November 20, 2025

Roche Molecular Systems, Inc.
Khushvanreep Singh
Regulatory Affairs Specialist
4300 Hacienda Drive
Pleasanton, California 94588

Re: K243753
Trade/Device Name: cobas liat Bordetella panel nucleic acid test
Regulation Number: 21 CFR 866.3980
Regulation Name: Respiratory Viral Panel Multiplex Nucleic Acid Assay
Regulatory Class: Class II
Product Code: OZZ, OOI
Dated: December 04, 2024
Received: December 05, 2024

Dear Khushvanreep Singh:

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

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

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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

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

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

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Bryan M. Grabias -S
2025.11.20 10:25:01 -05'00'

Bryan Grabias
Acting Branch Chief
Bacterial Respiratory and Medical Countermeasures Branch
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)*
K243753

Device Name
cobas liat Bordetella panel nucleic acid test

Indications for Use *(Describe)*
The cobas liat Bordetella panel nucleic acid test (cobas liat Bordetella panel) is an automated real-time polymerase chain reaction (PCR) test intended for the simultaneous qualitative detection and differentiation of Bordetella pertussis (Bp), Bordetella parapertussis (Bpp), and Bordetella holmesii (Bh) nucleic acid in human nasopharyngeal swabs taken from patients with suspected pertussis respiratory infection.

The test is meant to be used in conjunction with other clinical and epidemiological information and laboratory findings. When clinical factors suggest that B. pertussis, B. parapertussis or B. holmesii may not be the cause of respiratory infection, other clinically appropriate investigation(s) should be carried out in accordance with published guidelines.

Negative results do not preclude Bp, Bpp, or Bh infection and should not be used as the sole basis for treatment or other patient management decisions. Conversely, positive results do not rule out co-infection with other bacteria or viruses. The agent detected may not be the definite cause of disease.

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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cobas® liat Bordetella panel nucleic acid test (K243753)

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

Submitter Name	Roche Molecular Systems, Inc.
Address	4300 Hacienda Drive, Pleasanton, CA 94588-2722
Contact	Khushvanreep Singh Phone: (908) 253-7864 Email: Khushvanreep.singh@roche.com
Date Prepared	November 19, 2025
Proprietary Name	**cobas® liat** Bordetella panel nucleic acid test
Common Name	**cobas® liat** Bordetella panel
Classification	21 CFR 866.3980 Respiratory viral panel multiplex nucleic acid assay
Product Codes	OZZ OOI
Predicate Devices	Verigene® Respiratory Pathogens Flex Nucleic Acid Test (Verigene® RP Flex) (K143653)
Establishment Registration	Roche Molecular Systems, Inc. (2243471)

1. DEVICE DESCRIPTION

The **cobas® liat** Bordetella panel nucleic acid test (**cobas® liat** Bordetella panel) is an automated multiplex real-time polymerase chain reaction (PCR) assay for the rapid in vitro qualitative detection and differentiation of *B. pertussis* (Bp), *B. parapertussis* (Bpp), and *B. holmesii* (Bh) DNA in human nasopharyngeal swabs taken from patients with suspected pertussis respiratory infection.

The different fluorescent dye designs enable the specific detection and differentiation of the three microorganisms (Bp, Bpp, and Bh) independently in a multiplex system. The system automates all nucleic acid amplification test sample processing steps, including inhibitor removal, nucleic acid extraction, purification, amplification, real-time detection, and result interpretation in a rapid manner. The test is designed for use in near-patient settings to deliver results in approximately 15 minutes.

The **cobas® liat** system is comprised of the **cobas® liat** analyzer (analyzer) hardware with integrated **cobas® liat** system software (analyzer software + liat assay specific package (script)) for running tests and analyzing the results, and a single-use disposable **cobas® liat** assay tube (assay tube).

- **cobas® liat** analyzer is a system component that consists of one software subsystem and three hardware units:
  - Infrastructure unit, which consists of the hardware and embedded software (firmware).
  - Thermal, loading and motion unit: the processing module that interacts physically with the assay tube during the assay execution.
  - Detection unit consisting of the photodetectors that is used for the fluorescence detection during the PCR reaction
- The assay script provides a set of instructions to the analyzer hardware and software for assay tube processing, PCR, result calculation and interpretation and result reporting. The assay script can be installed on the analyzer independently of the analyzer software.

The **cobas® liat** Bordetella panel nucleic acid test is supported with a Liat Assay Specific Package (Assay Script): **cobas® liat** Bordetella panel LASP (BPTA).

- The assay tube holds all reagents needed for sample preparation and PCR processes. The assay specific reagents are packaged into a single assay tube in separate segments that are separated by frangible seals. An internal control (IC) is also included. The IC is present to control for adequate processing of the target bacteria through all steps of the assay process and to monitor the presence of inhibitors in the PCR reaction.

2. INDICATIONS FOR USE

The **cobas® liat** Bordetella panel nucleic acid test (**cobas® liat** Bordetella panel) is an automated real-time polymerase chain reaction (PCR) test intended for the simultaneous qualitative detection and differentiation of *Bordetella pertussis* (Bp), *Bordetella parapertussis* (Bpp), and *Bordetella holmesii* (Bh) nucleic acid in human nasopharyngeal swabs taken from patients with suspected pertussis respiratory infection.

The test is meant to be used in conjunction with other clinical and epidemiological information and laboratory findings. When clinical factors suggest that *B. pertussis*, *B. parapertussis* or *B. holmesii* may not be the cause of respiratory infection, other clinically appropriate investigation(s) should be carried out in accordance with published guidelines.

Negative results do not preclude *Bp*, *Bpp*, or *Bh* infection and should not be used as the sole basis for treatment or other patient management decisions. Conversely, positive results do not rule out co-infection with other bacteria or viruses. The agent detected may not be the definite cause of disease.

3. TECHNOLOGICAL CHARACTERISTICS

The primary technological characteristics and intended use of the RMS **cobas® liat** Bordetella panel are substantially equivalent to other legally marketed nucleic acid amplification tests intended for the qualitative detection of pertussis respiratory infection.

As indicated in Table 1, the RMS **cobas® liat** Bordetella panel is substantially equivalent to significant characteristics of the identified predicate device, the currently cleared Verigene® RP Flex) (K143653).

Table 1: Comparison of the cobas® liat Bordetella panel and the Predicate Device

	Submitted Device: cobas® liat Bordetella panel nucleic acid test	**Predicate Device: Verigene® RP Flex (K143653)**
Regulation Name	866.3980	866.3980
Product Code	OZZ OOI	OZZ OOI OCC OEM OEP OOU OZE
Intended Use	The **cobas® liat** Bordetella panel nucleic acid test (**cobas® liat** Bordetella panel) is an automated real-time polymerase chain reaction (PCR) test intended for the simultaneous qualitative detection and differentiation of *Bordetella pertussis* (Bp), *Bordetella parapertussis* (Bpp), and *Bordetella holmesii* (Bh) nucleic acid in human nasopharyngeal swabs taken from patients with suspected pertussis respiratory infection. The test is meant to be used in conjunction with other clinical and epidemiological information and laboratory findings. Negative results do not preclude *Bp*, *Bpp*, or *Bh* infection and should not be used as the sole basis for treatment or other patient management decisions. Conversely, positive results do not rule out co-infection with other bacteria or viruses. The agent detected may not be the definite cause of disease.	The Verigene® Respiratory Pathogens Flex Nucleic Acid Test (RP Flex) is a multiplexed qualitative test intended for the simultaneous detection and identification of multiple viral and bacterial nucleic acids in nasopharyngeal swabs (NPS) obtained from individuals suspected of respiratory tract infection. The test is performed on the automated Verigene System utilizing reverse transcription (RT), polymerase chain reaction (PCR), and microarray hybridization to detect gene sequences of the following organism types and subtypes: **Viruses:** Adenovirus Human Metapneumovirus Influenza A Influenza A (Subtype H1) Influenza A (Subtype H3) Influenza B Parainfluenza 1 Parainfluenza 2 Parainfluenza 3 Parainfluenza 4 Respiratory Syncytial Virus A Respiratory Syncytial Virus B Rhinovirus **Bacteria:** Bordetella parapertussis/bronchiseptica, Bordetella holmesii, Bordetella pertussis
Sample Type	Nasopharyngeal swab (NPS)	Same
Analyte Targets	Bordetella pertussis (BP) Bordetella parapertussis (BPP) Bordetella holmesii (BH)	Bordetella parapertussis/bronchiseptica, Bordetella holmesii, Bordetella pertussis Adenovirus Human Metapneumovirus

	Submitted Device: cobas® liat Bordetella panel nucleic acid test	Predicate Device: Verigene® RP Flex (K143653)
		Influenza A Influenza A (Subtype H1) Influenza A (Subtype H3) Influenza B Parainfluenza 1 Parainfluenza 2 Parainfluenza 3 Parainfluenza 4 Respiratory Syncytial Virus A Respiratory Syncytial Virus B Rhinovirus
Ancillary Collection Kits	Flocked swab with Universal Transport Media (UTM)	Same
Time to result	About 15 minutes	~ 2 hours
Amplification Technology	Real-time PCR	Same
Detection Chemistry	TaqMan® probes with fluorescent dyes	Microarray hybridization, Gold nanoparticle probe with Light Scattering
Controls Used	Sample processing control (IC) Positive and negative control	Same
Instrumentation	**cobas® liat** System	Verigene System
User Complexity	CLIA-Waived	CLIA-waived

4. NON-CLINICAL PERFORMANCE EVALUATION

4.1. Analytical sensitivity (Limit of Detection)

Analytical sensitivity was determined by analyzing a dilution series of two representative strains of Bordetella pertussis (Bp, Strains A639 and E431), Bordetella parapertussis (Bpp, Strains E838 and A747), and Bordetella holmesii (Bh, Strains F061 and ATCC 51541). The Bp, Bpp, and Bh cultures were co-spiked and diluted in pooled negative nasopharyngeal swab (NPS) clinical specimens collected in UTM to seven (7) concentration levels in 2-fold dilutions. All levels were tested with at least twenty (20) replicates for each of three (3) unique lots of reagents. The limit of detection (LoD) for each specimen type is shown in colony forming units per mL (CFU/mL) for Bp (Table 2), Bpp (Table 3), and Bh (Table 4) respectively as the target concentration which can be detected in ≥ 95% of the replicates for the worst-performing of the reagent lots.

Table 2: Bp concentration levels with at least 95% observed hit rate for worst-performing lot tested

Strain	LoD (CFU/mL)	Hit rate (Mean Ct)
A639	43	95.2% (34.6)
E431	36	95.2% (34.3)

Table 3: Bpp concentration levels with at least 95% observed hit rate for worst-performing lot tested

Strain	LoD (CFU/mL)	Hit rate (Mean Ct)
E838	32	95.2% (33.5)
A747	36	95.2% (32.6)

Table 4: Bh concentration levels with at least 95% observed hit rate for worst-performing lot tested

Strain	LoD (CFU/mL)	Hit rate (Mean Ct)
F061	34	100% (29.1)
51541	21	95.2% (31.1)

A study was performed to demonstrate that the LoD with target co-spiked samples is comparable to single target spiked samples.

4.2. Reactivity/Inclusivity

Inclusivity testing was performed for 12 Bp, 6 Bpp, and 3 Bh strains using one lot of reagents. Testing was performed using Bp, Bpp, and Bh cultures that were diluted into pools of negative clinical specimens. Three replicates per dilution level were tested for each strain. The strains tested and the lowest concentrations detected are listed in Table 5, Table 6, and Table 7 for Bp, Bpp, and Bh respectively.

Table 5: Inclusivity testing for Bp strains

Strain	CFU/mL
ATCC 8467	0.12
ATCC BAA-589	0.006

Strain	CFU/mL
ATCC 51445	0.12
ATCC 53894	0.05
ATCC 9340	0.04
ATCC 10380	0.48
ATCC BAA-1335	0.3
ATCC 9306	0.3
ATCC 12743	0.12
ATCC 9797	0.12
ATCC 12742	5.0
ATCC 8478	40.0

Table 6: Inclusivity testing for Bpp strains

Strain	CFU/mL
ATCC 15311	2.5
E595	40.0
ATCC 15237	10.0
ATCC BAA-587	15.0
ATCC 9305	11.9
C510	47.6

Table 7: Inclusivity testing for Bh strains

Strain	CFU/mL
ATCC 700053	1.75
ATCC 700052	0.48
C690	12.5

4.3. Cross reactivity and microbial interference

A panel of bacteria, fungi and viruses, including those commonly found in patient specimens, were tested to assess analytical specificity. High titer stocks of the potentially cross-reacting microorganisms listed in Table 8 were tested in negative nasopharyngeal swab matrix for cross-reactivity with **cobas® liat** Bordetella panel, and also tested for microbial interference in the presence of Bp, Bpp, and Bh cultures at ~3x LoD concentrations. Three (3) replicates in target positive background and three (3) replicates in target negative background were tested for each

non-target organism. The testing concentrations for potentially interfering organisms were ≥ 1 x 106 units/mL for bacteria or fungi and ≥ 1 x 10^5 units/mL for viruses. Results indicated that none of the non-target organisms tested generated false positive or false negative results due to cross-reactivity or interference.

Table 8: Microorganisms tested for analytical specificity/cross-reactivity

Bacteria / Fungi		Virus
Bordetella bronchiseptica[1]	*Legionella pneumophila*	Cytomegalovirus[2]
Bordetella avium	*Moraxella catarrhalis*	Epstein-Barr virus
Bordetella hinzii	*Mycobacterium tuberculosis*	Influenza A
Bordetella petrii	*Mycoplasmoides pneumoniae*	Influenza B
Bordetella trematum	*Neisseria gonorrhoeae*	Human rhinovirus
Achromobacter denitrificans[1]	*Neisseria meningitidis*	Respiratory syncytial virus type A
Chlamydia pneumoniae	*Pseudomonas aeruginosa*	Adenovirus
Chlamydia trachomatis	Methicillin-resistant *Staphylococcus aureus*	Human coronavirus
Corynebacterium diphtheriae	*Staphylococcus epidermidis*	Herpes Simplex Virus Type 1
Escherichia coli	*Stenotrophomonas maltophilia*	Herpes Simplex Virus Type 2
Haemophilus influenzae	*Streptococcus pneumoniae*	Measles virus
Klebsiella pneumoniae	*Streptococcus pyogenes*	Mumps virus
Lactobacillus acidophilus	*Streptococcus salivarius*	SARS-CoV-2
Lactiplantibacillus plantarum	*Candida albicans* (fungus)	Human metapneumovirus
--	--	Human bocavirus[2]
--	--	Enterovirus[1]

1Three different strains were tested

2 Tested at highest concentration possible per stock concentration

4.4. Competitive inhibition

To assess competitive inhibition between Bp, Bpp, and Bh, a total of three different combinations of low concentration of target (~3x LoD) were mixed with high concentrations (1E7 CFU/mL) of the other two targets in pooled clinical specimen matrix. Each combination was tested in replicates of 5 using one lot of reagents. Testing results indicated that when two target microorganisms were present at high concentrations, no interference was observed for microorganisms that were present at low concentrations.

4.5. Endogenous and exogenous interference

Potentially interfering substances that may be commonly encountered in nasopharyngeal swab clinical specimens were evaluated. Testing was executed using pooled clinical specimens spiked with potential interferents. Potential interferents were tested with and without Bp, Bpp, and Bh at ~3x LoD using one lot of reagents. Five replicates each of Bp/Bpp/Bh negative sample and Bp/Bpp/Bh positive sample were tested with each substance.

The substances listed in Table 9 at the concentrations tested did not interfere in the detection of Bp, Bpp, or Bh. Flonase fluticasone nasal spray resulted in false negative results in one replicate when tested at concentrations higher than 5% v/v, and may interfere with the assay performance at concentrations greater than 5% v/v.

Table 9: List of products tested at concentrations that do not show interference

Potential Interferent	Concentration Tested
Human Cells (PBMC)	1E6 cells/mL
Mucin Bovine Type 1-S	10 mg/mL
Human Whole Blood	10% (v/v)
Afrin Pump Mist	10.0 % (v/v)
Flonase	5.0 % (v/v)
Chloraseptic Sore Throat Lozenges	10.0 mg/mL
Mupirocin	10.0 mg/mL
Relenza	10.0 mg/mL
Tamiflu	7.5 mg/mL
Tobramycin	0.6 mg/mL*
Albuterol Sulfate	5.0 % (w/v)
Sucrets Sore Throat & Cough Lozenges– Vapor Cherry	5.0 % (w/v)
Ampicillin powder	10.0 mg/mL
Azithromycin tablet	0.25 mg/mL*
Beconase AQ Nasal Spray	8.5 mg/mL
Children's Dimetapp Cold and Cough	5.0 % (v/v)
Ciprofloxacin	1.3 mg/mL
Erythromycin	0.47 mg/mL*
Neo-Synephrine Nasal Spray	15.0 % (v/v)
Rifampin	3.75 mg/mL*
Robitussin Cough + Chest Congestion DM liquid gel capsule	10.0 % (v/v)
Ocean Saline Nasal Spray (sodium chloride)	10.0 % (v/v)
Flumist	6.3 % (v/v)

*Note: For these substances, the concentration reflects the maximum amount soluble under the conditions tested.

4.6. Reproducibility study

A reproducibility study assessed the total variability of the **cobas® liat** Bordetella panel across study sites, operators, analyzers, testing days, and **cobas® liat** Bordetella panel reagent lots. The **cobas® liat** Bordetella panel was evaluated at three (3) sites. Two (2) operators at each site tested a three (3) member reproducibility panel in triplicate on five (5) non-consecutive days across three (3) reagent lots, for a total of 810 runs (3 panel members · 3 replicates · 2 operators · 5 days · 3 sites · 3 reagent lots). A total of nine (9) **cobas® liat** analyzers, three (3) at each study site, were used. The reproducibility panel, prepared by spiking *Bordetella* bacteria into a UTM-based human clinical matrix, comprised a negative, a low positive (1x-2x LOD), and a moderate positive (3x-5x LOD) for each of *B. pertussis*, *B. parapertussis* and *B. holmesii* bacteria. For a given bacteria, the expected result for the negative panel member is "Not Detected," while the expected result for the low positive and moderate positive panel member is "Detected".

The percent agreement with expected results is summarized in Table 10.

Table 10: cobas® liat Bordetella panel reproducibility: percentage agreement by target analyte and expected concentration

Target Analyte	Expected Concentration	Valid Tests (N)	Results in Agreement With Target Analyte (n)	Percent Agreement n/N x 100	95% Score CI
Negative	0	264	264	100.0	(98.6, 100.0)
Bp	1x-2x LOD	258	257	99.6	(97.8, 99.9)
Bp	3x-5x LOD	265	265	100.0	(98.6, 100.0)
Bpp	1x-2x LOD	258	257	99.6	(97.8, 99.9)
Bpp	3x-5x LOD	265	265	100.0	(98.6, 100.0)
Bh	1x-2x LOD	258	257	99.6	(97.8, 99.9)
Bh	3x-5x LOD	265	265	100.0	(98.6, 100.0)

Note: Results were in agreement when a positive panel member had a valid result of "Detected" for the target analyte or when the negative panel member had a valid result of "Not Detected" for the target analyte.

The variance component analyses for Ct values by target analyte and site are shown in the tables below respectively.

Table 11: cobas® liat Bordetella panel reproducibility: variance component analysis for Ct values by target analyte

Target Analyte	Expected Concen-tration	n/N[a]	Mean Ct	Site SD	Site CV%	Lot SD	Lot CV%	Day SD	Day CV%	Run SD	Run CV%	Within-Run (Residual) SD	Within-Run (Residual) CV%	Total SD	Total CV%
Bp	1x-2x LOD	257/258	33.2	0.05	0.1	0.35	1.1	0.23	0.7	0.15	0.5	0.59	1.8	0.74	2.2
Bp	3x-5x LOD	265/265	32.0	0.20	0.6	0.49	1.5	0.00	0.0	0.22	0.7	0.45	1.4	0.73	2.3
Bpp	1x-2x LOD	257/258	31.9	0.17	0.5	0.31	1.0	0.15	0.5	0.00	0.0	0.57	1.8	0.68	2.1
Bpp	3x-5x LOD	265/265	30.5	0.21	0.7	0.29	1.0	0.14	0.5	0.05	0.2	0.51	1.7	0.64	2.1
Bh	1x-2x LOD	257/258	27.8	0.00	0.0	0.27	1.0	0.14	0.5	0.11	0.4	0.56	2.0	0.65	2.3
Bh	3x-5x LOD	265/265	26.8	0.14	0.5	0.29	1.1	0.04	0.1	0.14	0.5	0.41	1.5	0.54	2.0

Ct: cycle threshold; LOD: Limit of Detection; SD: standard deviation; CV%: percent coefficient of variation.
[a] n is the number of positive tests, which contribute Ct values to the analysis. N is the total number of valid tests for the panel member.

Table 12: cobas® liat Bordetella panel reproducibility: variance component analysis for Ct values by site

Site	Target Analyte	Expected Concentration	n/N[a]	Mean Ct	Lot SD	Lot CV %	Day SD	Day CV %	Run SD	Run CV %	Within-Run (Residual) SD	Within-Run (Residual) CV%	Total SD	Total CV%
Site A	Bp	1x-2x LOD	85/ 85	33.1	0.55	1.7	0.19	0.6	0.19	0.6	0.58	1.8	0.85	2.6
Site A	Bp	3x-5x LOD	88/ 88	31.8	0.66	2.1	0.00	0.0	0.21	0.7	0.40	1.3	0.80	2.5
Site B	Bp	1x-2x LOD	85/ 85	33.2	0.34	1.0	0.00	0.0	0.06	0.2	0.65	2.0	0.73	2.2
Site B	Bp	3x-5x LOD	89/ 89	31.8	0.28	0.9	0.00	0.0	0.14	0.5	0.46	1.5	0.56	1.8
Site C	Bp	1x-2x LOD	87/ 88	33.3	0.37	1.1	0.06	0.2	0.11	0.3	0.53	1.6	0.65	2.0
Site C	Bp	3x-5x LOD	88/ 88	32.2	0.53	1.6	0.00	0.0	0.19	0.6	0.46	1.4	0.73	2.3
Site A	Bpp	1x-2x LOD	85/ 85	31.9	0.27	0.9	0.00	0.0	0.00	0.0	0.66	2.1	0.72	2.3
Site A	Bpp	3x-5x LOD	88/ 88	30.4	0.28	0.9	0.23	0.8	0.00	0.0	0.45	1.5	0.58	1.9
Site B	Bpp	1x-2x LOD	85/ 85	31.8	0.22	0.7	0.26	0.8	0.00	0.0	0.52	1.6	0.62	2.0
Site B	Bpp	3x-5x LOD	89/ 89	30.3	0.16	0.5	0.00	0.0	0.08	0.3	0.53	1.7	0.56	1.8
Site C	Bpp	1x-2x LOD	87/ 88	32.1	0.42	1.3	0.12	0.4	0.00	0.0	0.49	1.5	0.65	2.0
Site C	Bpp	3x-5x LOD	88/ 88	30.7	0.41	1.3	0.10	0.3	0.12	0.4	0.53	1.7	0.69	2.2
Site A	Bh	1x-2x LOD	85/ 85	27.8	0.25	0.9	0.17	0.6	0.00	0.0	0.52	1.9	0.60	2.2

Site	Target Analyte	Expected Concentration	n/N[a]	Mean Ct	Lot SD	Lot CV %	Day SD	Day CV %	Run SD	Run CV %	Within-Run (Residual) SD	Within-Run (Residual) CV%	Total SD	Total CV%
Site A	Bh	3x-5x LOD	88/ 89	26.7	0.25	0.9	0.15	0.5	0.00	0.0	0.41	1.5	0.50	1.9
Site B	Bh	1x-2x LOD	85/ 85	27.8	0.20	0.7	0.23	0.8	0.00	0.0	0.61	2.2	0.68	2.4
Site B	Bh	3x-5x LOD	89/ 89	26.7	0.21	0.8	0.00	0.0	0.20	0.8	0.40	1.5	0.49	1.8
Site C	Bh	1x-2x LOD	87/ 88	27.8	0.29	1.0	0.03	0.1	0.27	1.0	0.53	1.9	0.66	2.4
Site C	Bh	3x-5x LOD	88/ 88	26.9	0.38	1.4	0.09	0.3	0.08	0.3	0.41	1.5	0.57	2.1

Ct: cycle threshold; LOD: Limit of Detection; SD: standard deviation; CV%: percent coefficient of variation.
Note: Site A = MCR; Site B = APR; Site C = URM.
[a] n is the number of positive tests, which contribute Ct values to the analysis. N is the total number of valid tests for the panel member.

5. CLINICAL PERFORMANCE EVALUATION

The clinical performance of **cobas**® **liat** Bordetella panel (BP, BPP, and BH) was evaluated in a multi-site prospective study. Over 800 patients with suspected pertussis respiratory infection were enrolled between July 2023 – February 2024, and nasopharyngeal specimens were prospectively collected from patients presenting to point-of-care (POC) settings (e.g. emergency rooms, outpatient clinics, etc.). Subject demographics for evaluable, prospective clinical subjects are provided in Table 13. Archived clinical specimens and contrived samples were supplemented to fulfil the sample size requirement. The archived positive specimens were previously collected from symptomatic patients and characterized using an FDA-cleared Nucleic Acid Amplification Test (NAAT). Specimens were tested using **cobas**® **liat** Bordetella panel, the reference comparator methods per respective IFU and, if required, with a validated sequencing method to confirm the comparator result.

Table 13: Subject Demographics– Evaluable Prospective Population

Characteristics	Statistic	Estimates
Total	N	769
Age (Years)		
	Mean ± SD	33.9 ± 22.33
	Median	35.0
	Min , Max	0.1 , 85.0
Age Category		
< 1	n (%)	27 (3.51%)
1 to <5	n (%)	89 (11.57%)

Characteristics	Statistic	Estimates
5 to <12	n (%)	69 (8.97%)
12 to <18	n (%)	32 (4.16%)
18 to <40	n (%)	219 (28.48%)
40 to <65	n (%)	270 (35.11%)
>=65	n (%)	63 (8.19%)
Sex at Birth		
Male	n (%)	338 (43.95%)
Female	n (%)	431 (56.05%)
Ethnicity		
Hispanic / Latino	n (%)	194 (25.23%)
Not Hispanic / Latino	n (%)	568 (73.86%)
Not Reported	n (%)	2 (0.26%)
Unknown	n (%)	5 (0.65%)
Race		
American Indian / Alaska Native	n (%)	22 (2.86%)
Asian	n (%)	27 (3.51%)
Black / African American	n (%)	164 (21.33%)
White	n (%)	527 (68.53%)
Mixed-Race [a]	n (%)	22 (2.86%)
Other	n (%)	2 (0.26%)
Not Reported	n (%)	5 (0.65%)

Note: Unknown category indicates subjects for whom the corresponding information is not available.
[a] Mixed-Race combinations include: American Indian or Alaska Native/White (n=3), Asian/Black or African American (n=1), Asian/White (n=1), Asian/White/Other (n=1), Black or African American/White (n=15), Native Hawaiian or Other Pacific Islander/White (n=1).

The **cobas® liat** Bordetella panel's clinical performance was assessed by comparing results to FDA-cleared target specific NAAT. For Bpp and Bh, NAAT was used as the reference comparator. For Bp, the reference method was a composite of NAAT and a validated bi-directional sequencing method to confirm the presence of Bp.

The **cobas® liat** Bordetella Panel clinical performance results, PPA and NPA versus the comparator reference method, are summarized in Table 14.

Table 14: Summary Clinical Performance cobas® liat Bordetella panel by Target and Specimen Type

Target	Specimen type	Total (N)	PPA	PPA LCL 95% Score CI	PPA UCL 95% Score CI	NPA	NPA LCL 95% Score CI	NPA UCL 95% Score CI
Bp	Prospective	743	NC	NC	NC	100.0% (743/743)	99.5%	100.0%
Bp	Archived	160	100% (42/42)	91.6%	100.0%	99.2% (117/118)	95.4%	99.9%

Target	Specimen type	Total (N)	PPA	PPA LCL 95% Score CI	PPA UCL 95% Score CI	NPA	NPA LCL 95% Score CI	NPA UCL 95% Score CI
Bp	Contrived	327	98.8% (80/81)	93.3%	99.8%	99.6% (245/246)	97.7%	99.9%
Bp	Overall	1230	99.2% (122/123)	95.5%	99.9%	99.8% (1105/1107)	99.3%	100.0%
Bpp	Prospective	743	0.0% (0/1)	0.0%	79.3%	100.0% (742/742)	99.5%	100.0%
Bpp	Archived	170	100.0% (28/28)	87.9%	100.0%	100.0% (142/142)	97.4%	100.0%
Bpp	Contrived	327	100.0% (108/108)	96.6%	100.0%	99.5% (218/219)	97.5%	99.9%
Bpp	Overall	1240	99.3% (136/137)	96.0%	99.9%	99.9% (1102/1103)	99.5%	100.0%
Bh	Prospective	702	NC	NC	NC	99.9% (701/702)	99.2%	100.0%
Bh	Contrived	328	100.0% (139/139)	97.3%	100.0%	98.9% (187/189)	96.2%	99.7%
Bh	Overall	1030	100.0% (139/139)	97.3%	100.0%	99.7% (888/891)	99.0%	99.9%

Abbreviations: Bp = B.pertussis, Bpp = *B. parapertussis*, Bh = *B. holmesii*, CI = confidence interval, PPA = Positive Percent Agreement, NPA = Negative Percent Agreement, LCL = Lower Confidence Limit, UCL = Upper Confidence Limit, NC = Not Calculable.

Note: For prospective and archived specimens, the reference method is the respective comparator results. For contrived specimens the reference method is the expected result.

6. CONCLUSIONS

A comparison of the intended use, technological characteristics, and the results of non-clinical analytical and clinical performance studies demonstrate that **cobas® liat** Bordetella panel nucleic acid test is **substantially equivalent** to the predicate device.