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

I Background Information:

A 510(k) Number

K253453

B Applicant

Aptitude Medical Systems, Inc.

C Proprietary and Established Names

Metrix COVID Test; Metrix COVID Test Pro

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
QWB	Class II	21 CFR 866.3984	MI

II Submission/Device Overview:

A Purpose for Submission:

The purpose of this submission is to show that the Metrix COVID Test and Metrix COVID Test Pro is substantially equivalent to the Cue COVID-19 Molecular Test and to obtain 510(k) clearance for the Metrix COVID Test and Metrix COVID Test Pro.

B Measurand:

Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) nucleic acid

C Type of Test:

Reverse Transcription Loop-Mediated Isothermal Amplification (RT-LAMP)

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for 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 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.

C Special Conditions for Use Statement(s):

OTC – Over the Counter

D Special Instrument Requirements:

The Metrix COVID Test and Metrix COVID Test Pro is to be used with the Metrix Reader (Gen 2) running firmware version 2.0 or higher.

IV Device/System Characteristics:

A Device Description:

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. The candidate device requires the use of the Metrix Reader (Gen 2), which is available separately.

The 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.

B Principle of Operation:

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. 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.

C Instrument Description Information:

1. Instrument Name:
   Metrix Reader (Gen 2)

2. Specimen Identification:

Single use cartridge that is identified by test-specific electrical contacts encoded into sensor insertion pins, for use with anterior nasal swabs (ANS).

3. Specimen Sampling and Handling:
   Once the sample has been collected, the sample swab is inserted directly into the sample collector, the cap is attached to the collector, the collector and cap are connected to the sensor. The sample loaded sensor is inserted into the Metrix Reader.

4. Calibration:
   Not applicable

5. Quality Control:
   Internal control: The internal control targets MS2 Phage, which is contained within the on-board reagents of the device and monitors for adequate release of genomic material from host cells present in the specimens during the lysis step, potential reagent failure, reverse transcription, efficiency of RT-LAMP amplification, and electrochemical detection steps. This internal control also monitors for inhibitors in the specimen that may reduce amplification efficiency.

   External quality control materials are not included in the test kit

V Substantial Equivalence Information:

A Predicate Device Name(s):
Cue COVID-19 Molecular Test

B Predicate 510(k) Number(s):
DEN220028

C Comparison with Predicate(s):

Device & Predicate Device(s):	K253453	DEN220028
Device Trade Name	Metrix COVID Test; Metrix COVID Test Pro	Cue COVID-19 Molecular Test
Regulation Name/Number	21 CFR 866.3984: Over-the-counter molecular test to detect SARS-CoV-2 from clinical specimens	Same
Product Code	QWB	Same
General Device Characteristic Similarities		
Intended Use/Indications For Use	**Metrix COVID Test** The Metrix COVID Test is a single-use	The Cue COVID-19 Molecular Test is a nucleic acid amplification assay that

	(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.	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). 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.

	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.	
Assay Target	SARS-CoV-2 viral RNA	Same
Sample Type	Anterior Nasal Swab (ANS)	Same
Time to Result	20 Minutes	Same
Technology	Nucleic Acid Amplification	Same
General Device Characteristic Differences		
Result Interpretation	Results displayed by LEDs on top of reader	Results sent to companion app
Instrumentation	Metrix Reader (Gen 2)	Cue Reader

VI Standards/Guidance Documents Referenced:

- Standard Practice for Performance Testing of Shipping Containers and Systems. ASTM D4169-22.
- Standard Practice for Conditioning Containers Packages or Packaging Components for Testing. ASTM D4332-22.
- Interference Testing in Clinical Chemistry. CLSI EP07 3rd Edition.
- Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline - Second Edition. CLSI EP17-A2.
- Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline. CLSI EP25-A (Replaces EP25-P).
- Clinical investigation of medical devices for human subjects - Good clinical practice. ISO 14155 Third edition 2020-07.
- Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements. ISO 15223-1 Fourth Edition 2021-07.
- Medical electrical equipment - Part 1: General requirements for basic safety and essential performance - Note: This standard is recognized with relevant US national differences applied see references #1 and #2 in the Relevant FDA Guidance and/or Supportive Publication section below. IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION
- Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests [Including Amendment 1 (2021)]. ANSI AAMI IEC 60601-1-2:2014 [Including AMD 1:2021]
- Medical device software - Software life cycle processes [Including Amendment 1 (2016)], ANSI AAMI IEC 62304:2006/A1:2016
- Temperature Test for Transport Packaging. ISTA 7D:2007
- Technical Information Report Risk management of radio-frequency wireless coexistence for medical devices and systems. AAMI TIR69:2017/(R2020)
- Safety requirements for electrical equipment for measurement control and laboratory use - Part 1: General requirements [Including: Corrigendum 1 (2019)] - Note: This standard is recognized with relevant US national differences applied see reference #1 in Relevant FDA Guidance and/or Supportive Publication section. IEC 61010-1 Edition 3.1 2017-01 CONSOLIDATED VERSION
- Safety requirements for electrical equipment for measurement, control, and laboratory use - Particular requirements for in vitro diagnostic (IVD) medical equipment. IEC 61010-2-101

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision:

This study was performed to demonstrate the precision of the candidate device. Positive study samples were created by spiking inactivated SARS-CoV-2 (USA-WA1/2020) into negative clinical matrix to achieve 2x and 5x LoD of the device. Negative clinical matrix without SARS-

CoV-2 was used as the negative panel member. Each sample set was tested with three lots of reagents over 12 nonconsecutive days, two runs per day with two replicates per day, by two operators for a total of 288 replicates per panel member. Study results are presented in **Table 1** below. The overall agreement rate was 100% for all panel members demonstrating reproducible results across operators, device lots, days of testing, within days, and within runs.

Table 1: Precision Study Results for The Candidate Device

Reagent Lot	Operator	Run	Percent Agreement (95% CI)		
			Negative	1x LoD	2x LoD
1	A	1	100% (24/24) (86.2%-100.0%)	100% (24/24) (86.2%-100.0%)	100% (24/24) (86.2%-100.0%)
		2	100% (24/24) (86.2%-100.0%)	100% (24/24) (86.2%-100.0%)	100% (24/24) (86.2%-100.0%)
	B	1	100% (24/24) (86.2%-100.0%)	100% (24/24) (86.2%-100.0%)	100% (24/24) (86.2%-100.0%)
		2	100% (24/24) (86.2%-100.0%)	100% (24/24) (86.2%-100.0%)	100% (24/24) (86.2%-100.0%)
2	A	1	100% (24/24) (86.2%-100.0%)	100% (24/24) (86.2%-100.0%)	100% (24/24) (86.2%-100.0%)
		2	100% (24/24) (86.2%-100.0%)	100% (24/24) (86.2%-100.0%)	100% (24/24) (86.2%-100.0%)
	B	1	100% (24/24) (86.2%-100.0%)	100% (24/24) (86.2%-100.0%)	100% (24/24) (86.2%-100.0%)
		2	100% (24/24) (86.2%-100.0%)	100% (24/24) (86.2%-100.0%)	100% (24/24) (86.2%-100.0%)
3	A	1	100% (24/24) (86.2%-100.0%)	100% (24/24) (86.2%-100.0%)	100% (24/24) (86.2%-100.0%)
		2	100% (24/24) (86.2%-100.0%)	100% (24/24) (86.2%-100.0%)	100% (24/24) (86.2%-100.0%)
	B	1	100% (24/24) (86.2%-100.0%)	100% (24/24) (86.2%-100.0%)	100% (24/24) (86.2%-100.0%)
		2	100% (24/24) (86.2%-100.0%)	100% (24/24) (86.2%-100.0%)	100% (24/24) (86.2%-100.0%)
Overall			100% (288/288) (98.7%-100.0%)	100% (288/288) (98.7%-100.0%)	100% (288/288) (98.7%-100.0%)

2. Linearity:
   This study is not applicable as the candidate device is a qualitative assay.

3. Analytical Specificity/Interference:
   a. Inclusivity
      This study was performed to determine the analytical reactivity of the candidate device with 14 clinically relevant strains of the assay target. Testing was performed by diluting each viral strain into pooled negative clinical nasal matrix and spiking onto the sample swab at 3x LoD and tested in triplicate. For strains that did not test positive at 3x LoD, increased concentrations were tested until all three replicates produce positive results. The strains evaluated are presented in **Table 2** and the study results demonstrate that all tested strains were detected at 3x LoD.

Table 2: SARS-CoV-2 Inclusivity of the Candidate Device

SARS-CoV-2 Strains	Working Concentration (GE/swab)	SARS-CoV-2 Detection Rate
2019-nCoV/USA-WA1/2020	3x LoD	100 % (3/3)
UK B.1.1.7 (Alpha)	3x LoD	100 % (3/3)
hCoV-19/USA/CA_CDC_5574/2020 (Alpha)	3x LoD	100 % (3/3)
South Africa B.1.351 (Beta)	3x LoD	100 % (3/3)
MD-HP01542/2021 (Beta)	3x LoD	100 % (3/3)
B.1.617.2 USA/PHC658/2021 (Delta)	3x LoD	100 % (3/3)
MD-HP05285/2021 (Delta)	3x LoD	100 % (3/3)
USA/COR-22-063113/2022 (Omicron)	3x LoD	100 % (3/3)
GA-EHC-2811C/2021 (Omicron)	3x LoD	100 % (3/3)
USA/NY-Wadsworth-21025952-01/2021 (Iota)	3x LoD	100 % (3/3)
HongKong/VM20001061/2020	3x LoD	100 % (3/3)
Italy-INMI1	3x LoD	100 % (3/3)
USA/CA-Stanford-15_S02/2021 (Kappa)	3x LoD	100 % (3/3)
Japan/TY7-503/2021 (Gamma)	3x LoD	100 % (3/3)

In silico analysis of sequences from NCBI are conducted routinely to assess the ability of the candidate device to detect the most recent SARS-CoV-2 strains. As of July 2026, 3,133,963 total sequences were evaluated, demonstrating that the candidate device is expected to detect 99.91% of all SARS-CoV-2 variants.

b. Cross-Reactivity/Microbial Interference

The cross-reactivity of the candidate device was evaluated by testing bacteria (27), fungi (3), and viruses (24) at high concentrations ($5x10^6$ CFU/mL for bacteria and fungi and $5x10^5$ TCID50/mL for viruses, unless otherwise specified). Microorganisms were spiked into pooled negative clinical nasal matrix to create stock concentrations. Testing was conducted by spiking the sample swab with the stock concentration of each organism to be tested. Each test organism was evaluated in the absence of target analyte and tested in replicates of three. If any false positive results were observed, an additional ten replicates would be run. For each of the organisms tested, no cross-reactivity was observed. Results can be found in **Table 3**, below.

Microbial interference was evaluated by testing bacteria (27), fungi (3), and viruses (24) at high concentrations ($5x10^6$ CFU/mL for bacteria and fungi and $5x10^5$ TCID50/mL for viruses, unless otherwise specified). Each organism was prepared at concentrations listed in **Table 3**. Inactivated SARS-CoV-2 (USA-WA1/2020) was prepared at 2x LoD in pooled negative clinical nasal matrix. Each microorganism was co-spiked with SARS-CoV-2 onto sample swabs. Each sample was tested in triplicate. No interference was observed. Results can be found in **Table 3** below.

Table 3: Cross-Reactivity and Microbial Interference Results for The Candidate Device

Organism	Test	SARS-CoV-2 Detection Rate

	Concentration	Cross-Reactivity Testing	Interference Testing
Bordetella parapertussis	$5x10^6$ CFU/mL	0/3	3/3
Bordetella pertussis	$5x10^6$ CFU/mL	0/3	3/3
Chlamydophila pneumoniae	$5x10^6$ IFU/mL	0/3	3/3
Corynebacterium diphtheriae	$5x10^6$ CFU/mL	0/3	3/3
Eikenella corrodens	$5x10^6$ CFU/mL	0/3	3/3
Escherichia coli	$5x10^6$ CFU/mL	0/3	3/3
Fusobacterium necrophorum	$5x10^6$ CFU/mL	0/3	3/3
Haemophilus influenzae	$5x10^6$ CFU/mL	0/3	3/3
Lactobacillus salivarius	$5x10^6$ CFU/mL	0/3	3/3
Legionella pneumophila	$5x10^6$ CFU/mL	0/3	3/3
Moraxella catarrhalis	$5x10^6$ CFU/mL	0/3	3/3
Mycobacterium tuberculosis	$5x10^6$ CFU/mL	0/3	3/3
Mycoplasma genitalium	$1x10^5$ bacteria/mL[a]	0/3	3/3
Mycoplasma pneumoniae	$5x10^6$ CCU/mL	0/3	3/3
Neisseria meningitidis	$5x10^6$ CFU/mL	0/3	3/3
Neisseria mucosa	$5x10^6$ CFU/mL	0/3	3/3
Nocardia asteroides	$1x10^6$ CFU/mL[a]	0/3	3/3
Porphyromonas gingivalis	$5x10^6$ CFU/mL	0/3	3/3
Prevotella oralis	$5x10^6$ CFU/mL	0/3	3/3
Pseudomonas aeruginosa	$5x10^6$ CFU/mL	0/3	3/3
Staphylococcus aureus	$5x10^6$ CFU/mL	0/3	3/3
Staphylococcus epidermidis	$5x10^6$ CFU/mL	0/3	3/3
Streptococcus mitis	$5x10^6$ CFU/mL	0/3	3/3
Streptococcus mutans	$5x10^6$ CFU/mL	0/3	3/3
Streptococcus pneumoniae	$5x10^6$ CFU/mL	0/3	3/3
Streptococcus pyogenes	$5x10^6$ CFU/mL	0/3	3/3
Streptococcus salivarius	$5x10^6$ CFU/mL	0/3	3/3
Aspergillus sp (flavus)	$5x10^6$ CFU/mL	0/3	3/3
Candida albicans	$5x10^6$ CFU/mL	0/3	3/3
Pneumocystis jiroveci - S. cerevisiae[b]	$5x10^6$ CFU/mL	0/3	3/3
Adenovirus 7A	$5x10^5$ $TCID_{50}$/mL	0/3	3/3
Adenovirus C1	$5x10^5$ $TCID_{50}$/mL	0/3	3/3
Cytomegalovirus	$5x10^5$ $TCID_{50}$/mL	0/3	3/3
Enterovirus 68	$5x10^5$ $TCID_{50}$/mL	0/3	3/3
Epstein-Barr virus	$5x10^5$ cp/mL	0/3	3/3
Herpes simplex virus type 1 (HSV-1)	$5x10^5$ $TCID_{50}$/mL	0/3	3/3
Herpes simplex virus type 2 (HSV-2)	$5x10^5$ $TCID_{50}$/mL	0/3	3/3
Human coronavirus 229E (Inactivated Virus)	$5x10^5$ $TCID_{50}$/mL	0/3	3/3
Human coronavirus HKU1 (Synthetic RNA)	$5x10^5$ cp/mL	0/3	3/3
Human coronavirus NL63 (Synthetic RNA)	$5x10^5$ cp/mL	0/3	3/3

Human coronavirus OC43 (Inactivated Virus)	$5x10^5$ $TCID_{50}$/mL	0/3	3/3
Human Metapneumovirus 16 (hMPV-16) Type A1	$5x10^5$ $TCID_{50}$/mL	0/3	3/3
Influenza A	$5x10^5$ $CEID_{50}$/mL	0/3	3/3
Influenza B	$5x10^5$ $CEID_{50}$/mL	0/3	3/3
Measles (B3)	$1x10^5$ $TCID_{50}$/mL[a]	0/3	3/3
MERS-coronavirus (Synthetic RNA)	$5x10^5$ cp/mL	0/3	3/3
Mumps	$5x10^5$ $TCID_{50}$/mL	0/3	3/3
Parainfluenza 1	$5x10^5$ $TCID_{50}$/mL	0/3	3/3
Parainfluenza 2	$5x10^5$ IU/mL	0/3	3/3
Parainfluenza 3	$5x10^5$ $TCID_{50}$/mL	0/3	3/3
Parainfluenza 4	$5x10^5$ $TCID_{50}$/mL	0/3	3/3
Respiratory syncytial virus	$5x10^5$ IU/mL	0/3	3/3
Rhinovirus	$5x10^5$ IU/mL	0/3	3/3
SARS-coronavirus (Extracted RNA)	$5x10^5$ cp/mL	0/3	3/3
Pooled Human Nasal Wash	10% v/v	0/3	3/3

$TCID_{50}$ = Median Tissue Culture Infectious Dose; cp/mL = copies/mL; CCU/mL = Color-Changing Units/mL; IFU/mL = Infectious Units/mL; IU/ml = International Units/mL

[a] Unable to obtain higher stock concentrations

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

c. Interfering Substances

This study evaluated the performance of the candidate device in the presence of endogenous and exogenous substances that may be encountered in a clinical nasal swab sample. The assay was evaluated with potentially interfering substances in the presence and absence of the target analyte. For analyte negative samples, potentially interfering substances were combined with pooled negative clinical nasal matrix and spiked onto test swabs. For analyte positive samples, potentially interfering substances were combined with inactivated SARS-CoV-2 (USA-WA1/2020) at a concentration of 2x LoD in pooled negative clinical nasal matrix and then spiked onto test swabs. Three replicates were tested in the presence and absence of SARS-CoV-2 for each interferant. The substances evaluated are listed in **Table 4** below.

Table 4: Interfering Substances Results for the Candidate Device

Organism	**Test Concentration**	**SARS-CoV-2 Detection Rate**	
		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
NeoSynepthrine 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

4. Detection Limit:
The Limit of Detection (LoD) of the candidate device was determined by testing inactivated SARS-CoV-2 (USA-WA1/2020) in pooled negative clinical nasal matrix. The preliminary LoD was determined by testing serial dilutions of SARS-CoV-2 in triplicate. The lowest concentration at which achieved 100% detection was determined to be the preliminary LoD. The preliminary LoD was confirmed by testing 20 replicates each at 0.5x, 1x, and 2x preliminary LoD, where confirmation was achieved when at least 19/20 replicates returned a positive result. The LoD testing result for the candidate device is summarized in **Table 5** below.

Additionally, the LoD of inactivated SARS-CoV-2 (NIBSC, 22/252) was also determined. The preliminary LoD was determined by spiking inactivated SARS-CoV-2 (NIBSC, 22/252) into pooled negative clinical nasal matrix at serial dilutions and tested in triplicate. The lowest concentration that achieved 100% detection was determined to be the preliminary LoD. The preliminary LoD was confirmed by testing 20 replicates each at 0.3x, 1x, and 3x preliminary LoD, where confirmation was achieved when at least 19/20 replicates returned a positive result. The LoD of inactivated SARS-CoV-2 (NIBSC, 22/252) was confirmed to be $1x10^{4.8}$ IU/mL.

Table 5: LoD Determination for SARS CoV-2

Strain	**Concentration (GE/swab)**	**N Positive/N Tested (Detection Rate)**
SARS-CoV-2 Isolate USA-WA1/2020, gamma irradiated	1000 (2x LoD)	20/20 (100%)
	500 (1x LoD)	19/20 (95%)
	250 (0.5x LoD)	12/20 (60%)

GE– genomic equivalents

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):
   a. Controls
      i. Internal Controls
      The internal control targets MS2 Phage, which is contained within the on-board reagents of the device and monitors for adequate release of genomic material from host cells present in the specimens during the lysis step, potential reagent failure,

reverse transcription, efficiency of RT-LAMP amplification, and electrochemical detection steps. This internal control also monitors for inhibitors in the specimen that may reduce amplification efficiency. Detection of MS2 Phage is required to report negative SARS-CoV-2 results. The internal positive control is automatically assessed by the Metrix Reader and is not reported separately.

ii. External Controls
External quality control materials are not included in the test kit.

b. Unopened Kit Stability
A multi-lot reagent stability study was conducted to establish the shelf-life of the candidate device. Test kits were stored at 30°C ± 2°C. Three reagent lots were tested at 100 days. Positive test panels were created by diluting inactivated SARS-CoV-2 (USA-WA1/2020) into pooled negative clinical nasal matrix and inoculating test swabs at 2x LoD. Negative test panels were created by adding uninoculated negative clinical matrix onto test swabs prior to testing. Ten positive and ten negative samples were tested with each lot at each storage condition. All tested negative and positive samples produced 100% agreement with expected results. The study demonstrates the candidate device is stable up to 91 days when stored at 15°C-30°C.

c. Shipping Stability
A shipping stability study was conducted to evaluate the performance of the candidate device and Metrix Reader Kit (Gen 2) under conditions representing extreme cold and hot temperatures for durations anticipated during a 56 hour shipping period. The study used ten test kit shippers exposed to temperature profiles using a temperature-controlled chamber, each with 12 Test kits, for a total of 120 test kits, 60 per temperature profile. The study also used wo reader kit shippers, each with 10 readers, for a total of 20 reader kits, 10 reader kits per temperature profile. Samples for testing included a low positive (2x LoD), a high positive (5x LoD), and a negative sample. Positive and negative samples were prepared in pooled negative clinical nasal matrix in the presence or absence of inactivated SARS-CoV-2, respectively. Low positive samples were tested in replicates of 20 and high positive and negative samples were tested in replicates of ten. All samples produced expected positive or negative results at all temperature profiles tested.

6. Assay Cut-Off:
The assay cutoff is determined through analyzing the amplification curve generated during testing. A positive result is characterized by a signal curve that decreases over time, while a negative result is characterized by a curve that remains constant over time.

B Comparison Studies:

1. Method Comparison with Predicate Device:
Not applicable. See C. Clinical Studies.

2. Matrix Comparison:
Not applicable

C Clinical Studies:

1. Clinical Sensitivity:

Clinical performance of the candidate device was evaluated in a prospectively collected, all comers clinical study using anterior nasal swab specimens obtained through self-collection from symptomatic individuals age 14 and older. The study was conducted at multiple, geographically diverse sites in the United States during two respiratory seasons, November 2023 - March 2024 and October 2024 - April 2025. Testing was performed by lay users in a simulated at-home environment, using only the Quick Reference Instructions (QRI) for guidance. An additional nasopharyngeal swab (NPS) was collected by a healthcare provider for comparator testing with an FDA-cleared molecular device.

Respiratory Season November 2023 – March 2024

A total of 597 subjects aged 14 years and older were enrolled, of whom 540 were evaluable and included in the data analysis. Of the 57 excluded subjects, 19 withdrew before completing the study, 3 had no comparator result, 31 did not receive a valid candidate device result, and 4 received invalid results upon retesting. The overall invalid rate observed was 0.7% (4/540). The demographics and results for the evaluable subjects are described in **Table 6** and **Table 7** below.

Table 6: Demographics Information for the Candidate Device for Respiratory Season 2023-2024

Prospectively Collected Samples	**N = 540**	
Age (years)		
14-21	73	13.5%
22-59	410	75.9%
≥ 60	57	10.6%
Sex		
Male	183	33.9%
Female	356	65.9%
Non-Binary	1	0.2%
Race		
White or Caucasian	308	57.0%
Black or African American	180	33.3%
Asian	24	4.4%
NA or Prefer Not to Answer	28	5.2%

Table 7: Clinical Performance of the Candidate Device for Respiratory Season 2023-2024

Analyte					**Positive Percent Agreement**			**Negative Percent Agreement**		
	TP	**FP**	**FN**	**TN**	**TP/ (TP+FN)**	**%**	**95% CI**	**TN/ (TN+FP)**	**%**	**95% CI**
SARS-CoV-2	83	2	4	451	83/87	95.4%	88.9%-98.2%	451/453	99.6 %	98.4%-99.9%

Respiratory Season October 2024 – April 2025

A total of 646 subjects aged 14 years and older were enrolled in the study, of whom 631 were deemed evaluable and included in the data analysis. Of the 15 excluded subjects, 5 withdrew before completing the study, 5 had no usable comparator sample, 3 did not receive a valid candidate device result, and 2 received invalid results upon retesting. The overall invalid rate was 0.3% (2/631). The demographics and results for the evaluable subjects are described in **Table 8** and **Table 9** below.

Table 8: Demographics Information for the Candidate Device for Respiratory Season 2024-2025

Prospectively Collected Samples	**N = 631**	
Age (years)		
14-21	52	8.1%
22-59	525	83.2%
≥ 60	54	8.6%
Sex		
Male	200	31.7%
Female	429	68.0%
Non-Binary	2	3.2%
Race		
White or Caucasian	416	65.9%
Black or African American	188	29.8%
Asian	8	1.3%
NA or Prefer Not to Answer	19	3.0%

Table 9: Clinical Performance of the Candidate Device for Respiratory Season 2024-2025

Analyte					**Positive Percent Agreement**			**Negative Percent Agreement**		
	TP	**FP**	**FN**	**TN**	**TP/ (TP+FN)**	**%**	**95% CI**	**TN/ (TN+FP)**	**%**	**95% CI**
SARS-CoV-2	62	3	2	564	62/64	96.9%	89.3%-99.1%	564/567	99.5%	98.5%-99.8%

D Expected Values/Reference Range:

The prospective clinical evaluation of the candidate device included a total of 597 subjects from respiratory season 2023/2024 and 646 subjects from respiratory season 2024/2025. The study evaluated self-collected nasal swab specimens from five geographically diverse locations in the US. **Table 10** shows the positivity rate based on the candidate device result for subjects enrolled at each site and **Table 11** shows positivity rate stratified by age.

Table 10: Positivity Rate for the Candidate Device by Location

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)

Table 11: Positivity Rate for the Candidate Device by Age

Age	2023-2024		2024-2025	
	N	Percent Positive	N	Percent Positive
14-21	52	5.9% (3/52)	73	5.5% (4/73)
22-59	525	11.1% (58/525)	410	17.1% (70/410)
≥ 60	54	5.6% (3/54)	57	22.8% (13/57)
Total	631	10.1% (64/631)	540	16.1% (87/540)

E Other Supportive Instrument Performance Characteristics Data:

1. Usability and User Comprehension

   Device usability and user comprehension was assessed in a simulated home environment in a study with 32 participants of different ages, backgrounds, and education levels. The lay users evaluated the entire testing process, from device set-up through obtaining test results and demonstrating understanding of the appropriate next steps based on test results. An observer recorded successful scenario completion, user error, close calls, and any observed difficulties. All performance and comprehension tasks were completed without errors by over 94% of participants.

   User comprehension was also assessed via a questionnaire completed by 540 clinical study participants for the 2023-2024 respiratory season and 631 clinical study participants for the 2024-2025 respiratory season. The questionnaire assessed user's understanding of label comprehension concepts such as the test purpose, interpretation of results, and follow-up actions. The outcome of the study was used to validate the mitigations in the labeling.

2. Frequently Asked Questions

   To improve user label comprehension, the labeling includes a Frequently Asked Questions (FAQ) section. The FAQ section was created to provide users information to adequately understand the purpose, limitations, and meaning of the test results as well as where users

can access additional information regarding SARS-CoV-2 pathology and epidemiology. The concepts covered in the FAQ section include:

- The purpose of the test and description of the test and the analyte.
- Who should and who should not use the test (self-selection).
- Significance of the test results.
- When to re-test (e.g., following an invalid result).
- Follow-up for appropriate health management.

3. Hazard Analysis

A comprehensive hazard assessment for the candidate device was conducted in accordance with ISO 14971:2019. The hazard assessment identified foreseeable events that may lead to hazardous situations with the potential to cause specific, identified harms. Risk control measures and their verifications were documented. The severity of potential harms, their likelihood of occurrence, and the overall risk level were assessed both pre- and post-control. The hazard assessment considered hazards arising from errors in design, manufacturing, use (i.e. human factors), storage, and operation.

Potential sources of errors that could adversely affect system performance were identified and mitigated first through system design and then through additional cautions in the product labeling. The identified risks that could result in erroneous test results were evaluated in flex studies that evaluated the functionality of failsafe design features and stressed the functional limits of the device (see below).

4. Fail-safe and Failure Alert Mechanisms

The device contains the following failsafe features designed to minimize false results:

- Test type detection - The Metrix Reader (Gen 2) automatically detects the test type of the inserted sensor and deploys the proper assay to run it. If the reader does not recognize the inserted sensor, it will not initiate the test.
- Internal control - Monitors for sample lysis, reverse transcription, amplification, potential interference from the sample, and chemical function of assay reagents.
- Fluid fill detection - The Metrix Reader (Gen 2) checks that each chamber of the sensor has filled properly with sample prior to test initiation.
- Used sensor detection - Prevents previously-used test sensors from returning valid test results.
- Device power interruption - A complete loss of power to the reader during a test in progress will cause the test to be halted and an error to be reported when power is restored.
- Early sensor removal - The Metrix Reader (Gen 2) displays an error status if the sensor is removed prior to test completion.

5. Flex Studies

Flex Studies were performed to evaluate the robustness of the candidate device workflow run on the Metrix Reader (Gen 2) when challenged outside the operational limits of the system and with variations in workflow and operating environment that may be reasonably be expected to occur when used by untrained end users. Studies were run by trained operators using a testing panel of contrived positive samples consisting of inactivated SARS-CoV-2 at 2x LoD in pooled negative clinical nasal matrix and negative samples consisting of pooled negative clinical nasal matrix without target analyte, unless otherwise specified. For each test condition, five replicates were tested per condition unless otherwise specified.

The Flex Study results in **Table 12** demonstrate that the test is robust to stresses of environmental conditions and potential user errors.

Table 12: Flex Studies

Test Case	Nominal	Conclusion
Variation in Sample Mixing Times	Shake the collector/cap assembly for 5 seconds to mix the swab and the sample buffer	System generated expected valid results when the collector/cap assembly was mixed for 0, 5, 10 and 20 seconds. Labeling clearly states that the user should shake the collector/cap assembly for 5 seconds.
Device Positioning – Non-level Surface	The Metrix Reader (Gen 2) should be used on a level surface without movement	System generated **expected valid results** when devices were run following assembly with the following orientations: • ~45° degrees angle pitch axis of the Metrix Reader during run. • ~45° degrees angle roll axis of the Metrix Reader during run. A labeling mitigation has been included that instructs users that the device should be used on a level surface.
Delay in Operational Steps	User should complete the entire procedure without delay between steps	System generated **expected valid results** when testing delays were introduced in the following operational steps: • Sample collection prior to sample capping - delays of 5, 10 and 30 mins • Sample capping prior to sample loading into the sensor - delays of 5, 10 and 30 mins • Sample loading into the sensor prior to sensor insertion into the Metrix Reader - delays of 5, 10 and 30 mins Labeling mitigation includes instructions that the device should be used immediately after unwrapping and that users should add sample and close the slider without any delay.
Disturbance While Testing	The Metrix Reader (Gen 2) should be used on a level surface without movement	The system generated **expected valid results** when devices were moved in the following manner 5 minutes after the start of testing: • Vertical movement up and down ~50 cm, horizontal movement left and right ~50 cm, and a tilt of ~90°

		perpendicular to the ground along pitch and roll axes of the Metrix Reader. • Vibration through duration of test along x, y, and z axes. Labeling mitigation includes instructions that the Metrix Reader (Gen 2) should be used on a level surface without movement.
Mishandling of Cartridge and Metrix reader - Dropping	Do not use a Swab/Collector/Cap/Sensor assembly if it has been dropped. Repeat testing with a new kit.	System generated **expected valid results** when the Swab/Collector/Cap/Sensor assembly and Metrix Reader were separately dropped from a height of ~3 feet prior to inserting the dropped Swab/Collector/Cap/Sensor assembly into the dropped Metrix Reader to initiate the test. Labeling clearly states that testing should not be performed if the assembled Swab/Collector/Cap/Sensor assembly has been dropped. The user should use a new kit for testing.
Temperature, Humidity, and Altitude	Test should be used between 15-30°C; RH not indicated. Metrix Reader operates in the following range: • 5° to 45°C • 10 to 90% RH • 0 m – 2000 m (6560 ft) altitude	The system generated expected valid results when the components (in pouches were applicable) were pre-equilibrated for 30 minutes at and then operated under the following ranges of relative humidity and temperature: • 5% RH; 45°C • 10% RH; 5, 35 and 45°C • 20% RH; 10 and 35°C • 50% RH; 5, 20, 45°C • 80% RH; 10 and 35°C • 90 % RH; 5, 10 and 45°C • 95% RH; 5 and 45°C The system generated expected valid results when operated under the following altitudes: ≥2000m above sea level. Labeling clearly states that test should be used at temperatures between 15 °C-30 °C and relative humidity between 10%-90%.
Packaging and Shipping Stability[a]	Test components should be used between 15-30°C	The system generated expected valid results when components were cycled through the following simulated shipping conditions for 24 hours (8 hours for each condition). • 0% RH; -10°C

		• 85% RH; 5°C • 90% RH; 40°C Extreme Shipping conditions: The system generated expected valid results when components were exposed to the summer and winter temperature profiles listed below: Summer Profile: • Cycle 1: 40°C for 8 hours • Cycle 2: 22°C for 4 hours • Cycle 3: 40°C for 2 hours • Cycle 4: 30°C for 36 hours • Cycle 5: 40°C for 6 hours Winter Profile: • Cycle 1: -10°C for 8 hours • Cycle 2: 18°C for 4 hours • Cycle 3: -10°C for 2 hours • Cycle 4: 10°C for 36 hours • Cycle 5: -10°C for 6 hours Labeling clearly states that test should be used at temperatures between 15 °C-30 °C and relative humidity between 10%-90%.
Device Power Interruptions	USB-C power adapter should be a minimum of 5 volts and 3 amps minimum If a power failure occurs or if the Metrix reader is unplugged while the sensor is inserted, the test result is invalid and should be repeated with a new test kit.	System generated **expected error message** when: • The device was unplugged (after running for 5 minutes) and plugged back in (1 minute after unplugging) during a test run. Labeling clearly states that if a power failure occurs, the test is invalid and testing should be repeated with a new kit.
Result Interpretation in Sunlight[b]	Test is best used in a room with adequate lighting away from glare	When viewed in outdoor sunlit conditions, the five untrained operators **correctly interpreted** the Metrix Reader statuses as displayed on the LCD screen. Labeling clearly instructs users to use the device in a room with adequate lighting away from glare.
Open Kit Storage	Do not open kit components until you are ready to perform testing	The system generated **expected valid and invalid results** when the test consumables (Collector, Cap and Sensor) were removed from their packaging and stored under the following conditions prior to use:

		• 30°C; 50% relative humidity (environmental chamber) for 15 mins • 30°C; 50% relative humidity (environmental chamber) for 30 mins • Outside in direct sunlight for 15 min • Outside in direct sunlight for 30 min The swab was stored in its pouch under these conditions but was removed from the primary kit box. Labeling clearly instructs users to keep open test kits out of direct sunlight.
Low Temperature Kit Storage	Test components should be used between 15-30°C	The system generated **expected valid results** when test consumables (sensor, cap, collector and swab) were left in their pouches at the following temperature and time conditions before being used for testing: • 4 C for 72 h - then equilibrate to RT 0 hours (use directly from fridge) before use • 4 C for 72 h - then equilibrate to RT 12 hours before use • -20 C for 72 h - then equilibrate to RT 12 hours before use Labeling clearly states that the kit should not be frozen.
Test Assembly Reuse	Single use only. Only use the test components provided. Do not re-use any components for another test. Only the Metrix Reader (Gen 2) can be re-used multiple times.	System generated **expected valid results** for the initial test run of the negative and low positive samples. System generated the **expected invalid results** when an attempt is made to reuse the previously run Swab/Collector/Cap/Sensor assembly either immediately or 30 minutes after completing the initial test on the same Metrix Reader. Labeling clearly states that the test is "*Single use only. Only use the test components provided. Do not re-use any components for another test.*" Labeling also notes that, "*Only the Metrix Reader (Gen 2) can be re-used multiple times*."
Bluetooth Interruption	The Metrix Reader firmware can be updated	System generated **expected valid results** when Bluetooth connectivity was

	using Bluetooth connectivity through an app downloaded into a mobile device. Only complete firmware updates when testing is not being performed.	connected 3-5 minutes after test initiation and disconnected 2 minutes following connection.

[a] For each temperature profile conducted in the extreme shipping conditions flex study, total of 20 low positive (2x LoD) samples, 10 high positive (5x LoD), and 10 negative samples were run.
[b] To evaluate results interpretation in sunlight, a total of five lay users age 18 years and older were enrolled in an all-comers fashion with a wide range of education levels, races, ethnicities, and genders.

6. Carry-Over:
   The purpose of this study is to determine the carryover contamination rate of the candidate device. The carryover contamination rate was established by testing high titer SARS-CoV-2 samples interspersed with negative samples through eight continuous rounds of tests on five readers in close proximity to each other. Each round of testing started with testing the positive samples followed by testing the negative samples, without a delay in testing. Positive samples were created by spiking inactivated SARS-CoV-2 into pooled negative clinical nasal matrix at $2.5x10^5$ GE/swab. Negative samples consisted of pooled negative clinical nasal matrix without target analyte. All negative samples tested negative for SARS-CoV-2 and all high titer positive samples tested positive for SARS-CoV-2, no carryover contamination was observed.

7. Electrical safety and electromagnetic compatibility (EMC) testing were performed, and the system was found to be acceptable.

8. Software and cybersecurity documentation was reviewed and found to be acceptable.

VIII Proposed Labeling:

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

IX Conclusion:

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