August 7, 2026

Aptitude Medical Systems, Inc.
Tyler Chozinski
Head of Scientific and Medical Affairs
125 Cremona D
Suite 100
Goleta, California 93117

Re: K253453
Trade/Device Name: Metrix COVID Test; Metrix COVID Test Pro
Regulation Number: 21 CFR 866.3984
Regulation Name: Over-the-counter test to detect SARS-CoV-2 from clinical specimens
Regulatory Class: Class II
Product Code: QWB
Dated: October 3, 2025
Received: October 6, 2025

Dear Tyler Chozinski:

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 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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

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

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

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

JOSEPH BRIGGS -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K253453

Device Name
Metrix COVID Test; Metrix COVID Test Pro

Indications for Use *(Describe)*
Metrix COVID Test:

The Metrix COVID Test is a single-use (disposable) molecular in vitro diagnostic test for the qualitative detection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) viral RNA, that is used with the Metrix Reader (Gen 2). This test is intended for use with anterior nasal (AN) swab specimens, self-collected from individuals aged 14 years or older. This test is intended for individuals with signs and symptoms of COVID-19 (i.e., symptomatic).

When testing without healthcare provider oversight, a negative test result is presumptive. Presumptive negative results should be confirmed with a lab-based molecular assay when determined to be appropriate by a healthcare provider. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for treatment.

Individuals who test negative and experience continued or worsening respiratory symptoms such as fever, cough and/or shortness of breath should seek follow-up care with their healthcare provider.

Positive results do not rule out infection with other respiratory pathogens. This test is not a substitute for visits to a healthcare provider or appropriate follow-up and should not be used to determine any treatments without provider supervision.

Metrix COVID Test Pro:
The Metrix COVID Test Pro is a single-use (disposable) molecular in vitro diagnostic test for the qualitative detection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) viral RNA, that is used with the Metrix Reader (Gen 2). This test is intended for use with anterior nasal (AN) swab specimens, self-collected from individuals aged 14 years or older. This test is intended for individuals with signs and symptoms of COVID-19 (i.e., symptomatic).

When testing without healthcare provider oversight, a negative test result is presumptive. Presumptive negative results should be confirmed with a lab-based molecular assay when determined to be appropriate by a healthcare provider. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for treatment.

Individuals who test negative and experience continued or worsening respiratory symptoms such as fever, cough and/or shortness of breath should seek follow-up care with their healthcare provider.

Positive results do not rule out infection with other respiratory pathogens. This test is not a substitute for visits to a healthcare provider or appropriate follow-up and should not be used to determine any treatments without provider supervision.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) SUMMARY *21 CFR 807.92(a)(1), (2), (3)*

Date Prepared:	03 AUG 2026
Submitter:	Aptitude Medical Systems, Inc. 125 Cremona Dr. Ste 100 Goleta, CA 93117 Registration Number: 3017638293
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Trade Name:	Metrix COVID Test; Metrix COVID Test Pro
Common Name:	Metrix COVID Test; Metrix COVID Test Pro
Classification:	Class II
Regulation:	Over-the-counter molecular test to detect SARS-CoV-2 from clinical specimens 21 CFR 866.3984
Product Code(s):	QWB
Panel:	MI – Microbiology
Predicate Device:	Cue COVID-19 Molecular Test (DEN220028) Regulation: 21 CFR 866.3984 Classification: Class II Product Code: QWB

Device Description *21 CFR 807.92(a)(4)*

The Metrix COVID Test and Metrix COVID Test Pro (collectively, the candidate device) are compact nucleic acid amplification tests (NAATs) that detect RNA of SARS-CoV-2 in unprocessed nasal swab specimens using an isothermal molecular amplification reaction that is an equivalent alternative to polymerase chain reaction (PCR). The candidate device requires the use of the Metrix Reader (Gen 2), which is available separately.

The consumable candidate device kit consists of four components: Collector, Cap, Sensor, and Nasal Swab. The candidate device kit is used with the reusable Metrix Reader (Gen 2), sold separately. To prepare for a test, an anterior nasal swab sample is first placed in the Collector. Then, the Cap is attached to the Collector to release neutralization buffer (NB) from the Cap to mix with the sample. The NB is designed to lyse SARS-CoV-2 to release nucleic acids for downstream detection. The Collector is then connected to the Sensor to allow the sample to mix with reagents stored within the Sensor. Finally, the Sensor is inserted into the Metrix Reader (Gen 2) to initiate the reaction and detect the presence of SARS-CoV-2 RNA. The reaction proceeds automatically and generates a result within 20 minutes.

Intended Use *21 CFR 807.92(a)(5)*

Metrix COVID Test:

The Metrix® COVID Test is a single-use (disposable) molecular in vitro diagnostic test for the qualitative detection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) viral RNA, that is used with the Metrix Reader (Gen 2). This test is intended for use with anterior nasal (AN) swab specimens, self-collected from individuals aged 14 years or older. This test is intended for individuals with signs and symptoms of COVID-19 (i.e., symptomatic).

When testing without healthcare provider oversight, a negative test result is presumptive. Presumptive negative results should be confirmed with a lab-based molecular assay when determined to be appropriate by a healthcare provider. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for treatment.

Individuals who test negative and experience continued or worsening respiratory symptoms such as fever, cough and/or shortness of breath should seek follow-up care with their healthcare provider.

Positive results do not rule out infection with other respiratory pathogens. This test is not a substitute for visits to a healthcare provider or appropriate follow-up and should not be used to determine any treatments without provider supervision.

Metrix COVID Test Pro:

The Metrix® COVID Test Pro is a single-use (disposable) molecular in vitro diagnostic test for the qualitative detection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) viral RNA, that is used with the Metrix Reader (Gen 2). This test is intended for use with anterior nasal (AN) swab specimens, self-collected from individuals aged 14 years or older. This test is intended for individuals with signs and symptoms of COVID-19 (i.e., symptomatic).

When testing without healthcare provider oversight, a negative test result is presumptive. Presumptive negative results should be confirmed with a lab-based molecular assay when determined to be appropriate by a healthcare provider. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for treatment.

Individuals who test negative and experience continued or worsening respiratory symptoms such as fever, cough and/or shortness of breath should seek follow-up care with their healthcare provider.

Positive results do not rule out infection with other respiratory pathogens. This test is not a substitute for visits to a healthcare provider or appropriate follow-up and should not be used to determine any treatments without provider supervision.

Technological Characteristics *21 CFR 807.92(a)(6)*

The candidate device utilizes a multi-gene amplification method utilizing primers that target both the nucleocapsid (N) and open reading frame (ORF-1) genes of SARS-CoV-2. The candidate device also contains an on-board internal process control to monitor for sample lysis, reverse transcription, amplification, reagent function, and potential inhibition.

The system utilizes an electrochemical reporting technology to monitor the amplified double-stranded cDNA concentration in real-time in respective reaction chambers. The amplification creates a characteristic electrochemical signal analogous to the fluorescence signal of a laboratory PCR reaction. The electrochemical signal is analyzed automatically by the Metrix Reader (Gen 2), and the test result is reported as a combination of colors and positions of LED lights on the Reader. A result is obtained within 20 minutes.

A positive result occurs when the SARS-CoV-2 channel passes the detection threshold. A negative result occurs when only the internal control channel passes the detection threshold. An invalid result occurs when both SARS-CoV-2 and internal control channels fail to pass the detection threshold.

Substantial Equivalence

Characteristic	**Metrix COVID Test; Metrix COVID Test Pro**	**Cue COVID-19 Molecular Test (DEN220028)**
FDA Product Code	QWB	Same
Regulation Number/Name	21 CFR 866.3984: Over-the-counter molecular test to detect SARS-CoV-2 from clinical specimens	Same
Intended Use	**Metrix COVID Test** The Metrix® COVID Test is a single-use (disposable) molecular in vitro diagnostic test for the qualitative detection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) viral RNA, that is used with the Metrix Reader (Gen 2). This test is intended for use with anterior nasal (AN) swab specimens, self-collected from individuals	The Cue COVID-19 Molecular Test is a nucleic acid amplification assay that is used with the Cue Health Monitoring System (Cue Cartridge Reader) for the rapid, qualitative detection of SARS-CoV-2 nucleic acid directly in anterior nasal swab specimens from individuals with signs and symptoms of COVID-19 (i.e., symptomatic).

	aged 14 years or older. This test is intended for individuals with signs and symptoms of COVID-19 (i.e., symptomatic). When testing without healthcare provider oversight, a negative test result is presumptive. Presumptive negative results should be confirmed with a lab-based molecular assay when determined to be appropriate by a healthcare provider. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for treatment. Individuals who test negative and experience continued or worsening respiratory symptoms such as fever, cough and/or shortness of breath should seek follow-up care with their healthcare provider. Positive results do not rule out infection with other respiratory pathogens. This test is not a substitute for visits to a healthcare provider or appropriate follow-up and should not be used to determine any	A negative test result is presumptive, and it is recommended these results be confirmed by a lab-based molecular SARS-CoV-2 assay if necessary for patient management. Negative results do not preclude SARS-CoV-2 infections and should not be used as the sole basis for treatment. Positive results do not rule out co-infection with other respiratory pathogens. This test is not a substitute for visits to a healthcare provider or appropriate follow-up and should not be used to determine any treatments without provider supervision. This test is intended to be sold over-the-counter (OTC) for testing of individuals 18 years of age and older.

	treatments without provider supervision. **<u>Metrix COVID Test Pro:</u>** The Metrix® COVID Test Pro is a single-use (disposable) molecular in vitro diagnostic test for the qualitative detection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) viral RNA, that is used with the Metrix Reader (Gen 2). This test is intended for use with anterior nasal (AN) swab specimens, self-collected from individuals aged 14 years or older. This test is intended for individuals with signs and symptoms of COVID-19 (i.e., symptomatic). When testing without healthcare provider oversight, a negative test result is presumptive. Presumptive negative results should be confirmed with a lab-based molecular assay when determined to be appropriate by a healthcare provider. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for treatment.	

	Individuals who test negative and experience continued or worsening respiratory symptoms such as fever, cough and/or shortness of breath should seek follow-up care with their healthcare provider. Positive results do not rule out infection with other respiratory pathogens. This test is not a substitute for visits to a healthcare provider or appropriate follow-up and should not be used to determine any treatments without provider supervision.	
Assay Target	SARS-CoV-2 viral RNA	Same
SARS-CoV-2 Target	N Gene ORF-1 Gene	N Gene
Sample Type	Anterior Nares Swab	Same
Internal Control	Yes	Same
Assay Results	Qualitative	Same
Assay Technology	Nucleic Acid Amplification	Same
Instrument	Amplification performed and controlled by the Metrix Reader (Gen 2)	Amplification performed and controlled by the Cue Reader
Time to Result	20 minutes	Same
Result Interpretation	Results displayed by LEDs on top of the reader	Results sent to companion app

Performance Characteristics *21 CFR 807.92(b)*

Non-Clinical Testing *21 CFR 807.92(b)(1)*

Limit of Detection (LoD):
The Limit of Detection (LoD) for SARS-CoV-2 was determined by finding the lowest detectable viral concentration at which at least 95% of all true positive replicates yield positive results using the candidate device. This study was performed by diluting inactivated SARS-CoV-2 (USA-WA1/2020) into pooled negative nasal matrix (confirmed by qPCR to be free of SARS-CoV-2).

A tentative LoD was first determined by identifying the lowest concentration from a wide range of dilutions at which 3/3 replicates yielded positive results. The LoD was then confirmed using a narrow dilution series (two-fold above and below the tentative LoD) with 20 replicates. The confirmed LoD was defined as the lowest concentration at which at least 19/20 (95%) of replicates yielded positive results. The LoD was then confirmed with another 20 replicates. Replicate negative samples were also included.

The LoD for SARS-CoV-2 was determined to be 500 GE/swab. All negative samples produced negative results as expected.

Round	Swab Viral Load (GE/Swab)	# Positive / # Tested	% Positive
1	1,000	20/20	100%
1	**500**	**19/20**	**95%**
1	250	10/20	50%
2	**500**	**20/20**	**100%**

The LoD was also evaluated using the Second WHO International standard for SARS-CoV-2 in a similar manner as SARS-CoV-2 (USA-WA1/2020) and was determined to be 1e4.8 IU/mL (4.8 Log10 or 104.8 IU/mL).

Inclusivity/Analytical Reactivity:
Both *in silico* and in vitro studies were conducted to demonstrate the analytical reactivity of the candidate device primers with SARS-CoV-2.

In Silico Testing (Predicted Reactivity)
In order to predict reactivity, candidate device primer sequences were aligned against complete SARS-CoV-2 sequences compiled from the NCBI database via a BLAST protocol. For each primer set of the candidate device, reactivity towards each viral variant/strain was positively predicted if: (1) a viral sequence had at most one base pair mismatch with respect to each primer in a primer set and (2) no base pair mismatches within 5 nucleotides of the leading edge (i.e., 3' end) for any primer in a primer set.

A total of 3,133,963 complete SARS-CoV-2 sequences (obtained on 17 JUL 2026) were analyzed as described above. A total of 3,131,003 sequences (99.91%) were found to be reactive with the candidate device.

As with all SARS-CoV-2 tests, performance may be affected by the emergence of new variants. Aptitude routinely evaluates test inclusivity against emerging variants through in silico and, as appropriate, wet-testing analyses. If a novel or emerging variant is suspected and test results are inconsistent with clinical presentation, testing with an alternative validated method should be considered.

Viral Target	Number of Sequences Tested	Number of Reactive Sequences	Percent Reactive
SARS-CoV-2	3,133,963	3,131,003	99.91%

In Vitro Testing (Wet Testing)
Reactivity between the candidate device and SARS-CoV-2 was also confirmed via an in vitro study. Targets were prepared in pooled negative nasal matrix at 3x LoD and were spiked onto dry swabs, which were then processed according to the test instructions and run in triplicate. Negative control samples (NTC) were also run in triplicate. All NTC replicates produced negative results as expected, and all positive replicates produced positive results, confirming reactivity with the candidate device.

SARS-CoV-2 Strain	Concentration (GE/Swab)	# Positive / # Tested
NTC (No Virus)	0	0/3
2019-nCoV/USA-WA1/2020	1,500	3/3
UK B.1.1.7 (Alpha)	1,500	3/3
hCoV-19/USA/CA_CDC_5574/2020 (Alpha)	1,500	3/3
South Africa B.1.351 (Beta)	1,500	3/3

MD-HP01542/2021 (Beta)	1,500	3/3
B.1.617.2 USA/PHC658/2021 (Delta)	1,500	3/3
MD-HP05285/2021 (Delta)	1,500	3/3
USA/COR-22-063113/2022 (Omicron)	1,500	3/3
GA-EHC-2811C/2021 (Omicron)	1,500	3/3
USA/NY-Wadsworth-21025952-01/2021 (Iota)	1,500	3/3
Hong Kong/VM20001061/2020	1,500	3/3
Italy-INMI1	1,500	3/3
USA/CA-Stanford-15_S02/2021 (Kappa)	1,500	3/3
Japan/TY7-503/2021 (Gamma)	1,500	3/3

Microorganism Cross-Reactivity and Interference:
The analytical specificity of the candidate device was demonstrated by testing cross-reactivity with and interference from non-target microorganisms that could potentially affect assay performance.

For the following tests, a negative sample refers to negative pooled nasal matrix (confirmed to be negative for SARS-CoV-2 via qPCR) and a positive sample refers to negative pooled nasal matrix spiked with inactivated SARS-CoV-2 at 2x LoD.

Microorganisms were also spiked into the above samples at high concentration to represent the worst-case scenario. Viruses were tested at 5e5 TCID50/mL or PFU/mL (37,500 TCID50/swab or PFU/swab) and bacteria and fungi were tested at 5e6 CFU/mL (375,000 CFU/swab). Please note that Measles was tested at 1e5 PFU/mL, *Nocardia asteroides* was tested at 1e6 CFU/mL, and *Mycoplasma genitalium* was tested at 1e5 CFU/mL due to stock concentration limitations. Pooled human nasal wash was also tested at 10% v/v to assess other potential interfering microorganisms.

All testing was performed with live microbes unless otherwise noted.

Microorganism Cross-Reactivity
The cross-reactivity of microorganisms was evaluated by running the candidate device with triplicates of negative swab samples spiked with microorganisms, tabulated below. No cross-reactivity was observed at the concentrations tested.

Microorganism Interference

The interference of microorganisms was evaluated by running the candidate device with triplicates of positive swab samples spiked with microorganisms, tabulated below. No interference was observed at the concentrations tested.

Microorganism		Concentration	# Positive / # Tested	
			Cross-Reactivity Testing	Interference Testing
Bacteria	*Bordetella parapertussis*	5e6 CFU/mL	0/3	3/3
Bacteria	*Bordetella pertussis*	5e6 CFU/mL	0/3	3/3
Bacteria	*Chlamydophila pneumoniae*	5e6 IFU/mL	0/3	3/3
Bacteria	*Corynebacterium diphtheriae*	5e6 CFU/mL	0/3	3/3
Bacteria	*Eikenella corrodens*	5e6 CFU/mL	0/3	3/3
Bacteria	*Escherichia coli*	5e6 CFU/mL	0/3	3/3
Bacteria	*Fusobacterium necrophorum*	5e6 CFU/mL	0/3	3/3
Bacteria	*Haemophilus influenzae*	5e6 CFU/mL	0/3	3/3
Bacteria	*Lactobacillus salivarius*	5e6 CFU/mL	0/3	3/3
Bacteria	*Legionella pneumophila*	5e6 CFU/mL	0/3	3/3
Bacteria	*Moraxella catarrhalis*	5e6 CFU/mL	0/3	3/3
Bacteria	*Mycobacterium tuberculosis*	5e6 CFU/mL	0/3	3/3
Bacteria	*Mycoplasma genitalium*	1e5 bacteria/mL	0/3	3/3
Bacteria	*Mycoplasma pneumoniae*	5e6 CCU/mL	0/3	3/3
Bacteria	*Neisseria meningitidis*	5e6 CFU/mL	0/3	3/3
Bacteria	*Neisseria mucosa*	5e6 CFU/mL	0/3	3/3
Bacteria	*Nocardia asteroides*	1e6 CFU/mL	0/3	3/3
Bacteria	*Porphyromonas gingivalis*	5e6 CFU/mL	0/3	3/3
Bacteria	*Prevotella oralis*	5e6 CFU/mL	0/3	3/3
Bacteria	*Pseudomonas aeruginosa*	5e6 CFU/mL	0/3	3/3
Bacteria	*Staphylococcus aureus*	5e6 CFU/mL	0/3	3/3
Bacteria	*Staphylococcus epidermidis*	5e6 CFU/mL	0/3	3/3
Bacteria	*Streptococcus mitis*	5e6 CFU/mL	0/3	3/3
Bacteria	*Streptococcus mutans*	5e6 CFU/mL	0/3	3/3

Bacteria	*Streptococcus pneumoniae*	5e6 CFU/mL	0/3	3/3
Bacteria	*Streptococcus pyogenes*	5e6 CFU/mL	0/3	3/3
Bacteria	*Streptococcus salivarius*	5e6 CFU/mL	0/3	3/3
Fungus	*Aspergillus sp (flavus)*	5e6 CFU/mL	0/3	3/3
Fungus	*Candida albicans*	5e6 CFU/mL	0/3	3/3
Fungus	*Pneumocystis jiroveci - S. cerevisiae**	5e6 CFU/mL	0/3	3/3
Virus	Adenovirus 7A	5e5 TCID50/mL	0/3	3/3
Virus	Adenovirus C1	5e5 TCID50/mL	0/3	3/3
Virus	Cytomegalovirus	5e5 TCID50/mL	0/3	3/3
Virus	Enterovirus 68	5e5 TCID50/mL	0/3	3/3
Virus	Epstein-Barr virus	5e5 cp/mL	0/3	3/3
Virus	Herpes simplex virus type 1	5e5 TCID50/mL	0/3	3/3
Virus	Herpes simplex virus type 2	5e5 TCID50/mL	0/3	3/3
Virus	Human coronavirus 229E (Inactivated Virus)	5e5 TCID50/mL	0/3	3/3
Virus	Human coronavirus HKU1 (Synthetic RNA)	5e5 cp/mL	0/3	3/3
Virus	Human coronavirus NL63 (Synthetic RNA)	5e5 cp/mL	0/3	3/3
Virus	Human coronavirus OC43 (Inactivated Virus)	5e5 TCID50/mL	0/3	3/3
Virus	Human Metapneumovirus 16 (hMPV-16) Type A1	5e5 TCID50/mL	0/3	3/3
Virus	Influenza A	5e5 CEID50/mL	0/3	3/3
Virus	Influenza B	5e5 CEID50/mL	0/3	3/3
Virus	Measles (B3)	1e5 TCID50/mL	0/3	3/3
Virus	MERS-coronavirus (Synthetic RNA)	5e5 cp/mL	0/3	3/3
Virus	Mumps	5e5 TCID50/mL	0/3	3/3
Virus	Parainfluenza 1	5e5 TCID50/mL	0/3	3/3
Virus	Parainfluenza 2	5e5 IU/mL	0/3	3/3
Virus	Parainfluenza 3	5e5 TCID50/mL	0/3	3/3
Virus	Parainfluenza 4	5e5 TCID50/mL	0/3	3/3
Virus	Respiratory syncytial virus	5e5 IU/mL	0/3	3/3

Virus	Rhinovirus	5e5 IU/mL	0/3	3/3
Virus	SARS-coronavirus (Extracted RNA)	5e5 cp/mL	0/3	3/3
Other	Pooled Human Nasal Wash	10% v/v	0/3	3/3

* A gene specific to *Pneumocystis jirovecii* was inserted into the *S. cerevisiae* genome.

Substance Cross-Reactivity and Interference:
The analytical specificity of the candidate device was demonstrated by testing cross-reactivity with and interference from exogenous and endogenous substances found in a clinical nasal swab sample that could potentially affect assay performance.

For the following tests, a negative sample refers to negative pooled nasal matrix (confirmed to be negative for SARS-CoV-2 via qPCR) and a positive sample refers to negative pooled nasal matrix spiked with inactivated SARS-CoV-2 at 2x LoD.

The substances tabulated below were also spiked into the above samples prepared in negative pooled nasal matrix.

Substance Cross-Reactivity
The cross-reactivity of select substances was evaluated by running the candidate device with triplicates of negative swab samples spiked with test substances, tabulated below. No cross-reactivity was observed at the concentrations tested.

Substance Interference
The interference of select substances was evaluated by running the candidate device with triplicates of positive swab samples spiked with test substances, tabulated below. No interference was observed at the concentrations tested.

Substance	**Concentration**	**# Positive / # Tested**	
		Cross-Reactivity Testing	**Interference Testing**
Afrin	5% v/v	0/3	3/3
Human whole blood	1% v/v	0/3	3/3
Chloraseptic Sore Throat Spray	5% v/v	0/3	3/3
Flonase allergy relief	5% v/v	0/3	3/3

Mucin	1 mg/mL	0/3	3/3
NeoSynephrine Cold and Sinus Extra Strength Spray	5% v/v	0/3	3/3
NeilMed NasoGel	1.25% v/v	0/3	3/3
Relenza (Zanamivir)	1 mg/mL	0/3	3/3
Tamiflu	6 mg/mL	0/3	3/3
Tobramycin	2.5 mg/mL	0/3	3/3
Flunisolide	7.5% v/v	0/3	3/3
Zicam Allergy Relief	5% v/v	0/3	3/3
Method All-Purpose Surface Cleaner	5% v/v	0/3	3/3
Mupirocin	1 mg/mL	0/3	3/3
FluMist Quadrivalent	5% v/v	0/3	3/3
Dexamethasone	1 mg/mL	0/3	3/3
Mometasone	1 mg/mL	0/3	3/3
Beclomethasone	1 mg/mL	0/3	3/3
Budesonide	1 mg/mL	0/3	3/3
Galphimia Glauca	5% v/v	0/3	3/3

Precision:

The precision of the candidate device was evaluated internally by 2 untrained operators over 12 days. A total of 3 lots of test kits were used for the study. Each operator ran a blinded and randomized panel consisting of negative (NTC) samples, 2x LoD samples, and 5x LoD samples. All samples were prepared in pooled negative nasal matrix and positive samples were prepared using inactivated SARS-CoV-2 virus. Each operator ran the sample panel twice a day running each sample in duplicate each time. All NTC samples produced negative results and all 2x and 5x LoD produced positive results.

Lot	Operator	Percent Agreement with Expected Results (n/N)		
		Negative	2x LoD	5x LoD
1	**Operator 1**	100% (48/48)	100% (48/48)	100% (48/48)
	Operator 2	100% (48/48)	100% (48/48)	100% (48/48)
	Overall	100% (96/96)	100% (96/96)	100% (96/96)
2	**Operator 1**	100% (48/48)	100% (48/48)	100% (48/48)
	Operator 2	100% (48/48)	100% (48/48)	100% (48/48)

	Overall	100% (96/96)	100% (96/96)	100% (96/96)
3	**Operator 1**	100% (48/48)	100% (48/48)	100% (48/48)
	Operator 2	100% (48/48)	100% (48/48)	100% (48/48)
	Overall	100% (96/96)	100% (96/96)	100% (96/96)
Overall		100% (288/288)	100% (288/288)	100% (288/288)

Reproducibility:

A multisite study was conducted to demonstrate the reproducibility of the candidate device near the LoD. Untrained operators at 3 study sites (1 internal, 2 external) participated in the study and performed a total of 270 tests using 3 separate lots of kits. The sample panel consisted of negative (NTC) samples, 1x LoD (low positive) samples, and 5x LoD (moderate positive) samples. Each site ran the sample panel in triplicate twice per day over 5 non-consecutive days for a total of 30 replicates per concentration per site. For all sites, all NTC samples produced negative results and all 1x and 5x LoD produced positive results.

Sample Concentration	**% Agreement with Expected Results (n/N)**			
	Site 1	**Site 2**	**Site 3**	**Overall**
Negative (NTC)	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)
Low Positive (1x LoD)	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)
Moderate Positive (5x LoD)	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)

Carryover Contamination:

A carryover contamination study was performed in order to evaluate the potential for samples with high concentrations of target viruses to contaminate other tests run in close proximity, both spatially and temporally. To evaluate the potential for carryover contamination, 5 readers all in close proximity with one another were each subjected to 8 rounds of alternating high positive and negative samples run in quick succession (40 positive replicates and 40 negative replicates across 5 readers). Positive samples were co-spiked with each target virus at a high concentration such that each virus was present at a concentration of 2.5e5 GE/swab. All positive samples were prepared with inactivated SARS-CoV-2 virus. Negative samples (NTC) contained only pooled negative nasal matrix. All positive samples produced positive

results for each target and all negative samples produced negative results, indicating that the potential for carryover contamination is minimal.

Human Factors/Usability:
Aptitude conducted a human factors usability study to evaluate the ability of users to successfully complete the workflow of the candidate device. Thirty-two subjects were recruited with a wide range of age and education demographics. The study was conducted in a simulated home environment; subjects were provided with standard items found in a common home setting such as a sturdy work surface, electrical power outlets, tissues, handwashing area, and a trash can. Subjects were asked to perform a test following printed instructions found in the test kits, or a step-by-step video guide accessible on smart devices via a QR code in the printed instructions. All subjects (100%, 32/32) successfully completed all critical steps.

Flex Studies:
The candidate device was evaluated for robustness against several sample preparation, test handling, and environmental variables. Appropriate labelling precautions were introduced to mitigate potential errors that could occur when the test is performed without healthcare provider supervision.

Clinical Testing *21 CFR 807.92(b)(2)*

Clinical validation of the candidate device was conducted during the 2023/2024 and 2024/2025 respiratory seasons.

The study was conducted as a multi-site study which enrolled symptomatic participants only in an all-comers basis. Each participant performed the entire test, from sampling to interpretation of results, using only the provided test instructions. All testing was conducted in simulated home environments and lay users completed all testing without guidance or training. For each participant, a comparator nasopharyngeal (NP) swab was collected and analyzed with a high-sensitivity FDA-cleared SARS-CoV-2 assay.

Clinical Performance During the 2024/2025 Respiratory Season:
A total of 631 specimens prospectively collected from symptomatic participants were included in the analysis. Of these, a total of 65 specimens were positive for SARS-CoV-2 (as measured by the comparator). The positive percent agreement (PPA) was determined to be 96.9% (62/64) and the negative percent agreement

(NPA) was determined to be 99.5% (564/567). A total of 2 participants (0.3%) were unevaluable due to invalid results.

2024/2025 Respiratory Season		**Comparator:** NP Swab on High Sensitivity FDA-Cleared SARS-CoV-2 and Flu A/B RT-PCR Assay		
		Positive	Negative	Total
Candidate Device	Positive	62	3	65
	Negative	2	564	567
	Total	64	567	631
PPA: 96.9% (95% CI: 89.3% - 99.1%)				
NPA: 99.5% (95% CI: 98.5% - 99.8%)				

Demographics	**Category**	**Number of Participants**
Ethnicity	Hispanic or Latino	207
	Other/Prefer Not to Answer	423
	N/A	1
	Total	**631**
Race	Black or African American	188
	White or Caucasian	416
	Asian	8
	Other/Prefer Not to Answer	18
	N/A	1
	Total	**631**
Gender	Male	200
	Female	429
	Non-Binary	2
	Total	**631**

Clinical Performance During the 2023/2024 Respiratory Season:
A total of 540 specimens prospectively collected from symptomatic participants were included in the analysis. Of these, a total of 87 specimens were positive for SARS-CoV-2 (as measured by the comparator). The positive percent agreement (PPA) was determined to be 95.4% (83/87) and the negative percent agreement (NPA) was determined to be 99.6% (451/453). A total of 4 participants (0.7%) were unevaluable due to invalid results.

2023/2024 Respiratory Season		Comparator: NP Swab on High Sensitivity FDA-Cleared SARS-CoV-2 and Flu A/B RT-PCR Assay		
		Positive	Negative	Total
Candidate Device	Positive	83	2	85
	Negative	4	451	455
	Total	87	453	540
PPA: 95.4% (95% CI: 88.8% - 98.2%)				
NPA: 99.6% (95% CI: 98.4% - 99.9%)				

Demographics	Category	Number of Participants
Ethnicity	Hispanic or Latino	27
	Other/Prefer Not to Answer	493
	N/A	20
	Total	**540**
Race	Black or African American	180
	White or Caucasian	308
	Asian	24
	Other/Prefer Not to Answer	8
	N/A	20
	Total	**540**
Gender	Male	183
	Female	356
	Non-Binary	1
	Total	**540**

Expected Values:
In the clinical studies described above, a total of 540 anterior nasal swab specimens collected during the 2023/2024 respiratory season and 631 anterior nasal swab specimens collected during the 2024/2025 respiratory season were included in the analyses. The observed positivity rates of SARS-CoV-2 as determined by the candidate device during each study period were as follows:

Age	2023/2024		2024/2025	
	N	% Positive	N	% Positive
14-21	73	6.8% (5/73)	52	5.8% (3/52)
22-59	410	16.6% (68/410)	525	11.2% (59/525)
≥ 60	57	21.1% (12/57)	54	5.6% (3/54)
Total	540	15.7% (85/540)	631	10.3% (65/631)

Collection Site	N	Percent Positive
2023/2024		
Site 1	348	14.9% (52/348)
Site 2	139	18.0% (25/139)
Site 3	9	33.3% (3/9)
Site 4	24	16.7% (4/24)
Site 5	20	5.0% (1/20)
Total	540	15.7% (85/540)
2024/2025		
Site 3	102	0.0% (0/102)
Site 4	53	1.9% (1/53)
Site 6	294	11.6% (34/294)
Site 7	182	16.5% (30/182)
Total	631	10.3% (65/631)

Conclusion *21 CFR 807.92(b)(3)*

The analytical and clinical studies have demonstrated that the candidate device is substantially equivalent to the Cue COVID-19 Molecular Test (DEN220028).