmania/503/2020	IRR	FR-1790	1 FFU/mL
	A/Darwin/06/2021	IRR	FR-1837	1.6 FFU/mL
	A/Darwin/9/2021	IRR	FR-1845	2.7 CEID ₅₀ /mL
	A/Massachusetts/18/2022	IRR	FR-1859	0.4 FFU/mL
	A/Florida/57/2022	IRR	FR-1861	0.05 TCID ₅₀ /mL
	A/New York/66/2022	IRR	FR-1868	1.3 FFU/mL
	A/Michigan/60/2022	IRR	FR-1871	1.5 FFU/mL
	A/Montana/08/2023	IRR	FR-1873	6.5 FFU/mL
	A/Macha/O1237/2021	BEI	NR-59461	0.2 FFU/mL
	A/Baltimore/JH-0586/2022	BEI	NR-59462	17 TCID ₅₀ /mL
H1N1-09	A/Indiana/02/2020	IRR	FR-1763	670 CEID ₅₀ /mL
	A/Macha/O1453/2021	BEI	NR-59464	40 TCID ₅₀ /mL
	A/Baltimore/JH-22377/2022	BEI	NR-59465	67 CEID ₅₀ /mL
	A/Baltimore/JH-22400/2022	BEI	NR-59466	9.6 CEID ₅₀ /mL
	Clinical specimen/2020	NA	NA	77 Copies/mL
	Clinical specimen/2020	NA	NA	77 Copies/mL
	Clinical specimen/2020	NA	NA	77 Copies/mL
	Clinical specimen/2020	NA	NA	77 Copies/mL
	Clinical specimen/2020	NA	NA	67 Copies/mL
	Clinical specimen/2020	NA	NA	168 Copies/mL
	Clinical specimen/2020	NA	NA	

H1N1	Swine 1976/31	ATCC	VR-99	3 CEID ₅₀ /mL
	A/Texas/14/2008	IRR	FR-587	67 CEID ₅₀ /mL
H5N1	A/duck/Hunan/795/2002	IRR	FR-265 (219)	65 Copies/mL
	A/Japanese white eye/Hong Kong/1038/2006	IRR	FR-270	258 Copies/mL
	A/bovine/Ohio/B240 SU-439/2024 (genomic RNA)	BEI	NR-59885	65 Copies/mL
H5N2	A/pheasant/New Jersey/1355/1998-PR8-IBCDC-4	IRR	FR-729	59 CEID ₅₀ /mL
H7N2	A/turkey/Virginia/4529/2002-PR8-IBCDC-5	IRR	FR-730	36 CEID ₅₀ /mL
H7N7	A/mallard/Netherlands/12/2000/PR8-IBCDC-1	IRR	FR-731	8.2 CEID ₅₀ /mL
H7N9	A/Shanghai/2/2013-PR8-IDCDC-RG32A	IRR	FR-1389	7.7 CEID ₅₀ /mL
H9N2	A/chicken/Hong Kong/G9/1997-PR8-IBCDC-2	IRR	FR-732	104 CEID ₅₀ /mL
Influenza B	Type/ Strain	Vendor	Part Number	Lowest Concentration With 100% Positivity (N=5)
Victoria Lineage	B/Washington/02/2019	IRR	FR-1709	6.7 CEID ₅₀ /mL
	B/Hawaii/01/2018 (NA D197N)	IRR	FR-1661	0.8 TCID ₅₀ /mL
	B/New Hampshire/01/2021	IRR	FR-1796	0.03 TCID ₅₀ /mL
	B/Michigan/01/2021	IRR	FR-1800	0.05 TCID ₅₀ /mL
Yamagata Lineage	B/Oklahoma/10/2018 (NA D197N)	IRR	FR-1660	1.7 TCID ₅₀ /mL
NA	Clinical specimen/2020	NA	NA	17 Copies/mL
	Clinical specimen/2020	NA	NA	25 Copies/mL
Respiratory Syncytial Virus	Type/ Strain	Vendor	Part Number	Lowest Concentration With 100% Positivity (N=5)
RSV A	Type A2	ATCC	VR1540	2 PFU/mL
	Type A Long	ATCC	VR-26	2 PFU/mL
RSV B	Type B WV/ 14617/85	ATCC	VR-1400	0.3 TCID ₅₀ /mL
	Type B 9320	ATCC	VR-955	0.2 PFU/mL
	Type B 18537	ATCC	VR-1580	0.01 PFU/mL
<i>Bordetella parapertussis</i>	Type/ Strain	Vendor	Part Number	Lowest Concentration With 100% Positivity (N=5)
<i>B. parapertussis</i>	E595	ZeptoMetrix	801462	118 CFU/mL
	508 and 344 (NCTC 10853)	ATCC	15237	29 CFU/mL

	NCTC 5952 (522)	ATCC	15311	88 CFU/mL
	12822	ATCC	BAA-587	24 CFU/mL
<i>Bordetella pertussis</i>	Type/ Strain	Vendor	Part Number	Lowest Concentration With 100% Positivity (N=5)
<i>B. pertussis</i>	E431	ZeptoMetrix	801460	275 CFU/mL
	F	ATCC	8467	2 CFU/mL
	5 (17921)	ATCC	9340	824 CFU/mL
	18323 (NCTC 10739)	ATCC	9797	0.5 CFU/mL
	10-536	ATCC	10380	8 CFU/mL
	CNCTC Hp 12/63 (623)	ATCC	51445	1 CFU/mL
	MN2531	ATCC	BAA-1335	2 CFU/mL
<i>Chlamydia pneumoniae</i>	Type/ Strain	Vendor	Part Number	Lowest Concentration With 100% Positivity (N=5)
<i>C. pneumoniae</i>	TW-183	ATCC	VR-2282	132 IFU/mL
	CWL-029	ATCC	VR-1310	66 IFU/mL
	AR-39	ATCC	53592	17 IFU/mL
<i>Mycoplasma pneumoniae</i>	Type/ Strain	Vendor	Part Number	Lowest Concentration With 100% Positivity (N=5)
<i>M. pneumoniae</i>	Type1 M129-B7	ATCC	29342	321 Copies/mL
	Type 2 Mac	ATCC	15492	321 Copies/mL
	M52	ATCC	15293	321 Copies/mL
	Bru	ATCC	15377	642 Copies/mL
	Mutant 22	ATCC	39505	321 Copies/mL
	UTMB-10P	ATCC	49894	642 Copies/mL

^a Adenovirus B3, B34, and B35 were detected at 19x, 128x, and 43x LoD, respectively. Adenovirus B34 and B35 are uncommonly recovered from humans with respiratory tract infection.

^b Human metapneumovirus B1 synthetic ssDNA was detected at 900x LoD. Infectious hMPV B1 was detected at <0.1x LoD.

^c Due to limited volume of Rhinovirus clinical specimen, this specimen was run in replicates of 3 instead of 5.

^d Rhinovirus C20 synthetic ssDNA was detected at 400x LoD. Rhinovirus C20 is uncommonly recovered from humans with respiratory tract infection.

^e Enterovirus D68 “Fermon” strain was detected at 48x LoD. This is an unknown clade. Known D68 clades A2/D, B1, B2, and B3 were all detected at ≤10x LoD.

^f Polioviruses and poliovirus synthetic ssDNA were detected at ≥50x LoD or not detected. Polioviruses are not associated with respiratory tract infection.

In Silico Analyses

The inclusivity of the Xpert Respiratory Panel was evaluated using *in silico* analysis of the oligonucleotide sequences for SARS-CoV-2 against SARS-CoV-2 sequence records in NCBI Datasets v18.9.0 accessed on January 4, 2026. The analysis of the three SARS-CoV-2 targets (E, N2 and RdRP) was conducted with over 1.6 million SARS-CoV-2 genomic RNA sequences. Results of the in-silico analysis predict that the Xpert Respiratory Panel will detect greater than 99.99% of SARS-CoV-2 variants.

Analytical Specificity (Exclusivity)

Wet-Testing

Cross reactivity (exclusivity) of the Xpert Respiratory Panel test was evaluated by testing a panel of 52 non-target microorganisms (8 viruses, 39 bacteria, 5 fungi) and nasal wash (**Table 4**) to determine the assay's ability to detect on panel analytes in the presence of related pathogens, high prevalence disease agents, and normal or pathogenic microorganisms reasonably likely to be present in a clinical NPS sample. Each non-target organism was tested in triplicates. The bacterial and yeast strains were tested at concentrations of $\geq 1\text{E}6$ units/mL (CFU/mL, IFU/mL, copies/mL or CCU/mL) and viral strains were tested at $\geq 1\text{E}5$ units/mL (TCID₅₀/mL or copies/mL) in simulated nasopharyngeal swab (NPS) matrix, except for *Ureaplasma urealyticum* which was tested at 2E4 copies/mL. As no quantified stock was available, SARS-CoV-1 was tested at a dilution of 1:100. A non-target organism was considered negative if all three replicates were negative for all analytes detected by the Xpert Respiratory Panel test. If an exclusivity microorganism was reported POSITIVE with the Xpert Respiratory Panel test, the test was repeated with a lower concentration of the exclusivity microorganisms and the highest concentration that did not produce a false positive result was recorded.

The results of the analytical specificity study demonstrated that the primer/probe sets do not cross-react with the nucleic acids from non-intended respiratory microorganisms or phylogenetically related respiratory pathogens detected by the Xpert Respiratory Panel test. The one exception was SARS-CoV-1 which yielded the expected SARS-CoV-2 POSITIVE test result. Based on the *in silico* analysis, cross-reactivity with the E gene target of SARS-CoV-1 was expected due to the highly conserved E gene target shared among coronaviruses in the B lineage *Betacoronavirus*. Although the nasal wash sample reported Parainfluenza POSITIVE results in all replicates tested, sequencing result confirmed the presence of Parainfluenza in this diverse microbial human flora.

Table 5: Organisms Evaluated in Cross-Reactivity and Microbial Interference Study by Wet Testing

Count	Exclusivity Strain	Concentration Tested
0	Negative Control	Not Applicable
1	<i>Escherichia coli</i>	2E6 CFU/mL
2	<i>Lactobacillus plantarum</i>	2E6 CFU/mL
3	<i>Legionella longbeacheae</i>	2E6 CFU/mL
4	<i>Pseudomonas aeruginosa</i>	2E6 CFU/mL
5	<i>Enterobacter aerogenes</i>	2E6 CFU/mL
6	<i>Legionella pneumophila</i>	2E6 CFU/mL
7	<i>Staphylococcus epidermidis</i>	2E6 CFU/mL
8	<i>Stenotrophomonas maltophilia</i>	2E6 CFU/mL
9	<i>Klebsiella oxytoca</i>	2E6 CFU/mL
10	<i>Neisseria elongata</i>	2E6 CFU/mL
11	<i>Serratia marcescens</i>	2E6 CFU/mL
12	<i>Streptococcus pyogenes</i>	2E6 CFU/mL
13	<i>Klebsiella pneumoniae</i>	2E6 CFU/mL
14	<i>Mycoplasma hominis</i>	2E6 CCU/mL
15	<i>Proteus mirabilis</i>	2E6 CFU/mL
16	<i>Streptococcus pneumoniae</i>	2E6 CFU/mL

Count	Exclusivity Strain	Concentration Tested
17	<i>Candida albicans</i>	2E6 CFU/mL
18	<i>Mycoplasma orale</i>	2E6 CFU/mL
19	<i>Corynebacterium diphtheriae</i>	2E6 CFU/mL
20	<i>Streptococcus salivarius</i>	2E6 CFU/mL
21	<i>Neisseria gonorrhoeae</i>	2E6 CFU/mL
22	<i>Acinetobacter calcoaceticus</i>	2E6 CFU/mL
23	<i>Haemophilus influenzae</i>	2E6 CFU/mL
24	<i>Lactobacillus acidophilus</i>	2E6 CFU/mL
25	<i>Moraxella catarrhalis</i>	2E6 CFU/mL
26	<i>Neisseria meningitidis</i>	2E6 CFU/mL
27	<i>Streptococcus agalactiae</i>	2E6 CFU/mL
28	<i>Chlamydia trachomatis</i>	2E6 IFU/mL
29	<i>Aspergillus flavus</i>	2E6 CFU/mL
30	<i>Aspergillus fumigatus</i>	2E6 CFU/mL
31	<i>Cryptococcus neoformans</i>	2E6 CFU/mL
32	<i>Pneumocystis jirovecii</i>	2E6 CFU/mL
33	<i>Bordetella avium</i>	2E6 CFU/mL
34	<i>Bordetella hinzii</i>	2E6 CFU/mL
35	<i>Bordetella bronchiseptica</i>	2E6 CFU/mL
36	<i>Bordetella holmesii</i>	2E6 CFU/mL
37	Bocavirus	2E5 Cp/mL
38	Measles Virus	2E5 TCID ₅₀ /mL
39	Cytomegalovirus (CMV)	2E5 Cp/mL
40	Epstein-Barr Virus (EBV)	2E5 Cp/mL
41	<i>Mycobacterium tuberculosis</i>	2E6 Cp/mL
42	<i>Mycoplasma genitalium</i>	2E6 Cp/mL
43	<i>Ureaplasma urealyticum</i>	2E4 Cp/mL
44	<i>Staphylococcus aureus</i>	2E6 CFU/mL
45	Mumps	2E5 TCID ₅₀ /mL
46	Herpes Simplex Virus 1	1E6 TCID ₅₀ /mL
47	Middle East Respiratory (MERS)	2E5 Cp/mL
48	SARS-CoV-1	Not Applicable
49	<i>Legionella bozemanii</i>	2E6 CFU/mL
50	<i>Legionella dumofii</i>	2E6 CFU/mL
51	<i>Legionella feeleeii</i>	2E6 CFU/mL
52	<i>Legionella micdadei</i>	2E6 CFU/mL
53	Nasal wash	Not Applicable

In Silico Analysis

An *in silico* assessment was performed using the NCBI BLAST Core Nucleotide Database (January 9, 2026) to evaluate potential cross-reactivity of the Xpert Respiratory Panel primers and probes. All primer probe combinations across the multiplex panel were examined.

The predicted cross-reactivity was limited to a small number of non-target organisms with close

genetic relatedness to the test's intended targets, including non-human *Mastadenovirus*, embecoviruses related to Coronavirus OC43/HKU1, parainfluenza 3 and respirovirus, enteroviruses and other picornaviruses, and SARS-related coronaviruses. Additionally, cross-reactivity was predicted for human adenoviruses F and G, a few *Bordetella* species and *Achromobacter denitrificans*, which are known to infect humans (see limitation section). A summary of potential cross-reactivity is provided in **Table 5**.

Table 6: Summary of Predicted Cross-Reactivity

Oligonucleotide Target	Predicted Cross-Reactivity
Adenovirus	Non-human <i>Mastadenovirus</i> species (e.g., simian, bovine, porcine, lemur, bat) and enteric human adenoviruses (types 40, 41, 52)
Coronavirus OC43/HKU1	Non-human embecoviruses (e.g., bovine, canine respiratory, yak, dromedary camel, equine, and sambar deer coronaviruses)
SARS-CoV-2	SARS-related coronaviruses (e.g., bat SARS-like, bat SARS, civet SARS coronavirus, and other SARS-related betacoronaviruses)
Parainfluenza 1 / Parainfluenza 3	Non-human parainfluenza and respirovirus species (e.g., caprine parainfluenza virus 3, <i>Respirovirus bovis</i> , swine and wild boar parainfluenza virus 3)
RSV A / RSV B	Bovine orthopneumovirus and bovine respiratory syncytial virus (did not meet primer mismatch criteria of no more than 4)
Rhinovirus/Enterovirus	Non-human enteroviruses and other picornaviruses (e.g., canine, porcine, simian, bat, and rodent associated sequences)
<i>Bordetella pertussis</i>	<i>Bordetella bronchiseptica</i> and <i>Bordetella holmesii</i>
<i>Bordetella parapertussis</i>	<i>Bordetella bronchiseptica</i> and <i>Achromobacter denitrificans</i>

Microbial Interference

The microbial interference of the Xpert Respiratory Panel test was evaluated by testing the same panel of 52 pathogens (8 viruses, 39 bacteria, 5 fungi) used in the analytical specificity / exclusivity study (**Table 4**), in the presence of individual on-panel analyte at a concentration of ~3x LoD in simulated nasopharyngeal swab (NPS) matrix. Each on-panel analyte was tested in different pools of pathogens, with 6 replicates per pool. A sample was considered positive if all 6 replicates were positive for the on-panel analyte tested. The bacterial and yeast strains were tested at concentrations of $\geq 1\text{E}6$ units/mL (CFU/mL, IFU/mL, copies/mL or CCU/mL) and viral strains were tested at $\geq 1\text{E}5$ units/mL (TCID₅₀/mL or copies/mL) in simulated nasopharyngeal swab (NPS) matrix, except for *Ureaplasma urealyticum* which was tested at $2\text{E}4$ copies/mL. As no quantified stock was available, SARS-CoV-1 was tested at a dilution of 1:100. The pathogens tested are listed in **Table 4**. No microbial interference was observed.

Competitive Interference

A competitive interference study was conducted to evaluate the ability of the Xpert Respiratory Panel test to detect a low-level analyte (3 x LoD) in the presence of a high-level ($1\text{E}5$ copies/mL for viral strains and $1\text{E}6$ CFU/mL or IFU/mL for bacterial strains) on-panel organism. Samples were prepared in simulated NPS matrix. Testing was performed in 5 replicates, and the results are shown in **Table 6**.

Table 7: Combinations Tested for Competitive Interference

Combination	Analyte at 3x LoD			Competitive Analyte at High Titer	Number of Positive Results / Total Valid Replicates
	Target Pathogen	Conc.	Conc. (Copies/mL)		
1	Adenovirus	10.4 TCID ₅₀ /mL	272	Rhinovirus	5/5
2	Respiratory Syncytial Virus	0.66 TCID ₅₀ /mL	11,943	Rhinovirus	5/5
3	Coronavirus	0.94 TCID ₅₀ /mL	7.7	Rhinovirus	5/5
4	Respiratory Syncytial Virus	0.66 TCID ₅₀ /mL	11,943	Adenovirus	5/5
5	Adenovirus	10.4 TCID ₅₀ /mL	272	SARS-CoV-2	5/5
6	Rhinovirus	30.6 TCID ₅₀ /mL	13,023	SARS-CoV-2	5/5
7	Human Metapneumovirus	0.26 TCID ₅₀ /mL	5,018	SARS-CoV-2	5/5
8	Respiratory Syncytial Virus	0.66 TCID ₅₀ /mL	11,943	SARS-CoV-2	5/5
9	Rhinovirus	30.6 TCID ₅₀ /mL	13,023	Adenovirus	5/5
10	Rhinovirus	30.6 TCID ₅₀ /mL	13,023	Respiratory Syncytial Virus	5/5
11	Rhinovirus	30.6 TCID ₅₀ /mL	13,023	Coronavirus	5/5
12	Adenovirus	10.4 TCID ₅₀ /mL	272	Respiratory Syncytial Virus	5/5
13	SARS-CoV-2	3.8 TCID ₅₀ /mL	1,169	Adenovirus	5/5
14	SARS-CoV-2	3.8 TCID ₅₀ /mL	1,169	Rhinovirus	5/5
15	SARS-CoV-2	3.8 TCID ₅₀ /mL	1,169	Human Metapneumovirus	5/5
16	SARS-CoV-2	3.8 TCID ₅₀ /mL	1,169	Respiratory Syncytial Virus	5/5
17	<i>C. pneumoniae</i>	131.9 IFU/mL	NA	<i>B. pertussis</i>	5/5
18	<i>B. pertussis</i>	16.5 CFU/mL	NA	<i>C. pneumoniae</i>	5/5

Interfering Substances

The performance of the Xpert Respiratory Panel test was evaluated in the presence of endogenous and exogenous substances that may be commonly found in NPS specimens. Each substance was tested individually in the presence and absence of 6 representative on-panel viruses and bacteria (Adenovirus, SARS-CoV-2, Human Metapneumovirus, Rhinovirus, Influenza A, and Chlamydia pneumoniae), prepared at ~3x LoD in simulated nasopharyngeal swab (NPS) matrix. The viruses and bacteria were either tested in a pool of 4 pathogens or individually (e.g., SARS-CoV-2 and Rhinovirus). Positive and negative samples were tested with 6 replicates per substance. Positive and negative controls were also included in the study. A total of 34 substances were tested with the Xpert Respiratory Panel

test, and 32 demonstrated no interference with assay performance. Two substances, FluMist (6.7%) and Saline Nasal Gel (15%), showed interference with the Xpert Respiratory Panel test performance. As a safety precaution, a maximum bleach concentration of 1% is included as a limitation. The substances and concentrations tested are presented in **Table 7**.

Table 8: Potentially Interfering Substances Tested

Substance ID	Substance/Class	Highest Concentration Tested Without Interference
Control NPS Simulated Matrix	No substance	100% ^a
Human whole blood K2-EDTA	Endogenous substance	10 % v/v
Mucin	Endogenous substance	1% v/v ^b
Human genomic DNA	Endogenous substance	20 ng/mL
Tobramycin	Antibiotic	0.6 mg/mL
Mupirocin	Antibiotic	2% w/v
Saline Nasal Spray	Nasal spray	1% v/v
Nasal Decongestant Spray Oxymetazoline HCl 0.05%	Nasal spray	1% v/v ^c
Analgesic ointment (Vicks® VapoRub®)	Analgesic ointment	1% w/v
Petroleum Jelly (Vaseline®)	Topical ointment	1% w/v
Snuff (Nasal Tobacco)	Nasal tobacco	1% w/v
Zinc	Zinc supplement	0.1 µg/mL
FluMist	Influenza vaccine	6.7% v/v ^d
Zanamivir	Antiviral drug	7.5 mg/mL
Nasonex (mometasone furoate)	Allergy medication	1% v/v
Saline Nasal Gel	Nasal gel	15% w/v ^b
Throat lozenges	Throat lozenge	1.7 mg/mL
Bleach	Disinfectant	5% v/v
Disinfecting wipes	Disinfectant	0.5 inches ² (3.23 cm ²)
Ethanol (70%)	Disinfectant	7% v/v
DNAZap™	Nucleic acid degrading reagent	1% v/v
RNAseOUT™	Nucleic acid degrading reagent	1% v/v
Nasopharyngeal swab 168C	Specimen collection device	1 swab ^b
FloQSwab 552C	Specimen collection device	1 swab
Nasopharyngeal swab 175KS01	Specimen collection device	1 swab
Eswab 480c	Specimen collection device	1 swab
Puritan® Calgiswab® 25-800 A 50c	Specimen collection device	1 swab
Microtest™ M4-RT transport media	Transport media	100% ^a
UTM	Transport media	100% ^a
eNAT®	Transport media	100% ^a
BD universal viral transport medium	Transport media	100% ^a
Sigma Virocult transport medium	Transport media	100% ^a
Microtest™ M6 transport media	Transport media	100% ^a
Microtest™ M5 transport media	Transport media	100% ^a
PrimeStore® molecular transport medium	Transport media	100% ^a

^a Test concentration of 100% denotes the use of the substance directly and undiluted as a sample matrix.

- ^b Interference was observed when testing *Chlamydia pneumoniae* in a representative mix of on-panel analytes. No interference was observed when testing *Chlamydia pneumoniae* as a single analyte.
- ^c Interference was observed when testing Influenza A in a representative mix of on-panel analytes. No interference was observed when testing Influenza A as a single analyte.
- ^d False positive results for Influenza A and Influenza B were observed with FluMist at 6.7% v/v.

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

a) Controls

See Section IV.C.5. Quality Control.

b) Sample Stability

Sample stability testing demonstrated that NPS specimens can be stored and transported at the conditions listed below:

- Room temperature (15–30 °C) for up to 12 hours in UTM/VTM or up to 24 hours in eNAT until testing is performed on the GeneXpert Instrument Systems.
- Refrigerated (2–8 °C) up to 4 days in UTM/VTM or up to 7 days in eNAT until testing is performed on the GeneXpert Instrument Systems.

c) Freeze/Thaw Stability

Freeze/Thaw stability testing demonstrated that NPS specimens in UTM/VTM are stable for up to 2 freeze/thaw cycle when stored at -20 °C.

d) Kit Stability

Real-time kit stability data supports the recommended shelf-life stability claim when stored at 2–28 °C for up to 10 months.

5. Detection Limit:

The analytical sensitivity of the Xpert Respiratory Panel test was evaluated using two reagent lots per strain and testing limiting dilutions of on-panel viruses and bacteria (4 Adenovirus strains, 4 Human Coronavirus strains, 2 SARS-CoV-2 strains, 1 Human Metapneumovirus strain, 1 human Rhinovirus strain, 1 Enterovirus strain, 4 Parainfluenza subtypes, 1 Influenza A strain, 2 Influenza B strains [1 Yamagata and 1 Victoria lineage], one strain each of Respiratory Syncytial Virus A and B, one *Bordetella pertussis* strain, one *Bordetella parapertussis* strain, one *Mycoplasma pneumoniae* strain, and one *Chlamydia pneumoniae* strain) in pooled negative clinical nasopharyngeal swab (NPS) in Universal Transport Media (UTM) matrix. Preliminary LoD was established using Probit regression analysis on the dilution series test result for each target viral strain. The LoD of each analyte was confirmed as the dilution level where the level below reported positivity rate of < 95% and the level above resulted in a positivity rate of 100% through additional serial dilution testing of 20 replicates at each tested dilutions. Confirmed LoD are shown in **Table 8**.

Table 9: Xpert Respiratory Panel Limit of Detection in Clinical NPS-UTM Matrix

Virus/Bacteria Strain	LoD Concentration
Adenovirus B, Wan	3.0 TCID ₅₀ /mL
Adenovirus 1C	3.5 TCID ₅₀ /mL
Adenovirus 4(E)	0.62 TCID ₅₀ /mL
First WHO International Standard for human Adenovirus DNA for nucleic acid amplification techniques (NIBSC code: 16/324)	1,345 IU/mL
Coronavirus 229E	0.015 TCID ₅₀ /mL
Coronavirus HKU1	133.2 Cp/mL
Coronavirus NL63	0.0057 TCID ₅₀ /mL
Coronavirus OC43	0.31 TCID ₅₀ /mL
Second WHO International Standard for SARS-CoV-2 RNA (NIBSC code: 22/252)	2,584 IU/mL
SARS-CoV-2 Hong Kong/VM20001061/2020	1.32 TCID ₅₀ /mL
Human Metapneumovirus (hMPV) 18 B2, IA18-2003	0.088 TCID ₅₀ /mL
Human Rhinovirus 3, FEB	10.2 TCID ₅₀ /mL (7.1 PFU/mL)
Enterovirus D68, US/MO/14-18947	11.2 TCID ₅₀ /mL
Parainfluenza 1, C35	5.2 TCID ₅₀ /mL
Parainfluenza 2, Greer	0.8 TCID ₅₀ /mL
Parainfluenza 3, C 243	11.7 TCID ₅₀ /mL
Parainfluenza 4A	1.2 TCID ₅₀ /mL
Influenza A/Wisconsin/04/2018 (H3N2)	104 CEID ₅₀ /mL
Influenza B/Missouri/12/2018 (NA D197E) (Victoria Lineage)	1.4 TCID ₅₀ /mL
Influenza B/Indiana/17/2017 (NA I221T) (Yamagata Lineage)	4.4 TCID ₅₀ /mL
Respiratory Syncytial Virus (RSV) A	0.2 TCID ₅₀ /mL
Respiratory Syncytial Virus (RSV) B, WV/14617/85	0.02 TCID ₅₀ /mL
<i>Bordetella pertussis</i> , A639	5.49 CFU/mL
<i>Bordetella parapertussis</i> , A747	0.2 CFU/mL
<i>Mycoplasma pneumoniae</i> , M129	50.8 CCU/mL
<i>Chlamydia pneumoniae</i> , CM-1	0.156 TCID ₅₀ /mL (43.97 IFU/mL)

6. Assay Cut-Off:

The GeneXpert software is responsible for converting RT-PCR/PCR data from the test instrument into test results. Results for each analyte are reported as Detected, Not Detected, INVALID, ERROR, or NO RESULT, based on automated interpretation of the PCR amplification and melt curve data. The Xpert Respiratory Panel test reports Ct values for target pathogens detected by amplification.

B Comparison Studies:

1. Method Comparison with Predicate Device:

Not applicable.

2. Matrix Comparison:

Simulated Matrix Equivalence

Equivalent performance of simulated NPS matrix and natural clinical NPS matrix was established by testing three positive sample prepared by spiking 4-5 respiratory organisms into 3 pools of negative matrix at concentration levels of 5x LoD, 1-2x LoD and <1x LoD and tested with one Xpert Respiratory Panel reagent lot. Equivalent testing performance was observed for each organism and overall matrix equivalence was observed.

Collection Media Equivalence

The Xpert Respiratory Panel test was validated for use with nasopharyngeal swab (NPS) specimens collected in Universal Transport Medium (UTM)/Viral Transport Medium (VTM) or eNAT Molecular Collection and Preservation Medium. Clinical performance of the Xpert Respiratory Panel test was established using NPS specimens collected in UTM/VTM. Performance in Copan eNAT, Remel MicroTest M4RT, M5, and M6 transport media was established in analytical studies only; clinical performance in these media types was not established. Transport media containing guanidine thiocyanate (GTC), except for Copan eNAT, has not been evaluated with the Xpert Respiratory Panel test and may yield invalid or inaccurate results.

C Clinical Studies:

1. Clinical Sensitivity:

Not applicable

2. Clinical Specificity:

Not applicable

3. Clinical Cut-Off

Not applicable

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

Prospective Clinical Study

The clinical performance of the Xpert Respiratory Panel test was evaluated using clinical specimen prospectively collected in a multi-site study including 19 geographically diverse sites (15 U.S. sites and 4 O.U.S. sites). NPS specimens in UTM/VTM from leftover standard of care testing of pediatric and adult patients exhibiting clinical signs and symptoms of respiratory tract infection were enrolled prospectively from November 2024 to February 2025. Prospective frozen specimens were collected from January to March 2024 and during the month of September 2024. The results of the Xpert Respiratory Panel test were compared to results from an FDA-cleared molecular respiratory panel (NAAT 1) except for *B.*

parapertussis. PPA and NPA for *B. parapertussis* detection were determined by comparing results with a different FDA-cleared molecular respiratory panel (NAAT 2). Discrepant results for all analytes except *B. parapertussis* were investigated using NAAT 2. Discrepant *B. parapertussis* results were investigated using a molecular test for *B. parapertussis* (NAAT-Bordetella).

Initial enrollment included a total of 2643 unique prospectively collected specimens that met the pre-determined inclusion criteria. Of these, a total of 12 (0.45 %) specimens were excluded due to protocol deviations with specimen collection. **Table 9** provides a summary of the demographic information for the remaining 2,631 subjects included in the data analysis. Of the 2,631 samples included in the data analysis, 84% (2,231/2,631) were tested fresh while 16% (400/2,631) were tested frozen. Clinical performance of the Xpert Respiratory Panel with prospectively collected samples is presented in **Table 10**.

Table 10: Demographic Summary for the Prospective Symptomatic Population

Characteristics	Symptomatic Subjects
Total, N	2643
Age Group (Years), n (%)	
≤ 5 yr	556 (21.0%)
6-17 yr	365 (13.8%)
18-21 yr	104 (3.9%)
22-49 yr	657 (24.9%)
50-64 yr	374 (14.2%)
≥ 65 yr	587 (22.2%)
Sex, n (%)	
Male	1240 (46.9%)
Female	1403 (53.1%)
Ethnicity, n (%)	
Hispanic / Latino	592 (22.4%)
Not Hispanic / Not Latino	1529 (57.9%)
Not Available	522 (19.8%)
Race, n (%)	
American Indian / Alaskan Native	9 (0.3%)
Asian	61 (2.3%)
Black / African-American	533 (20.2%)
White	1094 (41.4%)
Other or Mixed Race	15 (0.6%)
Not Available	931 (35.2%)

Table 11: Clinical Performance of Xpert Respiratory Panel in Prospectively Collected Specimens

Analyte		TP	FN	PPA% TP/(TP+FN)	PPA 95% CI	TN	FP	NPA% TN/(TN+FP)	NPA 95% CI
Adenovirus ¹	Prospective Overall	36	1	97.3% 36/37	86.2% - 99.5%	2448	20	99.2% 2448/2468	98.8% - 99.5%
	Fresh	33	1	97.1% 33/34	85.1% - 99.5%	2084	19	99.1% 2084/2103	98.6% - 99.4%
	Frozen	3	0	100% 3/3	43.9% - 100%	364	1	99.7% 364/365	98.5% - 100%
Coronavirus ²	Prospective Overall	128	4	97.0% 128/132	92.5% - 98.8%	2345	28	98.8% 2345/2373	98.3% - 99.2%
	Fresh	115	4	96.6% 115/119	91.7% - 98.7%	1996	22	98.9% 1996/2018	98.4% - 99.3%
	Frozen	13	0	100% 13/13	77.2% - 100%	349	6	98.3% 349/355	96.4% - 99.2%
SARS-CoV-2 ³	Prospective Overall	143	6	96.0% 143/149	91.5% - 98.1%	2297	59	97.5% 2297/2356	96.8% - 98.1%
	Fresh	53	1	98.1% 53/54	90.2% - 99.7%	2069	14	99.3% 2069/2083	98.9% - 99.6%
	Frozen	90	5	94.7% 90/95	88.3% - 97.7%	228	45	83.5% 228/273	78.7% - 87.4%
Human Metapneumovirus ⁴	Prospective Overall	30	0	100% 30/30	88.7% - 100%	2472	3	99.9% 2472/2475	99.6% - 100%
	Fresh	23	0	100% 23/23	85.7% - 100%	2113	1	99.9% 2113/2114	99.7% - 100%
	Frozen	7	0	100% 7/7	64.6% - 100%	359	2	99.4% 359/361	98.0% - 99.8%
Rhinovirus/ Enterovirus ⁵	Prospective Overall	362	16	95.8% 362/378	93.2% - 97.4%	2056	71	96.7% 2056/2127	95.8% - 97.3%
	Fresh	295	11	96.4% 295/306	93.7% - 98.0%	1767	64	96.5% 1767/1831	95.6% - 97.3%
	Frozen	67	5	93.1% 67/72	84.8% - 97.0%	289	7	97.6% 289/296	95.2% - 98.9%
Parainfluenza ⁶	Prospective Overall	57	1	98.3% 57/58	90.9% - 99.7%	2426	21	99.1% 2426/2447	98.7% - 99.4%
	Fresh	54	1	98.2% 54/55	90.4% - 99.7%	2063	19	99.1% 2063/2082	98.6% - 99.4%
	Frozen	3	0	100% 3/3	43.9% - 100%	363	2	99.5% 363/365	98.0% - 99.8%
Influenza A ⁷	Prospective Overall	297	5	98.3% 297/302	96.2% - 99.3%	2178	25	98.9% 2178/2203	98.3% - 99.2%
	Fresh	222	2	99.1% 222/224	96.8% - 99.8%	1906	7	99.6% 1906/1913	99.2% - 99.8%
	Frozen	75	3	96.2% 75/78	89.3% - 98.7%	272	18	93.8% 272/290	90.4% - 96.0%

Analyte		TP	FN	PPA% TP/(TP+FN)	PPA 95% CI	TN	FP	NPA% TN/(TN+FP)	NPA 95% CI
Influenza B	Prospective Overall	8	0	100% 8/8	67.6% - 100%	2497	0	100% 2497/2497	99.8% - 100%
	Fresh	8	0	100% 8/8	67.6% - 100%	2129	0	100% 2129/2129	99.8% - 100%
	Frozen	0	0	N/A	N/A	368	0	100% 368/368	99.0% - 100%
Respiratory Syncytial Virus ⁸	Prospective Overall	153	6	96.2% 153/159	92.0% - 98.3%	2319	27	98.8% 2319/2346	98.3% - 99.2%
	Fresh	152	6	96.2% 152/158	92.0% - 98.2%	1954	25	98.7% 1954/1979	98.1% - 99.1%
	Frozen	1	0	100% 1/1	20.7% - 100%	365	2	99.5% 365/367	98.0% - 99.9%
<i>Bordetella pertussis</i> ⁹	Prospective Overall	10	2	83.3% 10/12	55.2% - 95.3%	2488	5	99.8% 2488/2493	99.5% - 99.9%
	Fresh	9	1	90.0% 9/10	59.6% - 98.2%	2122	5	99.8% 2122/2127	99.5% - 99.9%
	Frozen	1	1	50.0% 1/2	9.4% - 90.6%	366	0	100% 366/366	99.0% - 100%
<i>Bordetella parapertussis</i> ¹⁰	Prospective Overall	0	0	N/A	N/A	2613	1	99.9% 2613/2614	99.8% - 100%
	Fresh	0	0	N/A	N/A	2218	0	100% 2218/2218	99.8% - 100%
	Frozen	0	0	N/A	N/A	395	1	99.7% 395/396	98.6% - 100%
<i>Mycoplasma pneumoniae</i> ¹¹	Prospective Overall	66	8	89.2% 66/74	80.1% - 94.4%	2409	22	99.1% 2409/2431	98.6% - 99.4%
	Fresh	65	8	89.0% 65/73	79.8% - 94.3%	2043	21	99.0% 2043/2064	98.4% - 99.3%
	Frozen	1	0	100% 1/1	20.7% - 100%	366	1	99.7% 366/367	98.5% - 100%
<i>Chlamydia pneumoniae</i> ¹²	Prospective Overall	1	0	100% 1/1	20.7% - 100%	2503	1	99.9% 2503/2504	99.8% - 100%
	Fresh	0	0	N/A	N/A	2137	0	100% 2137/2137	99.8% - 100%
	Frozen	1	0	100% 1/1	20.7% - 100%	366	1	99.7% 366/367	98.5% - 100%

¹ Discrepant test results based on NAAT 2: In specimens with FN results, 1/1 AdV negative. In specimens with FP results, 13/20 AdV positive, 7/20 AdV negative.

² Discrepant test results based on NAAT 2: In specimens with FN results, 3/4 CoV negative, 1/4 CoV positive. In specimens with FP results, 19/28 CoV positive, 9/28 CoV negative.

³ Discrepant test results based on NAAT 2: In specimens with FN results, 5/6 SARS-CoV-2 negative, 1/6 SARS-CoV-2 positive. In specimens with FP results, 22/59 SARS-CoV-2 positive, 37/59 SARS-CoV-2 negative.

⁴ Discrepant test results based on NAAT 2: In specimens with FP results, 1/3 hMPV positive, 2/3 hMPV negative.

⁵ Discrepant test results based on NAAT 2: In specimens with FN results, 3/16 RV/EV negative, 13/16 RV/EV positive. In specimens with FP results, 59/71 RV/EV positive, 12/71 RV/EV negative.

⁶ Discrepant test results based on NAAT 2: In specimens with FN results, 1/1 PIV negative. In specimens with FP results, 16/21 PIV positive, 5/21 PIV negative.

⁷ Discrepant test results based on NAAT 2: In specimens with FN results, 4/5 Flu A negative, 1/5 Flu A positive. In specimens with FP results, 11/25 Flu A positive, 13/25 Flu A negative, 1/25 with invalid results.

Analyte	TP	FN	PPA% TP/(TP+FN)	PPA 95% CI	TN	FP	NPA% TN/(TN+FP)	NPA 95% CI
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⁸ Discrepant test results based on NAAT 2: In specimens with FN results, 3/6 RSV negative, 3/6 RSV positive. In specimens with FP results, 20/27 RSV positive, 7/27 RSV negative.

⁹ Discrepant test results based on NAAT 2: In specimens with FN results, 2/2 *B. pertussis* negative. In specimens with FP results, 5/5 *B. pertussis* negative.

¹⁰ Discrepant test results based on NAAT-Bordetella: In specimens with FP results, 1/1 not sent for discrepant testing.

¹¹ Discrepant test results based on NAAT 2: In specimens with FN results, 7/8 *M. pneumoniae* negative, 1/8 *M. pneumoniae* positive. In specimens with FP results, 8/22 *M. pneumoniae* positive, 14/22 *M. pneumoniae* negative.

¹² Discrepant test results based on NAAT 2: In the specimen with FP results, 1/1 *C. pneumoniae* positive.

The Xpert Respiratory Panel test detected 2 or more analytes in a total of 215 specimens. Of the 215 specimens with multi-analyte detection, RV/EV was most commonly co-detected with another analyte (47.4%), followed by Flu A (34.0%), and SARS-CoV-2 (31.6%). The positivity rates of multi-analyte detection by Xpert are presented in **Table 11**.

Table 12: Xpert Positivity Rates of Multi-Analyte Detection

Analyte	Multi-analyte Detection (N = 215)
RV/EV	47.4% (102)
Flu A	34.0% (73)
SARS-CoV-2	31.6% (68)
RSV	24.7% (53)
CoV	23.7% (51)
AdV	17.2% (37)
PIV	14.4% (31)
<i>M. pneumoniae</i>	12.6% (27)
<i>B. pertussis</i>	4.7% (10)
hMPV	4.7% (10)
<i>B. paraptussis</i>	0.5% (1)

Retrospective/Archived Study:

To supplement the clinical study results for analytes with low prevalence (AdV, hMPV, Flu B, *B. pertussis*, *B. paraptussis* and *C. pneumoniae*), pre-selected archived specimens collected from individuals with signs and symptoms of respiratory infection (collection dates May 2009 to September 2025) were tested from January 2023 to August 2026. A summary of the demographic information of the tested retrospective specimens is provided in **Table 12** below. A total of 277 archived specimens were tested in this study. The same comparators as the prospective study was used. Clinical performance for archived samples is shown in **Table 13**.

Table 13: Demographic Results of Archived Specimens by Site

Category		Overall (N=279)	Site 1 (N=3)	Site 2 (N=36)	Site 3 (N=26)	Site 4 (N=103)	Site 5 (N=4)	Site 6 (N=20)	Site 7 (N=87)
Sex	Male	134 (48.0%)	2 (66.7%)	16 (44.4%)	7 (26.9%)	53 (51.5%)	2 (50.0%)	7 (35.0%)	47 (54.0%)
	Female	145 (52.0%)	1 (33.3%)	20 (55.6%)	19 (73.1%)	50 (48.5%)	2 (50.0%)	13 (65.0%)	40 (46.0%)
Age*	≤ 5	86 (30.8%)	3 (100%)	11 (30.6%)	6 (23.1%)	45 (43.7%)	2 (50.0%)	1 (5.0%)	18 (20.7%)
	6-17	93 (33.3%)	0 (0%)	9 (25.0%)	7 (26.9%)	54 (52.4%)	1 (25.0%)	9 (45.0%)	13 (14.9%)
	18-21	10 (3.6%)	0 (0%)	1 (2.8%)	3 (11.5%)	3 (2.9%)	0 (0%)	2 (10.0%)	1 (1.1%)
	22-49	31 (11.1%)	0 (0%)	6 (16.7%)	4 (15.4%)	1 (1.0%)	0 (0%)	7 (35.0%)	13 (14.9%)
	50-64	16 (5.7%)	0 (0%)	0 (0%)	1 (3.8%)	0 (0%)	0 (0%)	1 (5.0%)	14 (16.1%)
	≥ 65	33 (11.8%)	0 (0%)	0 (0%)	5 (19.2%)	0 (0%)	0 (0%)	0 (0%)	28 (32.2%)

*There were 10 specimens with unknown age groups

Table 14: Clinical Performance of Xpert Respiratory Panel in Archived Specimens

Analyte	TP	FN	PPA% TP/(TP+FN)	PPA 95% CI	TN	FP	NPA% TN/(TN+FP)	NPA 95% CI
AdV ¹	22	0	100% 22/22	85.1% - 100%	250	4	98.4% 250/254	96.0% - 99.4%
hMPV ²	102	1	99.0% 102/103	94.7% - 99.8%	173	0	100% 173/173	97.8% - 100%
Flu B	63	0	100% 63/63	94.3% - 100%	212	1	99.9% 212/213	97.4% - 100%
<i>B. pertussis</i> ³	57	2	96.6% 57/59	88.5% - 99.1%	217	0	100% 217/217	98.3% - 100%
<i>B. parapertussis</i>	18	0	100% 18/18	82.4% - 100%	260	0	100% 260/260	98.5% - 100%
<i>C. pneumoniae</i>	19	0	100% 19/19	83.2% - 100%	24	0	100% 24/24	86.2% - 100%

¹ Discrepant test results based on NAAT 2: In specimens with FP results, 3/4 AdV positive, 1/4 AdV negative.

² Discrepant test results based on NAAT 2: In specimens with FN results, 1/1 hMPV positive.

³ Discrepant test results based on NAAT 2: In specimens with FN results, 2/2 *B. pertussis* negative.

Contrived Study:

Contrived samples were tested from November to December 2024 to supplement the prospective and archived study data for *B. parapertussis* and *C. pneumoniae*. A total of 116 samples were contrived at 1x LoD, 3x LoD and 10x LoD and tested. The results of contrived specimen testing with the Xpert Respiratory Panel are presented in **Table 14** below.

Table 15: Summary of Xpert Performance in Contrived Samples

Analyte	TP	FN	PPA% TP/(TP+FN)	PPA 95% CI	TN	FP	NPA% TN/(TN+FP)	NPA 95% CI
<i>B. parapertussis</i>	40	0	100% 40/40	91.2% - 100%	32	0	100% 32/32	89.3% - 100%
1x LoD	20	0	100% 20/20	83.9% - 100%				
3x LoD	10	0	100% 10/10	72.3% - 100%				
10x LoD	10	0	100% 10/10	72.3% - 100%				
<i>C. pneumoniae</i>	44	0	100% 44/44	92.0% - 100%	32	0	100% 32/32	89.3% - 100%
1x LoD	22	0	100% 22/22	85.1% - 100%				
3x LoD	11	0	100% 11/11	74.1% - 100%				
10x LoD	11	0	100% 11/11	74.1% - 100%				

A total of 3,026 specimens (prospective fresh and frozen = 2,631; archived = 279; contrived = 116) were tested with the Xpert Respiratory Panel. The initial and final non-determinate rates were 2.8% (86/3,026) and 0.3% (8/3,026), respectively.

D Expected Values/Reference Range:

The positivity rate for each analyte as determined by the Xpert Respiratory Panel, are shown below, stratified by the study site (**Table 15**), by age group (**Table 16**), and by sex (**Table 17**).

Table 16: Xpert Positivity Rates in Prospective Specimens by Study Site

Analyte	Overall I ¹ (N=25 05)	Site 1 (N=28 6)	Site 2 (N=27 0)	Site 3 (N=24 4)	Site 4 (N=20 7)	Site 5 (N=4 6)	Site 6 (N=23 7)	Site 7 (N=19 5)	Site 8 (N=17 2)	Site 9 (N=36 8)	Site 10 (N=18 1)	Site 11 (N=29 9)
Adenovirus	2.2% (56)	1.0% (3)	0.7% (2)	8.2% (20)	0.5% (1)	4.3 % (2)	3.4% (8)	1.0% (2)	3.5% (6)	1.1% (4)	1.1% (2)	2.0% (6)
Coronavirus	6.2% (156)	2.4% (7)	4.8% (13)	14.8 % (36)	4.3% (9)	8.7 % (4)	6.3% (15)	6.2% (12)	5.2% (9)	5.2% (19)	8.3% (15)	5.7% (17)
SARS-CoV-2	8.1% (202)	3.8% (11)	2.6% (7)	2.9% (7)	4.3% (9)	2.2 % (1)	7.6% (18)	5.6% (11)	0% (0)	36.7 % (135)	0% (0)	1.0% (3)
Human Metapneumovirus	1.3% (33)	1.0% (3)	0.4% (1)	1.6% (4)	1.9% (4)	0% (0)	1.3% (3)	0.5% (1)	0.6% (1)	2.4% (9)	1.7% (3)	1.3% (4)
Rhinovirus/Enter ovirus	17.3% (433)	17.8 % (51)	9.3% (25)	33.6 % (82)	10.6 % (22)	8.7 % (4)	19.4 % (46)	17.9 % (35)	26.7 % (46)	20.1 % (74)	8.8% (16)	10.7 % (32)
Parainfluenza	3.1% (78)	1.4% (4)	0.7% (2)	7.0% (17)	1.9% (4)	2.2 % (1)	4.6% (11)	3.1% (6)	5.2% (9)	1.4% (5)	4.4% (8)	3.7% (11)

Analyte	Overall I ¹ (N=25 05)	Site 1 (N=28 6)	Site 2 (N=27 0)	Site 3 (N=24 4)	Site 4 (N=20 7)	Site 5 (N=4 6)	Site 6 (N=23 7)	Site 7 (N=19 5)	Site 8 (N=17 2)	Site 9 (N=36 8)	Site 10 (N=18 1)	Site 11 (N=29 9)
Influenza A	12.9% (322)	5.6% (16)	5.9% (16)	23.0 % (56)	5.8% (12)	10.9 % (5)	27.8 % (66)	3.1% (6)	9.3% (16)	25.3 % (93)	5.0% (9)	9.0% (27)
Influenza A H1N1-09	5.0% (126)	1.7% (5)	3.0% (8)	7.4% (18)	2.4% (5)	4.3 % (2)	10.1 % (24)	2.1% (4)	1.7% (3)	13.3 % (49)	1.1% (2)	2.0% (6)
Influenza B	0.3% (8)	0% (0)	0% (0)	0.4% (1)	0% (0)	0% (0)	0.8% (2)	0% (0)	0% (0)	0% (0)	0% (0)	1.7% (5)
Respiratory Syncytial Virus	7.2% (180)	4.5% (13)	2.6% (7)	20.5 % (50)	6.3% (13)	6.5 % (3)	10.1 % (24)	1.5% (3)	15.1 % (26)	0.8% (3)	4.4% (8)	10.0 % (30)
<i>Bordetella pertussis</i>	0.6% (15)	0.3% (1)	0.4% (1)	0% (0)	0% (0)	0% (0)	0.4% (1)	5.6% (11)	0% (0)	0.3% (1)	0% (0)	0% (0)
<i>Mycoplasma pneumoniae</i>	3.5% (88)	2.4% (7)	3.7% (10)	7.0% (17)	1.9% (4)	4.3 % (2)	3.8% (9)	9.2% (18)	4.1% (7)	0.5% (2)	3.3% (6)	2.0% (6)
<i>Chlamydia pneumoniae</i>	0.1% (2)	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)	0.5% (2)	0% (0)	0% (0)
Analyte	Overall I ² (N=26 14)	Site 1 (N=29 7)	Site 2 (N=27 3)	Site 3 (N=25 3)	Site 4 (N=23 4)	Site 5 (N=4 6)	Site 6 (N=25 1)	Site 7 (N=19 6)	Site 8 (N=18 5)	Site 9 (N=39 6)	Site 10 (N=18 3)	Site 11 (N=30 0)
<i>Bordetella parapertussis</i>	0.1% (1)	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)	0.3% (1)	0% (0)	0% (0)

¹ Positivity rate calculations included the number of specimens with valid Xpert and Qiagen results.

² Positivity rate calculations included the number of specimens with valid Xpert and BioFire results.

Table 17: Xpert Positivity Rates in Prospective Specimens by Age Group

Analyte	Overall I (N=2505)	≥ 5 Years (N =529)	6-17 Years (N=347)	18-21 Years (N=94)	22-49 Years (N=628)	50-64 Years (N=358)	≥65 Years (N=549)
AdV	2.2% (56)	8.9% (47)	0.9% (3)	0% (0)	0.5% (3)	0.6% (2)	0.2% (1)
CoV	6.2% (156)	10.2% (54)	8.1% (28)	4.3% (4)	4.6% (29)	5.6% (20)	3.8% (21)
SARS- CoV-2	8.1% (202)	2.8% (15)	5.8% (20)	9.6% (9)	10.8% (68)	10.3% (37)	9.7% (53)
hMPV	1.3% (33)	2.5% (13)	0.3% (1)	1.1% (1)	1.1% (7)	1.1% (4)	1.3% (7)
RV/EV	17.3% (433)	31.4% (166)	20.7% (72)	13.8% (13)	15.1% (95)	9.2% (33)	9.8% (54)
PIV	3.1% (78)	7.2% (38)	3.7% (13)	2.1% (2)	1.1% (7)	2.0% (7)	2.0% (11)
Flu A	12.9% (322)	14.9% (79)	17.0% (59)	3.2% (3)	15.0% (94)	11.5% (41)	8.4% (46)
Flu A H1N1-09	5.0% (126)	4.5% (24)	6.3% (22)	0% (0)	6.5% (41)	5.0% (18)	3.8% (21)
Flu B	0.3% (8)	0.4% (2)	0.6% (2)	0% (0)	0.3% (2)	0.6% (2)	0% (0)

RSV	7.2% (180)	23.8% (126)	3.5% (12)	1.1% (1)	2.7% (17)	2.0% (7)	3.1% (17)
<i>B. pertussis</i>	0.6% (15)	0.2% (1)	2.6% (9)	0% (0)	0.5% (3)	0.3% (1)	0.2% (1)
<i>M. pneumoniae</i>	3.5% (88)	4.7% (25)	9.5% (33)	5.3% (5)	3.8% (24)	0% (0)	0.2% (1)
<i>C. pneumoniae</i>	0.1% (2)	0% (0)	0% (0)	0% (0)	0.3% (2)	0% (0)	0% (0)
Analyte	Overall² (N=2505)	≥ 5 Years (N=529)	6-17 Years (N=347)	18-21 Years (N=94)	22-49 Years (N=628)	50-64 Years (N=358)	≥65 Years (N=549)
<i>B. parapertussis</i>	0.0% (1)	0% (0)	0% (0)	0% (0)	0% (0)	0.3% (1)	0.0% (1)

¹ Positivity rate calculations included the number of specimens with valid Xpert and Qiagen results.

² Positivity rate calculations included the number of specimens with valid Xpert and BioFire results.

Table 18: Positivity Rate Stratified by Sex

Analyte	Overall (N=2505)	Female (N=1333)	Male (N=1172)
Adenovirus	2.2% (56)	2.1% (28)	2.4% (28)
Coronavirus	6.2% (156)	5.4% (72)	7.2% (84)
SARS-CoV-2	8.1% (202)	9.2% (122)	6.8% (80)
Human Metapneumovirus	1.3% (33)	1.3% (17)	1.4% (16)
Rhinovirus/Enterovirus	17.3% (433)	17.1% (228)	17.5% (205)
Parainfluenza	3.1% (78)	2.4% (32)	3.9% (46)
Influenza A	17.9% (448)	19.1% (254)	16.6% (194)
Influenza B	0.3% (8)	0.4% (5)	0.3% (3)
Respiratory Syncytial Virus	7.2% (180)	6.4% (85)	8.1% (95)
<i>Bordetella pertussis</i>	0.6% (15)	0.9% (12)	0.3% (3)
<i>Mycoplasma pneumoniae</i>	3.5% (88)	3.6% (48)	3.4% (40)
<i>Chlamydia pneumoniae</i>	0.1% (2)	0.2% (2)	0% (0)
Analyte	Overall (N=2614)	Female (N=1389)	Male (N=1225)
<i>Bordetella parapertussis</i>	0% (1)	0.1% (1)	0% (0)

E Other Supportive Instrument Performance Characteristics Data:

1. Electrical safety and electromagnetic compatibility (EMC) testing were performed, and the system was found to be acceptable.
2. Software and cybersecurity documentation was reviewed and found to be acceptable.
3. Carry-Over:

A study was conducted to evaluate risk of carry-over contamination of the single-use, self-contained Xpert Respiratory Panel test cartridges when very high titer positive samples were processed prior to testing of negative samples in the same GeneXpert module. The following

on-panel viruses and bacteria were tested: Adenovirus (1E6 TCID₅₀/mL), SARS-CoV-2 (1E6 TCID₅₀/mL), Human Metapneumovirus (1E6 TCID₅₀/mL), Influenza A H1N1-09 (1E7 CEID₅₀/mL), Influenza B (1E6 TCID₅₀/mL), B. pertussis (1E7 CFU/mL), M. pneumoniae (1E6 copies/mL), and C. pneumoniae (1E6 TCID₅₀/mL). The viruses and bacteria were tested in pools of 2-4 pathogens, except for SARS-CoV-2 which was tested individually. The negative sample consisted of simulated NPS matrix.

A high titer positive sample was tested, immediately followed by testing a negative sample in the same GeneXpert instrument module. The testing scheme was repeated 10 times for each high titer positive sample, and two different modules were included in the study. Each replicate of the positive samples was correctly reported as positive for the on-panel viruses and bacteria tested. Each replicate of the negative sample, processed immediately following a replicate of the high titer positive sample, was correctly reported as negative. No evidence of specimen or amplicon carry-over contamination was observed.

VII Proposed Labeling:

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

VIII Conclusion:

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