February 13, 2026

LEX Diagnostics Limited
Joanne Channon
Director of Program Management
Melbourn Science Park
Melbourn, SG8 6EE
United Kingdom

Re: K251742
Trade/Device Name: VELO Respiratory Test
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: June 6, 2025
Received: June 6, 2025

Dear Joanne Channon:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 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 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 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)*
K251742

Device Name
VELO Respiratory Test

Indications for Use *(Describe)*
The VELO Respiratory Test is an automated rapid multiplex real-time, reverse transcriptase polymerase chain reaction (RT-PCR) test performed on the VELO Instrument and is intended for the simultaneous qualitative detection and differentiation of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), influenza A, and influenza B virus nucleic acid in anterior nasal swab (ANS) specimens from individuals with signs and symptoms of respiratory tract infection. Clinical signs and symptoms of respiratory tract infection due to SARS-CoV-2 and influenza can be similar.

The VELO Respiratory Test is intended for use as an aid in the differential diagnosis of SARS-CoV-2, influenza A, and/or influenza B infection if used in conjunction with other clinical and epidemiological information, and laboratory findings. SARS-CoV-2, influenza A and influenza B viral nucleic acid are generally detectable in ANS specimens during the acute phase of infection.

Positive results do not rule out co-infection with other organisms. The agent(s) detected by the VELO Respiratory Test may not be the definite cause of disease.

Negative results do not preclude SARS-CoV-2, influenza A, and/or influenza B infection. The results of this test should not be used as the sole basis for diagnosis, treatment, or other patient management decisions.

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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LEX Diagnostics Limited
Melbourn Science Park
Melbourn, SG8 6EE, UK
+44 1223 752144
enquiries@lexdiagnostics.com
lexdiagnostics.com

VELO Respiratory Test
510(k) Summary

Date Prepared:	04 February 2026
Submitter's Name:	Heather Danks
Submitter's email:	Heather.Danks@LEXDiagnostics.com
Submitter's phone:	+44 1223 752144
Device Trade Name:	VELO Respiratory Test
Common Name:	VELO Respiratory Test
Classification 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. (21 CFR § 866.3981)
Product Code:	QOF
Predicate Device:	cobas® SARS-CoV-2 & Influenza A/B for use on the cobas Liat System (K223591)

DEVICE DESCRIPTION

The VELO System is comprised of a single-use VELO Respiratory Test, and a reusable VELO Instrument:

- The **Test** contains individually packaged consumables: a "Test Cartridge" and an anterior nasal swab.
- The **Instrument** is a small, benchtop device with preloaded software for running tests and viewing the results. For a full description of the VELO Instrument, please refer to the VELO Instrument Manual.

Each Test Cartridge contains all necessary reagents for the detection of Flu A, Flu B and SARS-CoV-2 viral RNA from anterior nasal swab specimens. Primers and probes in the VELO Respiratory Test are designed to amplify and detect unique sequences within the following regions of each target pathogen: influenza A genome (matrix protein gene), influenza B genome (non-structural protein gene), and SARS-CoV-2 genome (ORF 1a/b non-structural region, and membrane protein gene). Each Test Cartridge also contains an endogenous Sample and Process Control (SPC). The SPC acts as an Internal Control (IC), to control for adequate sample collection and processing, the detection of failures in the reaction resulting from PCR inhibition, or a failure of the reagents. The SPC also ensures that the RT-PCR reaction conditions (temperature and time) are appropriate for the amplification reaction and that the resulting signal can be detected and processed by the system. Test outcomes are reported to the operator in real-time via the Instrument viewscreen with 'Not Detected' results available in under 10 minutes, when all cycles have completed. When the Test ends, all results can be viewed via the Instrument viewscreen, and the Test Cartridge may be removed for disposal.

INTENDED USE

The VELO Respiratory Test is an automated rapid multiplex real-time, reverse transcriptase polymerase chain reaction (RT-PCR) test performed on the VELO Instrument and is intended for the simultaneous qualitative detection and differentiation of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2),

influenza A, and influenza B virus nucleic acid in anterior nasal swab (ANS) specimens from individuals with signs and symptoms of respiratory tract infection. Clinical signs and symptoms of respiratory tract infection due to SARS-CoV-2 and influenza can be similar.

The VELO Respiratory Test is intended for use as an aid in the differential diagnosis of SARS-CoV-2, influenza A, and/or influenza B infection if used in conjunction with other clinical and epidemiological information, and laboratory findings. SARS-CoV-2, influenza A and influenza B viral nucleic acid are generally detectable in ANS specimens during the acute phase of infection.

Positive results do not rule out co-infection with other organisms. The agent(s) detected by the VELO Respiratory Test may not be the definite cause of disease.

Negative results do not preclude SARS-CoV-2, influenza A, and/or influenza B infection. The results of this test should not be used as the sole basis for diagnosis, treatment, or other patient management decisions.

INTENDED OPERATORS AND USE ENVIRONMENTS (CLIA STATEMENT):

The VELO Respiratory Test is intended for use by non-laboratory trained healthcare professionals in healthcare facilities, operating under a CLIA Certificate of Waiver.

PRINCIPLES OF THE PROCEDURE

Each VELO Respiratory Test Cartridge contains all necessary reagents for the detection of influenza A (Flu A), influenza B (Flu B) and SARS-CoV-2 viral RNA from anterior nasal swab specimens. Reverse Transcription-Polymerase Chain Reaction (RT-PCR) is used with specific primers and probes within the Cartridge to amplify and detect sequences unique to each target pathogen. Specifically, the matrix protein gene of Flu A, the non-structural gene of Flu B and the ORF1a/b non-structural region and membrane protein gene of SARS-CoV-2.

Each Test Cartridge also contains an endogenous Sample Process Control (SPC). The SPC serves as an Internal Control (IC) mechanism to ensure adequate sample collection and processing. It also monitors for under performance of the RT-PCR reaction, resulting from sample mediated inhibition or failure of the reagents. Additionally, the SPC verifies that the RT-PCR reaction conditions (temperature and duration) are optimal for the amplification process. This ensures that the resulting signal can be accurately detected and processed by the system.

Within the Test Cartridge, reagents are prepackaged and require no special handling. The anterior nasal specimen is directly entered into the Test Cartridge with the swab shaft removed at a pre-specified breakpoint. All further operational steps are automatically executed, eliminating the need for transfer media, reagent preparation, pipetting, temperature monitoring or timing. No complex nucleic acid extraction or purification is performed, rather, thermal lysis is used with the lysed materials directly rehydrating lyophilized RT-PCR reagents. Each target amplification reaction proceeds in an independent PCR chamber.

The VELO System is based upon proprietary technology that allows ultra-fast thermal cycling. This is achieved by combining the rapid transfer of heat into and out of the reaction with rapid thermalization from low volume and a high surface area to volume ratio of the reaction chamber. This ultra-fast thermal cycling enables rapid amplification, with typical thermal cycle durations of less than 10 seconds (per cycle), while still retaining the high sensitivity and specificity associated with hydrolysis probe detection.

In the event of amplification, a fluorescence signal is generated through the degradation of oligonucleotide probes modified with 5’ fluorophores and 3’ quenchers. Fluorescence is monitored by the Instrument with every thermal cycle and reports as “Detected” once meeting pre-determined criteria. Test outcomes are

reported to the operator in real-time via the Instrument view screen with 'Not Detected' results available in under 10 minutes with the completion of all cycles. When the Test ends, all results can be viewed via the Instrument view screen, and the Test Cartridge may be removed for disposal.

PREDICATE

The VELO Respiratory Test is predicated on the cobas® SARS-CoV-2 & Influenza A/B for use on the cobas Liat System (K223591, Roche Molecular Systems).

TECHNOLOGICAL CHARACTERISTICS

A comparison of the VELO Respiratory Test and VELO Instrument to the predicate is provided in the table below.

Differences in technological characteristics between the VELO Respiratory Test and VELO Instrument and the predicate are limited to the following:

1. VELO employs the use of direct swab elution within the Test Cartridge.
2. VELO employs the use of an endogenous (RNaseP) Sample Process Control
3. VELO employs thermal lysis followed by direct RT-PCR amplification
4. VELO's second SARS-CoV-2 viral target is within the Membrane protein gene.
5. VELO provides test results in 10 minutes or less

Table 1 Comparison Table

Parameter	VELO Respiratory Test	cobas® SARS-CoV-2 & Influenza A/B for use on the cobas Liat System
510(k) Number	K251742	K223591
510(k) Manufacturer	LEX Diagnostics Limited	Roche Molecular Systems, Inc
Regulation	Same	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
Regulatory Class	Same	Class II (Special Controls)
Classification Product Code	Same	QOF
Panel	Same	Microbiology
Assay Technology	Same	Multiplexed PCR amplification with qualitative fluorescence detection
Indications for Use	**The VELO Respiratory Test** is an automated rapid multiplex real-time, reverse transcriptase polymerase chain reaction (RT-PCR) test performed on the VELO	**The cobas SARS-CoV-2 & Influenza A/B nucleic acid test for use on the cobas Liat System (cobas SARS-CoV-2 & Influenza A/B)** is an automated rapid multiplex real-

Parameter	VELO Respiratory Test	cobas® SARS-CoV-2 & Influenza A/B for use on the cobas Liat System
	Instrument and is intended for the simultaneous qualitative detection and differentiation of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), influenza A, and/or influenza B virus nucleic acid in anterior nasal swab (ANS) specimens from individuals with signs and symptoms of respiratory tract infection. Clinical signs and symptoms of respiratory tract infection due to SARS-CoV-2 and influenza can be similar. **The VELO Respiratory Test** is intended for use as an aid in the differential diagnosis of SARS-CoV-2, influenza A, and/or influenza B infection if used in conjunction with other clinical and epidemiological information, and laboratory findings. SARS-CoV-2, influenza A, and influenza B viral nucleic acid are generally detectable in **ANS specimens** during the acute phase of infection. Positive results do not rule out co-infection with other organisms. The agent(s) detected by the VELO Respiratory Test may not be the definitive cause of disease. Negative results do not preclude SARS-CoV-2, influenza A, and/or influenza B infection. The results of this test should not be used as the sole basis for diagnosis, treatment, or other patient management decisions.	time, reverse transcriptase polymerase chain reaction (RT-PCR) test intended for the simultaneous qualitative detection and differentiation of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), influenza A, and/or influenza B virus nucleic acid in nasopharyngeal swab (NPS) and anterior nasal swab (ANS) specimens from individuals with signs and symptoms of respiratory tract infection. Clinical signs and symptoms of respiratory tract infection due to SARS-CoV-2 and influenza can be similar. **cobas SARS-CoV-2 & Influenza A/B** is intended for use as an aid in the differential diagnosis of SARS-CoV-2, influenza A, and/or influenza B infection if used in conjunction with other clinical and epidemiological information, and laboratory findings. SARS-CoV-2, influenza A, and influenza B viral nucleic acid are generally detectable in **NPS and ANS specimens** during the acute phase of infection. Positive results do not rule out co-infection with other organisms. The agent(s) detected by the cobas SARS-CoV-2 & Influenza A/B may not be the definitive cause of disease. Negative results do not preclude SARS-CoV-2, influenza A, and/or influenza B infection. The results of this test should not be used as the sole basis for diagnosis, treatment, or other patient management decisions.
Intended Users and Use Locations	Same	Healthcare facilities operating under a CLIA Certificate of Waiver
CLIA Complexity	Same	Waived
Analyte Targets	SARS-CoV-2: ORF1a/b nonstructural region SARS-CoV-2: **membrane protein gene** Influenza A: matrix gene Influenza B: non-structural protein gene	SARS-CoV-2: ORF1a/b nonstructural region SARS-CoV-2: **nucleocapsid protein gene** Influenza A: matrix gene Influenza B: non-structural protein gene

Parameter	VELO Respiratory Test	cobas® SARS-CoV-2 & Influenza A/B for use on the cobas Liat System
Sample Types	Anterior Nasal Swabs (ANS)	Anterior Nasal Swabs (ANS), and **Nasopharyngeal Swabs (NPS)**
Instrumentation	VELO Instrument	cobas Liat System
Reagents / Kit Components	Included in VELO Respiratory Test Cartridge, with no user involvement required	Included in Liat assay tube, with no user involvement required
Ancillary Collection Kits	Copan FLOQSwabs™	Copan FLOQSwabs **with UTM™, UVT,0.9% and other swabs with other VTM**
Elution	**Direct elution within the VELO Respiratory Test Cartridge**	**Swab eluted in transfer media (VTM/UTM)**
Sample Preparation	**Thermal lysis for nucleic acid release from cells / viral particles**	**Automated silica magnetic particle-based nucleic acid extraction**
Detection	Multiplexed assay using **fluorescent probes**, detected automatically by the VELO Instrument, not reliant on user judgement	Multiplexed assay using **different reporter dyes for target and control**, detected automatically by the cobas® Liat instrument, not reliant on user judgement
Internal Controls	Yes – **Endogenous RNaseP** Sample Process Control	Yes – **Exogenous** Sample Process Control ('Internal Process control')
External Control	Yes – commercially available	Yes – sold separately as the cobas® SARS-CoV-2 & Influenza A/B Quality Control Kit
Assay Results	Qualitative – as determined by an algorithm within the instrument (VELO)	Qualitative – as determined by an algorithm within the instrument (Liat)
Results Interpretation	Same	Visual read of automated results on a viewscreen
Time to Result	**In 10 minutes or less**	**In approximately 20 minutes**

Material differences are provided in **bold typeface** for ease of reference

A rigorous analytical performance assessment demonstrated comparable performance of the VELO Respiratory Test used on the VELO Instrument against the predicate device. No safety or efficacy risks have been identified in relation to the similarities and/or differences identified herein.

PERFORMANCE CHARACTERISTICS

Analytical Sensitivity (Limit of Detection)

The Limit of Detection (LoD) of the VELO Respiratory Test in pooled anterior nasal matrix was evaluated by testing limiting dilutions of two (2) strains of Influenza A H1N1 (A/PR/8/34 and A/New Cal/20/99), two (2) strains of Influenza A H3N2 (A/Hong Kong/8/68 and A/South Australia/55/14), Influenza B Yamagata Lineage (B/Wisconsin/1/2010), Influenza B Victoria Lineage (Malaysia/2506/04), the 2nd WHO International Standard for SARS-CoV-2 (Beta CoV/Australia/VIC01/2020) and an inactivated Omicron (BA.5) strain of SARS-CoV-2 (hCoV-19/USA/COR-22-06-3113/2022).

The preliminary LoD for each virus strain per lot was established as the minimum concentration for which 3/3 replicates returned a 'Detected' result for the VELO Respiratory Test. The confirmatory LoD for each virus strain was determined by retesting the preliminary LoD and at least one (1) higher concentration and one (1) lower concentration for each viral target with at least 20 replicates of each concentration/batch across a minimum of three (3) days. Confirmatory LoD was determined as the lowest concentration of each virus strain that was consistently detected (defined as ≥95% of samples) by both lots of tests. The highest (least sensitive) LoD value for the two (2) lots was reported as the final LoD. These LoD values were then verified with one (1) additional batch for each strain. The verified LoD values for each virus tested are shown in the table below.

Table 2 LoD Determination of influenza A, influenza B and SARS-CoV-2

Virus	Strain	Limit of Detection
SARS-CoV-2	BetaCoV/Australia/VIC01/2020	3,000 IU/swab
	hCoV-19/USA/COR-22-06-3113/2022	0.5 $TCID_{50}$/swab
Influenza A H1N1	A/PR/8/34	3,000 cp/swab
	A/New Cal/20/99	2.5 $TCID_{50}$/swab
Influenza A H3N2	A/Hong Kong/8/68	3,000 cp/swab
	A/South Australia/55/14	2.5 $TCID_{50}$/swab
Influenza B (Yamagata)	B/Wisconsin/1/2010	3,000 cp/swab
Influenza B (Victoria)	Malaysia/2506/04	1.0 $TCID_{50}$/swab

Analytical Reactivity (Inclusivity) - Inclusivity wet testing

The inclusivity of the VELO Respiratory Test on the VELO instrument was established through wet testing by evaluating ten (10) strains of SARS-CoV-2, ten (10) strains of influenza A H1N1, ten (10) strains of influenza H3N2 and eight (8) strains of influenza B. Each strain was tested individually initially at 3x LoD in pooled negative nasal matrix (NNM) in replicates of three (3) in a blinded and randomized fashion. Inclusivity was determined if the virus was detected in 3/3 replicates. If the initial test did not return 3/3 detected results, template concentration was increased until 3/3 was detected. The lowest concentration of template returning 3/3 detected results is detailed below.

Inclusivity of SARS-CoV-2

Table 3 Inclusivity results for SARS-CoV-2 strains

Virus	Strain	Concentration	Number detected/number tested (% detected)
SARS-CoV-2	2019-nCoV/USA-WA1/2020	9,000 cp/swab	3/3 (100%)
SARS-CoV-2 (Alpha-Variant)	Alpha (B.1.1.7) VOC202012/01	9,000 cp/swab	3/3 (100%)
SARS-CoV-2 (Beta-Variant)	Beta (B.1.351) VOC202012/02	9,000 cp/swab	3/3 (100%)
SARS-CoV-2 (Gamma-Variant)	Gamma (P.1)	9,000 cp/swab	3/3 (100%)
SARS-CoV-2 (Delta-Variant)	Delta (B.1.617.2) VOC21APR-02	9,000 cp/swab	3/3 (100%)
SARS-CoV-2 (Omicron-Variant)	BA.2.12.1; USA/NY-Wadsworth-22014351-01/2022	1.5 $TCID_{50}$/swab	3/3 (100%)
SARS-CoV-2 (Omicron-Variant)	BA.4.6; USA/MD-HP35538/2022	1.5 $TCID_{50}$/swab	3/3 (100%)
SARS-CoV-2 (Omicron-Variant)	BF.7; USA/NY-Wadsworth-22042128-01/2022	1.5 $TCID_{50}$/swab	3/3 (100%)
SARS-CoV-2 (Omicron-Variant)	XBB; USA/CA-Stanford-109_S21/2022	1.5 $TCID_{50}$/swab	3/3 (100%)
SARS-CoV-2 (Omicron-Variant)	XBB.1.5; USA/NY-Wadsworth-22061020-01/2022	1.5 $TCID_{50}$/swab	3/3 (100%)

These SARS-CoV-2 strains are in addition to the BetaCoV/Australia/VIC01/2020 and hCoV-19/USA/COR-22-06-3113/2022 used in the analytical sensitivity study.

In addition, the two (2) SARS-CoV-2 assay targets (Orf1ab and M) within the VELO Respiratory Test were subject to in silico analysis to ensure coverage of the assay as a whole. *In silico* analysis of 137,277 SARS-CoV-2 sequences (as of May 2025) indicate that 100% of sequences for SARS-CoV-2 have no changes within the primer and/or probe binding regions that would be predicted to affect the performance of both assay targets. Therefore, all known variants are predicted to be detected.

Influenza A inclusivity

Table 4 Inclusivity results for influenza A H1N1 strains

Virus	Strain	Concentration	Number detected/number tested (% detected)
Influenza A (H1N1pdm)	A/California/07/09	7.5 TCID50/swab	3/3 (100%)
Influenza A (H1N1pdm)	A/NY/01/09	10 $TCID_{50}$/swab [a]	3/3 (100%)
Influenza A (H1N1pdm)	A/Victoria/4897/2022	9,000 cp/swab	3/3 (100%)
Influenza A (H1N1pdm)	A/Wisconsin/67/2022	9,000 cp/swab	3/3 (100%)
Influenza A (H1N1pdm)	A/California/08/2009	168 $CEID_{50}$/swab [b]	3/3 (100%)
Influenza A H1N1	A/Denver/1/1957	112 $CEID_{50}$/swab [a]	3/3 (100%)
Influenza A H1N1	A/New Jersey/8/1976	168 $CEID_{50}$/swab [c]	3/3 (100%)
Influenza A H1N1	A/NWS/33	84 $CEID_{50}$/swab	3/3 (100%)
Influenza A H1N1	A/Solomon Island/3/2006	84 $CEID_{50}$/swab	3/3 (100%)
Influenza A H1N1	A/Swine/Iowa/15/30	140 $CEID_{50}$/swab [d]	3/3 (100%)

[a] Results for 4x LoD, results at 3x LoD were 5/6 detected
[b] Results for 6x LoD as inclusivity at 3x LoD could not be determined (4/6 detected), results at 5x LoD were 5/6 detected.
[c] Results for 6x LoD as inclusivity at 3x LoD could not be determined (0/3 detected), results at 5x LoD were 5/6 detected
[d] Results for 5x LoD as inclusivity at 3x LoD could not be determined (3/6 detected)

Table 5 Inclusivity results for influenza A H3N2 strains

Virus	Strain	Concentration	Number detected/number tested (% detected)
Influenza A (H3N2)	A/Aichi/2/68	236.4 $CEID_{50}$/swab	3/3 (100%)
Influenza A (H3N2)	A/Brisbane/10/07	236.4 $CEID_{50}$/swab	3/3 (100%)
Influenza A (H3N2)	A/California/122/2022	9,000 cp/swab	3/3 (100%)
Influenza A (H3N2)	A/Switzerland/9715293/13	7.5 $TCID_{50}$/swab	3/3 (100%)
Influenza A (H3N2)	A/Sydney/5/1997	236.4 $CEID_{50}$/swab	3/3 (100%)
Influenza A (H3N2)	A/Texas/50/12	7.5 $TCID_{50}$/swab	3/3 (100%)
Influenza A (H3N2)	A/Thailand/8/2022	9,000 cp/swab	3/3 (100%)
Influenza A (H3N2)	A/Uruguay/716/2007	236.4 $CEID_{50}$/swab	3/3 (100%)
Influenza A (H3N2)	A/Victoria/361/2011	236.4 $CEID_{50}$/swab	3/3 (100%)
Influenza A (H3N2)	A/Wisconsin/67/05	7.5 $TCID_{50}$/swab	3/3 (100%)

These influenza A strains are in addition to the A/PR/8/34, A/New Cal/20/99, A/Hong Kong/8/68 and A/South Australia/55/14 strains used in the analytical sensitivity study.

In addition, in silico analysis (May 2025) of 57,399 available influenza A H1N1 and H3N2 sequences predicts that the VELO Respiratory Test would detect ≥99.8% of the isolates/variants available for analysis.

Influenza B inclusivity

Table 6 Inclusivity results for influenza B strains

Virus	Strain	Concentration	Number detected/number tested (% detected)
Influenza B	B/Lee/1940	26.4 $CEID_{50}$/swab	3/3 (100%)
Influenza B (Victoria Lineage)	B/Michigan/1/2021	9,000 cp/swab	3/3 (100%)
Influenza B (Victoria Lineage)	B/Brisbane/60/2008	26.4 $CEID_{50}$/swab	3/3 (100%)
Influenza B	B/Nevada/03/2011	26.4 $CEID_{50}$/swab	3/3 (100%)

(Victoria Lineage)			
Influenza B (Victoria Lineage)	B/Hong Kong/330/2001	26.4 $CEID_{50}$/swab	3/3 (100%)
Influenza B (Yamagata Lineage)	B/Guangdong/120/00	3 $TCID_{50}$/swab	3/3 (100%)
Influenza B (Yamagata Lineage)	B/Massachusetts/2/12	3 $TCID_{50}$/swab	3/3 (100%)
Influenza B (Yamagata Lineage)	B/Texas/6/11	3 $TCID_{50}$/swab	3/3 (100%)

These influenza B strains are in addition to the B/Wisconsin/1/2010 and Malaysia/2506/04 strains used in the analytical sensitivity study.

In addition, *in silico* analysis (as of May 2025) of 12,876 influenza B sequences predicts that the VELO Respiratory Test would detect ≥98.4% of the isolates/variants available for analysis.

Cross-reactivity and Microbial Interference

Exclusivity (cross-reactivity) and microbial interference of the VELO Respiratory Test on the VELO Instrument were evaluated by wet testing 52 different viruses, bacteria and fungi that are common in respiratory infections. All samples were prepared in pooled negative nasal matrix in the presence of influenza A H3N2, influenza B and SARS-CoV-2 at 3x LoD (to determine microbial interference) or in the absence of viral targets (to determine exclusivity). Each sample type was tested in replicates of three (3). Exclusivity was determined if 0/3 replicates returned a detected result for each of the three (3) viral targets. Absence of microbial interference was determined if 3/3 replicates returned a detected result for each of the three (3) viral targets. None of the 52 microorganisms tested were found to show any interference or cross-reactivity with the VELO Respiratory Test at the concentrations tested.

Table 7 Exclusivity (cross reactivity) wet testing results

Microorganism	Concentration (per mL)	% negative agreement
Adenovirus Type 1	3.45 $x10^6$ $TCID_{50}$	100% (0/3 detected)
Adenovirus Type 7	3.37 $x10^6$ $TCID_{50}$	100% (0/3 detected)
Adenovirus Type 10	9.6 $x10^5$ $TCID_{50}$	100% (0/3 detected)
Adenovirus Type 21	2 $x10^5$ $TCID_{50}$	100% (0/3 detected)
Human Coronavirus OC43	2 $x10^5$ $TCID_{50}$	100% (0/3 detected)
Human Coronavirus 229E	2 $x10^5$ copies	100% (0/3 detected)
Human Coronavirus NL63	2.13$x10^5$ $TCID_{50}$	100% (0/3 detected)
Human Coronavirus HKU1 [a]	2 $x10^5$ copies	100% (0/3 detected)

Cytomegalovirus	2.02 x10^5 $TCID_{50}$	100% (0/3 detected)
Enterovirus Coxsackievirus CV-A16	2 x10^5 $TCID_{50}$	100% (0/3 detected)
Enterovirus D68	2 x10^5 $TCID_{50}$	100% (0/3 detected)
Enterovirus Type 71	2 x10^5 $TCID_{50}$	100% (0/3 detected)
Epstein Barr Virus	2 x10^5 $TCID_{50}$	100% (0/3 detected)
Human parainfluenza Type 1	1.6 x10^5 $TCID_{50}$	100% (0/3 detected)
Human parainfluenza Type 2	2 x10^5 $TCID_{50}$	100% (0/3 detected)
Human parainfluenza Type 3	2 x10^5 $TCID_{50}$	100% (0/3 detected)
Human parainfluenza Type 4	2 x10^5 $TCID_{50}$	100% (0/3 detected)
Measles	1.9 x10^5 $TCID_{50}$	100% (0/3 detected)
MERS-CoV [b]	NA [d]	100% (0/3 detected)
Human Metapneumovirus Type 1A	2 x10^5 $TCID_{50}$	100% (0/3 detected)
Mumps virus	1.1 x10^5 $TCID_{50}$	100% (0/3 detected)
Respiratory syncytial virus A1998/3-2	2 x10^5 $TCID_{50}$	100% (0/3 detected)
Respiratory syncytial virus A Long	2 x10^5 $TCID_{50}$	100% (0/3 detected)
Respiratory syncytial virus B	2 x10^5 $TCID_{50}$	100% (0/3 detected)
Rhinovirus A50, A2	1.33 x10^5 $TCID_{50}$	100% (0/3 detected)
Rhinovirus 20, 15-CV19	2 x10^5 $TCID_{50}$	100% (0/3 detected)
Aspergillus fumigatus	4.65 x10^5 CFU	100% (0/3 detected)
Aspergillus niger	2 x10^6 CFU	100% (0/3 detected)
Bordatella parapertussis	2 x10^6 CFU	100% (0/3 detected)
Bordetella pertussis	2 x10^6 CFU	100% (0/3 detected)
Candida albicans	2 x10^6 CFU	100% (0/3 detected)
Chlamydia pneumoniae	2 x10^6 IFU	100% (0/3 detected)
Corynebacterium xerosis	2 x10^6 CFU	100% (0/3 detected)
Escherichia coli	2 x10^6 CFU	100% (0/3 detected)
Fusobacterium necrophorum	2 x10^6 CFU	100% (0/3 detected)
Hemophilus influenzae	2 x10^6 CFU	100% (0/3 detected)
Klebsiella pneumoniae	2 x10^6 CFU	100% (0/3 detected)

Lactobacillus acidophilus	5.79 x10^6 CFU	100% (0/3 detected)
Legionella pneumophila	2 x10^6 CFU	100% (0/3 detected)
Moraxella catarrhalis	2 x10^6 CFU	100% (0/3 detected)
Mycoplasma genitalium [b]	2 x10^6 CFU	100% (0/3 detected)
Mycobacterium tuberculosis [c]	2 x10^6 copies	100% (0/3 detected)
Mycoplasma pneumoniae	2 x10^6 CCU	100% (0/3 detected)
Neisseria meningitidis	2 x10^6 CFU	100% (0/3 detected)
Neisseria mucosa	2 x10^6 CFU	100% (0/3 detected)
Pneumocystis jirovecii (PJP) [a]	2 x10^6 copies	100% (0/3 detected)
Pseudomonas aeruginosa	2 x10^6 CFU	100% (0/3 detected)
Staphylococcus aureus	2 x10^6 CFU	100% (0/3 detected)
Staphylococcus epidermis	2 x10^6 CFU	100% (0/3 detected)
Streptococcus pneumoniae	2 x10^6 CFU	100% (0/3 detected)
Streptococcus pyogenes	2 x10^6 CFU	100% (0/3 detected)

[a] Synthetic nucleic acid
[b] Inactivated whole organism
[c] Genomic nucleic acid
[d] Swabs contrived with 8µl of NATrol™ MERS-CoV Stock (Ct 25.7)

Table 8 Microbial interference wet testing results

Microorganism	Concentration (per mL)	3x LoD SARS-CoV-2/Influenza A/Influenza B % positive agreement
Adenovirus Type 1	3.45 x10^6 $TCID_{50}$	100% (3/3 detected)
Adenovirus Type 7	3.37 x10^6 $TCID_{50}$	100% (3/3 detected)
Adenovirus Type 10	9.6 x10^5 $TCID_{50}$	100% (3/3 detected)
Adenovirus Type 21	2 x10^5 $TCID_{50}$	100% (3/3 detected)
Human Coronavirus OC43	2 x10^5 $TCID_{50}$	100% (3/3 detected)
Human Coronavirus 229E	2 x10^5 copies	100% (3/3 detected)
Human Coronavirus NL63	2.13x10^5 $TCID_{50}$	100% (3/3 detected)
Human Coronavirus HKU1 [a]	2 x10^5 copies	100% (3/3 detected)
Cytomegalovirus	2.02 x10^5 $TCID_{50}$	100% (3/3 detected)

Enterovirus Coxsackievirus CV-A16	2 x10^5 $TCID_{50}$	100% (3/3 detected)
Enterovirus D68	2 x10^5 $TCID_{50}$	100% (3/3 detected)
Enterovirus Type 71	2 x10^5 $TCID_{50}$	100% (3/3 detected)
Epstein Barr Virus	2 x10^5 $TCID_{50}$	100% (3/3 detected)
Human parainfluenza Type 1	1.6 x10^5 $TCID_{50}$	100% (3/3 detected)
Human parainfluenza Type 2	2 x10^5 $TCID_{50}$	100% (3/3 detected)
Human parainfluenza Type 3	2 x10^5 $TCID_{50}$	100% (3/3 detected)
Human parainfluenza Type 4	2 x10^5 $TCID_{50}$	100% (3/3 detected)
Measles	1.9 x10^5 $TCID_{50}$	100% (3/3 detected)
MERS-CoV [b]	NA [d]	100% (3/3 detected)
Human Metapneumovirus Type 1A	2 x10^5 $TCID_{50}$	100% (3/3 detected)
Mumps virus	1.1 x10^5 $TCID_{50}$	100% (3/3 detected)
Respiratory syncytial virus A1998/3-2	2 x10^5 $TCID_{50}$	100% (3/3 detected)
Respiratory syncytial virus A Long	2 x10^5 $TCID_{50}$	100% (3/3 detected)
Respiratory syncytial virus B	2 x10^5 $TCID_{50}$	100% (3/3 detected)
Rhinovirus A50, A2	1.33 x10^5 $TCID_{50}$	100% (3/3 detected)
Rhinovirus 20, 15-CV19	2 x10^5 $TCID_{50}$	100% (3/3 detected)
Aspergillus fumigatus	4.65 x10^5 CFU	100% (3/3 detected)
Aspergillus niger	2 x10^6 CFU	100% (3/3 detected)
Bordatella parapertussis	2 x10^6 CFU	100% (3/3 detected)
Bordetella pertussis	2 x10^6 CFU	100% (3/3 detected)
Candida albicans	2 x10^6 CFU	100% (3/3 detected)
Chlamydia pneumoniae	2 x10^6 IFU	100% (3/3 detected)
Corynebacterium xerosis	2 x10^6 CFU	100% (3/3 detected)
Escherichia coli	2 x10^6 CFU	100% (3/3 detected)
Fusobacterium necrophorum	2 x10^6 CFU	100% (3/3 detected)
Hemophilus influenzae	2 x10^6 CFU	100% (3/3 detected)
Klebsiella pneumoniae	2 x10^6 CFU	100% (3/3 detected)
Lactobacillus acidophilus	5.79 x10^6 CFU	100% (3/3 detected)

Legionella pneumophila	2 x10^6 CFU	100% (3/3 detected)
Moraxella catarrhalis	2 x10^6 CFU	100% (3/3 detected)
Mycoplasma genitalium [b]	2 x10^6 CFU	100% (3/3 detected)
Mycobacterium tuberculosis [c]	2 x10^6 copies	100% (3/3 detected)
Mycoplasma pneumoniae	2 x10^6 CCU	100% (3/3 detected)
Neisseria meningitidis	2 x10^6 CFU	100% (3/3 detected)
Neisseria mucosa	2 x10^6 CFU	100% (3/3 detected)
Pneumocystis jirovecii (PJP) [a]	2 x10^6 copies	100% (3/3 detected)
Pseudomonas aeruginosa	2 x10^6 CFU	100% (3/3 detected)
Staphylococcus aureus	2 x10^6 CFU	100% (3/3 detected)
Staphylococcus epidermis	2 x10^6 CFU	100% (3/3 detected)
Streptococcus pneumoniae	2 x10^6 CFU	100% (3/3 detected)
Streptococcus pyogenes	2 x10^6 CFU	100% (3/3 detected)
Streptococcus salivaris	2 x10^6 CFU	100% (3/3 detected)

[a] Synthetic nucleic acid
[b] Inactivated whole organism
[c] Genomic nucleic acid
[d] Swabs contrived with 8µl of NATrol™ MERS-CoV Stock (Ct 25.7)

Competitive Interference

The impact of competitive interference, caused by co-infections with on-target analytes, was evaluated for the VELO Respiratory Test on the VELO Instrument by testing contrived samples consisting of individual SARS-CoV-2, influenza A or influenza B strains at high concentrations in the presence of either one or both of the other target viruses at 3x LoD prepared in pooled negative nasal matrix. For this study, competitive interference was assessed using one strain each of SARSCoV-2 (USA-WA1/2020) and influenza B (B/Wisconsin/1/2010) and two strains of influenza A (A/ PR/8/34 -H1N1 strain and A/Hong Kong/8/68 -H3N2 strain). Testing was performed in triplicate. Absence of competitive interference was determined if all replicates for the low concentration (3x LoD) target(s) yielded positive results.

The study showed that influenza B at 1x10^6 copies/swab inhibited detection of influenza A (H1N1) at 3x LoD, in the presence of SARS-CoV-2 at 3x LoD. Subsequent testing using samples consisting of influenza A (H1N1) at 3x LoD, in the presence of influenza B at concentrations ranging from 1x10^5 – 1.5x10^6 copies/swab demonstrated no competitive interference. No competitive interference was observed for the other potential co-infections evaluated at the concentrations tested.

Table 9 Competitive Interference Results Summary

Viral Targets in Sample			Detection Rate		
Influenza A	Influenza B	SARS-CoV-2	Influenza A	Influenza B	SARS-CoV-2
H3N2 1x10^6 cp/swab*	3xLoD	3x LoD	3/3	3/3	3/3
H1N1 1x10^6 cp/swab	3xLoD	3x LoD	3/3	3/3	3/3
H3N2 3x LoD	N/A	1x10^6 cp/swab	3/3	0/3	3/3
H1N1 3x LoD	3x LoD	1x10^6 cp/swab	3/3	3/3	3/3
H3N2 3x LoD	1x10^6 cp/swab	N/A	3/3	3/3	0/3
H1N1 3x LoD	1x10^6 cp/swab	3x LoD	2/3	3/3	3/3
H1N1 3x LoD	1.5x10^6 cp/swab	N/A	3/3	3/3	0/3
	1x10^6 cp/swab	N/A	3/3	3/3	0/3
	9x10^5 cp/swab	N/A	3/3	3/3	0/3
	1x10^5 cp/swab	N/A	3/3	3/3	0/3

* cp/swab = copies/swab

Carry-over

An analytical study was performed to assess potential carry-over or cross contamination of the VELO Respiratory Test by running alternating no template (negative) and high positive samples on five (5) VELO instruments. The high positive samples consisted of a single viral target (influenza A H1N1, influenza A H3N2, influenza B or SARS-CoV-2) at 1x10^6 copies/swab prepared in pooled negative nasal matrix. Samples were tested across five (5) VELO instruments, where a no template control (NTC) sample was followed by a positive sample alternating eight (8) times before running a final negative sample to give 17 runs per VELO instrument. All high positive samples gave detected results for the viral target present in the sample, while 93% of the NTC samples gave the expected Invalid result. These results demonstrated that there is an acceptable, low likelihood of cross-contamination between samples when the VELO Respiratory Test Cartridge is performed on the VELO instrument according to the instructions for use.

Endogenous and Exogenous Interference

Endogenous and exogenous substances that may be found in the upper respiratory tract were evaluated to determine if they interfere with the performance of the VELO Respiratory Test on the VELO Instrument. All samples were prepared in negative nasal matrix and tested in replicates of three (3) positive and three (3) negative samples. Positive samples contained an individual exogenous or endogenous substance plus 3x LoD of SARS-CoV-2, influenza A and influenza B. Negative samples contained an individual exogenous or endogenous substance in negative nasal matrix. No interference was seen at the concentrations indicated.

Table 10 Summary of results for Interfering substance testing

Interfering Substance	Product	Active Ingredient	Concentration at which the interference is not observed
Blood (human)	N/A	None Specified	10% v/v [a]
Leukocytes		None Specified	1 x 10^6 cells/swab
Mucin: bovine submaxillary gland, type I-S		Purified mucin protein	2% v/v [b]
Nasal spray or drops	Zicam Intense Sinus Relief	Oxymetazoline HCl (0.05% w/v)	15% v/v
		Menthol	
	Phenylephrine	Phenylephrine	0.03 µg/ml
	Calpol saline nasal spray	Sodium chloride (0.9%) with preservatives	15% v/v
Nasal corticosteroids	Pirinase Hayfever once daily spray	Fluticasone propionate (50 µg/spray)	15% v/v
	Boots Adult Hay fever relief	Beclomethasone (50 µg/spray)	15% v/v
	Dexamethasone	Dexamethasone	12 µg/ml
	Flunisolide	Flunisolide	16 µg/swab
	Triamcinolone	Triamcinolone	10 µg/swab [c]
	Benacort Hayfever Relief Nasal Spray	Budesonide (64 µg/spray)	15% v/v
	Clarinaze Allergy Control 0.05% Nasal Spray	Mometasone furoate (50 µg/spray)	15% v/v

Nasal gel	Zicam, Powerful Allergy Relief	Sulfur	15% v/v
		Luffa opperculata,	
		Galphimia glauca	
		Histaminum hydrochloricum	
Sore throat and cough lozenges	Ultra Chloraseptic Spray	Benzocaine (0.71%)	15% v/v
Anti-viral drugs	N/A	Zanamivir	6.0 mg/ml [d]
	N/A	Oseltamivir phosphate	0.4 µg/ml
Antibiotics	N/A	Mupirocin	1.5 µg/ml
	N/A	Tobramycin	33 µg/ml
Zinc (common ingredient in nasal sprays)	Zinc chloride	Zinc	0.1 mg/ml
Nicotine or Tobacco	Nicorette (Nicotine 0.5 mg/spray)	Nicotine	15% v/v
Decongestant	Otravine Extra Dual Relief Nasal Spray	Xylometazoline hydrochloride	13.5% v/v [a]
		Ipratropium bromide	

[a] Potential interference observed with 15% v/v.
[b] Potential interference observed with 5 and 2.5% w/v.
[c] Potential interference observed 11 µg/swab.
[d] Potential interference observed with 7.5 and 6.75 mg/ml.
Note: FluMist Quadrivalent was not evaluated as cross-reactivity with targets is expected.

Precision (within-lab repeatability)

The repeatability of the VELO Respiratory Test to detect SARS-CoV-2, influenza A and influenza B was evaluated over a 12-day period at a single site with two (2) operators conducting the testing. A 3-member panel was evaluated consisting of a true negative (no analyte), low positive (2x LoD of all three [3] targets), and a moderate positive (4x LoD of all three [3] targets). The negative samples were contrived using simulated respiratory matrix and the positive samples were contrived using simulated respiratory matrix co-spiked with SARS-CoV-2, influenza A, and influenza B. The test samples were randomized and blinded to the operator running the VELO Instrument. The study was conducted using one (1) lot of VELO Respiratory Test cartridges tested by two (2) operators each performing two (2) replicates per run and two (2) runs per day. The study was performed over 12 days, totalling 96 replicates per panel member and 288 tests in total. Four (4) VELO Instruments were utilized during this study. The VELO Respiratory Test reported the expected

positive results for panel members in 97.9%-100% of samples at 2x LoD, 99.0%-100% of samples at 4x LoD and the expected negative results in 100% of negative samples.

Table 11 Summary of repeatability results by operator

		% Agreement with expected results (95% CI)		
Analyte	Panel member	Operator 1	Operator 2	Overall
SARS-CoV-2	Negative	100% (48/48) (92.6-100%)	100% (48/48) (92.6-100%)	100% (96/96) (96.2-100%)
	Low positive (2x LoD)	97.9% (47/48) (89.1-99.6%)	97.9% (47/48) (89.1-99.6%)	97.9% (94/96) (92.7-99.4%)
	Moderate positive (4x LoD)	97.9% (47/48) (89.1-99.6%)	100% (48/48) (92.6-100%)	99.0% (95/96) (94.3-99.8%)
Influenza A	Negative	100% (48/48) (92.6-100%)	100% (48/48) (92.6-100%)	100% (96/96) (96.2-100%)
	Low positive (2x LoD)	100% (48/48) (92.6-100%)	97.9% (47/48) (89.1-99.6%)	99.0% (95/96) (94.3-99.8%)
	Moderate positive (4x LoD)	100% (48/48) (92.6-100%)	100% (48/48) (92.6-100%)	100% (96/96) (96.2-100%)
Influenza B	Negative	100% (48/48) (92.6-100%)	100% (48/48) (92.6-100%)	100% (96/96) (96.2-100%)
	Low positive (2x LoD)	100% (48/48) (92.6-100%)	97.9% (47/48) (89.1-99.6%)	99.0% (95/96) (94.3-99.8%)
	Moderate positive (4x LoD)	100% (48/48) (92.6-100%)	100% (48/48) (92.6-100%)	100% (96/96) (96.2-100%)

Table 12 Summary of repeatability results by VELO Instrument

		% Agreement with expected results (95% CI)				
Analyte	Panel member	Instrument 1	Instrument 2	Instrument 3	Instrument 4	Overall
SARS-CoV-2	Negative	100% (25/25) (86.7-100%)	100% (22/22) (85.1-100%)	100% (24/24) (86.2-100%)	100% (25/25) (86.7-100%)	100% (96/96) (96.2-100%)
	Low positive (2x LoD)	95.8% (23/24) (79.8-99.3%)	95.8% (23/24) (79.8-99.3%)	100% (25/25) (86.7-100%)	100% (23/23) (85.7-100%)	97.9% (94/96) (92.7-99.4%)
	Moderate positive (4x LoD)	100% (23/23) (85.7-100%)	100% (23/23) (85.7-100%)	96.2% (25/26) (81.1-99.3%)	100% (24/24) (86.2-100%)	99.0% (95/96) (94.3-99.8%)
Influenza A	Negative	100% (25/25) (86.7-100%)	100% (22/22) (85.1-100%)	100% (24/24) (86.2-100%)	100% (25/25) (86.7-100%)	100% (96/96) (96.2-100%)
	Low positive (2x LoD)	95.8% (23/24) (79.8-99.3%)	100% (24/24) (86.2-100%)	100% (25/25) (86.7-100%)	100% (23/23) (85.7-100%)	99.0% (95/96) (94.3-99.8%)

	Moderate positive (4x LoD)	100% (23/23) (85.7-100%)	100% (23/23) (85.7-100%)	100% (26/26) (87.1-100%)	100% (24/24) (86.2-100%)	100% (96/96) (96.2-100%)
Influenza B	Negative	100% (25/25) (86.7-100%)	100% (22/22) (85.1-100%)	100% (24/24) (86.2-100%)	100% (25/25) (86.7-100%)	100% (96/96) (96.2-100%)
	Low positive (2x LoD)	100% (24/24) (86.2-100%)	100% (24/24) (86.2-100%)	96.0% (24/25) (80.5-99.3%)	100% (23/23) (85.7-100%)	99.0% (95/96) (94.3-99.8%)
	Moderate positive (4x LoD)	100% (23/23) (85.7-100%)	100% (23/23) (85.7-100%)	100% (26/26) (87.1-100%)	100% (24/24) (86.2-100%)	100% (96/96) (96.2-100%)

Clinical Performance

The clinical performance of the VELO Respiratory Test for the detection of influenza A, influenza B, and SARS-CoV-2 was evaluated using paired prospective clinical anterior nasal swab (ANS) specimens collected from individuals with signs and symptoms of upper respiratory viral infection. Testing of clinical samples was performed with the VELO Respiratory Test in nine (9) CLIA waived healthcare facilities (e.g., physician offices, primary care / outpatient clinics, and urgent care centers). The results of all three (3) viral targets (Instrument software v7.2.0) were compared to results from an FDA-cleared, CLIA waived RT-PCR assay (Comparator).

Prospective clinical specimens were collected and tested December 2024–March 2025. Initial enrollment in the prospective clinical study included 1815 anterior nasal swab specimens. Of these, 97 specimens were excluded from the performance analysis for major protocol deviations.Table 13 provides a summary of the demographic information for the remaining 1718 subjects enrolled in the clinical study.

Table 13 Subject Demographics- Prospective Symptomatic Population

Characteristics	Symptomatic Subjects
Total, N	1718
Age (years)	
Mean	41.0
Standard Deviation	17.97
Median	41
Range (minimum – maximum)	0 – 92
Age Group (Years), n (%)	
≤ 12	78 (4.5%)
13 to ≤18	96 (5.6%)
19 to <55	1130 (65.8%)
≥55	414 (24.1%)

Sex, n (%)	
Male	677 (39.4%)
Female	1041 (60.6%)
Ethnicity, n (%)	
Hispanic / Latino	191 (11.1%)
Not Hispanic / Not Latino	1516 (88.2%)
Note Reported	10 (0.6%)
Unknown	1 (0.1%)
Race, n (%)	
American Indian / Alaskan Native	30 (1.7%)
Asian	20 (1.2%)
Black / African-American	389 (22.6%)
Native Hawaiian / Pacific Islander	3 (0.2%)
White	1225 (71.3%)
Other	12 (0.7%)
More than one race	32 (1.9%)
Not Reported	7 (0.4%)

In addition, of the 1718 evaluable specimens collected in the prospective study a further six (6) specimens were excluded either due to invalid comparator tests results for all three (3) target analytes or the patient subsequently withdrew from the study. Of the remaining 1712 evaluable specimens from the prospective clinical study, additional exclusions due to invalid VELO Respiratory Test results upon retest resulted in the following final sample sizes for the performance evaluation, influenza A 1,677 (35 excluded), influenza B 1,665 (47 excluded), and SARS-CoV-2 1,670 (42 excluded). Three (3) influenza A / SARS-CoV-2 coinfections were detected by the Comparator.

Influenza A

For prospective symptomatic subjects, 342 ANS specimens tested positive for influenza A with both the VELO Respiratory Test and Comparator. A total of 1,295 ANS specimens tested negative for influenza A with both the VELO Respiratory Test and Comparator. Discrepant results were forwarded on to a central reference laboratory for testing on a second FDA-cleared, CLIA waived RT-PCR assay (secondary reference test). Results of discrepant analysis are included as a footnote to the results table.

For influenza A, the results of the clinical performance evaluation using ANS specimens from prospective symptomatic subjects demonstrated 92.4% positive percent agreement (PPA) (342/370; 95% score CI: 89.3% - 94.7%) and 99.1% negative percent agreement (NPA) (1,295/1,307; 95% score CI: 98.4% - 99.5%) as compared to the Comparator.

Table 14 Influenza A Results: Prospective, Paired ANS Specimens

Influenza A Prospective, Paired ANS Specimens		Comparator		
		Positive	Negative	Total
VELO Respiratory Test	Positive	342 [a]	12 [b]	354
	Negative	28 [c]	1,295	1,323
	Total	370	1,307	1,677

[a] Includes three (3) Influenza A / SARS-CoV-2 coinfections.
[b] Three (3) discrepant specimens tested positive on secondary reference testing.
[c] Two (2) discrepant specimens tested negative on secondary reference testing.

PPA	92.4%	95% CI: 89.3 – 94.7%
NPA	99.1%	95% CI: 98.4 – 99.5%

Influenza B

For prospective symptomatic subjects, 14 ANS specimens tested positive for influenza B with both the VELO Respiratory Test and Comparator. A total of 1,646 ANS specimens tested negative for influenza B with both the VELO Respiratory Test and Comparator. Discrepant results were forwarded on to a central reference laboratory for testing on a second FDA-cleared, CLIA waived RT-PCR assay. Results of discrepant analysis are included as a footnote to the results table.

For influenza B, the results of the clinical performance evaluation using ANS specimens from prospective symptomatic subjects demonstrated 93.3% PPA (14/15; 95% score CI: 70.2% - 98.8%) and 99.8% NPA (1,646/1,650; 95% score CI: 99.4% - 99.9%) as compared to the Comparator.

Table 15 Influenza B Results: Prospective, Paired ANS Specimens

Influenza B Prospective, Paired ANS Specimens		Comparator		
		Positive	Negative	Total
VELO Respiratory Test	Positive	14	4	18
	Negative	1 [a]	1,646	1,647
	Total	15	1,650	1,665

[a] One (1) discrepant specimen tested negative on secondary reference testing.

PPA	93.3%	95% CI: 70.2 – 98.8%
NPA	99.8%	95% CI: 99.4 – 99.9%

Due to the observed low prevalence of circulating influenza B virus, prospective influenza B testing was supplemented with paired retrospective clinical ANS specimens collected from individuals with signs and symptoms of influenza infection during the 2023-2024 North American respiratory season. Frozen paired positive and negative ANS (n=98) specimens prospectively obtained during the 2023-2024 flu season were distributed to a single site and tested during their daily workflow over a period of five (5) days.

For retrospective, paired specimens, 15 ANS specimens tested positive for influenza B with both the VELO Respiratory Test and a comparator RT-PCR assay. A total of 82 ANS specimens tested negative for influenza B with both the VELO Respiratory Test and comparator assay.

For influenza B, the results of the clinical performance evaluation using frozen, paired positive and negative ANS specimens from retrospective symptomatic subjects demonstrated 93.8% PPA (15/16; 95% score CI: 71.7% - 98.9%) and 100% NPA (82/82; 95% score CI: 95.5-100%) as compared to the comparator assay.

Table 16 Influenza B Results: Retrospective, Paired ANS Specimens

Influenza B Retrospective, Paired ANS Specimens		Comparator		
		Positive	Negative	Total
VELO Respiratory Test	Positive	15	0	15
	Negative	1	82	83
	Total	16	82	98

PPA	93.8%	95% CI: 71.7 – 98.9%
NPA	100%	95% CI: 95.5 – 100%

SARS-CoV-2

For prospective symptomatic subjects, 150 ANS specimens tested positive for SARS-CoV-2 with both the VELO Respiratory Test and Comparator; six (6) SARS-CoV-2-positive specimens tested negative for SARS-CoV-2 with the VELO Respiratory Test. A total of 1,507 ANS specimens tested negative for SARS-CoV-2 with both the VELO Respiratory Test and Comparator; seven (7) SARS-CoV-2-negative specimens tested

positive for SARS-CoV-2 with the VELO Respiratory Test. Discrepant results were forwarded on to a central reference laboratory for testing on a second FDA-cleared, CLIA waived RT-PCR assay. Results of discrepant analysis are included as a footnote to the results table.

For SARS-CoV-2, the results of the clinical performance evaluation using ANS specimens from prospective symptomatic subjects demonstrated 96.2% PPA (150/156; 95% score CI: 91.9% - 98.2%) and 99.5% NPA (1,507/1,514; 95% score CI: 99.1% - 99.8%) as compared to the Comparator.

Table 17 SARS-CoV-2 Results: Prospective, Paired ANS Specimens

SARS-CoV-2 Prospective, Paired ANS Specimens		Comparator		
		Positive	Negative	Total
VELO Respiratory Test	Positive	150 [a]	7	157
	Negative	6 [b]	1,507	1,513
	Total	156	1,514	1,670

[a] Includes three (3) Influenza A / SARS-CoV-2 coinfections.
[b] One (1) discrepant specimen tested negative on secondary reference testing.

PPA	96.2%	95% CI: 91.9 – 98.2%
NPA	99.5%	95% CI: 99.1 – 99.8%

Expected Values/Reference Range

For the prospective clinical performance evaluation of VELO Respiratory Test for use on the VELO Instrument ANS specimens from 1,718 evaluable subjects were freshly collected and tested at nine (9) point-of-care clinical sites in the United States between December 2024 – March 2025. Expected value (as determined by VELO Respiratory Test) summaries for prospective specimens, stratified by specimen collection/testing site are presented for influenza A, influenza B and SARS-CoV-2 targets:

Table 18 Expected value summary by clinical site for prospective clinical evaluation for influenza A from December 2024 – March 2025

Clinical Site ID	Site Location	ANS Specimens		
		Total No.	No. Positive for Influenza A	Expected Value
Overall		1,677	354	21.1%
1	Riverside, CA	138	26	18.8%

2	Orange City, FL	73	14	19.2%
3	DeLand, FL	20	1	5.0%
4	Brooklyn, NY	5	0	0.0%
5	Gulfport, MS	232	13	5.6%
6	Birmingham, AL	380	121	31.8%
7	Birmingham, AL	600	157	26.2%
8	Tulsa, OK	215	19	8.8%
9	Salt Lake City, UT	14	3	21.4%

Table 19 Expected value summary by clinical site for prospective clinical evaluation for influenza B from December 2024 – March 2025

Clinical Site ID	Site Location	ANS Specimens		
		Total No.	No. Positive for Influenza B	Expected Value
Overall		**1,665**	**18**	**1.1%**
1	Riverside, CA	138	6	4.3%
2	Orange City, FL	73	1	1.4%
3	DeLand, FL	20	0	0.0%
4	Brooklyn, NY	5	0	0.0%
5	Gulfport, MS	232	0	0.0%
6	Birmingham, AL	377	5	1.3%
7	Birmingham, AL	592	6	1.0%
8	Tulsa, OK	215	0	0.0%
9	Salt Lake City, UT	13	0	0.0%

Table 20 Expected value summary by clinical site for prospective clinical evaluation for SARS-CoV-2 from December 2024 – March 2025

Clinical Site ID	Site Location	ANS Specimens		
		Total No.	No. Positive for SARS-CoV-2	Expected Value
Overall		**1,670**	**157**	**9.4%**
1	Riverside, CA	138	1	0.7%
2	Orange City, FL	73	3	4.1%
3	DeLand, FL	20	2	10.0%
4	Brooklyn, NY	5	0	0.0%
5	Gulfport, MS	232	5	2.2%
6	Birmingham, AL	379	49	12.9%
7	Birmingham, AL	595	90	15.1%
8	Tulsa, OK	215	6	2.8%
9	Salt Lake City, UT	13	1	7.7%

Invalid rates

Of the 1716 tests performed for these subjects, there were a total of 90 (5.24%, 95% CI: 4.29 - 6.40%) invalid results obtained on initial testing with the VELO Respiratory Test run on the VELO Instrument. Of these, 34 were invalid upon retesting, for a final invalid rate of 1.98% (34/1716) with 95% CI: 1.42 – 2.76%.

Reproducibility

The reproducibility of the VELO Respiratory Test to detect SARS-CoV-2, Influenza A and Influenza B was established at three (3) external CLIA-waived sites using contrived nasal swabs and a 3-member panel consisting of a true negative (no analyte-matrix only), low positive (2x LoD of all three [3] targets), and a moderate positive (4x LoD of all three [3] targets). The negative samples were contrived using simulated respiratory matrix and the positive samples were contrived using simulated respiratory matrix co-spiked with SARS-CoV-2, influenza A and influenza B. The study was conducted using three (3) lots of VELO Respiratory Test cartridges tested by nine (9) untrained operators over three (3) sites (3 operators per site). Each panel member was tested in one (1) replicate/run with two (2) runs per day by each of the nine (9) operators. The study was performed over five (5) non-consecutive days, totalling 90 replicates per panel member and 270 tests in total. The VELO Respiratory Test reported the expected positive results for panel members in 97.8%-100% of samples at 2x LoD, 100% of samples at 4x LoD and the expected negative results in 100% of negative samples.

Table 21 Summary of reproducibility results by site

		% Agreement with expected results (95% CI)			
Analyte	Panel member	Site A	Site B	Site C	Overall
SARS-CoV-2	Negative	100% (30/30) (88.7-100%)	100% (30/30) (88.7-100%)	100% (30/30) (88.7-100%)	100% (90/90) (95.9-100%)
	Low positive (2x LoD)	100% (30/30) (88.7-100%)	96.7% (29/30) (83.3-99.4%)	96.7% (29/30) (83.3-99.4%)	97.8% (88/90) (92.3-99.4%)
	Moderate positive (4x LoD)	100% (30/30) (88.7-100%)	100% (30/30) (88.7-100%)	100% (30/30) (88.7-100%)	100% (90/90) (95.9-100%)
Influenza A	Negative	100% (30/30) (88.7-100%)	100% (30/30) (88.7-100%)	100% (30/30) (88.7-100%)	100% (90/90) (95.9-100%)
	Low positive (2x LoD)	100% (30/30) (88.7-100%)	100% (30/30) (88.7-100%)	100% (30/30) (88.7-100%)	100% (90/90) (95.9-100%)
	Moderate positive (4x LoD)	100% (30/30) (88.7-100%)	100% (30/30) (88.7-100%)	100% (30/30) (88.7-100%)	100% (90/90) (95.9-100%)
Influenza B	Negative	100% (30/30) (88.7-100%)	100% (30/30) (88.7-100%)	100% (30/30) (88.7-100%)	100% (90/90) (95.9-100%)
	Low positive (2x LoD)	100% (30/30) (88.7-100%)	100% (30/30) (88.7-100%)	100% (30/30) (88.7-100%)	100% (90/90) (95.9-100%)
	Moderate positive (4x LoD)	100% (30/30) (88.7-100%)	100% (30/30) (88.7-100%)	100% (30/30) (88.7-100%)	100% (90/90) (95.9-100%)

Table 22 Summary of reproducibility results by operator

		% Agreement with expected results (95% CI)			
Analyte	Panel member	A1	A2	A3	Overall
SARS-CoV-2	Negative	100% (10/10) (72.3 -100%)	100% (10/10) (72.3 -100%)	100% (10/10) (72.3 -100%)	100% (30/30) (88.7-100%)
	Low positive (2x LoD)	100% (10/10) (72.3 -100%)	100% (10/10) (72.3 -100%)	100% (10/10) (72.3 -100%)	100% (30/30) (88.7-100%)
	Moderate positive (4x LoD)	100% (10/10) (72.3 -100%)	100% (10/10) (72.3 -100%)	100% (10/10) (72.3 -100%)	100% (30/30) (88.7-100%)
Influenza A	Negative	100% (10/10) (72.3 -100%)	100% (10/10) (72.3 -100%)	100% (10/10) (72.3 -100%)	100% (30/30) (88.7-100%)
	Low positive (2x LoD)	100% (10/10) (72.3 -100%)	100% (10/10) (72.3 -100%)	100% (10/10) (72.3 -100%)	100% (30/30) (88.7-100%)
	Moderate positive (4x LoD)	100% (10/10) (72.3 -100%)	100% (10/10) (72.3 -100%)	100% (10/10) (72.3 -100%)	100% (30/30) (88.7-100%)
Influenza B	Negative	100% (10/10) (72.3 -100%)	100% (10/10) (72.3 -100%)	100% (10/10) (72.3 -100%)	100% (30/30) (88.7-100%)

	Low positive (2x LoD)	100% (10/10) (72.3 -100%)	100% (10/10) (72.3 -100%)	100% (10/10) (72.3 -100%)	100% (30/30) (887-100%)
	Moderate positive (4x LoD)	100% (10/10) (72.3 -100%)	100% (10/10) (72.3 -100%)	100% (10/10) (72.3 -100%)	100% (30/30) (88.7-100%)
Analyte	**Panel member**	**B1**	**B2**	**B3**	**Overall**
SARS-CoV-2	Negative	100% (10/10) (72.3 -100%)	100% (10/10) (72.3 -100%)	100% (10/10) (72.3 -100%)	100% (30/30) (88.7-100%)
	Low positive (2x LoD)	100% (10/10) (72.3 -100%)	100% (10/10) (72.3 -100%)	90% (9/10) (59.6-98.2%)	96.67% (29/30) (88.3-99.4%)
	Moderate positive (4x LoD)	100% (10/10) (72.3 -100%)	100% (10/10) (72.3 -100%)	100% (10/10) (72.3-100%)	100% (30/30) (88.7-100%)
Influenza A	Negative	100% (10/10) (72.3 -100%)	100% (10/10) (72.3 -100%)	100% (10/10) (72.3 -100%)	100% (30/30) (88.7-100%)
	Low positive (2x LoD)	100% (10/10) (72.3 -100%)	100% (10/10) (72.3 -100%)	100% (10/10) (72.3 -100%)	100% (30/30) (88.7-100%)
	Moderate positive (4x LoD)	100% (10/10) (72.3 -100%)	100% (10/10) (72.3 -100%)	100% (10/10) (72.3 -100%)	100% (30/30) (88.7-100%)
Influenza B	Negative	100% (10/10) (72.3 -100%)	100% (10/10) (72.3 -100%)	100% (10/10) (72.3-100%)	100% (30/30) (88.7-100%)
	Low positive (2x LoD)	100% (10/10) (72.3 -100%)	100% (10/10) (72.3 -100%)	100% (10/10) (72.3 -100%)	100% (30/30) (88.7-100%)
	Moderate positive (4x LoD)	100% (10/10) (72.3 -100%)	100% (10/10) (72.3 -100%)	100% (10/10) (72.3 -100%)	100% (30/30) (88.7-100%)
Analyte	**Panel member**	**C1**	**C2**	**C3**	**Overall**
SARS-CoV-2	Negative	100% (10/10) (72.3 -100%)	100% (10/10) (72.3 -100%)	100% (10/10) (72.3 -100%)	100% (30/30) (88.7-100%)
	Low –positive (2x LoD)	100% (10/10) (72.3 -100%)	100% (10/10) (72.3 -100%)	90% (9/10) (59.6 -98.2%)	96.7% (29/30) (83.3-99.4%)
	Moderate positive (4x LoD)	100% (10/10) (72.3 -100%)	100% (10/10) (72.3 -100%)	100% (10/10) (72.3 -100%)	100% (30/30) (88.7-100%)
Influenza A	Negative	100% (10/10) (72.3 -100%)	100% (10/10) (72.3 -100%)	100% (10/10) (72.3 -100%)	100% (30/30) (88.7-100%)
	Low –positive (2x LoD)	100% (10/10) (72.3 -100%)	100% (10/10) (72.3 -100%)	100% (10/10) (72.3 -100%)	100% (30/30) (88.7-100%)
	Moderate positive (4x LoD)	100% (10/10) (72.3 -100%)	100% (10/10) (72.3 -100%)	100% (10/10) (72.3 -100%)	100% (30/30) (88.7-100%)
Influenza B	Negative	100% (10/10) (72.3 -100%)	100% (10/10) (72.3 -100%)	100% (10/10) (72.3 -100%)	100% (30/30) (88.7-100%)
	Low –positive (2x LoD)	100% (10/10) (72.3 -100%)	100% (10/10) (72.3 -100%)	100% (10/10) (72.3 -100%)	100% (30/30) (88.7-100%)
	Moderate positive	100% (10/10)	100% (10/10)	100% (10/10)	100% (30/30)

	(4x LoD)	(72.3 -100%)	(72.3 -100%)	(72.3 -100%)	(88.7-100%)

Table 23 Summary of reproducibility results by cartridge lot

		% Agreement with expected results (95% CI)			
Analyte	Panel member	Lot 1	Lot 2	Lot 3	Overall
SARS-CoV-2	Negative	100% (25/25) (86.7-100%)	100% (30/30) (88.7-100%)	100% (35/35) (90.1-100%)	100% (90/90) (95.9-100%)
	Low –positive (2x LoD)	96.7% (29/30) (83.3-99.4%)	96.7% (29/30) (83.3-99.4%)	100% (30/30) (88.7-100%)	97.8% (88/90) (92.3-99.4%)
	Moderate positive (4x LoD)	100% (33/33) (89.6-100%)	100% (31/31) (89.0-100%)	100% (26/26) (87.1-100%)	100% (90/90) (95.9-100%)
Influenza A	Negative	100% (25/25) (86.7-100%)	100% (30/30) (88.7-100%)	100% (35/35) (90.1-100%)	100% (90/90) (95.9-100%)
	Low –positive (2x LoD)	100% (30/30) (88.7-100%)	100% (30/30) (88.7-100%)	100% (30/30) (88.7-100%)	100% (90/90) (95.9-100%)
	Moderate positive (4x LoD)	100% (33/33) (89.6-100%)	100% (31/31) (89.0-100%)	100% (26/26) (87.1-100%)	100% (90/90) (95.9-100%)
Influenza B	Negative	100% (25/25) (86.7-100%)	100% (30/30) (88.7-100%)	100% (35/35) (90.1-100%)	100% (90/90) (95.9-100%)
	Low –positive (2x LoD)	100% (30/30) (88.7-100%)	100% (30/30) (88.7-100%)	100% (30/30) (88.7-100%)	100% (90/90) (95.9-100%)
	Moderate positive (4x LoD)	100% (33/33) (89.6-100%)	100% (31/31) (89.0-100%)	100% (26/26) (87.1-100%)	100% (90/90) (95.9-100%)

Flex Studies

Flex studies were performed to evaluate the robustness of the VELO Respiratory Test on the VELO Instrument. Variations in workflow and operating environment that may reasonably be expected to occur with untrained operators in the intended use CLIA-waived setting were evaluated. Results of the flex studies conducted demonstrate robust performance of the VELO Respiratory Test on the VELO Instrument under conditions of stress.

CONCLUSIONS

A comparison of the intended use, technological characteristics, and the results of analytical and clinical performance studies demonstrate that the VELO Respiratory Test is substantially equivalent to the predicate device.

Results of non-clinical analytical, clinical performance and usability studies demonstrate that the VELO Respiratory Test's suitability for CLIA Waived Testing environments. Results demonstrate the VELO Respiratory Test is so simple and accurate as to render the likelihood of erroneous results by the user negligible.