October 30, 2026

GenMark Diagnostics, Inc.
Alyssa Agana
Regulatory Affairs Manager
5964 La Pl. Ct.
Carlsbad, California 92008

Re: K262938
Trade/Device Name: cobas eplex respiratory pathogen panel 3
Regulation Number: 21 CFR 866.3981
Regulation Name: Device to detect and identify nucleic acid targets in respiratory specimens from microbial agents that cause the SARS-CoV-2 respiratory infection and other microbial agents when in a multi-target test
Regulatory Class: Class II
Product Code: QOF
Dated: August 21, 2026
Received: August 21, 2026

Dear Alyssa Agana:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

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

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

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the

Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

JOSEPH BRIGGS -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K262938

Device Name
cobas eplex respiratory pathogen panel 3

Indications for Use *(Describe)*
The cobas eplex respiratory pathogen panel 3 (RP3 panel) is a multiplexed nucleic acid in vitro diagnostic test intended for use on the cobas eplex system for the simultaneous qualitative detection and identification of multiple respiratory viral and bacterial nucleic acids in nasopharyngeal swabs (NPS) obtained from individuals with signs and symptoms of respiratory tract infection.

The following organism types and subtypes are identified using the cobas eplex RP3 panel: adenovirus, human coronavirus (229E, HKU1, NL63, OC43), severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), human enterovirus/rhinovirus, human metapneumovirus, human parainfluenza virus 1, human parainfluenza virus 2, human parainfluenza virus 3, human parainfluenza virus 4, influenza A virus, influenza A virus H1, influenza A virus H1-2009, influenza A virus H3, influenza B virus, respiratory syncytial virus (RSV) A, respiratory syncytial virus (RSV) B, Bordetella pertussis, Chlamydia pneumoniae, and Mycoplasma pneumoniae.

Nucleic acids from viral and bacterial organisms identified by this test are generally detectable in NPS specimens during the acute phase of infection. The detection and identification of specific viral and bacterial nucleic acids from individuals exhibiting signs and symptoms of respiratory infection is indicative of the presence of the identified microorganism and aids in the diagnosis of respiratory infection if used in conjunction with other clinical and epidemiological information 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 this test, or due to lower respiratory tract infection that is not detected by an NPS specimen. Positive results do not rule out coinfection with other pathogens not detected by the cobas eplex RP3 panel. The agent(s) detected by the cobas eplex RP3 panel may not be the definite cause of disease. Additional laboratory testing (e.g., bacterial and viral culture, immunofluorescence, and radiography) may be necessary when evaluating a patient with possible respiratory tract infection.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

1. SUBMITTER INFORMATION

Submitter: GenMark Diagnostics, Incorporated

5964 La Place Court

Carlsbad, CA 92008

Manufacturer: GenMark Diagnostics, Incorporated

5964 La Place Court

Carlsbad, CA 92008

Establishment Registration Number: 3008632402

Contact: Alyssa Agana

Regulatory Affairs Manager

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Senior Regulatory Affairs Manager

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Date Prepared: October 9, 2026

2. NAME OF DEVICE AND CLASSIFICATION

Product Name: **cobas® eplex** respiratory pathogen panel 3

Device Classification: 866.3981 Device to detect and identify nucleic acid targets in respiratory specimens from microbial agents that cause the SARS-

	CoV-2 respiratory infection and other microbial agents when in a multi-target test
Product Code(s):	QOF (Class 2) - Multi-Target Respiratory Specimen Nucleic Acid Test Including Sars-Cov-2 And Other Microbial Agents

3. PREDICATE DEVICE

Predicate: BioFire Respiratory Panel 2.1 (RP2.1), DEN200031

4. DEVICE DESCRIPTION

The **cobas eplex** RP3 panel is based on the principles of competitive nucleic acid hybridization using a sandwich assay format, wherein a single-stranded target binds concurrently to a sequence-specific solution-phase signal probe and a solid-phase electrode-bound capture probe. The test employs nucleic acid extraction, target amplification via polymerase chain reaction (PCR) and/or reverse transcription PCR (RT-PCR) and detection of amplified target DNA. In the detection process, the double-stranded PCR amplicons are digested with an exonuclease to generate single-stranded DNA suitable for hybridization to a capture probe and signal probe.

Nucleic acid extraction from biological samples occurs within the cartridge via chemical lysis, nucleic acid captures onto magnetic beads, and release for amplification. The nucleic acid extraction is processed through microfluidic liquid handling. Once the nucleic acid is captured and inhibitors are washed away, the magnetic particles are delivered to the electrowetting environment on the printed circuit board (PCB) and the nucleic acid is eluted from the magnetic particles. Specific target nucleic acid is then amplified.

During hybridization, the single-stranded target DNA binds to a complementary, single-stranded capture probe immobilized on the working gold electrode surface. Single-stranded signal probes (labeled with electrochemically active ferrocenes) bind to specific target sequences/regions adjacent to the capture probe. Simultaneous hybridization of target to signal probes and capture probe is detected by alternating current voltammetry (ACV). Each working electrode on the array contains specific capture probes, and sequential analysis of each electrode allows detection of multiple analyte targets.

The following virus types, subtypes, and bacteria are identified using the **cobas eplex** RP3 panel: adenovirus, human coronavirus (229E, HKU1, NL63, OC43), Severe Acute Respiratory

Syndrome Coronavirus 2 (SARS-CoV-2), human enterovirus/rhinovirus, human metapneumovirus, human parainfluenza virus 1, human parainfluenza virus 2, human parainfluenza virus 3, human parainfluenza virus 4, influenza A virus, influenza A virus H1, influenza A virus H1-2009, influenza A virus H3, influenza B virus, respiratory syncytial virus (RSV) A, respiratory syncytial virus (RSV) B, *Bordetella pertussis, Chlamydia pneumoniae,* and *Mycoplasma pneumoniae*.

5. INTENDED USE/INDICATIONS FOR USE

The **cobas® eplex** respiratory pathogen panel 3 (RP3 panel) is a multiplexed nucleic acid in vitro diagnostic test intended for use on the **cobas® eplex** system for the simultaneous qualitative detection and identification of multiple respiratory viral and bacterial nucleic acids in nasopharyngeal swabs (NPS) obtained from individuals with signs and symptoms of respiratory tract infection.

The following organism types and subtypes are identified using the **cobas® eplex** RP3 panel: adenovirus, human coronavirus (229E, HKU1, NL63, OC43), severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), human enterovirus/rhinovirus, human metapneumovirus, human parainfluenza virus 1, human parainfluenza virus 2, human parainfluenza virus 3, human parainfluenza virus 4, influenza A virus, influenza A virus H1, influenza A virus H1-2009, influenza A virus H3, influenza B virus, respiratory syncytial virus (RSV) A, respiratory syncytial virus (RSV) B, *Bordetella pertussis*, *Chlamydia pneumoniae*, and *Mycoplasma pneumoniae*.

Nucleic acids from viral and bacterial organisms identified by this test are generally detectable in NPS specimens during the acute phase of infection. The detection and identification of specific viral and bacterial nucleic acids from individuals exhibiting signs and symptoms of respiratory infection is indicative of the presence of the identified microorganism and aids in the diagnosis of respiratory infection if used in conjunction with other clinical and epidemiological information 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 this test, or due to lower respiratory tract infection that is not detected by an NPS specimen. Positive results do not rule out coinfection with other pathogens not detected by the **cobas® eplex** RP3 panel. The agent(s) detected by the **cobas® eplex** RP3 panel may not

be the definite cause of disease. Additional laboratory testing (e.g., bacterial and viral culture, immunofluorescence, and radiography) may be necessary when evaluating a patient with possible respiratory tract infection.

6. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE

The **cobas® eplex** respiratory pathogen panel 3 ("Subject Device") and the legally marketed device, BioFire Respiratory Panel 2.1 ("Predicate Device") are described below:

Characteristic	Subject Device	Predicate Device
Proprietary Name	**cobas® eplex** respiratory pathogen panel 3	BIOFIRE Respiratory Panel 2.1 (RP2.1)
Manufacturer	GenMark Diagnostics	BIOFIRE Diagnostics
Regulation	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	21 CFR 866.3981 Device to detect and identify nucleic acid targets in respiratory specimens from microbial agents that cause the SARS-CoV-2 respiratory infection and other microbial agents when in a multi-target test
Product Code(s)	QOF	QOF
Device Class	Class II	Class II

Indications for Use	The **cobas® eplex** respiratory pathogen panel 3 (RP3 panel) is a multiplexed nucleic acid in vitro diagnostic test intended for use on the **cobas® eplex** system for the simultaneous qualitative detection and identification of multiple respiratory viral and bacterial nucleic acids in nasopharyngeal swabs (NPS) obtained from individuals with signs and symptoms of respiratory tract infection. The following organism types and subtypes are identified using the **cobas® eplex** RP3 panel: adenovirus, human coronavirus (229E, HKU1, NL63, OC43), severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), human enterovirus/rhinovirus, human metapneumovirus, human parainfluenza virus 1, human parainfluenza virus 2, human parainfluenza virus 3, human parainfluenza virus 4, influenza A virus, influenza A virus H1, influenza A virus H1-2009, influenza A virus H3, influenza B virus, respiratory syncytial virus (RSV) A, respiratory syncytial virus (RSV) B, *Bordetella pertussis*, *Chlamydia pneumoniae*, and *Mycoplasma pneumoniae*. Nucleic acids from viral and bacterial organisms identified by this test are generally detectable in NPS specimens during the acute phase of infection. The detection and identification of specific viral and bacterial nucleic acids from individuals exhibiting signs and symptoms of respiratory infection is indicative of the presence of the identified microorganism and aids in the diagnosis of respiratory infection if used in conjunction with other clinical and epidemiological information 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 this test, or due to lower respiratory tract infection that is not detected by an NPS specimen. Positive results do not rule out coinfection with other pathogens not detected by the **cobas® eplex** RP3 panel. The agent(s) detected by the **cobas® eplex** RP3 panel may not be the definite cause of disease. Additional laboratory testing (e.g., bacterial and viral culture, immunofluorescence, and radiography) may be necessary when	The BIOFIRE Respiratory Panel 2.1 (RP2.1) is a PCR-based multiplexed nucleic acid test intended for use with the BIOFIRE® FILMARRAY® 2.0 or BIOFIRE® FILMARRAY® Torch Systems for the simultaneous qualitative detection and identification of multiple respiratory viral and bacterial nucleic acids in nasopharyngeal swabs (NPS) obtained from individuals suspected of respiratory tract infections, including COVID-19. The following organism types and subtypes are identified using the BIOFIRE RP2.1: Adenovirus Coronavirus 229E Coronavirus HKU1 Coronavirus NL63 Coronavirus OC43 Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) Human metapneumovirus Human rhinovirus/enterovirus Influenza A virus Influenza A virus A/H1 Influenza A virus A/H3 Influenza A virus A/H1-2009 Influenza B virus Parainfluenza virus 1 Parainfluenza virus 2 Parainfluenza virus 3 Parainfluenza virus 4 Respiratory syncytial virus *Bordetella parapertussis* *Bordetella pertussis* *Chlamydia pneumoniae* *Mycoplasma pneumoniae* Nucleic acids from the respiratory viral and bacterial organisms identified by this test are generally detectable in NPS specimens during the acute phase of infection. The detection and identification of specific viral and bacterial nucleic acids from individuals exhibiting signs and/or symptoms of respiratory infection is indicative of the presence of the identified microorganism and aids in the diagnosis of respiratory infection if used in conjunction with other clinical and epidemiological information.

Characteristic	Subject Device	Predicate Device
	evaluating a patient with possible respiratory tract infection.	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 setting of a respiratory illness may be due to infection with pathogens that are not detected by this test, or lower respiratory tract infection that may not be detected by an NPS specimen. Positive results do not rule out co-infection with other organisms. The agent(s) detected by the BIOFIRE RP2.1 may not be the definite cause of disease. Additional laboratory testing (e.g. bacterial and viral culture, immunofluorescence, and radiography) may be necessary when evaluating a patient with possible respiratory tract infection.
Organisms Detected	Adenovirus, Human coronavirus (229E, HKU1, NL63, OC43) Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Human metapneumovirus Human enterovirus/rhinovirus Influenza A virus Influenza A virus H1 Influenza A virus H1-2009 Influenza A virus H3 Influenza B virus Human parainfluenza virus 1 Human parainfluenza virus 2 Human parainfluenza virus 3 Human parainfluenza virus 4 Respiratory Syncytial Virus (RSV) A Respiratory Syncytial Virus (RSV) B *Bordetella pertussis* *Chlamydia pneumoniae* *Mycoplasma pneumoniae*	Adenovirus Coronavirus 229E Coronavirus HKU1 Coronavirus NL63 Coronavirus OC43 Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Human Metapneumovirus Human Rhinovirus/Enterovirus Influenza A virus Influenza A virus A/H1 Influenza A virus A/H1-2009 Influenza A virus A/H3 Influenza B virus Parainfluenza Virus 1 Parainfluenza Virus 2 Parainfluenza Virus 3 Parainfluenza Virus 4 Respiratory Syncytial Virus *Bordetella parapertussis* *Bordetella pertussis* *Chlamydia pneumoniae* *Mycoplasma pneumoniae*
Specimen Type	Nasopharyngeal swabs (NPS)	Nasopharyngeal swabs (NPS)
Chemistry	Reagents contained within cartridge to allow: sample lysis and nucleic acid extraction, RT-PCR amplification, and hybridization-based electrochemical detection reagents.	Nested multiplex RT-PCR followed by high resolution melting analysis to confirm identity of amplified product.

Characteristic	Subject Device	Predicate Device
Instrumentation	**cobas® eplex** instrument	BIOFIRE® FILMARRAY® 2.0 or BIOFIRE® FILMARRAY® Torch Systems

Analysis of the similarities and differences indicate that the devices are substantially equivalent in their intended uses/indications for use, and are generally the same regarding user process, ease of use and general operator protocol. Comparison of technological similarities and differences between the proposed device and the predicate do not raise new or different questions of safety and effectiveness, and therefore render the proposed device as substantially equivalent to the predicate device.

7. SUMMARY OF PERFORMANCE DATA

7.1. Clinical Performance

7.1.1. Expected values

A prospective, multicenter clinical study was conducted to evaluate the clinical performance of the **cobas® eplex** RP3 panel in nasopharyngeal swab samples. A total of 3319 nasopharyngeal swab samples were prospectively collected at 6 collection sites from patients of all ages and genders presenting with signs and/or symptoms of respiratory infection. In the first phase from November 2023 through February 2024, 398 samples were prospectively collected and frozen (Table 1 and Table 4). In the second phase from January 2025 through April 2025, 2103 samples were prospectively collected and tested fresh (never frozen)(Table 2 and Table 5). In the third phase, an additional 818 samples were prospectively collected and frozen from December 2025 through April 2026 (Table 3 and 6). The expected values of individual analytes based on **cobas® eplex** RP3 panel results in prospective samples for each phase by age and by site are summarized in **Table 1**: Expected values (as determined by cobas® eplex RP3 panel) summary by Age Group in Frozen Prospective Samples (Phase 1: November 2023 – February 2024)

Organism	All Ages (N=398) n(%)	Age 0-1 (N=1) n(%)	Age >1-5 (N=20) n(%)	Age >5-21 (N=37) n(%)	Age >21-65 (N=172) n(%)	Age >65 (N=168) n(%)
Adenovirus	4 (1.0)	0 (0.0)	1 (5.0)	2 (5.4)	1 (0.6)	0 (0.0)
Human enterovirus/rhinovirus	26 (6.5)	0 (0.0)	7 (35.0)	6 (16.2)	7 (4.1)	6 (3.6)
Human coronavirus	19 (4.8)	0 (0.0)	2 (10.0)	3 (8.1)	7 (4.1)	7 (4.2)
SARS-CoV-2	14 (3.5)	0 (0.0)	0 (0.0)	2 (5.4)	6 (3.5)	6 (3.6)

Organism	All Ages (N=398) n(%)	Age 0-1 (N=1) n(%)	Age >1-5 (N=20) n(%)	Age >5-21 (N=37) n(%)	Age >21-65 (N=172) n(%)	Age >65 (N=168) n(%)
Human metapneumovirus	4 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (1.7)	1 (0.6)
Human parainfluenza virus 1	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)
Human parainfluenza virus 2	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Human parainfluenza virus 3	2 (0.5)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	1 (0.6)
Human parainfluenza virus 4	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)
Influenza A virus	19 (4.8)	0 (0.0)	1 (5.0)	2 (5.4)	5 (2.9)	11 (6.5)
Influenza A virus H1	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Influenza A virus H1-2009	9 (2.3)	0 (0.0)	0 (0.0)	1 (2.7)	3 (1.7)	5 (3.0)
Influenza A virus H3	11 (2.8)	0 (0.0)	1 (5.0)	2 (5.4)	2 (1.2)	6 (3.6)
Influenza B virus	2 (0.5)	0 (0.0)	0 (0.0)	1 (2.7)	1 (0.6)	0 (0.0)
RSV	18 (4.5)	0 (0.0)	4 (20.0)	3 (8.1)	9 (5.2)	2 (1.2)
RSV A	6 (1.5)	0 (0.0)	1 (5.0)	2 (5.4)	2 (1.2)	1 (0.6)
RSV B	12 (3.0)	0 (0.0)	3 (15.0)	1 (2.7)	7 (4.1)	1 (0.6)
Bordetella pertussis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Chlamydia pneumoniae	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Mycoplasma pneumoniae	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Table 2: Expected values (as determined by cobas® eplex RP3 panel) summary by Age Group in Fresh Prospective Samples (Phase 2: January 2025 – April 2025)

Organism	All Ages (N=2103) n(%)	Age 0-1 (N=71) n(%)	Age >1-5 (N=174) n(%)	Age >5-21 (N=197) n(%)	Age >21-65 (N=976) n(%)	Age >65 (N=685) n(%)
Adenovirus	15 (0.7)	2 (2.8)	7 (4.0)	3 (1.5)	3 (0.3)	0 (0.0)
Human enterovirus/rhinovirus	216 (10.3)	12 (16.9)	47 (27.0)	39 (19.8)	70 (7.2)	48 (7.0)
Human coronavirus	119 (5.7)	10 (14.1)	19 (10.9)	14 (7.1)	47 (4.8)	29 (4.2)
SARS-CoV-2	67 (3.2)	0 (0.0)	9 (5.2)	2 (1.0)	27 (2.8)	29 (4.2)
Human metapneumovirus	52 (2.5)	1 (1.4)	8 (4.6)	6 (3.0)	20 (2.0)	17 (2.5)
Human parainfluenza virus 1	1 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)
Human parainfluenza virus 2	1 (0.0)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)
Human parainfluenza virus 3	17 (0.8)	0 (0.0)	2 (1.1)	1 (0.5)	6 (0.6)	8 (1.2)
Human parainfluenza virus 4	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.1)
Influenza A virus	139 (6.6)	4 (5.6)	23 (13.2)	37 (18.8)	50 (5.1)	25 (3.6)
Influenza A virus H1	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Influenza A virus H1-2009	83 (3.9)	1 (1.4)	12 (6.9)	19 (9.6)	32 (3.3)	19 (2.8)

Organism	All Ages (N=2103) n(%)	Age 0-1 (N=71) n(%)	Age >1-5 (N=174) n(%)	Age >5-21 (N=197) n(%)	Age >21-65 (N=976) n(%)	Age >65 (N=685) n(%)
Influenza A virus H3	54 (2.6)	3 (4.2)	12 (6.9)	18 (9.1)	18 (1.8)	3 (0.4)
Influenza B virus	12 (0.6)	0 (0.0)	1 (0.6)	4 (2.0)	7 (0.7)	0 (0.0)
RSV	92 (4.4)	11 (15.5)	25 (14.4)	13 (6.6)	27 (2.8)	16 (2.3)
RSV A	63 (3.0)	8 (11.3)	22 (12.6)	10 (5.1)	12 (1.2)	11 (1.6)
RSV B	29 (1.4)	3 (4.2)	3 (1.7)	3 (1.5)	15 (1.5)	5 (0.7)
Bordetella pertussis	3 (0.1)	1 (1.4)	1 (0.6)	1 (0.5)	0 (0.0)	0 (0.0)
Chlamydia pneumoniae	2 (0.1)	0 (0.0)	0 (0.0)	1 (0.5)	1 (0.1)	0 (0.0)
Mycoplasma pneumoniae	10 (0.5)	0 (0.0)	3 (1.7)	4 (2.0)	2 (0.2)	1 (0.1)

Table 3: Expected values (as determined by cobas® eplex RP3 panel) summary by Age Group in Frozen Prospective Samples (Phase 3: December 2025 – April 2026)

Organism	All Ages (N=818) n(%)	Age 0-1 (N=261) n(%)	Age >1-5 (N=288) n(%)	Age >5-21 (N=269) n(%)
Adenovirus	32 (3.9)	17 (6.5)	14 (4.9)	1 (0.4)
Human enterovirus/rhinovirus	194 (23.7)	73 (28.0)	74 (25.7)	47 (17.5)
Human coronavirus	59 (7.2)	26 (10.0)	19 (6.6)	14 (5.2)
SARS-CoV-2	12 (1.5)	6 (2.3)	4 (1.4)	2 (0.7)
Human metapneumovirus	40 (4.9)	15 (5.7)	16 (5.6)	9 (3.3)
Human parainfluenza virus 1	9 (1.1)	6 (2.3)	2 (0.7)	1 (0.4)
Human parainfluenza virus 2	3 (0.4)	0 (0.0)	0 (0.0)	3 (1.1)
Human parainfluenza virus 3	3 (0.4)	2 (0.8)	1 (0.3)	0 (0.0)
Human parainfluenza virus 4	12 (1.5)	3 (1.1)	8 (2.8)	1 (0.4)
Influenza A virus	118 (14.4)	19 (7.3)	57 (19.8)	42 (15.6)
Influenza A virus H1	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Influenza A virus H1-2009	18 (2.2)	0 (0.0)	10 (3.5)	8 (3.0)
Influenza A virus H3	97 (11.9)	18 (6.9)	48 (16.7)	31 (11.5)
Influenza B virus	33 (4.0)	4 (1.5)	10 (3.5)	19 (7.1)
RSV	74 (9.0)	25 (9.6)	43 (14.9)	6 (2.2)
RSV A	42 (5.1)	13 (5.0)	26 (9.0)	3 (1.1)
RSV B	32 (3.9)	12 (4.6)	17 (5.9)	3 (1.1)
Bordetella pertussis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Chlamydia pneumoniae	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Mycoplasma pneumoniae	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Table 4: Expected values (as determined by cobas® eplex RP3 panel) summary by Collection Site in Frozen Prospective Samples (Phase 1: November 2023 – February 2024)

Organism	All Sites (N=398) n(%)	Site 1 (N=398) n(%)
Adenovirus	4 (1.0)	4 (1.0)
Human enterovirus/rhinovirus	26 (6.5)	26 (6.5)
Human coronavirus	19 (4.8)	19 (4.8)
SARS-CoV-2	14 (3.5)	14 (3.5)
Human metapneumovirus	4 (1.0)	4 (1.0)
Human parainfluenza virus 1	1 (0.3)	1 (0.3)
Human parainfluenza virus 2	0 (0.0)	0 (0.0)
Human parainfluenza virus 3	2 (0.5)	2 (0.5)
Human parainfluenza virus 4	1 (0.3)	1 (0.3)
Influenza A virus	19 (4.8)	19 (4.8)
Influenza A virus H1	0 (0.0)	0 (0.0)
Influenza A virus H1-2009	9 (2.3)	9 (2.3)
Influenza A virus H3	11 (2.8)	11 (2.8)
Influenza B virus	2 (0.5)	2 (0.5)
RSV	18 (4.5)	18 (4.5)
RSV A	6 (1.5)	6 (1.5)
RSV B	12 (3.0)	12 (3.0)
Bordetella pertussis	0 (0.0)	0 (0.0)
Chlamydia pneumoniae	0 (0.0)	0 (0.0)
Mycoplasma pneumoniae	0 (0.0)	0 (0.0)

Table 5: Expected values (as determined by cobas® eplex RP3 panel) summary by Collection Site in Fresh Prospective Samples (Phase 2: January 2025 – April 2025)

Organism	All Sites (N=2103) n(%)	Site 1 (N=600) n(%)	Site 2 (N=255) n(%)	Site 3 (N=600) n(%)	Site 4 (N=648) n(%)
Adenovirus	15 (0.7)	4 (0.7)	2 (0.8)	2 (0.3)	7 (1.1)
Human enterovirus/rhinovirus	216 (10.3)	50 (8.3)	35 (13.7)	64 (10.7)	67 (10.3)
Human coronavirus	119 (5.7)	20 (3.3)	30 (11.8)	31 (5.2)	38 (5.9)
SARS-CoV-2	67 (3.2)	26 (4.3)	2 (0.8)	0 (0.0)	39 (6.0)

Organism	All Sites (N=2103) n(%)	Site 1 (N=600) n(%)	Site 2 (N=255) n(%)	Site 3 (N=600) n(%)	Site 4 (N=648) n(%)
Human metapneumovirus	52 (2.5)	10 (1.7)	6 (2.4)	15 (2.5)	21 (3.2)
Human parainfluenza virus 1	1 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)
Human parainfluenza virus 2	1 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
Human parainfluenza virus 3	17 (0.8)	4 (0.7)	1 (0.4)	6 (1.0)	6 (0.9)
Human parainfluenza virus 4	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
Influenza A virus	139 (6.6)	12 (2.0)	60 (23.5)	17 (2.8)	50 (7.7)
Influenza A virus H1	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Influenza A virus H1-2009	83 (3.9)	8 (1.3)	29 (11.4)	11 (1.8)	35 (5.4)
Influenza A virus H3	54 (2.6)	4 (0.7)	32 (12.5)	4 (0.7)	14 (2.2)
Influenza B virus	12 (0.6)	3 (0.5)	2 (0.8)	4 (0.7)	3 (0.5)
RSV	92 (4.4)	4 (0.7)	35 (13.7)	29 (4.8)	24 (3.7)
RSV A	63 (3.0)	4 (0.7)	27 (10.6)	18 (3.0)	14 (2.2)
RSV B	29 (1.4)	0 (0.0)	8 (3.1)	11 (1.8)	10 (1.5)
Bordetella pertussis	3 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.5)
Chlamydia pneumoniae	2 (0.1)	2 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
Mycoplasma pneumoniae	10 (0.5)	0 (0.0)	3 (1.2)	4 (0.7)	3 (0.5)

Table 6: Expected values (as determined by cobas® eplex RP3 panel) summary by Collection Site in Frozen Prospective Samples (Phase 3: December 2025 – April 2026)

Organism	All Sites (N=818) n(%)	Site 1 (N=500) n(%)	Site 2 (N=318) n(%)
Adenovirus	32 (3.9)	19 (3.8)	13 (4.1)
Human enterovirus/rhinovirus	194 (23.7)	108 (21.6)	86 (27.0)
Human coronavirus	59 (7.2)	29 (5.8)	30 (9.4)
SARS-CoV-2	12 (1.5)	5 (1.0)	7 (2.2)
Human metapneumovirus	40 (4.9)	20 (4.0)	20 (6.3)
Human parainfluenza virus 1	9 (1.1)	4 (0.8)	5 (1.6)
Human parainfluenza virus 2	3 (0.4)	2 (0.4)	1 (0.3)
Human parainfluenza virus 3	3 (0.4)	2 (0.4)	1 (0.3)
Human parainfluenza virus 4	12 (1.5)	10 (2.0)	2 (0.6)
Influenza A virus	118 (14.4)	106 (21.2)	12 (3.8)
Influenza A virus H1	0 (0.0)	0 (0.0)	0 (0.0)
Influenza A virus H1-2009	18 (2.2)	18 (3.6)	0 (0.0)

Organism	All Sites (N=818) n(%)	Site 1 (N=500) n(%)	Site 2 (N=318) n(%)
Influenza A virus H3	97 (11.9)	87 (17.4)	10 (3.1)
Influenza B virus	33 (4.0)	29 (5.8)	4 (1.3)
RSV	74 (9.0)	64 (12.8)	10 (3.1)
RSV A	42 (5.1)	39 (7.8)	3 (0.9)
RSV B	32 (3.9)	25 (5.0)	7 (2.2)
Bordetella pertussis	0 (0.0)	0 (0.0)	0 (0.0)
Chlamydia pneumoniae	0 (0.0)	0 (0.0)	0 (0.0)
Mycoplasma pneumoniae	0 (0.0)	0 (0.0)	0 (0.0)

to **Table 6.**

Table 1: Expected values (as determined by cobas® eplex RP3 panel) summary by Age Group in Frozen Prospective Samples (Phase 1: November 2023 – February 2024)

Organism	All Ages (N=398) n(%)	Age 0-1 (N=1) n(%)	Age >1-5 (N=20) n(%)	Age >5-21 (N=37) n(%)	Age >21-65 (N=172) n(%)	Age >65 (N=168) n(%)
Adenovirus	4 (1.0)	0 (0.0)	1 (5.0)	2 (5.4)	1 (0.6)	0 (0.0)
Human enterovirus/rhinovirus	26 (6.5)	0 (0.0)	7 (35.0)	6 (16.2)	7 (4.1)	6 (3.6)
Human coronavirus	19 (4.8)	0 (0.0)	2 (10.0)	3 (8.1)	7 (4.1)	7 (4.2)
SARS-CoV-2	14 (3.5)	0 (0.0)	0 (0.0)	2 (5.4)	6 (3.5)	6 (3.6)
Human metapneumovirus	4 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (1.7)	1 (0.6)
Human parainfluenza virus 1	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)
Human parainfluenza virus 2	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Human parainfluenza virus 3	2 (0.5)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	1 (0.6)
Human parainfluenza virus 4	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)
Influenza A virus	19 (4.8)	0 (0.0)	1 (5.0)	2 (5.4)	5 (2.9)	11 (6.5)
Influenza A virus H1	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Influenza A virus H1-2009	9 (2.3)	0 (0.0)	0 (0.0)	1 (2.7)	3 (1.7)	5 (3.0)
Influenza A virus H3	11 (2.8)	0 (0.0)	1 (5.0)	2 (5.4)	2 (1.2)	6 (3.6)
Influenza B virus	2 (0.5)	0 (0.0)	0 (0.0)	1 (2.7)	1 (0.6)	0 (0.0)
RSV	18 (4.5)	0 (0.0)	4 (20.0)	3 (8.1)	9 (5.2)	2 (1.2)
RSV A	6 (1.5)	0 (0.0)	1 (5.0)	2 (5.4)	2 (1.2)	1 (0.6)
RSV B	12 (3.0)	0 (0.0)	3 (15.0)	1 (2.7)	7 (4.1)	1 (0.6)
Bordetella pertussis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Organism	All Ages (N=398) n(%)	Age 0-1 (N=1) n(%)	Age >1-5 (N=20) n(%)	Age >5-21 (N=37) n(%)	Age >21-65 (N=172) n(%)	Age >65 (N=168) n(%)
Chlamydia pneumoniae	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Mycoplasma pneumoniae	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Table 2: Expected values (as determined by cobas® eplex RP3 panel) summary by Age Group in Fresh Prospective Samples (Phase 2: January 2025 – April 2025)

Organism	All Ages (N=2103) n(%)	Age 0-1 (N=71) n(%)	Age >1-5 (N=174) n(%)	Age >5-21 (N=197) n(%)	Age >21-65 (N=976) n(%)	Age >65 (N=685) n(%)
Adenovirus	15 (0.7)	2 (2.8)	7 (4.0)	3 (1.5)	3 (0.3)	0 (0.0)
Human enterovirus/rhinovirus	216 (10.3)	12 (16.9)	47 (27.0)	39 (19.8)	70 (7.2)	48 (7.0)
Human coronavirus	119 (5.7)	10 (14.1)	19 (10.9)	14 (7.1)	47 (4.8)	29 (4.2)
SARS-CoV-2	67 (3.2)	0 (0.0)	9 (5.2)	2 (1.0)	27 (2.8)	29 (4.2)
Human metapneumovirus	52 (2.5)	1 (1.4)	8 (4.6)	6 (3.0)	20 (2.0)	17 (2.5)
Human parainfluenza virus 1	1 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)
Human parainfluenza virus 2	1 (0.0)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)
Human parainfluenza virus 3	17 (0.8)	0 (0.0)	2 (1.1)	1 (0.5)	6 (0.6)	8 (1.2)
Human parainfluenza virus 4	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.1)
Influenza A virus	139 (6.6)	4 (5.6)	23 (13.2)	37 (18.8)	50 (5.1)	25 (3.6)
Influenza A virus H1	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Influenza A virus H1-2009	83 (3.9)	1 (1.4)	12 (6.9)	19 (9.6)	32 (3.3)	19 (2.8)
Influenza A virus H3	54 (2.6)	3 (4.2)	12 (6.9)	18 (9.1)	18 (1.8)	3 (0.4)
Influenza B virus	12 (0.6)	0 (0.0)	1 (0.6)	4 (2.0)	7 (0.7)	0 (0.0)
RSV	92 (4.4)	11 (15.5)	25 (14.4)	13 (6.6)	27 (2.8)	16 (2.3)
RSV A	63 (3.0)	8 (11.3)	22 (12.6)	10 (5.1)	12 (1.2)	11 (1.6)
RSV B	29 (1.4)	3 (4.2)	3 (1.7)	3 (1.5)	15 (1.5)	5 (0.7)
Bordetella pertussis	3 (0.1)	1 (1.4)	1 (0.6)	1 (0.5)	0 (0.0)	0 (0.0)
Chlamydia pneumoniae	2 (0.1)	0 (0.0)	0 (0.0)	1 (0.5)	1 (0.1)	0 (0.0)
Mycoplasma pneumoniae	10 (0.5)	0 (0.0)	3 (1.7)	4 (2.0)	2 (0.2)	1 (0.1)

Table 3: Expected values (as determined by cobas® eplex RP3 panel) summary by Age Group in Frozen Prospective Samples (Phase 3: December 2025 – April 2026)

Organism	All Ages (N=818) n(%)	Age 0-1 (N=261) n(%)	Age >1-5 (N=288) n(%)	Age >5-21 (N=269) n(%)
Adenovirus	32 (3.9)	17 (6.5)	14 (4.9)	1 (0.4)
Human enterovirus/rhinovirus	194 (23.7)	73 (28.0)	74 (25.7)	47 (17.5)
Human coronavirus	59 (7.2)	26 (10.0)	19 (6.6)	14 (5.2)
SARS-CoV-2	12 (1.5)	6 (2.3)	4 (1.4)	2 (0.7)
Human metapneumovirus	40 (4.9)	15 (5.7)	16 (5.6)	9 (3.3)
Human parainfluenza virus 1	9 (1.1)	6 (2.3)	2 (0.7)	1 (0.4)
Human parainfluenza virus 2	3 (0.4)	0 (0.0)	0 (0.0)	3 (1.1)
Human parainfluenza virus 3	3 (0.4)	2 (0.8)	1 (0.3)	0 (0.0)
Human parainfluenza virus 4	12 (1.5)	3 (1.1)	8 (2.8)	1 (0.4)
Influenza A virus	118 (14.4)	19 (7.3)	57 (19.8)	42 (15.6)
Influenza A virus H1	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Influenza A virus H1-2009	18 (2.2)	0 (0.0)	10 (3.5)	8 (3.0)
Influenza A virus H3	97 (11.9)	18 (6.9)	48 (16.7)	31 (11.5)
Influenza B virus	33 (4.0)	4 (1.5)	10 (3.5)	19 (7.1)
RSV	74 (9.0)	25 (9.6)	43 (14.9)	6 (2.2)
RSV A	42 (5.1)	13 (5.0)	26 (9.0)	3 (1.1)
RSV B	32 (3.9)	12 (4.6)	17 (5.9)	3 (1.1)
Bordetella pertussis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Chlamydia pneumoniae	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Mycoplasma pneumoniae	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Table 4: Expected values (as determined by cobas® eplex RP3 panel) summary by Collection Site in Frozen Prospective Samples (Phase 1: November 2023 – February 2024)

Organism	All Sites (N=398) n(%)	Site 1 (N=398) n(%)
Adenovirus	4 (1.0)	4 (1.0)
Human enterovirus/rhinovirus	26 (6.5)	26 (6.5)
Human coronavirus	19 (4.8)	19 (4.8)
SARS-CoV-2	14 (3.5)	14 (3.5)
Human metapneumovirus	4 (1.0)	4 (1.0)

Organism	All Sites (N=398) n(%)	Site 1 (N=398) n(%)
Human parainfluenza virus 1	1 (0.3)	1 (0.3)
Human parainfluenza virus 2	0 (0.0)	0 (0.0)
Human parainfluenza virus 3	2 (0.5)	2 (0.5)
Human parainfluenza virus 4	1 (0.3)	1 (0.3)
Influenza A virus	19 (4.8)	19 (4.8)
Influenza A virus H1	0 (0.0)	0 (0.0)
Influenza A virus H1-2009	9 (2.3)	9 (2.3)
Influenza A virus H3	11 (2.8)	11 (2.8)
Influenza B virus	2 (0.5)	2 (0.5)
RSV	18 (4.5)	18 (4.5)
RSV A	6 (1.5)	6 (1.5)
RSV B	12 (3.0)	12 (3.0)
Bordetella pertussis	0 (0.0)	0 (0.0)
Chlamydia pneumoniae	0 (0.0)	0 (0.0)
Mycoplasma pneumoniae	0 (0.0)	0 (0.0)

Table 5: Expected values (as determined by cobas® eplex RP3 panel) summary by Collection Site in Fresh Prospective Samples (Phase 2: January 2025 – April 2025)

Organism	All Sites (N=2103) n(%)	Site 1 (N=600) n(%)	Site 2 (N=255) n(%)	Site 3 (N=600) n(%)	Site 4 (N=648) n(%)
Adenovirus	15 (0.7)	4 (0.7)	2 (0.8)	2 (0.3)	7 (1.1)
Human enterovirus/rhinovirus	216 (10.3)	50 (8.3)	35 (13.7)	64 (10.7)	67 (10.3)
Human coronavirus	119 (5.7)	20 (3.3)	30 (11.8)	31 (5.2)	38 (5.9)
SARS-CoV-2	67 (3.2)	26 (4.3)	2 (0.8)	0 (0.0)	39 (6.0)
Human metapneumovirus	52 (2.5)	10 (1.7)	6 (2.4)	15 (2.5)	21 (3.2)
Human parainfluenza virus 1	1 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)
Human parainfluenza virus 2	1 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
Human parainfluenza virus 3	17 (0.8)	4 (0.7)	1 (0.4)	6 (1.0)	6 (0.9)
Human parainfluenza virus 4	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
Influenza A virus	139 (6.6)	12 (2.0)	60 (23.5)	17 (2.8)	50 (7.7)
Influenza A virus H1	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Influenza A virus H1-2009	83 (3.9)	8 (1.3)	29 (11.4)	11 (1.8)	35 (5.4)
Influenza A virus H3	54 (2.6)	4 (0.7)	32 (12.5)	4 (0.7)	14 (2.2)

Organism	All Sites (N=2103) n(%)	Site 1 (N=600) n(%)	Site 2 (N=255) n(%)	Site 3 (N=600) n(%)	Site 4 (N=648) n(%)
Influenza B virus	12 (0.6)	3 (0.5)	2 (0.8)	4 (0.7)	3 (0.5)
RSV	92 (4.4)	4 (0.7)	35 (13.7)	29 (4.8)	24 (3.7)
RSV A	63 (3.0)	4 (0.7)	27 (10.6)	18 (3.0)	14 (2.2)
RSV B	29 (1.4)	0 (0.0)	8 (3.1)	11 (1.8)	10 (1.5)
Bordetella pertussis	3 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.5)
Chlamydia pneumoniae	2 (0.1)	2 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
Mycoplasma pneumoniae	10 (0.5)	0 (0.0)	3 (1.2)	4 (0.7)	3 (0.5)

Table 6: Expected values (as determined by cobas® eplex RP3 panel) summary by Collection Site in Frozen Prospective Samples (Phase 3: December 2025 – April 2026)

Organism	All Sites (N=818) n(%)	Site 1 (N=500) n(%)	Site 2 (N=318) n(%)
Adenovirus	32 (3.9)	19 (3.8)	13 (4.1)
Human enterovirus/rhinovirus	194 (23.7)	108 (21.6)	86 (27.0)
Human coronavirus	59 (7.2)	29 (5.8)	30 (9.4)
SARS-CoV-2	12 (1.5)	5 (1.0)	7 (2.2)
Human metapneumovirus	40 (4.9)	20 (4.0)	20 (6.3)
Human parainfluenza virus 1	9 (1.1)	4 (0.8)	5 (1.6)
Human parainfluenza virus 2	3 (0.4)	2 (0.4)	1 (0.3)
Human parainfluenza virus 3	3 (0.4)	2 (0.4)	1 (0.3)
Human parainfluenza virus 4	12 (1.5)	10 (2.0)	2 (0.6)
Influenza A virus	118 (14.4)	106 (21.2)	12 (3.8)
Influenza A virus H1	0 (0.0)	0 (0.0)	0 (0.0)
Influenza A virus H1-2009	18 (2.2)	18 (3.6)	0 (0.0)
Influenza A virus H3	97 (11.9)	87 (17.4)	10 (3.1)
Influenza B virus	33 (4.0)	29 (5.8)	4 (1.3)
RSV	74 (9.0)	64 (12.8)	10 (3.1)
RSV A	42 (5.1)	39 (7.8)	3 (0.9)
RSV B	32 (3.9)	25 (5.0)	7 (2.2)
Bordetella pertussis	0 (0.0)	0 (0.0)	0 (0.0)
Chlamydia pneumoniae	0 (0.0)	0 (0.0)	0 (0.0)
Mycoplasma pneumoniae	0 (0.0)	0 (0.0)	0 (0.0)

7.1.2. Clinical performance of the cobas® eplex RP3 panel

7.1.2.1. Comparator method

The performance of the **cobas® eplex** RP3 panel was compared to an FDA-cleared multiplexed molecular respiratory pathogen panel for 2 targets: SARS-CoV-2 and *B. pertussis.* For the remaining targets, the RP3 panel was compared to a composite comparator method consisting of up to 3 FDA-cleared multiplexed respiratory pathogen panels. Results for the composite comparator method were determined based on the interpretation shown in **Table 7** below.

Table 7: Comparator methods used to assess cobas® eplex RP3 panel clinical performance

Three multiplex assay results (any order)	Composite Comparator Result
Detected/Detected/Any	Detected (based on 2 assays detecting the target)
Not Detected/Not Detected/Any	Not Detected (based on 2 assays not detecting the target)
Detected/Not Detected/Missing*	Indeterminate (based on discordant results between 2 of the assays)
Missing*/Missing*/Any	Indeterminate (based on unavailable results from 2 of the assays)

*Results may be missing due to invalid results or insufficient volume to perform testing.

7.1.3. Prospective clinical samples

Clinical performance was evaluated in nasopharyngeal swab samples in VTM prospectively collected at 6 clinical sites. A total of 3355 samples were collected. Prior to the start of investigational testing, 30 samples were withdrawn due to sample handling or eligibility deviations. Of the 3325 prospectively collected samples eligible for testing, 3319 were evaluable. Samples with final, valid results and a valid comparator result were considered evaluable. Six prospectively collected samples were not evaluable because they did not have final, valid cobas® eplex RP3 panel results and were excluded from performance evaluations. Demographic information for prospectively collected samples is described in **Table 8** and **Table 9**. Subjects enrolled in this study were from a diverse demographic distribution and represent the intended patient population.

Table 8: Subject demographic data (sex) for prospectively collected samples by collection site (N=3319)

Sex	All sites N=3319 n (%)	Site 1 N=500 n (%)	Site 2 N=998 n (%)	Site 3 N=318 n (%)	Site 4 N=255 n (%)	Site 5 N=600 n (%)	Site 6 N=648 n (%)
Male	1646 (49.6)	259 (51.8)	473 (47.4)	165 (51.9)	123 (48.2)	301 (50.2)	325 (50.2)
Female	1671 (50.3)	241 (48.2)	525 (52.6)	153 (48.1)	131 (51.4)	298 (49.7)	323 (49.8)
Unknown	2 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.2)	0 (0.0)

Table 9: Subject demographic data (age) for prospectively collected samples by collection site (N=3319)

Age	All sites N=3319 n (%)	Site 1 N=500 n (%)	Site 2 N=998 n (%)	Site 3 N=318 n (%)	Site 4 N=255 n (%)	Site 5 N=600 n (%)	Site 6 N=648 n (%)
Age: 0 – 1 years	333 (10.0)	118 (23.6)	4 (0.4)	143 (45.0)	16 (6.3)	10 (1.7)	42 (6.5)
Age: > 1 – 5 years	482 (14.5)	212 (42.4)	49 (4.9)	76 (23.9)	47 (18.4)	13 (2.2)	85 (13.1)
Age: > 5 – 21 years	503 (15.2)	170 (34.0)	60 (6.0)	99 (31.1)	68 (26.7)	29 (4.8)	77 (11.9)
Age: > 21 – 65 years	1148 (34.6)	0 (0.0)	477 (47.8)	0 (0.0)	77 (30.2)	327 (54.5)	267 (41.2)
Age: > 65 years	853 (25.7)	0 (0.0)	408 (40.9)	0 (0.0)	47 (18.4)	221 (36.8)	177 (27.3)

7.1.3.1. Prospective clinical performance

Positive percent agreement (PPA) was calculated by dividing the number of true positive (TP) results by the sum of TP and false negative (FN) results, while negative percent agreement (NPA) was calculated by dividing the number of true negative (TN) results by the sum of TN and false positive (FP) results. A TP result was one where the detected **cobas® eplex** RP3 panel result matched the detected comparator method result, while a TN result was one where a negative **cobas® eplex** RP3 panel result matched a negative comparator method result. The two-sided 95% confidence interval was also calculated.

SARS-CoV-2 and *B. pertussis* were evaluated versus a single comparator method. Discrepant FP or FN results were further investigated with either a qPCR test and/or another FDA-cleared multiplexed molecular respiratory pathogen panel to assess the presence or absence of the pathogen. For the targets evaluated versus the composite comparator method, the third assay result was used to assess the presence of the pathogen in discrepant FP results. These results are summarized in footnotes in the tables below.

A total of 3319 prospectively collected samples (2103 tested fresh and 1216 tested after previously frozen) were evaluated for 19 **cobas® eplex** RP3 panel reportable targets. PPA and NPA results are summarized by target in Error! Reference source not found. below.

Table 10: Positive percent agreement (PPA) and negative percent agreement (NPA) of the cobas® eplex RP3 panel with the comparator method in the clinical study (prospective)

Organism	Prevalence	Positive % agreement TP/TP+FN	Positive % agreement PPA (95% CI)	Negative % agreement TN/TN+FP	Negative % agreement NPA (95% CI)
Adenovirus	1.3%	39/42	92.9 (81.0-97.5)	3262/3274[a]	99.6 (99.4-99.8)
Human enterovirus/rhinovirus	12.4%	393/411	95.6 (93.2-97.2)	2862/2905[b]	98.5 (98.0-98.9)
Human coronavirus	5.9%	183/196	93.4 (89.0-96.1)	3105/3118[c]	99.6 (99.3-99.8)
SARS-CoV-2	2.8%	86/94[d]	91.5 (84.1-95.6)	3216/3223[e]	99.8 (99.6-99.9)
Human metapneumovirus	3.0%	96/101	95.0 (88.9-97.9)	3215/3215	100 (99.9-100)
Human parainfluenza virus 1	0.4%	11/12	91.7 (64.6-98.5)	3304/3304	100 (99.9-100)
Human parainfluenza virus 2	0.1%	4/4	100 (51.0-100)	3312/3312	100 (99.9-100)
Human parainfluenza virus 3	0.8%	21/25	84.0 (65.3-93.6)	3291/3291	100 (99.9-100)
Human parainfluenza virus 4	0.4%	13/13	100 (77.2-100)	3302/3303[f]	100 (99.8-100)
Influenza A virus[g]	8.4%	272/280	97.1 (94.5-98.5)	3031/3035[h]	99.9 (99.7-99.9)
Influenza A virus H1	0.0%	0/0	---	3316/3316	100 (99.9-100)
Influenza A virus H1-2009	3.2%	106/106	100 (96.5-100)	3206/3209[i]	99.9 (99.7-100)
Influenza A virus H3	5.1%	159/169	94.1 (89.5-96.8)	3144/3147[j]	99.9 (99.7-100)
Influenza B virus	1.4%	47/47	100 (92.4-100)	3269/3269	100 (99.9-100)
RSV A	3.3%	103/108	95.4 (89.6-98.0)	3192/3197[k]	99.8 (99.6-99.9)
RSV B	2.1%	68/71	95.8 (88.3-98.6)	3231/3234[l]	99.9 (99.7-100)
Bordetella pertussis	0.1%	3/3	100 (43.9-100)	3314/3314	100 (99.9-100)
Chlamydia pneumoniae	0.1%	2/3	66.7 (20.8-93.9)	3313/3313	100 (99.9-100)
Mycoplasma pneumoniae	0.5%	10/16	62.5 (38.6-81.5)	3300/3300	100 (99.9-100)

Organism	Prevalence	Positive % agreement TP/TP+FN	Positive % agreement PPA (95% CI)	Negative % agreement TN/TN+FP	Negative % agreement NPA (95% CI)

[a] Adenovirus was detected in 5 of 12 FP samples by 1 of the 3 composite comparator assays.

[b] Human enterovirus/rhinovirus was detected in 19 of 43 FP samples by 1 of the 3 composite comparator assays.

[c] Human coronavirus was detected in 6 of 13 FP samples by 1 of the 3 composite comparator assays.

[d] SARS-CoV-2 was not detected in 7 of 8 FN samples by a multiplex assay.

[e] SARS-CoV-2 was detected in 3 of 7 FP samples by a multiplex assay.

[f] Human parainfluenza virus 4 was detected in 1 of 1 FP samples by 1 of the 3 composite comparator assays.

[g] Influenza A comparator results contain 104 samples with A H1-2009, 165 samples with A H3, 2 samples with both A H1-2009 and A H3, and 9 samples with no subtype detected.

[h] Influenza A virus was detected in 3 of 4 FP samples by 1 of the 3 composite comparator assays.

[i] Influenza A virus H1-2009 was detected in 1 of 2 FP samples by 1 of the 3 composite comparator assays. In the other FP sample, Influenza A without a subtype was detected by 2 of the 3 composite comparator assays.

[j] Influenza A virus H3 was detected in 3 of 3 FP samples by 1 of the 3 composite comparator assays.

[k] RSV was detected in 3 of 5 FP samples by 1 of the 3 composite comparator assays.

[l] RSV or RSV B was detected in 3 of 3 FP samples by 1 of the 3 composite comparator assays.

The **cobas® eplex** RP3 panel detects the influenza A virus and the H1, H1-2009, and H3 subtypes using unique assays for each. While most samples will result in detection of the influenza A virus matrix and a subtype, it is possible to generate a result of an influenza A virus matrix without a subtype or an influenza A virus subtype without the matrix. This can occur due to low virus titer or the presence of a novel strain. The prevalence of influenza A virus and influenza A virus subtypes detected by the **cobas® eplex** RP3 panel from the initial testing during the prospective clinical collection is summarized in **Table 11** below.

Table 11: Summary of Influenza A virus and subtype results with the cobas® eplex RP3 panel in prospectively collected samples

Organism	n (% of total influenza A virus samples)
Samples with any influenza A virus detected	285 (100%)
Influenza A virus (no subtype detected)	17 (6.0%)
Influenza A virus H1-2009 (no matrix detected)	6 (2.1%)
Influenza A virus H3 (no matrix detected)	3 (1.1%)
Influenza A virus and Influenza A virus H1-2009	103 (36.1%)
Influenza A virus and Influenza A virus H3	154 (54.0%)
Influenza A virus, Influenza A virus H1-2009, and Influenza A virus H3	2 (0.7%)

7.1.4. Retrospective clinical samples

To supplement the number of positives for targets that were not sufficiently represented in the prospective collection, additional nasopharyngeal swabs in VTM were retrospectively collected from 7 sites. A total of 255 nasopharyngeal swab samples that had previously tested positive for one or more of the target organisms during standard-of-care (SOC) testing were collected and stored frozen. No samples were withdrawn prior to the start of investigational testing. Prior to investigational testing, the composition and integrity of the retrospective samples were confirmed with qPCR testing or an FDA cleared multiplexed respiratory pathogen panel. All 255 samples were evaluable. Demographic information for retrospectively collected samples is described in **Table 12** and **Table 13.** Subjects enrolled in this study were from a diverse demographic distribution and represent the intended patient population.

Table 12: Subject demographic data (sex) for retrospectively collected samples (N=255)

Sex	All sites N=255 n (%)
Male	99 (38.8)
Female	85 (33.3)
Unknown	71 (27.8)

Table 13: Subject demographic data (age) for retrospectively collected samples (N=255)

Age	All sites N=255 n (%)
Age: 0 – 1 years	34 (13.3)
Age: > 1 – 5 years	33 (12.9)
Age: > 5 – 21 years	32 (12.5)
Age: > 21 – 65 years	54 (21.2)
Age: > 65 years	31 (12.2)
Unknown	71 (27.8)

7.1.4.1. Retrospective clinical performance

A total of 255 retrospectively collected samples were evaluated for 19 **cobas® eplex** RP3 panel reportable targets. PPA and NPA (versus the same comparator methods described above) were calculated and are summarized by target in **Table 14**.

Table 14: Positive percent agreement (PPA) and negative percent agreement (NPA) of the cobas® eplex RP3 panel with comparator method (retrospective collection)

Organism	Positive % agreement TP/TP+FN	Positive % agreement PPA (95% CI)	Negative % agreement TN/TN+FP	Negative % agreement NPA (95% CI)
Adenovirus	21/22	95.5 (78.2-99.2)	199/200	99.5 (97.2-99.9)
Human enterovirus/rhinovirus	18/21	85.7 (65.4-95.0)	195/197[a]	99.0 (96.4-99.7)
Human coronavirus	4/4	100 (51.0-100)	217/218[b]	99.5 (97.4-99.9)
SARS-CoV-2	72/74[c]	97.3 (90.7-99.3)	168/170	98.8 (95.8-99.7)
Human metapneumovirus	2/2	100 (34.2-100)	220/220	100 (98.3-100)
Human parainfluenza virus 1	17/17	100 (81.6-100)	205/205	100 (98.2-100)
Human parainfluenza virus 2	15/15	100 (79.6-100)	207/207	100 (98.2-100)
Human parainfluenza virus 3	14/14	100 (78.5-100)	208/208	100 (98.2-100)
Human parainfluenza virus 4	12/12	100 (75.8-100)	210/210	100 (98.2-100)
Influenza A virus	0/0	---	221/221	100 (98.3-100)
Influenza A virus H1	0/0	---	222/222	100 (98.3-100)
Influenza A virus H1-2009	0/0	---	222/222	100 (98.3-100)
Influenza A virus H3	0/0	---	222/222	100 (98.3-100)
Influenza B virus	23/23	100 (85.7-100)	199/199	100 (98.1-100)
RSV A	2/2	100 (34.2-100)	219/219	100 (98.3-100)
RSV B	2/2	100 (34.2-100)	219/219	100 (98.3-100)
Bordetella pertussis	18/18	100 (82.4-100)	225/226[d]	99.6 (97.5-99.9)
Chlamydia pneumoniae	19/20	95.0 (76.4-99.1)	202/202	100 (98.1-100)
Mycoplasma pneumoniae	21/21	100 (84.5-100)	201/201	100 (98.1-100)

[a] Human enterovirus/rhinovirus was detected in 1 of 2 FP samples by 1 of the 3 composite comparator assays.

[b] Human coronavirus was detected in 1 of 1 FP samples by 1 of the 3 composite comparator assays.

[c] SARS-CoV-2 was not detected in 1 of 2 FN samples by a multiplex assay.

[d] *B. pertussis* was detected in 1 of 1 FP samples by qPCR testing and a multiplex assay.

7.1.5. Contrived sample performance

There were 410 contrived samples created and tested to supplement the low prevalence targets on the RP3 panel; 237 contained one low prevalence organism and did not contain the other contrived organisms and 173 were negative for the contrived organisms. Two samples were not evaluable due to a final, invalid investigational test result. A total of 408 contrived samples were evaluable with the **cobas® eplex** RP3 panel. PPA and NPA results (versus known contrived organism) are summarized for these low prevalence organisms in **Table 15**.

Table 15: Positive percent agreement (PPA) and negative percent agreement (NPA) of the cobas® eplex RP3 panel with comparator method (contrived samples)

Organism	Positive % agreement TP/TP+FN	Positive % agreement PPA (95% CI)	Negative % agreement TN/TN+FP	Negative % agreement NPA (95% CI)
Influenza A virus	54/54	100 (93.4-100)	354/354	100 (98.9-100)
Influenza A virus H1	52/54	96.3 (87.5-99.0)	354/354	100 (98.9-100)
Bordetella pertussis	61/62	98.4 (91.4-99.7)	346/346	100 (98.9-100)
Chlamydia pneumoniae	61/61	100 (94.1-100)	347/347	100 (98.9-100)
Mycoplasma pneumoniae	58/58	100 (93.8-100)	350/350	100 (98.9-100)

7.1.6. Co-detections in prospective clinical samples

The **cobas® eplex** RP3 panel identified a total of 151 co-detections (4.5%) in 3319 prospectively collected samples. Of these, 140 (4.2%) had two organisms detected, 10 (0.3%) had three organisms detected, and 1 (<0.1%) had four organisms detected. Of the 151 co-detected samples, 39 included 1 or more organisms that had not been detected by the comparator method(s). Results are summarized in **Table 16.**

Table 16: Distinct co-detection combinations detected by the cobas® eplex RP3 panel and discrepancies with comparator method in the prospective clinical samples

Organism 1	Organism 2	Organism 3	Organism 4	Total number Of co-detections (% of samples)	Number of discrepant co-detections	Discrepant organism(s)[a]
ADV	CoV	-	-	1 (0.03%)	0	
ADV	CoV	EV/RV	-	1 (0.03%)	0	
ADV	CoV	EV/RV	Flu AH3	1 (0.03%)	0	
ADV	CoV	HMPV	-	1 (0.03%)	0	
ADV	EV/RV	-	-	16 (0.48%)	5	ADV (5), EV/RV (1)
ADV	EV/RV	RSV B	-	2 (0.06%)	1	ADV (1)
ADV	EV/RV	SARS	-	1 (0.03%)	1	SARS (1)
ADV	Flu AH3	-	-	3 (0.09%)	0	
ADV	HMPV	-	-	1 (0.03%)	0	
ADV	Mpneum	-	-	1 (0.03%)	0	
ADV	PIV 3	PIV 4	-	1 (0.03%)	1	PIV 4 (1)

Organism 1	Organism 2	Organism 3	Organism 4	Total number Of co-detections (% of samples)	Number of discrepant co-detections	Discrepant organism(s)[a]
ADV	PIV 4	-	-	1 (0.03%)	0	
ADV	RSV A	-	-	1 (0.03%)	0	
ADV	RSV B	-	-	2 (0.06%)	1	ADV (1)
Bpert	EV/RV	-	-	2 (0.06%)	0	
CoV	EV/RV	-	-	14 (0.42%)	3	CoV (1), EV/RV (2)
CoV	Flu A(unk)	-	-	1 (0.03%)	0	
CoV	Flu AH3	-	-	4 (0.12%)	0	
CoV	Flu B	-	-	1 (0.03%)	0	
CoV	FluA09H1N1	-	-	3 (0.09%)	0	
CoV	HMPV	-	-	2 (0.06%)	0	
CoV	PIV 1	-	-	1 (0.03%)	0	
CoV	PIV 4	-	-	1 (0.03%)	0	
CoV	RSV A	-	-	5 (0.15%)	2	CoV (2)
CoV	RSV B	-	-	6 (0.18%)	2	CoV (1), RSV B (1)
CoV	SARS	-	-	3 (0.09%)	1	CoV (1)
EV/RV	Flu A(unk)	-	-	1 (0.03%)	1	Flu A(unk) (1)
EV/RV	Flu AH3	-	-	10 (0.30%)	3	EV/RV (3)
EV/RV	Flu AH3	RSV A	-	2 (0.06%)	1	EV/RV (1), RSV A (1)
EV/RV	Flu B	-	-	2 (0.06%)	1	EV/RV (1)
EV/RV	FluA09H1N1	-	-	6 (0.18%)	5	EV/RV (5)
EV/RV	FluA09H1N1	RSV A	-	1 (0.03%)	1	EV/RV (1)
EV/RV	FluA09H1N1	SARS	-	1 (0.03%)	1	SARS (1)
EV/RV	HMPV			9 (0.27%)	1	EV/RV (1)
EV/RV	Mpneum			2 (0.06%)	0	
EV/RV	PIV 1			1 (0.03%)	0	
EV/RV	PIV 3	-	-	2 (0.06%)	0	
EV/RV	PIV 4	-	-	2 (0.06%)	1	EV/RV (1)
EV/RV	RSV A	-	-	15 (0.45%)	3	EV/RV (3)
EV/RV	RSV B	-	-	4 (0.12%)	0	
EV/RV	SARS	-	-	4 (0.12%)	2	EV/RV (1), SARS (1)
Flu AH3	FluA09H1N1	-	-	2 (0.06%)	0	
Flu AH3	PIV 1	-	-	1 (0.03%)	0	
Flu AH3	PIV 4	-	-	2 (0.06%)	0	

Organism 1	Organism 2	Organism 3	Organism 4	Total number Of co-detections (% of samples)	Number of discrepant co-detections	Discrepant organism(s)[a]
Flu AH3	RSV A	-	-	1 (0.03%)	1	RSV A (1)
Flu B	SARS	-	-	1 (0.03%)	0	
FluA09H1N1	RSV A	-	-	1 (0.03%)	0	
HMPV	RSV A	-	-	1 (0.03%)	0	
Mpneum	RSV A	-	-	1 (0.03%)	0	
PIV 1	SARS	-	-	1 (0.03%)	0	
PIV 3	RSV B	-	-	1 (0.03%)	1	RSV B (1)
PIV 4	SARS	-	-	1 (0.03%)	0	

Note: ADV= adenovirus, CoV= human coronavirus (229E, HKU1, NL63, OC43), SARS =SARS-CoV-2, HMPV= human metapneumovirus, EV/RV= human enterovirus/rhinovirus, Flu= Influenza virus, (unk)= unknown subtype, PIV= human parainfluenza virus, RSV= respiratory syncytial virus, Bpert = *B. pertussis* , Cpneum= *C. pneumoniae*, Mpneum= *M. pneumoniae*

[a] A discrepant organism is defined as one that was detected by the **cobas® eplex** RP3 panel but not by the comparator method(s).

Table 17: Total Distinct co-detection combinations detected by the cobas® eplex RP3 panel in the prospective clinical samples

Distinct co-detection combinations detected by the cobas® eplex RP3 Panel	Total number Of co-detections (% of samples)	Number of discrepant co-detections	Discrepant organism(s)[a,b]
Total Number of Co-Detections	151 (4.5%)	39	41/314
Total Number with 2 Organisms Detected	140 (4.2%)	33	34/280
Total Number with 3 Organisms Detected	10 (0.3%)	6	7/30
Total Number with 4 Organisms Detected	1 (0.0%)	0	0/4

[a] A discrepant organism is defined as one that was detected by the **cobas® eplex** RP3 panel but not by the comparator method(s).

[b] Of the 41 discrepant organisms, the discrepant organism was detected by a multiplex test in 24/41:

-In 4/7 samples, adenovirus was detected by a multiplex test.

-In 1/5 samples, human coronavirus was detected by a multiplex test.

-In 12/20 samples, Human enterovirus/Rhinovirus was detected by a multiplex test.

-In 1/1 sample, influenza A virus was detected by a multiplex test.

-In 1/1 sample, human parainfluenza virus 4 was detected by a multiplex test.

-In 1/2 samples, RSV A was detected by a multiplex test.

-In 2/2 samples, RSV B was detected by a multiplex test.

-In 2/3 samples, SARS-CoV-2 was detected by a multiplex test.

Table 18: Additional distinct co-detection combinations not detected by the RP3 panel and detected with comparator methods in the prospective clinical samples

Organism 1	Organism 2	Organism 3	Number Of co-detections (% of samples)	Number of discrepant co-detections	Discrepant organism(s)[a]
ADV	CoV	RSV A	1 (0.03%)	1	ADV (1)
ADV	EV/RV	-	2 (0.06%)	2	ADV (2)
ADV	Mpneum	PIV 3	1 (0.03%)	1	PIV 3 (1)
CoV	EV/RV	-	3 (0.09%)	3	CoV (2), EV/RV (1)
CoV	Flu AH3	-	1 (0.03%)	1	CoV (1)
CoV	RSV B	-	1 (0.03%)	1	RSV B (1)
CoV	SARS	-	1 (0.04%)	1	SARS (1)
EV/RV	Flu A(unk)	-	1 (0.03%)	1	Flu A(unk) (1)
EV/RV	Flu AH3	-	1 (0.03%)	1	Flu AH3 (1)
EV/RV	FluA09H1N1	-	1 (0.03%)	1	EV/RV (1)
EV/RV	HMPV	-	3 (0.09%)	1	EV/RV (2), HMPV (1)
EV/RV	Mpneum	-	2 (0.06%)	2	Mpneum (2)
EV/RV	Mpneum	SARS	1 (0.03%)	1	Mpneum (1)
EV/RV	PIV 1	-	1 (0.03%)	1	PIV 1 (1)
EV/RV	RSV B	-	1 (0.03%)	1	EV/RV (1), RSV B (1)
EV/RV	SARS	-	1 (0.03%)	1	SARS (1)
Flu AH3	HMPV		1 (0.03%)	1	Flu AH3 (1), HMPV (1)
Flu AH3	PIV 3		1 (0.03%)	1	PIV 3 (1)
Flu AH3	PIV 4		1 (0.03%)	1	Flu AH3 (1)
Flu AH3	SARS		2 (0.06%)	2	SARS (2)
Mpneum	RSV B		1 (0.03%)	1	Mpneum (1)
RSV B	SARS		1 (0.03%)	1	SARS (1)

[a] A discrepant organism is defined as one that was detected by the comparator method(s) but not by the **cobas® eplex** RP3 panel.

Table 19: Total Distinct co-detection combinations not detected by the cobas® eplex RP3 panel and discrepancies with comparator methods in the prospective clinical samples

Distinct co-detection combinations not detected by the cobas® eplex RP3 Panel	Total number Of co-detections (% of samples)	Number of discrepant co-detections	Discrepant organism(s)[a]
Total Number of Co-Detections	29 (0.9%)	29	31/61

Distinct co-detection combinations not detected by the cobas® eplex RP3 Panel	Total number Of co-detections (% of samples)	Number of discrepant co-detections	Discrepant organism(s)[a]
Total Number with 2 Organisms Detected	26 (0.8%)	26	28/52
Total Number with 3 Organisms Detected	3 (0.1%)	3	3/9
Total Number with 4 Organisms Detected	0 (0.0%)	0	0/0

[a] A discrepant organism is defined as one that was not detected by the **cobas® eplex** RP3 panel but was detected by the comparator method(s).

7.1.7. Clinical study for cobas® eplex RP3 panel system performance

A total of 4010 samples (including prospective, retrospective, and contrived samples) were initially tested in the clinical evaluations and 96.1% (3855/4010; 95% CI: 95.5%-96.7%) generated valid results on the first attempt. The 155 invalid samples were re-tested and after re-test, 8 samples had invalid results. The final validity rate was 4002/4010 = 99.8% (95% CI: 99.6%-99.9%).

7.2. Selected Analytical Studies

7.2.1. Limit of Detection

The limit of detection (LoD), or analytical sensitivity was identified and verified for each viral and bacterial target on the **cobas® eplex** RP3 panel using quantified reference strains/isolates. Serial dilutions were prepared in a natural clinical matrix (pooled, negative nasopharyngeal swab in VTM samples) with one or more organisms per series, and at least 20 replicates per target were tested in the study. The limit of detection was defined as the lowest concentration at which each target is detected at least 95% of the time. The confirmed LoD for each cobas® eplex RP3 panel organism is shown in **Table 20**.

Table 20: LoD results summary

Target	Strain	LoD concentration
Adenovirus	Type 1 (C)	1×10^{2} $TCID_{50}$/mL
Adenovirus	Type 7A (B)	2×10^{0} $TCID_{50}$/mL
Human enterovirus/rhinovirus	Enterovirus Type 68 (2007)	1×10^{-1} $TCID_{50}$/mL
Human enterovirus/rhinovirus	Rhinovirus 1A	1.5×10^{-1} $TCID_{50}$/mL
Human enterovirus/rhinovirus	Rhinovirus B14	3×10^{-1} $TCID_{50}$/mL
Human enterovirus/rhinovirus	Rhinovirus C[a]	1×10^{4} copies/mL
Human coronavirus 229E	229E	1×10^{-1} $TCID_{50}$/mL

Target	Strain	LoD concentration
Human coronavirus HKU1	HKU1[a]	5 x 10^3 copies/mL
Human coronavirus NL63	NL63	7.5 x 10^{-2} $TCID_{50}$/mL
Human coronavirus OC43	OC43	5 x 10^{-1} $TCID_{50}$/mL
SARS-CoV-2	USA-WA1/2020	1 x 10^{-1} $TCID_{50}$/mL
SARS-CoV-2	Lin.BQ.1.1; Omicron Var. (USA/MD-HP38861/2022)	5 x 10^{-2} $TCID_{50}$/mL
SARS-CoV-2	WHO 2nd International standard (Beta CoV/Australia/VIC01/2020)	6.31 x 10^3 IU/mL
Human metapneumovirus	A1, Type 9 (strain: A1 IA3-2002)	6 x 10^{-2} $TCID_{50}$/mL
Human metapneumovirus	A2, Type 29 (strain: I27-2004)	2 x 10^1 $TCID_{50}$/mL
Human metapneumovirus	B1, Type 3 (strain: B1 Peru2-2002)	2 x 10^0 $TCID_{50}$/mL
Human metapneumovirus	B2, Type 4 (strain: B2 Peru1-2002)	2.25 x 10^1 $TCID_{50}$/mL
Human parainfluenza Virus 1	Clinical Isolate	4 x 10^0 $TCID_{50}$/mL
Human parainfluenza Virus 2	Clinical Isolate	1.5 x 10^2 $TCID_{50}$/mL
Human parainfluenza Virus 3	Clinical Isolate	1.5 x 10^1 $TCID_{50}$/mL
Human parainfluenza Virus 4	4a	9 x 10^1 $TCID_{50}$/mL
Influenza A virus	A/Brisbane/59/07	3 x 10^{-1} $TCID_{50}$/mL
Influenza A virus H1	A/Brisbane/59/07	3 x 10^{-1} $TCID_{50}$/mL
Influenza A virus H1-2009	A/Victoria/4897/22	3 x 10^{-1} $TCID_{50}$/mL
Influenza A virusH3	A/Darwin/9/21	3 x 10^{-1} $TCID_{50}$/mL
Influenza A virus H3	A/Perth/16/2009	1 x 10^1 $TCID_{50}$/mL
Influenza A virus H3	A/Victoria/361/2011	5 x 10^{-1} $TCID_{50}$/mL
Influenza A virus H3	H3N2 Brisbane/10/07	5 x 10^0 $TCID_{50}$/mL
Influenza B virus (Victoria Lineage)	B/Austria/1359417/21	1 x 10^{-1} $TCID_{50}$/mL
Influenza B virus (Victoria Lineage)	B/Colorado/6/17	1 x 10^{-1} $TCID_{50}$/mL
Influenza B virus (Yamagata Lineage)	B/Massachusetts/02/2012	1 x 10^0 $TCID_{50}$/mL
Influenza B virus (Yamagata Lineage)	B/Texas/06/2011	1 x 10^0 $TCID_{50}$/mL
Influenza B virus (Yamagata Lineage)	B/Wisconsin/01/2010	1 x 10^{-1} $TCID_{50}$/mL
RSV A	2006 Isolate	1.5 x 10^{-1} $TCID_{50}$/mL
RSV B	CH93(18)-18	6 x 10^{-2} $TCID_{50}$/mL
Bordetella pertussis	18323 [NCTC 10739]	1.5 x 10^3 CFU/mL
Chlamydia pneumoniae	AR-39	9 x 10^2 IFU/mL
Mycoplasma pneumoniae	FH strain of Eaton Agent [NCTC 10119]	3 x 10^1 CFU/mL

Target	Strain	LoD concentration

[a] Clinical samples confirmed positive for human coronavirus HKU1 and rhinovirus C by bi-directional sequencing and quantified by digital PCR were used for determination of LoD.

$TCID_{50}$/mL= 50% tissue culture infectious dose per mL; IU/mL= international units per mL; CFU/mL= colony forming units per mL; IFU/mL= inclusion forming units per mL.

7.2.2. Analytical Reactivity (Inclusivity)

Inclusivity of all RP3 panel targets was evaluated using a panel of strains/isolates representing the genetic, temporal, and geographic diversity of each target on the panel to demonstrate analytical reactivity. Each strain/isolate was tested in triplicate at 3x LoD in natural clinical matrix (pooled, negative nasopharyngeal swab in VTM samples); if the organism was not detected at this concentration, testing of higher concentrations was performed. Additional in silico analysis was also performed on adenovirus, human enterovirus/rhinovirus, SARS-CoV-2, influenza A virus, and *M. pneumoniae* strains.

All of the strains/isolates tested for inclusivity were detected by the cobas® eplex RP3 panel. Results of analytical reactivity are shown in **Table 21** to **Table 34.** Strains/isolates tested as part of the limit of detection studies were not retested; results for that study can be found in **Table 20.**

Table 21: Analytical reactivity (inclusivity) results for adenovirus

Adenovirus species	Serotype	Concentration	Multiple of LoD detected
A	Type 31	3×10^2 $TCID_{50}$/mL	3x
B	Type 3	6×10^0 $TCID_{50}$/mL	3x
B	Type 11	2×10^3 $TCID_{50}$/mL	1000x[a]
B	De Wit Type 14	6×10^0 $TCID_{50}$/mL	3x
B	Ch.79 Type 16	3×10^2 $TCID_{50}$/mL	100x[b]
B	Type 21	6×10^0 $TCID_{50}$/mL	3x
B	Compton Type 34	2×10^2 $TCID_{50}$/mL	100x[a]
B	Holden Type 35	2×10^1 $TCID_{50}$/mL	10x
C	Type 2	3×10^2 $TCID_{50}$/mL	3x
C	Type 5	1×10^3 $TCID_{50}$/mL	10x
C	Type 6	1×10^5 $TCID_{50}$/mL	1000x[b]
D	Type 26	3×10^2 $TCID_{50}$/mL	3x
D	Type 37	3×10^2 $TCID_{50}$/mL	3x
E	Type 4	3×10^2 $TCID_{50}$/mL	3x
F	Type 40/Strain Dugan	3×10^2 $TCID_{50}$/mL	3x
F	Type 41/ Strain Tak	3×10^2 $TCID_{50}$/mL	3x

Adenovirus species	Serotype	Concentration	Multiple of LoD detected

[a] In silico analysis revealed that lower sensitivity may be a result of mismatches in the adenovirus assay primers and/or probe sequences.

[b] In silico analysis revealed good homology to adenovirus primers and probe sequences. Reduced sensitivity may be the result of incorrect estimation of genetic material present in the culture of this or the reference strain (TCID50/mL value is based only on infectious virus particles).

Additional in silico analysis was conducted for an adenovirus serotype previously tested with earlier panel versions (the RP and RP2 panels) but no longer commercially available for purchase to assess the ability of the **cobas® eplex** RP3 panel to detect this strain.

Table 22: Predicted (in silico) reactivity (inclusivity) results for adenovirus

Adenovirus species	Serotype	Predicted Adenovirus Result
B	WanType 50	Detected

Table 23: Analytical reactivity (inclusivity) results for human enterovirus/rhinovirus

Human enterovirus/rhinovirus Target	Strain	Concentration	Multiple of LoD detected
Coxsackievirus	A9	1×10^{1} $TCID_{50}$/mL	100x[a]
Coxsackievirus	A10	1×10^{2} $TCID_{50}$/mL	1000x[b]
Coxsackievirus	A21	1×10^{0} $TCID_{50}$/mL	10x
Coxsackievirus	A24	4.5×10^{-1} $TCID_{50}$/mL	3x
Coxsackievirus	B2	4.5×10^{-1} $TCID_{50}$/mL	3x
Coxsackievirus	B3	4.5×10^{-1} $TCID_{50}$/mL	3x
Coxsackievirus	B4	4.5×10^{-1} $TCID_{50}$/mL	3x
Coxsackievirus	B5	4.5×10^{-1} $TCID_{50}$/mL	3x
Echovirus	9	4.5×10^{-1} $TCID_{50}$/mL	3x
Echovirus	E6	1×10^{1} $TCID_{50}$/mL	100x[b]
Echovirus	30	4.5×10^{-1} $TCID_{50}$/mL	3x
Enterovirus	Type 71	3×10^{-1} $TCID_{50}$/mL	3x
Enterovirus	Type D68 (Isolate: US/NY/22-42858)	1×10^{1} $TCID_{50}$/mL	100x[b]
Rhinovirus	Type A2	1.5×10^{1} $TCID_{50}$/mL	100x[b]
Rhinovirus	Type A7	4.5×10^{-1} $TCID_{50}$/mL	3x
Rhinovirus	Type A16	1.5×10^{1} $TCID_{50}$/mL	100x[b]
Rhinovirus	Type A18	4.5×10^{-1} $TCID_{50}$/mL	3x

Human enterovirus/rhinovirus Target	Strain	Concentration	Multiple of LoD detected
Rhinovirus	Type A34	1.5 x 10^0 $TCID_{50}$/mL	10x
Rhinovirus	Type A57	1.5 x 10^1 $TCID_{50}$/mL	100x[b]
Rhinovirus	Type A77	4.5 x 10^{-1} $TCID_{50}$/mL	3x
Rhinovirus	277G	4.5 x 10^{-1} $TCID_{50}$/mL	3x
Rhinovirus	Type B17	3 x 10^1 PFU/mL	100x[b]
Rhinovirus	Type B42	9 x 10^{-1} $TCID_{50}$/mL	3x
Rhinovirus	Type B83	3 x 10^2 $TCID_{50}$/mL	1000x[b]
Rhinovirus	Type B84	9 x 10^{-1} $TCID_{50}$/mL	3x
Rhinovirus	FO2-2547	9 x 10^{-1} $TCID_{50}$/mL	3x

[a] In silico analysis revealed good homology to the human enterovirus/rhinovirus primers and/or probe sequences. Reduced sensitivity may be the result of incorrect estimation of genetic material present in the culture of this or the reference strain (TCID50/mL value is based only on infectious virus particles).

[b] In silico analysis revealed that lower sensitivity may be a result of mismatches in the human enterovirus/rhinovirus primers and/or probe sequences.

PFU/mL= placque forming units per mL

Additional in silico analysis was conducted for a human enterovirus/rhinovirus strain previously tested with earlier panel versions (the RP and RP2 panels) but no longer commercially available for purchase to assess the ability of the **cobas® eplex** RP3 panel to detect this strain.

Table 24: Predicted (in silico) reactivity (inclusivity) results for human enterovirus/rhinovirus

Human enterovirus/rhinovirus Target	Strain	Predicted Human enterovirus/rhinovirus Result
Rhinovirus B	Type B3	Detected

Table 25: Analytical reactivity (inclusivity) results for SARS-CoV-2

Target	Strain	Concentration	Multiple of LoD detected
SARS-CoV-2	Lineage B.1.1.7; Alpha Variant (England/204820464/2020)	1 x 10^0 $TCID_{50}$/mL	10x
SARS-CoV-2	Lineage B.1.351; Beta Variant (South Africa/KRISP-K005325/2020)	3 x 10^{-1} $TCID_{50}$/mL	3x
SARS-CoV-2	Lineage P.1; Gamma Variant (Japan/TY7-503/2021)	3 x 10^{-1} $TCID_{50}$/mL	3x
SARS-CoV-2	Lineage B.1.617.2; Delta Variant (USA/PHC658/2021)	3 x 10^{-1} $TCID_{50}$/mL	3x
SARS-CoV-2	Lineage B.1.617.1; Kappa Variant (USA/CA-Stanford-15_S02/2021)	1 x 10^0 $TCID_{50}$/mL	10x
SARS-CoV-2	Lineage P2_2021; Zeta Variant (NY-Wadsworth-21006055-01/2021)	1 x 10^0 $TCID_{50}$/mL	10x
SARS-CoV-2	Lineage BA.2.3; Omicron Variant (USA/MD-HP24556/2022)	3 x 10^{-1} $TCID_{50}$/mL	3x

Target	Strain	Concentration	Multiple of LoD detected
SARS-CoV-2	Lineage BA.5; Omicron Variant (USA/COR-22-063113/2022)	3 x 10^{-1} $TCID_{50}$/mL	3x
SARS-CoV-2	Lineage XBB; Omicron Variant (USA/CA-Stanford-109_S21/2022)	3 x 10^{-1} $TCID_{50}$/mL	3x
SARS-CoV-2	Lineage BF.7; Omicron Variant (USA/NY-Wadsworth-22042128-01/2022)	3 x 10^{-1} $TCID_{50}$/mL	3x
SARS-CoV-2	Lineage BF.5; Omicron Variant (USA/MD-HP34985/2022)	3 x 10^{-1} $TCID_{50}$/mL	3x
SARS-CoV-2	Lineage BA.5.5; Omicron Variant (USA/NY-Wadsworth-22023478-01/2022)	3 x 10^{-1} $TCID_{50}$/mL	3x

Predicted (in silico) reactivity (inclusivity) results for SARS-CoV-2

In silico analysis of sequences from GISAID are conducted routinely to assess the ability of the **cobas® eplex** RP3 panel to detect the most recent SARS-CoV-2 strains. The results of these analyses, as of June 2026, show that the RP3 panel will detect all variants in circulation.

Table 26: Analytical reactivity (inclusivity) results for human parainfluenza virus

Target	Strain	Concentration	Multiple of LoD detected
Human parainfluenza virus 1	C35	1.2 x 10^{1} $TCID_{50}$/mL	3x
Human parainfluenza virus 2	Greer	4.5 x 10^{2} $TCID_{50}$/mL	3x
Human parainfluenza virus 3	C-243	1.5 x 10^{2} $TCID_{50}$/mL	10x
Human parainfluenza virus 4	Type 4b	2.7 x 10^{2} $TCID_{50}$/mL	3x

Table 27: Analytical reactivity (inclusivity) results for influenza A

Note: Due to different assays for influenza A matrix and influenza A virus subtypes on the **cobas® eplex** RP3 panel, if different LoDs are observed for inclusivity for an Influenza A virus matrix vs. subtype, the differences are noted in the Multiple of LoD Detected column

Influenza A virus subtype	Strain	Concentration	Multiple of LoD detected
H1	A/New Caledonia/20/1999	3 x 10^{0} $TCID_{50}$/mL	10x (influenza A virus matrix)
H1	A/New Caledonia/20/1999	3 x 10^{1} $TCID_{50}$/mL	100x (influenza A virus H1 subtype)[a]
H1	A/Fort Monmouth/1/1947 (H1N1)	3 x 10^{1} $CEID_{50}$/mL	100x (influenza A virus matrix)[b]
H1	A/Fort Monmouth/1/1947 (H1N1)	3 x 10^{2} $CEID_{50}$/mL	Not detected[c]
H1	A/Mal/302/54	9 x 10^{-1} $CEID_{50}$/mL	3x (influenza A virus matrix)
H1	A/Mal/302/54	3 x 10^{1} $CEID_{50}$/mL	Not detected[c]
H1	A/Solomon Islands/3/2006	9 x 10^{-1} $TCID_{50}$/mL	3x (influenza A virus matrix)
H1	A/Solomon Islands/3/2006	9 x 10^{-1} $TCID_{50}$/mL	3x (influenza A virus H1 subtype)

Influenza A virus subtype	Strain	Concentration	Multiple of LoD detected
H1	A/Taiwan/42/06	3 x 10^0 $TCID_{50}$/mL	10x (influenza A virus matrix)
H1	A/Taiwan/42/06	3 x 10^0 $TCID_{50}$/mL	10x (influenza A virus H1 subtype)
H1	A/Denver/1/57	3 x 10^1 $CEID_{50}$/mL	100x (influenza A virus matrix)[d]
H1	A/Denver/1/57	3 x 10^1 $CEID_{50}$/mL	Not detected[c]
H1	A/NWS/33	3 x 10^0 $CEID_{50}$/mL	10x (influenza A virus matrix)
H1	A/NWS/33	3 x 10^1 $CEID_{50}$/mL	Not detected[c]
H1	A/PR/8/34	9 x 10^{-1} $TCID_{50}$/mL	3x (Influenza A virus matrix)
H1	A/PR/8/34	3 x 10^2 $TCID_{50}$/mL	Not detected[c]
H1	A/New Jersey/8/76	3 x 10^1 $CEID_{50}$/mL	100x (influenza A virus matrix)[d]
H1	A/New Jersey/8/76	3 x 10^2 $CEID_{50}$/mL	1000x (influenza A virus H1 subtype)[c]
H1-2009	A/California/7/2009	9 x 10^{-1} $TCID_{50}$/mL	3x (influenza A virus matrix)
H1-2009	A/California/7/2009	9 x 10^{-1} $TCID_{50}$/mL	3x (influenza A virus H1-2009 subtype)
H1-2009	A/Iowa/15/30	3 x 10^1 $TCID_{50}$/mL	100x (influenza A virus matrix)[e]
H1-2009	A/Iowa/15/30	3 x 10^1 $TCID_{50}$/mL	Not detected[f]
H1-2009	A/Mexico/4108/09	3 x 10^0 $TCID_{50}$/mL	10x (influenza A virus matrix)
H1-2009	A/Mexico/4108/09	3 x 10^{-0} $TCID_{50}$/mL	10x (influenza A virus H1-2009 subtype)
H1-2009	A/NY/01/2009	3 x 10^1 $TCID_{50}$/mL	100x (influenza A virus matrix)[g]
H1-2009	A/NY/01/2009	3 x 10^1 $TCID_{50}$/mL	100x (influenza A virus H1-2009 subtype)[g]
H1-2009	A/NY/02/2009	3 x 10^1 $TCID_{50}$/mL	100x (influenza A virus matrix)[g]
H1-2009	A/NY/02/2009	3 x 10^1 $TCID_{50}$/mL	100x (influenza A virus H1-2009 subtype)[g]
H1-2009	A/NY/03/2009	3 x 10^1 $TCID_{50}$/mL	100x (influenza A virus matrix)[g]
H1-2009	A/NY/03/2009	3 x 10^2 $TCID_{50}$/mL	1000x (influenza A virus H1-2009 subtype)[g]
H3	A/Aichi/2/68 H3N2	3 x 10^3 $CEID_{50}$/mL	3x (influenza A virus matrix)
H3	A/Aichi/2/68 H3N2	3 x 10^3 $CEID_{50}$/mL	3x (influenza A virus H3 subtype)
H3	A/Port Chalmers/1/73	3 x 10^3 $TCID_{50}$/mL	3x (influenza A virus matrix)
H3	A/Port Chalmers/1/73	3 x 10^3 $TCID_{50}$/mL	3x (influenza A virus H3 subtype)
H3	A/Wisconsin/67/05	3 x 10^3 $CEID_{50}$/mL	3x (influenza A virus matrix)
H3	A/Wisconsin/67/05	3 x 10^3 $CEID_{50}$/mL	3x (influenza A virus H3 subtype)
H3	A/Hong Kong/8/68	3 x 10^3 $CEID_{50}$/mL	3x (influenza A virus matrix)

Influenza A virus subtype	Strain	Concentration	Multiple of LoD detected
H3	A/Hong Kong/8/68	3 x 10^3 $CEID_{50}$/mL	3x (influenza A virus H3 subtype)
H3	A/Texas/50/2012	3 x 10^3 $TCID_{50}$/mL	3x (influenza A virus matrix)
H3	A/Texas/50/2012	3 x 10^3 $TCID_{50}$/mL	3x (influenza A virus H3 subtype)
H3	Alice (vaccine) A/England/42/72	3 x 10^3 $CEID_{50}$/mL	3x (influenza A virus matrix)
H3	Alice (vaccine) A/England/42/72	3 x 10^3 $CEID_{50}$/mL	3x (influenza A virus H3 subtype)

[a] *In silico* analysis revealed that lower sensitivity may be a result of mismatches in the influenza A virus H1 primers and/or probe sequences.

[b] *In silico* analysis revealed good homology to the influenza A virus primers and/or probe sequences. Reduced sensitivity may be the result of incorrect estimation of genetic material present in the culture or reference material ($TCID_{50}$/mL only measures infectious virus).

[c] *In silico* analysis revealed little homology between this non-contemporary strain sequence and the influenza A virus H1 primers and/or probe sequences.

[d] *In silico* analysis revealed good homology to the influenza A virus primers and/or probe sequences. Reduced sensitivity may be due to incorrect estimation of genetic material present in the culture or reference material ($TCID_{50}$/mL only measures infectious virus).

[e] *In silico* analysis revealed little homology between this non-contemporary strain sequence and the influenza A virus primers and/or probe sequences.

[f] *In silico* analysis revealed little homology between this non-contemporary strain sequence and the influenza A virus H1-2009 primers and/or probe sequences.

[g] No sequences available for *in silico* analysis. Mismatches could be present and/or the reduced sensitivity for this strain may be due to incorrect estimation of genetic material present in the culture or reference material ($TCID_{50}$/mL only measures infectious virus).

CEID/mL= chick embryo infectious dose per mL

Table 28: Analytical reactivity (inclusivity) results for influenza A strains titered with methods different from the reference strain

Target	Strain	Concentration Detected
Influenza A virus H7N9	A/ANHUI/1/2013	1 x 10^3 copies/mL
Influenza A virus H3N2v	A/Indiana/21/2012	1 x 10^2 copies/mL
Influenza A virus H5N2	A/Northern Pintail/Washington/40964/2014	1 x 10^3 copies/mL
Influenza A virus H5N8	A/Gyrfalcon/Washington/4108/8-6/2014	1 x 10^2 copies/mL

Supplemental analytical reactivity (inclusivity) for influenza A

For human, avian, and swine influenza strains not available for testing on the **cobas® eplex** RP3 panel, *in silico* analysis was performed. Bioinformatics analysis was used to predict a result

based on the number and location of mismatches in the primers, capture probes, and signal probes found in the **cobas® eplex** RP3 panel relative to an alignment of GenBank sequences.

Table 29: Predicted (*in silico*) reactivity (inclusivity) results for influenza A

Subtype	Host	Strain	Predicted Influenza A virus matrix result	Predicted Influenza A virus Subtype result
H2N2	Human	A/Albany/20/1957(H2N2)	Detected	Unknown[1]
H2N2	Avian	A/chicken/New York/13828-3/1995(H2N2)	Detected	Unknown[1]
H2N2	Avian	A/Japan/305/1957(H2N2)	Detected	Unknown[1]
H2N2	Avian	A/Korea/426/1968(H2N2)	Detected	Unknown[1]
H4N6	Avian	A/blue-winged teal/Minnesota/Sg-00043/2007(H4N6)	Detected	Unknown[1]
H5N1	Avian	A/peregrine falcon/Aomori/7/2011	Detected	Unknown[1]
H5N1	Avian	A/chicken/West Bengal/239022/2010	Detected	Unknown[1]
H5N1	Avian	A/chicken/West Bengal/193936/2009	Detected	Unknown[1]
H5N1	Avian	A/chicken/Hunan/1/2009	Detected	Unknown[1]
H5N1	Avian	A/chicken/Hunan/8/2008	Detected	Unknown[1]
H5N1	Avian	A/chicken/West Bengal/106181/2008	Detected	Unknown[1]
H5N1	Avian	A/chicken/Primorsky/85/2008	Detected	Unknown[1]
H5N1	Avian	A/chicken/West Bengal/82613/2008	Detected	Unknown[1]
H5N1	Avian	A/duck/France/080036/2008	Detected	Unknown[1]
H5N1	Avian	A/duck/Vietnam/G12/2008	Detected	Unknown[1]
H5N1	Avian	A/chicken/Thailand/PC-340/2008	Detected	Unknown[1]
H5N1	Avian	A/great egret/Hong Kong/807/2008	Detected	Unknown[1]
H5N1	Avian	A/rook/Rostov-on-Don/26/2007(H5N1)	Detected	Unknown[1]
H5N1	Avian	A/turkey/VA/505477-18/2007(H5N1)	Detected	Unknown[1]
H5N1	Avian	A/chicken/Bangladesh/1151-10/2010(H5N1)	Detected	Unknown[1]
H5N1	Human	A/Michigan/90/2024(H5N1)	Detected	Unknown[1]
H5N1	Human	A/Texas/37/2024(H5N1)	Detected	Unknown[1]
H5N1	Human	A/Colorado/109/2024(H5N1)	Detected	Unknown[1]
H5N1	Human	A/California/152/2024(H5N1)	Detected	Unknown[1]
H5N1	Human	A/Louisiana/12/2024 OR_IR(H5N1)	Detected	Unknown[1]
H5N1	Human	A/Washington/240/2024(H5N1)	Detected	Unknown[1]
H5N1	Human	A/Bangladesh/3233/2011	Detected	Unknown[1]
H5N1	Human	A/Cambodia/R0405050/2007(H5N1)	Detected	Unknown[1]
H5N1	Human	A/Cambodia/S1211394/2008	Detected	Unknown[1]
H5N1	Human	A/Hong Kong/486/97(H5N1)	Detected	Unknown[1]
H5N1	Swine	A/Swine/East Java/UT6010/2007(H5N1)	Detected	Unknown[1]

Subtype	Host	Strain	Predicted Influenza A virus matrix result	Predicted Influenza A virus Subtype result
H5N2	Avian	A/Duck/Pennsylvania/10218/1984(H5N2)	Detected	Unknown[1]
H5N2	Avian	A/American black duck/Illinois/08OS2688/2008	Detected	Unknown[1]
H5N2	Avian	A/American green-winged teal/California/HKWF609/2007	Detected	Unknown[1]
H5N2	Avian	A/Canada goose/New York/475813-2/2007	Detected	Unknown[1]
H5N2	Avian	A/Blue-winged teal/Saskatchewan/22542/2007	Detected	Unknown[1]
H5N2	Avian	A/Chicken/Taiwan/A703-1/2008	Detected	Unknown[1]
H5N2	Avian	A/Duck/France/080032/2008	Detected	Unknown[1]
H5N2	Avian	A/Duck/New York/481172/2007	Detected	Unknown[1]
H5N2	Avian	A/Gadwall/Altai/1202/2007	Detected	Unknown[1]
H5N2	Avian	A/Mallard/Louisiana/476670-4/2007	Detected	Unknown[1]
H5N2	Avian	A/Waterfowl/Colorado/476466-2/2007	Detected	Unknown[1]
H5N3	Avian	A/Duck/Singapore/F119/3/1997(H5N3)	Detected	Unknown[1]
H6N1	Avian	A/Duck/PA/486/1969(H6N1)	Detected	Unknown[1]
H6N2	Avian	A/Mallard/Czech Republic/15902-17K/2009(H6N2)	Detected	Unknown[1]
H7N2	Avian	A/Chicken/Hebei/1/2002	Detected	Unknown[1]
H7N2	Avian	A/Chicken/PA/149092-1/02	Detected	Unknown[1]
H7N2	Avian	A/Chicken/NJ/294508-12/2004	Detected	Unknown[1]
H7N2	Avian	A/Chicken/New York/23165-6/2005	Detected	Unknown[1]
H7N2	Avian	A/Muscovy duck/New York/23165-13/2005	Detected	Unknown[1]
H7N2	Avian	A/Muscovy duck/New York/87493-3/2005	Detected	Unknown[1]
H7N2	Avian	A/Mallard/Netherlands/29/2006	Detected	Unknown[1]
H7N2	Avian	A/Northern shoveler/California/JN1447/2007	Detected	Unknown[1]
H7N2	Human	A/New York/107/2003(H7N2)	Detected	Unknown[1]
H7N3	Human	A/Canada/rv504/2004(H7N3)	Detected	Unknown[1]
H7N7	Avian	A/American green-winged teal/Mississippi/09OS046/2009	Detected	Unknown[1]
H7N7	Avian	A/Chicken/Germany/R28/03	Detected	Unknown[1]
H7N7	Avian	A/Chicken/Netherlands/1/03	Detected	Unknown[1]
H7N7	Avian	A/Mallard/California/HKWF1971/2007	Detected	Unknown[1]
H7N7	Avian	A/Mallard/Korea/GH171/2007	Detected	Unknown[1]
H7N7	Avian	A/Mute swan/Hungary/5973/2007	Detected	Unknown[1]
H7N7	Avian	A/Northern shoveler/Mississippi/09OS643/2009	Detected	Unknown[1]
H7N7	Human	A/Netherlands/219/03(H7N7)	Detected	Unknown[1]
H7N9	Avian	A/Northern shoverl/Mississippi/11OS145/2011(H7N9)	Detected	Unknown[1]

Subtype	Host	Strain	Predicted Influenza A virus matrix result	Predicted Influenza A virus Subtype result
H7N9	Avian	A/Ruddy turnstone/Delaware Bay/220/1995(H7N9)	Detected	Unknown[1]
H7N9	Avian	A/Turkey/Minnesota/1/1988(H7N9)	Detected	Unknown[1]
H7N9	Avian	A/Blue-winged teal/Ohio/566/2006(H7N9)	Detected	Unknown[1]
H9N2	Human	A/Hong Kong/1073/99(H9N2)	Detected	Unknown[1]
H9N2	Avian	A/Turkey/Wisconsin/1/1966(H9N2)	Detected	Unknown[1]
H10N7	Avian	A/chicken/Germany/N/1949(H10N7)	Detected	Unknown[1]
H11N9	Avian	A/Duck/Memphis/546/1974(H11N9)	Detected	Unknown[1]
H1N1	Swine	A/Swine/Wisconsin/1/1971 (H1N1)	Detected	Not Amplified
H1N1	Human	A/California/UR06-0393/2007(H1N1)	Detected	Detected
H1N2	Human	A/New York/297/2003(H1N2)	Detected	Detected
H1N1 (2009)	Human	A/Aalborg/INS133/2009(H1N1)	Detected	Detected
H1N1 (2009)	Human	A/South Carolina/2/2010 (A/H1 pdm09)	Detected	Detected
H1N2	Swine	A/Swine/Hong Kong/NS857/2001 (H1N2)	Detected	Not Amplified
H1N2	Swine	A/Swine/Sweden/1021/2009(H1N2)	Detected	Not Amplified
H3N1	Avian	A/Blue-winged teal/ALB/452/1983(H3N1)	Detected	Not Amplified
H3N2v	Human	A/Iowa/07/2011(H3N2)	Detected	Not Amplified
H3N2v	Human	A/Iowa/08/2011(H3N2)	Detected	Detected
H3N2v	Human	A/Iowa/09/2011(H3N2)	Detected	Detected
H3N2v	Human	A/Indiana/08/2011(H3N2)	Detected	Detected
H3N2v	Human	A/Maine/06/2011(H3N2)	Detected	Detected
H3N2v	Human	A/Maine/07/2011(H3N2)	Detected	Unknown[1]
H3N2v	Human	A/Pennsylvania/09/2011(H3N2)	Detected	Detected
H3N2v	Human	A/Pennsylvania/11/2011(H3N2)	Detected	Unknown[1]
H3N2v	Human	A/Pennsylvania/10/2011(H3N2)	Detected	Unknown[1]
H3N2v	Human	A/West Virginia/06/2011(H3N2)	Detected	Detected
H3N2v	Human	A/West Virginia/07/2011(H3N2)	Detected	Unknown[1]
H3N2v	Human	A/Indiana/10/2011(H3N2)	Detected	Detected
H3N2v	Swine	A/Swine/NY/A01104005/2011(H3N2v)	Detected	Detected
H3N2v	Swine	A/Indiana/08/2011(H3N2)	Detected	Detected
H3N2v	Human	A/Boston/38/2008(H3N2)	Detected	Detected
H3N2v	Avian	A/American black duck/North Carolina/675-075/2004(H3N2)	Detected	Not Amplified
H3N5	Avian	A/Mallard/Netherlands/2/1999(H3N5)	Detected	Not Amplified
H3N6	Avian	A/American black duck/New Brunswick/25182/2007(H3N6)	Detected	Not Amplified

Subtype	Host	Strain	Predicted Influenza A virus matrix result	Predicted Influenza A virus Subtype result
H3N7	Avian	A/Northern shoveler/California/HKWF1367/2007(H3N7)	Detected	Not Amplified
H3N8	Avian	A/American black duck/Western Australia/699/1978(H3N8)	Detected	Amplified

[1] Sequence unavailable at the time of *in silico* analysis

Table 30: Reactivity (inclusivity) results for influenza B

Influenza B virus subtype	Strain	Concentration	Multiple of LoD detected
Influenza B virus (Yamagata lineage)	B/Allen/45	3 x 10^0 $CEID_{50}$/mL	3x
Influenza B (Yamagata lineage)	B/Florida/4/2006	1 x 10^2 $CEID_{50}$/mL	100x[a]
Influenza B (Lineage unknown)	B/GL/1739/54	3 x 10^0 $CEID_{50}$/mL	3x
Influenza B (Victoria lineage)	B/Hong Kong/5/72	1 x 10^1 $CEID_{50}$/mL	10x
Influenza B (Yamagata lineage)	B/Lee/40	3 x 10^0 $TCID_{50}$/mL	3x
Influenza B (Victoria lineage)	B/Malaysia/2506/04	3 x 10^0 $TCID_{50}$/mL	3x
Influenza B (Yamagata lineage)	B/Maryland/1/59	3 x 10^0 $CEID_{50}$/mL	3x
Influenza B (Yamagata lineage)	B/Taiwan/2/62	3 x 10^0 $TCID_{50}$/mL	3x

[a] *In silico* analysis revealed mismatches between this strain and the influenza B virus primers, signal or capture probe sequences that could result in lower sensitivity.

Table 31: Analytical reactivity (inclusivity) results for respiratory syncytial virus

RSV Subtype	Strain	Concentration	Multiple of LoD detected
RSV A	A2	4.5 x 10^{-1} $TCID_{50}$/mL	3x
RSV A	Long	1.5 x 10^2 $TCID_{50}$/mL	1000x[a]
RSV B	9320	6 x 10^0 $TCID_{50}$/mL	100x[b]
RSV B	Wash/18537/62	6 x 10^{-1} $TCID_{50}$/mL	10x
RSV B	WV/14617/85	6 x 10^{-1} $TCID_{50}$/mL	10x

RSV Subtype	Strain	Concentration	Multiple of LoD detected

[a] *In silico* analysis revealed a single mismatch between this strain and the RSV A primers, signal or capture probe sequences that is unlikely to result in lower sensitivity. The reduced sensitivity for this strain may be due to incorrect estimation of genetic material present in the culture or reference material ($TCID_{50}$/mL only measures infectious virus).

[b] *In silico* analysis revealed mismatches between this strain and the RSV B virus primers, signal or capture probe sequences that could result in lower sensitivity.

Table 32: Analytical reactivity (inclusivity) results for *B. pertussis*

Strain	Concentration	Multiple of LoD detected
F	4.5×10^3 CFU/mL	3x
Tohama I	4.5×10^3 CFU/mL	3x
5 [17921]	4.5×10^3 CFU/mL	3x
10-536	1.5×10^4 CFU/mL	10x
A639	1.5×10^4 CFU/mL	10x
MN2531	4.5×10^3 CFU/mL	3x

Table 33: Analytical reactivity (inclusivity) results for *C. pneumoniae*

Strain	Concentration	Multiple of LoD detected
CWL-029	2.7×10^3 IFU/mL	3x

In silico analysis was conducted for *M. pneumoniae* strains previously tested with earlier panel versions (the RP and RP2 panels) but no longer commercially available for purchase to assess the ability of the **cobas® eplex** RP3 panel to detect these strains.

Table 34: Predicted (*in silico*) reactivity (inclusivity) results for *M. pneumoniae*

M. pneumoniae Strain	Predicted *M. pneumoniae* Result
M129-B7	Detected
M129-B170	Detected
[Mac]	Detected
PI 1428	Detected

7.2.3. Analytical Specificity (Cross-Reactivity and Exclusivity)

Cross-reactivity of each viral and bacterial target on the **cobas® eplex** RP3 panel was evaluated at high concentrations (1×10^5 $TCID_{50}$/mL for viruses, 1×10^6 CFU/mL or IFU/mL for bacterial isolates, or 1×10^6 copies/mL for in vitro transcripts) of quantified strains/isolates diluted in

simulated sample matrix. In vitro transcript for human coronavirus HKU1 was diluted in PBS. **Table 35** summarizes the results of the on-panel viral and bacterial strains/isolates tested. No cross-reactivity was observed between any of the on-panel viruses or bacteria.

Table 35: Cross-reactivity with cobas® eplex RP3 panel target organisms

Target	Strain	Concentration	Cross-reactivity results
Adenovirus	A Type 31	1 x 10^5 $TCID_{50}$/mL	Not observed
Adenovirus	B Type 7	1 x 10^5 $TCID_{50}$/mL	Not observed
Adenovirus	C Type 1	1 x 10^5 $TCID_{50}$/mL	Not observed
Adenovirus	D Type 9	1 x 10^5 $TCID_{50}$/mL	Not observed [a]
Adenovirus	E Type 4	1 x 10^5 $TCID_{50}$/mL	Not observed
Adenovirus	F Type 41	1 x 10^5 $TCID_{50}$/mL	Not observed
Human enterovirus/rhinovirus	1A	1 x 10^5 $TCID_{50}$/mL	Not observed
Human enterovirus/rhinovirus	Enterovirus Type 68 (2007)	1 x 10^5 $TCID_{50}$/mL	Not observed
Human coronavirus	229E	1 x 10^5 $TCID_{50}$/mL	Not observed
Human coronavirus	HKU1 in vitro transcript	1 x 10^6 copies/mL	Not observed
Human coronavirus	NL63	1 x $10^4$$TCID_{50}$/mL	Not observed[b]
Human coronavirus	OC43	1 x 10^5 $TCID_{50}$/mL	Not observed
SARS-CoV-2	USA-WA1/2020	1 x 10^5 $TCID_{50}$/mL	Not observed
Human metapneumovirus	B1, Type 3 (Strain: B1 Peru2-2002)	1 x 10^5 $TCID_{50}$/mL	Not observed
Human parainfluenza Virus 1	Parainfluenza Virus 1	1 x 10^5 $TCID_{50}$/mL	Not observed
Human parainfluenza Virus 2	Parainfluenza Virus 2	1 x 10^5 $TCID_{50}$/mL	Not observed
Human parainfluenza Virus 3	Parainfluenza Virus 3	1 x 10^5 $TCID_{50}$/mL	Not observed
Human parainfluenza Virus 4	Parainfluenza Virus 4	1 x 10^5 $TCID_{50}$/mL	Not observed
Influenza A virus H1	A/Brisbane/59/07	1 x 10^5 $TCID_{50}$/mL	Not observed
Influenza A virus H1	A/Victoria/4897/22	1 x 10^5 $TCID_{50}$/mL	Not observed
Influenza A virus H1	A/Wisconsin/67/22	1 x 10^5 $TCID_{50}$/mL	Not observed
Influenza A virus H1-2009	A/NY/01/2009	1 x 10^5 $TCID_{50}$/mL	Not observed
Influenza A virus H3	A/Brisbane/10/07	1 x 10^5 $TCID_{50}$/mL	Not observed
Influenza A virus H3	A/Darwin/6/21	1 x 10^5 $TCID_{50}$/mL	Not observed
Influenza A virus H3	A/Darwin/9/21	1 x 10^5 $TCID_{50}$/mL	Not observed
Influenza B virus	B/Austria/1359417/21	1 x 10^5 $TCID_{50}$/mL	Not observed

Target	Strain	Concentration	Cross-reactivity results
RSV A	2006 Isolate	1 x 10^5 $TCID_{50}$/mL	Not observed
RSV B	CH93(18)-18	1 x 10^5 $TCID_{50}$/mL	Not observed
B. pertussis	18323 [NCTC 10739]	1 x 10^6 CFU/mL	Not observed
C. pneumoniae	AR-39	1 x 10^6 IFU/mL	Not observed
M. pneumoniae	FH strain of Eaton Agent [NCTC 10119]	1 x 10^6 CFU/mL	Not observed

[a] One false positive result for human coronavirus 229E was detected likely due to sample contamination. Repeat testing generated the expected result of adenovirus detected and coronavirus 229E was not detected.

[b] Initial testing for human coronavirus NL63 at 1x10^5 $TCID_{50}$/mL resulted in 2 of 3 replicates being detected; PCR inhibition due to a high concentration of culture fluid in the sample was suspected (stock sample had a starting concentration close to the desired testing concentration and required higher volume for testing). Testing was repeated at a lower concentration.

Cross-reactivity of viruses, bacteria, and fungi that are not targets on the **cobas® eplex** RP3 panel was evaluated at high concentrations (1 x 10^5 $TCID_{50}$/mL for viruses, 1 x 10^6 CFU/mL for bacterial and yeast isolates, or 1 x 10^6 copies/mL for plasmid DNA or in vitro transcripts) by diluting quantified strains in simulated sample matrix or PBS for human bocavirus plasmid and in vitro transcripts. If organism was not available at the expected testing concentration (Mumps virus, *Mycoplasma genitalium,* and *Mycobacterium tuberculosis*), testing was done with the stock solution with concentration indicated in the results. If organism was not available for testing, *in silico* analysis was performed (poliovirus). **Table 36** summarizes the results of the strains tested. No cross-reactivity was observed between any of the off-panel viruses, bacteria or fungi with the **cobas® eplex** RP3 panel targets.

Table 36: Cross-reactivity with organisms not detected by the cobas® eplex RP3 panel (exclusivity)

Target	Strain	Concentration	Cross-reactivity results
Aspergillus flavus	Z013	1 x 10^6 CFU/mL	Not observed
Aspergillus fumigatus	Z014	1 x 10^6 CFU/mL	Not observed
Bordetella bronchiseptica	Z339	1 x 10^6 CFU/mL	Not observed
Bordetella bronchiseptica	Z341	1 x 10^6 CFU/mL	Not observed
Bordetella holmesii	F061	1 x 10^6 CFU/mL	Not observed
Candida albicans	Z006	1 x 10^6 CFU/mL	Not observed
Corynebacterium diphtheriae	Z116	1 x 10^6 CFU/mL	Not observed
Cytomegalovirus	Merlin	1 x 10^5 $TCID_{50}$/mL	Not observed
Epstein-Barr virus	B95-8	1 x 10^6 copies/mL	Not observed

Target	Strain	Concentration	Cross-reactivity results
Escherichia coli	1144993	1 x 10^6 CFU/mL	Not observed
Fusobacterium necrophorum	Z239	1 x 10^6 CFU/mL	Not observed
Haemophilus influenzae	Type B, Eagan	1 x 10^6 CFU/mL	Not observed
Herpes simplex virus	2	1 x 10^5 $TCID_{50}$/mL	Not observed
Human bocavirus plasmid	Plasmid	1 x 10^6 copies/mL	Not observed
Lactobacillus acidophilus	Z048	1 x 10^6 CFU/mL	Not observed
Lactobacillus plantarum	Z524	1 x 10^6 CFU/mL	Not observed
Legionella pneumophila	Philadelphia-1	1 x 10^6 CFU/mL	Not observed
Measles virus	Edmonston	1 x 10^5 $TCID_{50}$/mL	Not observed
MERS-CoV	MERS-CoV IVT	1 x 10^6 copies/mL	Not observed
Moraxella catarrhalis	Ne 11	1 x 10^6 CFU/mL	Not observed
Mumps virus	2	5.62 x 10^4 $TCID_{50}$/mL	Not observed
Mycobacterium tuberculosis	H37Ra	1 x 10^4 CFU/vial[a]	Not observed
Mycoplasma genitalium	G37	1 x 10^5 CCU/vial[a]	Not observed
Neisseria meningiditis	Serogroup A	1 x 10^6 CFU/mL	Not observed
Neisseria sicca	Z043	1 x 10^6 CFU/mL	Not observed
Porphyromonas gingivalis	2561	1 x 10^6 CFU/mL	Not observed
Pseudomonas aeruginosa	Z139	1 x 10^6 CFU/mL	Not observed
Pneumocystis jirovecii (carinii)	N/A	1 x 10^6 CFU/mL	Not observed
Staphylococcus aureus	MRSA COL	1 x 10^6 CFU/mL	Not observed
Staphylococcus epidermidis	Z291 (MRSE)	1 x 10^6 CFU/mL	Not observed
Streptococcus pneumoniae	Z022	1 x 10^6 CFU/mL	Not observed
Streptococcus pyogenes	Z018	1 x 10^6 CFU/mL	Not observed
Streptococcus salivarius	Z127	1 x 10^6 CFU/mL	Not observed
Varicella Zoster Virus	82	1 x 10^6 copies/mL	Not observed

[a] During initial testing, samples were tested at stock titer and resulted in invalid runs likely due to the clumpy nature of the sample which is predominantly bacterial growth media which can inhibit extraction. Samples were retested at 1:10 dilution at the concentrations indicated on the table.

Testing for poliovirus was not performed as this organism was not commercially available. *In silico* analysis of poliovirus sequence found that poliovirus is expected to cross-react with the human enterovirus/rhinovirus assays on the **cobas® eplex** RP3 panel.

7.2.4. Precision

A single-site within-laboratory precision study of the **cobas® eplex** RP3 panel was performed over six days using a 3-member precision panel consisting of nine organisms (representing 10 RP3 panel targets) at 3 concentrations (moderate positive-3x LoD, low positive-1.5x LoD, and negative). The nine organisms tested included adenovirus, human coronavirus 229E (which is

reported as part of the human coronavirus (229E, HKU1, NL63, OC43) target), SARS-CoV-2, human metapneumovirus, human parainfluenza virus 2, influenza A virus H3, RSV A, *Bordetella pertussis*, and *Mycoplasma pneumoniae*; organisms were diluted in simulated matrix. Testing was performed using 3 **cobas® eplex** instruments consisting of one base with at least 2 towers. For each instrument, 2 operators tested the precision panel in triplicate over 6 different days using 3 unique lots of RP3 panel cartridges (2 days of testing per lot) for a total of 324 replicate tests for each analyte target (3 panel members x 3 replicates x 3 instruments x 2 operators x 3 lots x 2 days/lot). For each **cobas® eplex** instrument on each day of testing, 2 external positive controls were run prior to or concurrent with precision panel testing. Different external positive controls representing all **cobas® eplex** RP3 panel targets were rotated throughout the 6 days of testing across the 3 instruments.

Percent agreement with the expected results was 100% for all 10 targets in the negative panel, as well as for 9 of the 10 targets in both the low positive and moderate positive panels (adenovirus, human coronavirus, SARS-CoV-2, human metapneumovirus, human parainfluenza virus 2, influenza A virus, influenza A virus H3, RSV A, and *Mycoplasma pneumoniae*). For *Bordetella pertussis*, percent agreement was 97.3% for the low positive panel and 99.1% for the moderate positive panel. Summary results for the 10 **cobas® eplex** RP3 panel targets are provided in **Table 37** through **Table 46**.

Table 37: Percent agreement for adenovirus detection by concentration

Adenovirus concentration	Agree/N	%	95% CI
Moderate positive - 3x LoD 3.0×10^2 $TCID_{50}$/mL	109/109	100	96.6-100
Low positive - 1.5x LoD 1.5×10^2 $TCID_{50}$/mL	114/114	100	96.7-100
Negative	108/108	100	96.6-100

CI = Confidence Interval

Table 38: Percent agreement of human coronavirus detection by concentration

Human coronavirus concentration	Agree/N	%	95% CI
Moderate positive - 3x LoD 3.0×10^{-1} $TCID_{50}$/mL	108/108	100	96.6-100

Human coronavirus concentration	Agree/N	%	95% CI
Low positive - 1.5x LoD 1.5 x 10^{-1} $TCID_{50}$/mL	108/108	100	96.6-100
Negative	108/108	100	96.6-100

Table 39: Percent agreement of SARS-CoV-2 detection by concentration

SARS-CoV-2 concentration	Agree/N	%	95% CI
Moderate positive - 3x LoD 1.5 x 10^{-1} $TCID_{50}$/mL	109/109	100	96.6-100
Low positive - 1.5x LoD 7.5 x 10^{-2} $TCID_{50}$/mL	114/114	100	96.7-100
Negative	108/108	100	96.6-100

Table 40: Percent agreement of human metapneumovirus detection by concentration

Human metapneumovirus concentration	Agree/N	%	95% CI
Moderate positive - 3x LoD 6.75 x 10^{1} $TCID_{50}$/mL	108/108	100	96.6-100
Low positive - 1.5x LoD 3.38 x 10^{1} $TCID_{50}$/mL	108/108	100	96.6-100
Negative	108/108	100	96.6-100

Table 41: Percent agreement of human parainfluenza virus 2 detection by concentration

Human parainfluenza virus 2 concentration	Agree/N	%	95% CI
Moderate positive - 3x LoD 4.5 x 10^{2} $TCID_{50}$/mL	108/108	100	96.6-100
Low positive - 1.5x LoD 2.25 x 10^{2} $TCID_{50}$/mL	108/108	100	96.6-100
Negative	108/108	100	96.6-100

Table 42: Percent agreement of influenza A virus detection by concentration

Influenza A virus concentration	Agree/N	%	95% CI
Moderate positive - 3x LoD 9.0 x 10^{-1} $TCID_{50}$/mL	108/108	100	96.6-100
Low positive - 1.5x LoD 4.5 x 10^{-1} $TCID_{50}$/mL	110/110	100	96.6-100
Negative	108/108	100	96.6-100

Table 43: Percent agreement of influenza A virus H3 detection by concentration

Influenza A virus H3 concentration	Agree/N	%	95% CI
Moderate positive - 3x LoD 9.0 x 10^{-1} $TCID_{50}$/mL	109/109	100	96.6-100
Low positive - 1.5x LoD 4.5 x 10^{-1} $TCID_{50}$/mL	114/114	100	96.7-100
Negative	108/108	100	96.6-100

Table 44: Percent agreement of RSV A detection by concentration

RSV A concentration	Agree/N	%	95% CI
Moderate positive - 3x LoD 4.5 x 10^{-1} $TCID_{50}$/mL	109/109	100	96.6-100
Low positive - 1.5x LoD 2.25 x 10^{-1} $TCID_{50}$/mL	111/111	100	96.7-100
Negative	108/108	100	96.6-100

Table 45: Percent agreement of *Bordetella pertussis* detection by concentration

Bordetella pertussis concentration	Agree/N	%	95% CI
Moderate positive - 3x LoD 4.5 x 10^{3} CFU/mL	108/109	99.1	95.0-99.8
Low positive - 1.5x LoD 2.25 x 10^{3} CFU/mL	110/113	97.3	92.5-99.1
Negative	108/108	100	96.6-100

Table 46: Percent agreement of *Mycoplasma pneumoniae* detection by concentration

Mycoplasma pneumoniae concentration	Agree/N	%	95% CI
Moderate positive - 3x LoD 9.0 x 10^1 CFU/mL	109/109	100	96.6-100
Low positive - 1.5x LoD 4.5 x 10^1 CFU/mL	114/114	100	96.7-100
Negative	108/108	100	96.6-100

7.2.5. Reproducibility

Reproducibility of the **cobas® eplex** RP3 panel was assessed using reproducibility data testing the **cobas® eplex** RP panel on the **cobas® eplex** system. A multisite reproducibility study of the **cobas® eplex** RP panel was performed to evaluate agreement with expected results across major sources of variability, such as site-to-site, lot-to-lot, day-to-day, and operator-to-operator. Testing occurred at 3 sites (2 external, 1 internal) on one **cobas® eplex** system per site with either 3 or 4 towers. Two operators performed testing at each site on 6 days (5 nonconsecutive days) with 3 unique lots of RP panel cartridges. A reproducibility panel consisting of 3 panel members with 6 organisms (representing 7 RP Panel targets) at 3 concentrations (moderate positive- 3x LoD, low positive- 1x LoD, and negative) was tested in triplicate. The 6 organisms tested included adenovirus, human coronavirus (229E, HKU1, NL63, OC43), human metapneumovirus, human parainfluenza virus 1, influenza A virus H3, and RSV A*;* organisms were diluted in natural clinical matrix (pooled, negative nasopharyngeal swab samples). Negative samples consisted of natural clinical matrix only. Each simulated sample was divided into aliquots and stored frozen (-70 °C) prior to testing. Each operator tested 9 samples (3 member reproducibility panel in triplicate) each day; each panel member was tested 108 times (3 replicates x 3 sites x 2 operators x 3 lots x 2 days of testing/operator/lot) for a maximum of 324 tests. After completion of initial and repeat testing for invalid results, 1 low positive sample tested at Site 3 had an invalid result and was excluded from reproducibility performance analyses.

Percent agreement (95% CI) with expected results was 100% for all 7 targets for the moderate positive and negative panel, and 100% for 6 of 7 low positive panel targets (human coronavirus, human metapneumovirus, human parainfluenza 1, influenza A virus, influenza A virus H3, and RSV A); percent agreement was 91.6% for adenovirus. Summary results for the 7 **cobas® eplex**

RP panel targets that correspond to the 6 organisms in the reproducibility panel are provided in **Table 47** to **Table 53.** Summary results for the **cobas® eplex** RP panel targets that did not have organisms included in the reproducibility panel are provided in **Table 54.**

Table 47: Percent agreement for adenovirus

Adenovirus concentration	Site	Agreement with expected results Agreed / N	Agreement with expected results %	Agreement with expected results 95% CI
Moderate positive - 3x LoD 6 x 10^0 $TCID_{50}$/mL	1	36/36	100	(90.4-100)
Moderate positive - 3x LoD 6 x 10^0 $TCID_{50}$/mL	2	36/36	100	(90.4-100)
Moderate positive - 3x LoD 6 x 10^0 $TCID_{50}$/mL	3	36/36	100	(90.4-100)
Moderate positive - 3x LoD 6 x 10^0 $TCID_{50}$/mL	All	108/108	100	(96.6-100)
Low positive - 1x LoD 2 x 10^0 $TCID_{50}$/mL	1	36/36	100	(90.4-100)
Low positive - 1x LoD 2 x 10^0 $TCID_{50}$/mL	2	34/36	94.4	(81.9-98.5)
Low positive - 1x LoD 2 x 10^0 $TCID_{50}$/mL	3	28/35	80.0	(64.1-90.0)
Low positive -1 x LoD 2 x 10^0 $TCID_{50}$/mL	All	98/107	91.6	(84.8-95.5)
Negative	1	36/36	100	(90.4-100)
Negative	2	36/36	100	(90.4-100)
Negative	3	36/36	100	(90.4-100)
Negative	All	108/108	100	(96.6-100)

CI=Confidence Interval

Table 48: Percent agreement for human coronavirus

Human coronavirus concentration	Site	Agreement with expected results Agreed / N	Agreement with expected results %	Agreement with expected results 95% CI
Moderate positive - 3x LoD 1.5 x 10^3 $TCID_{50}$/mL	1	36/36	100	(90.4-100)
Moderate positive - 3x LoD 1.5 x 10^3 $TCID_{50}$/mL	2	36/36	100	(90.4-100)

Human coronavirus concentration	Site	Agreement with expected results Agreed / N	Agreement with expected results %	Agreement with expected results 95% CI
Moderate positive - 3x LoD 1.5 x 10^3 $TCID_{50}$/mL	3	36/36	100	(90.4-100)
Moderate positive - 3x LoD 1.5 x 10^3 $TCID_{50}$/mL	All	108/108	100	(96.6-100)
Low positive - 1x LoD 5 x 10^2 $TCID_{50}$/mL	1	36/36	100	(90.4-100)
Low positive - 1x LoD 5 x 10^2 $TCID_{50}$/mL	2	36/36	100	(90.4-100)
Low positive - 1x LoD 5 x 10^2 $TCID_{50}$/mL	3	35/35	100	(90.1-100)
Low positive - 1x LoD 5 x 10^2 $TCID_{50}$/mL	All	107/107	100	(96.5-100)
Negative	1	36/36	100	(90.4-100)
Negative	2	36/36	100	(90.4-100)
Negative	3	36/36	100	(90.4-100)
Negative	All	108/108	100	(96.6-100)

Table 49: Percent agreement for human metapneumovirus

Human metapneumovirus concentration	Site	Agreement with expected results Agreed / N	Agreement with expected results %	Agreement with expected results 95% CI
Moderate positive - 3x LoD 6.75 x 10^2 $TCID_{50}$/mL	1	36/36	100	(90.4-100)
Moderate positive - 3x LoD 6.75 x 10^2 $TCID_{50}$/mL	2	36/36	100	(90.4-100)
Moderate positive - 3x LoD 6.75 x 10^2 $TCID_{50}$/mL	3	36/36	100	(90.4-100)
Moderate positive - 3x LoD 6.75 x 10^2 $TCID_{50}$/mL	All	108/108	100	(96.6-100)
Low positive - 1x LoD 2.25 x 10^2 $TCID_{50}$/mL	1	36/36	100	(90.4-100)
Low positive - 1x LoD 2.25 x 10^2 $TCID_{50}$/mL	2	36/36	100	(90.4-100)
Low positive - 1x LoD 2.25 x 10^2 $TCID_{50}$/mL	3	35/35	100	(90.1-100)

Human metapneumovirus concentration	Site	Agreement with expected results Agreed / N	Agreement with expected results %	Agreement with expected results 95% CI
Low positive - 1x LoD 2.25×10^2 $TCID_{50}$/mL	All	107/107	100	(96.5-100)
Negative	1	36/36	100	(90.4-100)
Negative	2	36/36	100	(90.4-100)
Negative	3	36/36	100	(90.4-100)
Negative	All	108/108	100	(96.6-100)

Table 50: Percent agreement for human parainfluenza virus 1

Human parainfluenza virus 1 concentration	Site	Agreement with expected results Agreed / N	Agreement with expected results %	Agreement with expected results 95% CI
Moderate positive - 3x LoD 1.2×10^0 $TCID_{50}$/mL	1	36/36	100	(90.4-100)
Moderate positive - 3x LoD 1.2×10^0 $TCID_{50}$/mL	2	36/36	100	(90.4-100)
Moderate positive - 3x LoD 1.2×10^0 $TCID_{50}$/mL	3	36/36	100	(90.4-100)
Moderate positive - 3x LoD 1.2×10^0 $TCID_{50}$/mL	All	108/108	100	(96.6-100)
Low positive - 1x LoD 4×10^{-1} $TCID_{50}$/mL	1	36/36	100	(90.4-100)
Low positive - 1x LoD 4×10^{-1} $TCID_{50}$/mL	2	36/36	100	(90.4-100)
Low positive - 1x LoD 4×10^{-1} $TCID_{50}$/mL	3	35/35	100	(90.1-100)
Low positive - 1x LoD 4×10^{-1} $TCID_{50}$/mL	All	107/107	100	(96.5-100)
Negative	1	36/36	100	(90.4-100)
Negative	2	36/36	100	(90.4-100)
Negative	3	36/36	100	(90.4-100)
Negative	All	108/108	100	(96.6-100)

Table 51: Percent agreement for influenza A virus

Influenza A virus concentration	Site	Agreement with expected results Agreed / N	Agreement with expected results %	Agreement with expected results 95% CI
Moderate positive - 3x LoD 1.5 x 10^2 $TCID_{50}$/mL	1	36/36	100	(90.4-100)
Moderate positive - 3x LoD 1.5 x 10^2 $TCID_{50}$/mL	2	36/36	100	(90.4-100)
Moderate positive - 3x LoD 1.5 x 10^2 $TCID_{50}$/mL	3	36/36	100	(90.4-100)
Moderate positive - 3x LoD 1.5 x 10^2 $TCID_{50}$/mL	All	108/108	100	(96.6-100)
Low positive - 1x LoD 5 x 10^1 $TCID_{50}$/mL	1	36/36	100	(90.4-100)
Low positive - 1x LoD 5 x 10^1 $TCID_{50}$/mL	2	36/36	100	(90.4-100)
Low positive - 1x LoD 5 x 10^1 $TCID_{50}$/mL	3	35/35	100	(90.1-100)
Low positive - 1x LoD 5 x 10^1 $TCID_{50}$/mL	All	107/107	100	(96.5-100)
Negative	1	36/36	100	(90.4-100)
Negative	2	36/36	100	(90.4-100)
Negative	3	36/36	100	(90.4-100)
Negative	All	108/108	100	(96.6-100)

Table 52: Percent agreement for influenza A virus H3

Influenza A virus H3 concentration	Site	Agreement with expected results Agreed / N	Agreement with expected results %	Agreement with expected results 95% CI
Moderate positive - 3x LoD 1.5 x 10^2 $TCID_{50}$/mL	1	36/36	100	(90.4-100)
Moderate positive - 3x LoD 1.5 x 10^2 $TCID_{50}$/mL	2	36/36	100	(90.4-100)
Moderate positive - 3x LoD 1.5 x 10^2 $TCID_{50}$/mL	3	36/36	100	(90.4-100)
Moderate positive - 3x LoD 1.5 x 10^2 $TCID_{50}$/mL	All	108/108	100	(96.6-100)

Influenza A virus H3 concentration	Site	Agreement with expected results Agreed / N	Agreement with expected results %	Agreement with expected results 95% CI
Low positive - 1x LoD 5 x 10^1 $TCID_{50}$/mL	1	36/36	100	(90.4-100)
Low positive - 1x LoD 5 x 10^1 $TCID_{50}$/mL	2	36/36	100	(90.4-100)
Low positive - 1x LoD 5 x 10^1 $TCID_{50}$/mL	3	35/35	100	(90.1-100)
Low positive - 1x LoD 5 x 10^1 $TCID_{50}$/mL	All	107/107	100	(96.5-100)
Negative	1	36/36	100	(90.4-100)
Negative	2	36/36	100	(90.4-100)
Negative	3	36/36	100	(90.4-100)
Negative	All	108/108	100	(96.6-100)

Table 53: Percent agreement for RSV A

RSV A Concentration	Site	Agreement with expected results Agreed / N	Agreement with expected results %	Agreement with expected results 95% CI
Moderate positive - 3x LoD 4.5 x 10^0 $TCID_{50}$/mL	1	36/36	100	(90.4-100)
Moderate positive - 3x LoD 4.5 x 10^0 $TCID_{50}$/mL	2	36/36	100	(90.4-100)
Moderate positive - 3x LoD 4.5 x 10^0 $TCID_{50}$/mL	3	36/36	100	(90.4-100)
Moderate positive - 3x LoD 4.5 x 10^0 $TCID_{50}$/mL	All	108/108	100	(96.6-100)
Low positive- 1x LoD 1.5 x 10^0 $TCID_{50}$/mL	1	36/36	100	(90.4-100)
Low positive - 1x LoD 1.5 x 10^0 $TCID_{50}$/mL	2	36/36	100	(90.4-100)
Low positive - 1x LoD 1.5 x 10^0 $TCID_{50}$/mL	3	35/35	100	(90.1-100)
Low positive - 1x LoD 1.5 x 10^0 $TCID_{50}$/mL	All	107/107	100	(96.5-100)
Negative	1	36/36	100	(90.4-100)
Negative	2	36/36	100	(90.4-100)
Negative	3	36/36	100	(90.4-100)

RSV A Concentration	Site	Agreement with expected results Agreed / N	Agreement with expected results %	Agreement with expected results 95% CI
Negative	All	108/108	100	(96.6-100)

Table 54: Negative percent agreement with organisms not included in the reproducibility panel

Target	Site	Agreement with expected negative results Agreed / N	Agreement with expected negative results %	Agreement with expected negative results 95% CI
Human enterovirus/rhinovirus	1	108/108	100	(96.6-100)
Human enterovirus/rhinovirus	2	108/108	100	(96.6-100)
Human enterovirus/rhinovirus	3	104/107	97.2	(92.1-99.0)
Human enterovirus/rhinovirus	All	320/323	99.1	(97.3-99.7)
Human parainfluenza virus 2	1	108/108	100	(96.6-100)
Human parainfluenza virus 2	2	108/108	100	(96.6-100)
Human parainfluenza virus 2	3	107/107	100	(96.5-100)
Human parainfluenza virus 2	All	323/323	100	(98.8-100)
Human parainfluenza virus 3	1	108/108	100	(96.6-100)
Human parainfluenza virus 3	2	108/108	100	(96.6-100)
Human parainfluenza virus 3	3	106/107	99.1	(94.9-99.8)
Human parainfluenza virus 3	All	322/323	99.7	(98.3-99.9)
Human parainfluenza virus 4	1	108/108	100	(96.6-100)
Human parainfluenza virus 4	2	108/108	100	(96.6-100)
Human parainfluenza virus 4	3	107/107	100	(96.5-100)
Human parainfluenza virus 4	All	323/323	100	(98.8-100)
Influenza A virus H1	1	108/108	100	(96.6-100)
Influenza A virus H1	2	108/108	100	(96.6-100)
Influenza A virus H1	3	107/107	100	(96.5-100)
Influenza A virus H1	All	323/323	100	(98.8-100)
Influenza A virus H1-2009	1	108/108	100	(96.6-100)
Influenza A virus H1-2009	2	108/108	100	(96.6-100)
Influenza A virus H1-2009	3	107/107	100	(96.5-100)
Influenza A virus H1-2009	All	323/323	100	(98.8-100)
Influenza B virus	1	108/108	100	(96.6-100)
Influenza B virus	2	108/108	100	(96.6-100)

Target	Site	Agreement with expected negative results Agreed / N	Agreement with expected negative results %	Agreement with expected negative results 95% CI
Influenza B virus	3	107/107	100	(96.5-100)
Influenza B virus	All	323/323	100	(98.8-100)
Respiratory syncytial virus B	1	108/108	100	(96.6-100)
Respiratory syncytial virus B	2	108/108	100	(96.6-100)
Respiratory syncytial virus B	3	107/107	100	(96.5-100)
Respiratory syncytial virus B	All	323/323	100	(98.8-100)
C. pneumoniae	1	108/108	100	(96.6-100)
C. pneumoniae	2	108/108	100	(96.6-100)
C. pneumoniae	3	107/107	100	(96.5-100)
C. pneumoniae	All	323/323	100	(98.8-100)
M. pneumoniae	1	108/108	100	(96.6-100)
M. pneumoniae	2	107/108	99.1	(94.9-99.8)
M. pneumoniae	3	106/107	99.1	(94.9-99.8)
M. pneumoniae	All	321/323	99.4	(97.8-99.8)

7.2.6. Samples with Co-Detected Organisms

Detection of more than one clinically relevant organism in a sample was evaluated with the **cobas® eplex** RP3 panel using a natural clinical matrix (pooled, negative nasopharyngeal swab samples) spiked with two RP3 panel organisms: one organism at a low concentration (3x LoD) and the second organism at a high concentration (1 x 10^5 $TCID_{50}$/mL for viruses or 1 x10^6 CFU/mL for bacteria). If organism was not available at the expected testing concentration (human coronavirus, influenza A virus H1-2009, influenza A virus H3, and influenza B virus), testing was done with the stock solution with concentration indicated in the results. **Table 55** contains the results of co-detection testing which demonstrated the ability of the **cobas® eplex** RP3 panel to detect 2 organisms in a sample at both high and low concentrations.

Table 55: Detection of co-detections

Organism 1	High titer	Organism 2	Low titer	Multiple of LoD
Human enterovirus/rhinovirus	1 x 10^5 $TCID_{50}$/mL	Influenza A virus H1-2009	9 x 10^{-1} $TCID_{50}$/mL	3x
Influenza A virus H1-2009	1 x 10^4 $TCID_{50}$/mL	Human enterovirus/rhinovirus	9 x 10^{-1} $TCID_{50}$/mL	3x

Organism 1	High titer	Organism 2	Low titer	Multiple of LoD
Human enterovirus/rhinovirus	1 x 10^5 $TCID_{50}$/mL	Adenovirus B	6 x 10^0 $TCID_{50}$/mL	3x
Adenovirus B	1 x 10^5 $TCID_{50}$/mL	Human enterovirus/rhinovirus	9 x 10^{-1} $TCID_{50}$/mL	3x
Human enterovirus/rhinovirus	1 x 10^5 $TCID_{50}$/mL	Human coronavirus	3 x 10^{-1} $TCID_{50}$/mL	3x
Human coronavirus	1 x 10^4 $TCID_{50}$/mL	Human enterovirus/rhinovirus	9 x 10^{-1} $TCID_{50}$/mL	3x
Human enterovirus/rhinovirus	1 x 10^5 $TCID_{50}$/mL	*M. pneumoniae*	9 x 10^1 CFU/mL	3x
M. pneumoniae	1 x 10^6 CFU/mL	Human enterovirus/rhinovirus	9 x 10^{-1} $TCID_{50}$/mL	3x
Human enterovirus/rhinovirus	1 x 10^5 $TCID_{50}$/mL	Human parainfluenza virus 3	4.5 x 10^1 $TCID_{50}$/mL	3x
Human parainfluenza virus 3	1 x 10^5 $TCID_{50}$/mL	Human enterovirus/rhinovirus	9 x 10^{-1} $TCID_{50}$/mL	3x
Human enterovirus/rhinovirus	1 x 10^5 $TCID_{50}$/mL	RSV A	4.5 x 10^{-1} $TCID_{50}$/mL	3x
RSV A	1 x 10^5 $TCID_{50}$/mL	Human enterovirus/rhinovirus	9 x 10^{-1} $TCID_{50}$/mL	3x
Human enterovirus/rhinovirus	1 x 10^5 $TCID_{50}$/mL	SARS-CoV-2	1.5 x 10^{-1} $TCID_{50}$/mL	3x
SARS-CoV-2	1 x 10^5 $TCID_{50}$/mL	Human enterovirus/rhinovirus	9 x 10^{-1} $TCID_{50}$/mL	3x
RSV A	1 x 10^5 $TCID_{50}$/mL	Adenovirus B	6 x 10^0 $TCID_{50}$/mL	3x
Adenovirus B	1 x 10^5 $TCID_{50}$/mL	RSV A	4.5 x 10^{-1} $TCID_{50}$/mL	3x
RSV A	1 x 10^5 $TCID_{50}$/mL	Human coronavirus	3 x 10^{-1} $TCID_{50}$/mL	3x
Human coronavirus	1 x 10^4 $TCID_{50}$/mL	RSV A	4.5 x 10^{-1} $TCID_{50}$/mL	3x
RSV A	1 x 10^5 $TCID_{50}$/mL	Influenza A virus H3	1.5 x 10^1 $TCID_{50}$/mL	3x
Influenza A virus H3	1 x 10^4 $TCID_{50}$/mL	RSV A	4.5 x 10^{-1} $TCID_{50}$/mL	3x
Adenovirus B	1 x 10^5 $TCID_{50}$/mL	Influenza A virus H3	1.5 x 10^1 $TCID_{50}$/mL	3x
Influenza A virus H3	1 x 10^4 $TCID_{50}$/mL	Adenovirus B	6 x 10^0 $TCID_{50}$/mL	3x
Adenovirus B	1 x 10^5 $TCID_{50}$/mL	Human metapneumovirus	6.75 x 10^1 $TCID_{50}$/mL	3x
Human metapneumovirus	1 x 10^5 $TCID_{50}$/mL	Adenovirus B	6 x 10^0 $TCID_{50}$/mL	3x
Human coronavirus	1 x 10^4 $TCID_{50}$/mL	SARS-CoV-2	1.5 x 10^{-1} $TCID_{50}$/mL	3x
SARS-CoV-2	1 x 10^5 $TCID_{50}$/mL	Human coronavirus	3 x 10^{-1} $TCID_{50}$/mL	3x
Influenza A virus H1-2009	1 x 10^4 $TCID_{50}$/mL	RSV B	1.8 x 10^{-1} $TCID_{50}$/mL	3x
RSV B	1 x 10^5 $TCID_{50}$/mL	Influenza A virus H1-2009	9 x 10^{-1} $TCID_{50}$/mL	3x
Influenza A virus H1-2009	1 x 10^4 $TCID_{50}$/mL	Human parainfluenza virus 3	4.5 x 10^1 $TCID_{50}$/mL	3x
Human parainfluenza virus 3	1 x 10^5 $TCID_{50}$/mL	Influenza A virus H1-2009	9 x 10^{-1} $TCID_{50}$/mL	3x
Influenza A virus H1-2009	1 x 10^4 $TCID_{50}$/mL	SARS-CoV-2	1.5 x 10^{-1} $TCID_{50}$/mL	3x
SARS-CoV-2	1 x 10^5 $TCID_{50}$/mL	Influenza A virus H1-2009	9 x 10^{-1} $TCID_{50}$/mL	3x
RSV A	1 x 10^5 $TCID_{50}$/mL	SARS-CoV-2	1.5 x 10^{-1} $TCID_{50}$/mL	3x
SARS-CoV-2	1 x 10^5 $TCID_{50}$/mL	RSV A	4.5 x 10^{-1} $TCID_{50}$/mL	3x
Adenovirus B	1 x 10^5 $TCID_{50}$/mL	SARS-CoV-2	1.5 x 10^{-1} $TCID_{50}$/mL	3x
SARS-CoV-2	1 x 10^5 $TCID_{50}$/mL	Adenovirus B	6 x 10^0 $TCID_{50}$/mL	3x
Influenza B virus	1 x 10^4 $TCID_{50}$/mL	SARS-CoV-2	1.5 x 10^{-1} $TCID_{50}$/mL	3x
SARS-CoV-2	1 x 10^5 $TCID_{50}$/mL	Influenza B virus	3 x 10^{-1} $TCID_{50}$/mL	3x

7.2.7. Sample Matrix Equivalency

All analytical studies that utilized viral and bacterial cultures close to LoD were performed by spiking the viral and bacterial cultures into a pool of natural negative NPS in VTM as sample matrix or in a simulated negative matrix that contained VTM with mucin and human cellular material. A sample matrix equivalency study was performed to demonstrate equivalency between natural clinical matrix (pooled, negative nasopharyngeal swab in VTM samples) and the simulated negative matrix when spiked with targets at a concentration of approximately 10x LoD. Quantified, representative viral and bacterial strains were diluted in a natural clinical matrix (pooled, negative nasopharyngeal swab in VTM samples) and in the simulated negative matrix. Twenty (20) replicates of all samples were tested. There was no difference observed in detection of targets in natural clinical matrix vs. viral transport media.

7.2.8. Interfering Substances

Substances commonly found in respiratory samples, substances that could be introduced during specimen collection, or medications commonly used to treat congestion, allergies, or asthma symptoms that could potentially interfere with the **cobas® eplex** RP3 panel were individually evaluated at clinically relevant concentrations. To simulate clinical samples, quantified representative viral and bacterial strains were diluted to 3x LoD in a natural clinical matrix (pooled, negative nasopharyngeal swab specimens) and tested in triplicate for negative and positive interference. Natural clinical matrix (pooled, negative nasopharyngeal swab samples) with no organisms added was used as a control. All substances and organisms tested for interference were shown to be compatible with the **cobas® eplex** RP3 panel. No potentially interfering substances were found to inhibit the **cobas® eplex** RP3 panel at the concentrations tested in **Table 56.**

Table 56: List of substances for testing

Potentially interfering substance	Active ingredient	Testing concentration
Antibiotic, nasal ointment	Mupirocin	2.0% w/v
Antibacterial, systemic	Tobramycin[a]	0.5% w/v
Anti-viral drugs	Oseltamivir	142 ng/mL
Anti-viral drugs	Zanamivir	550 ng/mL
Bacteria	*Corynebacterium diphtheriae*	1 x 10^6 CFU/mL
Bacteria	*Haemophilus influenzae*	1 x 10^6 CFU/mL
Bacteria	*Neisseria meningitidis*	1 x 10^6 CFU/mL

Potentially interfering substance	Active ingredient	Testing concentration
Bacteria	*Staphylococcus aureus*	1 x 10^6 CFU/mL
Bacteria	*Streptococcus pneumoniae*	1 x 10^6 CFU/mL
Blood (human)	Blood[b]	1.0% v/v
Blood (human)	Human gDNA	50 ng/rxn
Collection kit	**cobas** PCR media uni swab sample kit[c]	N/A
Control sample matrix	MicroTest™ M5™ VTM[c]	N/A
Flocked swabs	Copan Minitip	N/A
Flocked swabs	Copan regular Tip	N/A
Flocked swabs	**cobas** uni swab	N/A
Mucin	Purified mucin protein	1.0% w/v
Nasal corticosteroids	Beclomethasone[d]	1.0% w/v
Nasal corticosteroids	Budesonide (Rhinocort®)	0.9% v/v
Nasal corticosteroids	Dexamethasone	1.5% w/v
Nasal corticosteroids	Flunisolide	1.5% w/v
Nasal corticosteroids	Fluticasone (Flonase®)	1.5% v/v
Nasal corticosteroids	Mometasone furoate	1 mg/mL
Nasal corticosteroids	Triamcinolone (Nasacort®)	1.5% v/v
Nasal sprays or drops	Phenylephrine HCl (Neo-Synephrine®)	1.0% v/v
Nasal sprays or drops	Oxymetazoline HCl (Afrin®)	1.0% v/v
Nasal sprays or drops	Sodium chloride	0.8% w/v
Nasal sprays or drops	Zinc gluconate	1.5% w/v
Throat lozenges, oral anesthetic and analgesic	Benzocaine, menthol	26% w/v
Viral Transport Medium[c]	Becton Dickinson UVT	N/A
Viral Transport Medium[c]	MicroTest™ M4RT™ VTM	N/A
Viral Transport Medium[c]	MicroTest™ M6™ VTM	N/A
Viral Transport Medium[c]	Copan eSwab (Liquid Amies medium)	N/A
Viral Transport Medium[c]	PBS	N/A
Viral Transport Medium[c]	Saline	N/A
Viral Transport Medium[c]	PrimeStore® Molecular Transport Medium	N/A
Virus	Cytomegalovirus[e]	1 x 10^4 $TCID_{50}$/mL
ZICAM® allergy relief nasal gel	Galphimia glauca	1.0% v/v
ZICAM® allergy relief nasal gel	Histaminum hydrochloricum	1.0% v/v
ZICAM® allergy relief nasal gel	Luffa operculata	1.0% v/v
ZICAM® allergy relief nasal gel	Sulfur	1.0% v/v

Potentially interfering substance	Active ingredient	Testing concentration

[a] At concentrations greater than 0.5% weight/volume in the sample, tobramycin was found to inhibit assay performance.

[b] At concentrations greater than 1.0% volume/volume in the sample, blood was found to inhibit assay performance.

[c] Testing of media was done by adding a negative NPS collected in the specified media and diluting in the natural clinical matrix.

[d] At concentrations greater than 1.0% weight/volume in the sample, beclomethasone was found to inhibit assay performance.

[e] The initial testing concentration of 1 x 10^5 $TCID_{50}$/mL resulted in one false negative for *B. pertussis*. Testing was done using a stock solution that primarily consisted of culture fluid. It was suspected that the failure was due to the high percentage of culture fluid in the testing sample as culture fluids contain reagents that may inhibit assay performance.

w/v= weight per volume; v/v= volume per volume

7.2.9. Carryover and Cross-contamination

Carryover and cross-contamination of the **cobas® eplex** RP3 panel was assessed using carryover/cross-contamination data testing the **cobas® eplex** RP panel on the **cobas® eplex** system. The carryover/cross-contamination rate of the **cobas® eplex** RP panel and **cobas® eplex** system instrument was tested in a checkerboard approach by running high positive and negative samples interspersed in all bays of a four-tower **cobas® eplex** system (24 bays total) over 5 separate runs on 5 separate days. Quantified parainfluenza virus 3 was prepared in viral transport media at a high concentration (1 x 10^5 $TCID_{50}$/mL, 20,000x LoD) to simulate a clinically relevant high positive and was tested as a representative target organism. Viral transport media was used to represent negative samples. On each round of testing, 24 **cobas® eplex** RP panel cartridges were evaluated. 100% of parainfluenza 3-positive samples generated a result of Detected and 100% of parainfluenza virus 3-negative samples generated a parainfluenza virus 3 result of No Target Detected, indicating no carryover or cross-contamination was observed between bays or within bays with the **cobas® eplex** RP panel when testing consecutively or in adjacent bays.

8. CONCLUSION

The analytical and clinical performance observed demonstrate that the **cobas® eplex** respiratory pathogen panel 3 is substantially equivalent to the predicate device.