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

I Background Information:

A 510(k) Number
K253971

B Applicant
Visby Medical, Inc.

C Proprietary and Established Names
Visby Medical Flu and COVID-19 Test

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
SIA	Class II	21 CFR 866:3984	MI

II Submission/Device Overview:

A Purpose for Submission:
The purpose of this submission is to demonstrate that the Visby Medical Flu and COVID-19 Test is substantially equivalent to the Cue COVID-19 Molecular Test (DEN220028) and to obtain clearance for the Visby Medical Flu and COVID-19 Test.

B Measurand:
- Influenza A RNA
- Influenza B RNA
- Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) RNA

C Type of Test:
Qualitative reverse transcriptase polymerase chain reaction (RT-PCR)

III Intended Use/Indications for Use:

A Intended Use(s):
See Indications for Use below.

B Indication(s) for Use:
The Visby Medical Flu and COVID-19 Test is a single-use (disposable), fully integrated, automated RT PCR in vitro diagnostic test intended for the qualitative detection and

differentiation of influenza A, influenza B, and severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) viral RNA in anterior nasal swab samples from individuals with signs and symptoms of a viral respiratory infection. Clinical signs and symptoms of respiratory viral infection due to SARS-CoV-2 and influenza can be similar. This test is intended for individuals aged 14 years or older testing themselves, or adults testing individuals aged 2 years or older.

All negative results are presumptive and should be confirmed with a lab-based molecular assay when determined to be appropriate by a healthcare provider. Negative results do not rule out infection with influenza, SARS-CoV-2 or other pathogens.

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 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.

C Special Conditions for Use Statement(s):
OTC- Over the Counter

D Special Instrument Requirements:
A mobile smart device with the Visby Medical Application installed

IV Device/System Characteristics:

A Device Description:
The Visby Medical Flu and COVID-19 Test is a non-prescription, single-use (disposable), fully integrated, fast, compact device containing a reverse transcription polymerase chain reaction (RT-PCR) based assay for the qualitative detection and differentiation of influenza A, influenza B, and/or SARS-CoV-2 viral RNA from anterior nasal (AN) swab samples from individuals 14 years or older (self-collected) or 2 to 13 years of age (collected by an adult) with signs and symptoms of viral respiratory infection. The test uses dry swabs collected without viral transport media.

The Visby Medical Flu and COVID-19 Test system includes the Visby Medical Flu and COVID-19 device, anterior nasal swab, collection media tube, sample transfer syringe, a tube holder and a USB-C power cable. The test is designed for self-testing (or testing of children by an adult) in an at home setting. The test contains printed instructions to guide the user through the testing process, as well as pre- and post-test educational materials to ensure proper use of the test. A companion application (the Visby Medical Application) provides the users with video and onscreen instructions, automated results interpretation (using the camera of the mobile device), pre- and post-test educational information, and access to telemedicine providers.

The device contains all of the hardware and reagents required to perform the test. To help ensure proper test execution, the device has built in electronic controls, an internal process control assay, and a sample adequacy control assay. The electronic controls are driven by the device firmware which monitors the status of the device and communicates test progress and/or error states to the user via the LED status lights on the front of the device. The internal process control

assay targets an RNA template (Bacteriophage MS2) that is contained in the device at a specific concentration. The internal process control assay is designed to ensure that all steps in the testing process are working properly. The sample adequacy control assay is designed to ensure that the sample used in the test is adequate. This control targets a human gene (RNaseP) and the template for the control is DNA from the human cells contained in the patient sample.

B Principle of Operation:

The Visby Medical Flu and COVID-19 Test is designed to be simple to use. To conduct the test, the user self-collects a dual nostril anterior nasal specimen (or collects a specimen from a child) with the provided flocked swab and then places the swab in the Visby Medical Collection Media. The user then transfers the collection media containing the specimen into the sample port of the device using the provided fixed-volume syringe and slides the purple switch on the front of the device closed. Closing the switch both seals the liquid in the device and initiates the automated testing process. Upon test initiation, the sample enters a lysis (sample preparation) module, where a combination of chemical lysis and high temperature liberates nucleic acids which are then reverse transcribed to convert control/target-specific RNA to cDNA. The extracted cDNA enters a mixing chamber where it rehydrates lyophilized PCR reagents, followed by thermocycling to amplify control/target sequences. If present, the amplified pathogen target (influenza A, influenza B and/or SARS-CoV-2), the internal process control and the sample adequacy control amplicon hybridize to specific probes located on a flow channel. Detection of the control/target-specific PCR product is accomplished via an enzyme-linked colorimetric assay using streptavidin-bound horseradish peroxidase (HRP) and a colorimetric substrate that forms a purple precipitate.

Test results can be expected in approximately 30 minutes. When the run has successfully completed, the green light under "READY" is illuminated, and the user captures an image of the device using the Visby Medical App. The Visby Medical App automatically interprets the combination of the LED status lights and colorimetric output in the detection window and provides the user with on screen results and the option to generate a test report that can be shared with a healthcare professional.

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):	K253971	DEN220028
Device Trade Name	Visby Medical Flu and COVID-19 Test	Cue COVID-19 Molecular Test
General Device Characteristic Similarities		

Regulation	Same	21 CFR 866.3984
Device Class	Same	Class II
Indication for Use	Same	Symptomatic Subjects; Over-the-Counter Use
Specimen Type	Same	Anterior Nasal Swab
Assay Results	Same	Qualitative
General Device Characteristic Differences		
Intended Use/Indications For Use	The Visby Medical Flu and COVID-19 Test is a single-use (disposable), fully integrated, automated RT PCR in vitro diagnostic test intended for the qualitative detection and differentiation of influenza A, influenza B, and severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) viral RNA in anterior nasal swab samples from individuals with signs and symptoms of a viral respiratory infection. Clinical signs and symptoms of respiratory viral infection due to SARS-CoV-2 and influenza can be similar. This test is intended for individuals aged 14 years or older testing themselves, or adults testing individuals aged 2 years or older. All negative results are presumptive and should be confirmed with a lab-based molecular assay when determined to be appropriate by a healthcare provider. Negative results do not rule out infection with influenza, SARS-CoV-2 or other pathogens. Individuals who test negative and experience continued or worsening respiratory symptoms such as fever,	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). 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

	cough and/or shortness of breath should seek follow-up care with their healthcare provider. 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.	sold over-the-counter (OTC) for testing of individuals 18 years of age and older.
Product Code	SIA	QWB
Technology/ Detection	Reverse Transcription Polymerase Chain Reaction (RT-PCR) system, qualitative	Isothermal nucleic acid amplification
Target(s)	SARS-CoV-2, influenza A, and influenza B	SARS-CoV-2
Instrument System	N/A, self-contained assay and instrument system and Visby Medical App	Cue Health Monitoring System and Cue Health App

VI Standards/Guidance Documents Referenced:

ANSI AAMI IEC 60601-1-2:2014_AMD 1:2021 "Medical electrical equipment-Pat 1-2: General requirements for basic safety and essential performance-Collateral Standard: Electromagnetic disturbances - Requirements and tests [Including Amendment 1 (2021)]"

IEC TR 60601-4-2 Edition 1.0 2016-05 "Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems"

IEC 61010-1 Edition 3.1 2017-01 Consolidated Version "Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements"

ANSI AAMI IEC 62304:2006/A1:2016 "Medical device software-Software life cycle processes [Including Amendment 1(2016)]"

ANSI AAMI ISO 14971:2019 "Medical Devices – Application of Risk Management to Medical Devices"

AAMI TIR57:2016 "Principles for medical device security - Risk management."

AAMI TIR97:2019 "Principles for medical device security - Postmarket risk management for device manufacturers"

ANSI AAMI HE75:2009/(R)2018 “Human factors engineering - Design of medical devices”

ANSI AAMI IEC 62366-1:2015+ADMI:2020 Consolidated Text “Medical devices Part 1: Application of usability engineering to medical devices”

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:
   A precision study was performed to evaluate the variability of the Visby Medical Flu and COVID-19 Test. This study evaluated within-lab precision using a panel that were prepared by spiking viruses into pooled, concentrated nasal sample matrix (CN-NSM, previously determined to be negative for influenza A, influenza B, and SARS-CoV-2). The study was performed with negative (unspiked) and positive samples, spiked with low (2x Limit of Detection (LoD)) or moderate (5x LoD) concentrations of influenza A Brisbane/02/18 (H1N1), influenza B Washington/02/19, and inactivated SARS-CoV-2 USA-WA1/2020.

   A total of two study operators tested two replicates of the panel twice each testing day, over twelve non-consecutive days, using three reagent lots. A summary of the results (count correct / total count) and % agreement with expected results for each assay is presented in **Table 1**. The overall agreement rate was 99.4%, and the Visby Medical Flu and COVID-19 Test demonstrated reproducible results across operators, device lots, days of testing, within days, and within runs.

   Table 1. Summary of the Visby Medical Flu and COVID-19 Test Performance in the Precision Study

Panel Member		Lot 1	Lot 2	Lot 3	Overall Agreement	
					% Agreement (count)	95% Confidence Interval (CI)
Moderate Positive 5x LoD Influenza A, Influenza B, SARS-CoV-2	Influenza A	100.0% (32/32)	100.0% (32/32)	100.0% (32/32)	100.0% (96/96)	96.2%-100.0%
	Influenza B	100.0% (32/32)	100.0% (32/32)	100.0% (32/32)	100.0% (96/96)	96.2%-100.0%
	SARS-CoV-2	100.0% (32/32)	100.0% (32/32)	100.0% (32/32)	100.0% (96/96)	96.2%-100.0%
Low Positive 2x LoD Influenza A, Influenza B, SARS-CoV-2	Influenza A	100.0% (32/32)	100.0% (32/32)	100.0% (32/32)	100.0% (96/96)	96.2%-100.0%
	Influenza B	100.0% (32/32)	100.0% (32/32)	100.0% (32/32)	100.0% (96/96)	96.2%-100.0%
	SARS-CoV-2	93.8% (30/32)	96.9% (31/32)	96.9% (31/32)	95.8% (92/96)	89.8%-98.4%
Negative		100.0% (32/32)	100.0% (32/32)	100.0% (32/32)	100.0% (96/96)	96.2%-100.0%
Overall % Agreement (count)					99.4% (668/672)	98.5%-99.8%

2. Linearity:
This study is not applicable as this test device is a qualitative assay.

3. Analytical Specificity/Interference:
   a. Inclusivity
   In total, 10 strains of influenza A H1N1, 10 strains of influenza A H3N2, 4 strains of avian influenza A (RNA only, representing H5N1, H7N9, and H9N2), 12 strains of influenza B (5 each of Victoria and Yamagata lineages and 2 additional strains), and 6 strains of SARS-CoV-2 were tested. Each virus was individually spiked into a pooled, concentrated nasal sample matrix (CN-NSM) and tested at that lineage's 3x LoD concentration or as otherwise specified. Three device replicates were tested per strain. If the acceptance criteria of 3/3 positive results for the target were not met, the concentration was increased and retested in three device replicates until the acceptance criteria were met. The inclusivity testing results are shown in **Tables 2-4**.

Table 2. Analytical Reactivity (Inclusivity) of the Visby Medical Flu and COVID-19 Test for Influenza A

Influenza A Virus	Strain	Concentration (copies/swab)	X LoD	Detection Rate (# Positive for influenza A / # Valid Tests)
Influenza A H1N1 (pandemic 2009)	A/Brownsville/39H/2009	270	3x	3/3
	A/Hong Kong/H090-761-V1(0)/2009	270	3x	2/3
		540	6x	3/3
	A/Netherlands/2629/2009	270	3x	3/3
	A/Massachusetts/15/2013	270	3x	3/3
	A/Bangladesh/3002/2015	270	3x	3/3
	A/Michigan/45/2015	270	3x	3/3
	A/St. Petersburg/61/2015	270	3x	3/3
	A/Hawaii/66/2019	270	3x	3/3
	A/Indiana/02/2020	270	3x	3/3
	A/Wisconsin/588/2019	270	3x	3/3
Influenza A H3N2	A/Netherlands/22/2003	810	3x	3/3
	A/New York/55/2004	810	3x	3/3
	A/Brisbane/10/2007	810	3x	3/3
	A/Uruguay/716/2007	810	3x	3/3
	A/Hong Kong/H090-756-V1(0)/2009	810	3x	3/3
	A/Perth/16/2009	810	3x	3/3
	A/Victoria/361/2011	810	3x	3/3
	A/Texas/50/2012	810	3x	3/3
	A/Switzerland/9715293/2013	810	3x	3/3[1]
	A/Alaska/232/2015	810	3x	3/3

Influenza A Virus	Strain	Concentration (copies/swab)	X LoD	Detection Rate (# Positive for influenza A / # Valid Tests)
Influenza A Avian[2]	A/bovine/Ohio/B24OSU-439/2024 (H5N1)	810	3x	3/3
	A/Vietnam/1194/2004 (H5N1)	1.5 ng/mL	3x	3/3
	A/Anhui/1/2013 (H7N9)	1.5 ng/mL	3x	3/3[3]
	A/chicken/Hong Kong/G9/1997 (H9N2)	1.5 ng/mL	3x	3/3

[1] One device returned an initial invalid result and had valid result upon retesting.
[2] Purified genomic RNA materials were tested due to biosafety regulations.
[3] One valid device returned an unexpected influenza B positive result.

Table 3. Analytical Reactivity (Inclusivity) of the Visby Medical Flu and COVID-19 Test for Influenza B

Influenza B Virus	Strain	Concentration (copies/swab)	X LoD	Detection Rate (# Positive for influenza B / # Valid Tests)
Influenza B	B/Lee/1940	810	3x	3/3
	B/Maryland/1/1959	810	3x	3/3
Influenza B Victoria Lineage	B/Malaysia/2506/2004	810	3x	3/3
	B/St. Petersburg/14/2006	810	3x	3/3
	B/Brisbane/60/2008	810	3x	3/3
	B/Nevada/03/2011	810	3x	3/3
	B/New Jersey/1/2012	810	3x	3/3
Influenza B Yamagata Lineage	B/New York/1061/2004	810	3x	3/3
	B/Florida/4/2006	810	3x	3/3
	B/Texas/06/2011	810	3x	3/3
	B/Phuket/3073/2013	810	3x	3/3
	B/Guangdong-Liwan/1133/2014	810	3x	3/3[1]

[1] One device returned an initial invalid result and had valid result upon retesting.

Table 4. Analytical Reactivity (Inclusivity) of the Visby Medical Flu and COVID-19 Test for SARS-CoV-2

SARS-CoV-2 Virus	Strain	Concentration (copies/swab)	X LoD	Detection Rate (# Positive for SARS-CoV-2 / # Valid Tests)
	Alpha (B.1.1.7) England/204820464/2020	60	3x	1/3
		120	6x	3/3
	Beta (B.1.351) South Africa/ KRISP-K005325/2020	60	3x	2/3
		120	6x	3/3
		60	3x	2/3

SARS-CoV-2 Virus	Strain	Concentration (copies/swab)	X LoD	Detection Rate (# Positive for SARS-CoV-2 / # Valid Tests)
SARS-CoV-2	Gamma (P.1) Japan/TY7-503/2021	120	6x	3/3
	Delta (B.1.617.2) USA/PHC658/ 2021	60	3x	3/3
	Omicron (Lineage B.1.1.529) USA/MD-HP20874/2021	60	3x	0/3[1]
		120	6x	1/3
		240	12x	3/3
	Omicron (Lineage BA.2.3) USA/MD-HP24556/2022	60	3x	1/3
		120	6x	1/3
		240	12x	3/3
[1]One valid device returned an unexpected influenza A positive result.				

In silico analysis of sequences from NCBI are conducted routinely to assess the ability of the Visby Medical Flu and COVID-19 Test to detect the most recent SARS-CoV-2 strains. As of June 2025, analysis of 7,937,280 total sequences demonstrates that the Visby Medical Flu and COVID-19 Test is expected to detect all SARS-CoV-2 variants currently in circulation.

b. Cross-Reactivity and Microbial Interference

To evaluate potential cross-reactivity of the Visby Medical Flu and COVID-19 Test, 42 microorganisms were tested at high concentrations (10^5 units/mL for viruses and 10^6 units/mL for bacteria and yeast, unless otherwise specified). The microorganisms were spiked into a pooled, concentrated nasal sample matrix (CN-NSM) in groups of up to five microorganisms, and the samples were then tested on three devices to evaluate the ability of the device to produce the expected negative results and confirm that the microorganisms tested did not cause the device to report a false positive result.

To evaluate whether microbial interference would be detected, 42 microorganisms were tested at high concentrations (10^5 units/mL for viruses and 10^6 units/mL for bacteria and yeast, unless otherwise specified). The microorganisms were spiked into low positive samples that were triple-spiked with 3x LoD concentrations of influenza A (influenza A Brisbane/02/18 (H1N1)), influenza B (influenza B Washington/02/19), and SARS-CoV-2 (inactivated SARS-CoV-2 USA-WA1/2020) in pooled, concentrated nasal sample matrix (CN-NSM). The potentially interfering microorganisms were evaluated in groups of up to five microorganisms, and the samples were then tested on three devices to evaluate the ability of the device to provide the expected positive results and confirm that the microorganisms tested did not cause the device to report a false negative result.

All tests for both cross-reactivity and microbial interference returned expected results (negative in the cross-reactivity study and positive in the microbial interference study).

The study results demonstrate that the microorganisms tested did not cause cross-reactivity or microbial interference when tested using the Visby Medical Flu and COVID-19 Test at the concentrations tested. The results are shown in **Table 5**.

Table 5. Microorganisms Evaluated for Cross-Reactivity and Microbial Interference on the Visby Medical Flu and COVID-19 Test

Organism	Test Concentration	(# Expected Results / # Total Valid Tests)					
		Negative Samples			Low Positive Samples (3x LoD)		
		Influenza A	Influenza B	SARS-CoV-2	Influenza A	Influenza B	SARS-CoV-2
Human Coronavirus 229E	1.1 x 10^5 $TCID_{50}$/mL	3/3	3/3	3/3	3/3	3/3	3/3
Human Coronavirus OC43	1.1 x 10^5 $TCID_{50}$/mL	3/3	3/3	3/3	3/3	3/3	3/3
Human coronavirus HKU1*	1.1 x 10^5 copies/mL	3/3	3/3	3/3	3/3	3/3	3/3
Human Coronavirus NL63	1.1 x 10^5 $TCID_{50}$/mL	3/3	3/3	3/3	3/3	3/3	3/3
SARS-Coronavirus*	1.1 x 10^5 copies/mL	3/3	3/3	3/3	3/3	3/3	3/3
MERS-Coronavirus*	1.1 x 10^5 copies/mL	3/3[1]	3/3[1]	3/3[1]	3/3	3/3	3/3
Adenovirus strain 1, C1 Ad 71	1.1 x 10^5 $TCID_{50}$/mL	3/3[1]	3/3[1]	3/3[1]	3/3	3/3	3/3
Adenovirus strain 7	1.1 x 10^5 $TCID_{50}$/mL	3/3[1]	3/3[1]	3/3[1]	3/3	3/3	3/3
Cytomegalovirus	1.1 x 10^4 $TCID_{50}$/mL	3/3[1]	3/3[1]	3/3[1]	3/3	3/3	3/3
Epstein Barr virus	1.1 x 10^5 copies/mL	3/3[1]	3/3[1]	3/3[1]	3/3	3/3	3/3
Enterovirus 68	1.1 x 10^5 $TCID_{50}$/mL	3/3	3/3	3/3	3/3	3/3	3/3
Human metapneumovirus (hMPV)	1.1 x 10^5 $TCID_{50}$/mL	3/3	3/3	3/3	3/3	3/3	3/3
Human parainfluenza virus 1	1.1 x 10^5 $TCID_{50}$/mL	3/3	3/3	3/3	3/3	3/3	3/3
Human parainfluenza virus 2	1.1 x 10^5 $TCID_{50}$/mL	3/3	3/3	3/3	3/3	3/3	3/3
Human parainfluenza virus 3	1.1 x 10^5 $TCID_{50}$/mL	3/3	3/3	3/3	3/3	3/3	3/3
Human parainfluenza virus 4b	1.1 x 10^5 $TCID_{50}$/mL	3/3	3/3	3/3	3/3	3/3	3/3

Organism	Test Concentration	(# Expected Results / # Total Valid Tests)					
		Negative Samples			Low Positive Samples (3x LoD)		
		Influenza A	Influenza B	SARS-CoV-2	Influenza A	Influenza B	SARS-CoV-2
Measles	1.1 x 10^4 $TCID_{50}$/mL[2]	3/3	3/3	3/3	3/3	3/3	3/3
Mumps	1.1 x 10^5 $TCID_{50}$/mL	3/3	3/3	3/3	3/3[1]	3/3[1]	3/3[1]
Respiratory syncytial virus (Strain B)	1.1 x 10^5 $TCID_{50}$/mL	3/3	3/3	3/3	3/3	3/3	3/3
Human rhinovirus 1A (strain 2060)	1.1 x 10^5 PFU/mL	3/3	3/3	3/3	3/3	3/3	3/3
Bordetella parapertussis	1.1 x 10^6 cfu/mL	3/3	3/3	3/3	3/3	3/3	3/3
Bordetella pertussis	1.1 x 10^6 cfu/mL	3/3	3/3	3/3	3/3	3/3	3/3
Candida albicans	1.1 x 10^6 cfu/mL	3/3	3/3	3/3	3/3	3/3	3/3
Chlamydia pneumoniae	1.1 x 10^6 IFU/mL	3/3	3/3	3/3	3/3	3/3	3/3
Corynebacterium xerosis	1.1 x 10^6 cfu/mL	3/3	3/3	3/3	3/3	3/3	3/3
Escherichia coli	1.1 x 10^6 cfu/mL	3/3	3/3	3/3	3/3	3/3	3/3
Haemophilus influenzae	1.1 x 10^6 cfu/mL	3/3	3/3	3/3	3/3	3/3	3/3
Lactobacillus brevis	1.1 x 10^6 genomic copies/mL[3]	3/3	3/3	3/3	3/3	3/3	3/3
Legionella pneumophila	1.1 x 10^6 cfu/mL	3/3	3/3	3/3	3/3	3/3	3/3
Moraxella (Branhamella) catarrhalis	1.1 x 10^6 cfu/mL	3/3	3/3	3/3	3/3	3/3	3/3
Mycoplasma genitalium	1.1 x 10^6 genomic copies/mL[3]	3/3	3/3	3/3	3/3	3/3	3/3
Mycoplasma pneumoniae	1.1 x 10^6 cfu/mL	3/3	3/3	3/3	3/3	3/3	3/3
Mycobacterium tuberculosis	1.1 x 10^6 genomic copies/mL[3]	3/3	3/3	3/3	3/3	3/3	3/3
Neisseria meningitidis serogroup a	1.1 x 10^6 cfu/mL	3/3	3/3	3/3	3/3	3/3	3/3

Organism	Test Concentration	(# Expected Results / # Total Valid Tests)					
		Negative Samples			Low Positive Samples (3x LoD)		
		Influenza A	Influenza B	SARS-CoV-2	Influenza A	Influenza B	SARS-CoV-2
Neisseria mucosa	1.1 x 10^6 genomic copies/mL[3]	3/3	3/3	3/3	3/3	3/3	3/3
Pneumocystis jirovecii	1.1 x 10^6 nuclei/mL	3/3	3/3	3/3	3/3	3/3	3/3
Pseudomonas aeruginosa	1.1 x 10^6 cfu/mL	3/3	3/3	3/3	3/3	3/3	3/3
Staphylococcus aureus	1.1 x 10^6 cfu/mL	3/3	3/3	3/3	3/3	3/3	3/3
Staphylococcus epidermidis	1.1 x 10^6 cfu/mL	3/3	3/3	3/3	3/3	3/3	3/3
Streptococcus pneumoniae	1.1 x 10^6 genomic copies/mL[3]	3/3	3/3	3/3	3/3	3/3	3/3
Streptococcus pyogenes	1.1 x 10^6 cfu/mL	3/3	3/3	3/3	3/3	3/3	3/3
Streptococcus salivarius	1.1 x 10^6 genomic copies/mL[3]	3/3	3/3	3/3	3/3	3/3	3/3

[1] One device returned an initial invalid result (Process control fail). The results were valid upon retesting.
[2] Organism was tested at the stated concentration due to limitations of the vendor stock concentration.
[3] Whole organism was tested. The organism extracted, purified and nucleic acid quantified in genomic copies/mL.
* Purified RNA was tested for these organisms.

c. Competitive Interference

Each of the target viruses (influenza A Brisbane/02/18 (H1N1), influenza B Washington/02/19, and inactivated SARS-CoV-2 USA-WA1/2020) were spiked into pooled, concentrated nasal sample matrix (CN-NSM) at varying concentrations and then tested in triplicate. Low concentrations were prepared at 3x LoD for the respective viruses, and high concentrations were prepared at 1 x 10^5 copies/swab, unless otherwise specified. As shown in **Table 6**, all 6 mixed infection combinations returned 3/3 expected results demonstrating that the presence of high concentration of one virus does not interfere with the detection of low levels (3x LoD) of an alternate virus or cause false positive result for the virus that was not included in the sample.

Table 6. Competitive Interference for each Target Virus on Visby Medical Flu and COVID-19 Test

Virus and Concentration			Detection Rate (# Positive / # Tested)		
Influenza A	**Influenza B**	**SARS-CoV-2**	**Influenza A**	**Influenza B**	**SARS-CoV-2**
1 x 10^5 copies/swab	3x LoD	Neg	3/3	3/3	0/3
1 x 10^5 copies/swab	Neg	3x LoD	3/3	0/3	3/3

Virus and Concentration			Detection Rate (# Positive / # Tested)		
Influenza A	**Influenza B**	**SARS-CoV-2**	**Influenza A**	**Influenza B**	**SARS-CoV-2**
3x LoD	1×10^5 copies/swab	Neg	3/3	3/3	0/3
Neg	1×10^5 copies/swab	3x LoD	0/3	3/3	3/3
3x LoD	Neg	5×10^4 copies/swab [1]	3/3	0/3	3/3
Neg	3x LoD	5×10^4 copies/swab [1]	0/3	3/3	3/3
[1] Due to limitation in stock concentration, the highest concentration that is tested for SARS-CoV-2 is 5×10^4 copies/swab.					

d. Endogenous/Exogenous Interfering Substances

Potentially interfering substances that may be found in a clinical nasal sample were evaluated to determine if they interfere with the accuracy of test results. Negative samples were pooled, concentrated nasal sample matrix (CN-NSM). Low positive samples were created by spiking influenza A Brisbane/02/18 (H1N1), influenza B Washington/02/19, and inactivated SARS-CoV-2 USA-WA1/2020 into CN-NSM at 3x LoD concentration for each virus. For each potentially interfering substance, three positive and three negative samples were tested. If interference was observed, a substance was titrated down and retested until the concentration with no interference was reached.

Of the 26 substances tested, 23 provided the expected results when tested at the prespecified concentration, indicating that these substances do not cause interference. Three (3) substances had interference at the prespecified concentration and were titrated lower to determine the concentration where expected results were returned. Disinfectant spray, liquid hand soap, and Zicam (zinc) may cause erroneous results when present at a concentration higher than specified below.

- Disinfectant spray at 2.5% (v/v)
- Liquid hand soap at 2.5% (w/v)
- Zicam (zinc) at 2.5% (w/v)

Table 7 below lists the substances tested and the performance of the test at each concentration, separated by virus.

Table 7. Potentially Interfering Substances on Visby Medical Flu and COVID-19 Test

Interfering Substance	Concentration Tested	# Expected Results / # Valid Devices					
		Negative Samples			Low Positive Samples (3x LoD)		
		Influenza A	Influenza B	SARS-CoV-2	Influenza A	Influenza B	SARS-CoV-2
All-purpose Cleaner	5% (v/v)	3/3	3/3	3/3	3/3	3/3	3/3
Biotin	3.5 µg/mL	3/3	3/3	3/3	3/3	3/3	3/3

Interfering Substance	Concentration Tested	# Expected Results / # Valid Devices					
		Negative Samples			Low Positive Samples (3x LoD)		
		Influenza A	Influenza B	SARS-CoV-2	Influenza A	Influenza B	SARS-CoV-2
Bleach Based Cleaner	5% (v/v)	3/3	3/3	3/3	3/3	3/3	3/3
Disinfectant Spray	5% (v/v)	3/3	3/3	3/3	3/3	2/3	3/3
	2.5% (v/v)	N/A	N/A	N/A	3/3	3/3	3/3
Hand Lotion	5% (w/v)	3/3	3/3	3/3	3/3	3/3	3/3
Hand Sanitizer, 70% ethanol	5% (w/v)	3/3	3/3	3/3	3/3	3/3	3/3
Human Whole Blood	5% (v/v)	3/3	3/3	3/3	3/3	3/3	3/3
Liquid Hand Soap	5% (w/v)	3/3	3/3	3/3	3/3	3/3	0/3
	2.5% (w/v)	N/A	N/A	N/A	3/3 [1]	3/3 [1]	3/3 [1]
Mucin, bovine submaxillary gland	1% (w/v)	3/3	3/3	3/3	3/3	3/3	3/3
Mupirocin (anti-bacterial ointment)	12 mg/mL	3/3	3/3	3/3	3/3	3/3	3/3
Nasal Spray (Beclomethasone)	25% (v/v)	3/3	3/3	3/3	3/3	3/3	3/3
Nasal Spray (Budesonide)	25% (v/v)	3/3	3/3	3/3	3/3 [2]	3/3 [2]	3/3 [2]
Nasal Spray (Dexamethasone)	25% (v/v)	3/3	3/3	3/3	3/3	3/3	3/3
Nasal Spray (Flunisolide)	25% (v/v)	3/3	3/3	3/3	3/3	3/3	3/3
Nasal Spray (Galphimia glauca 4x, Luffa operculata 4x, Sabadilla 4x)	25% (v/v)	3/3	3/3	3/3	3/3	3/3	3/3
Nasal Spray (Mometasone)	25% (v/v)	3/3	3/3	3/3	3/3	3/3	3/3
Nasal Spray (Oxymetazoline)	25% (v/v)	3/3	3/3	3/3	3/3	3/3	3/3
Nasal Spray (Phenylephrine)	25% (v/v)	3/3	3/3	3/3	3/3	3/3	3/3
Nasal Spray (Saline)	25% (v/v)	3/3	3/3	3/3	3/3	3/3	3/3
Nasal Spray (Triamcinolone acetonide)	25% (v/v)	3/3	3/3	3/3	3/3	3/3	3/3
Nasal Spray Corticosteroid (Fluticasone propionate)	25% (v/v)	3/3	3/3	3/3	3/3	3/3	3/3
Nasal Wash	100%	3/3	3/3	3/3	3/3	3/3	3/3
Throat Lozenge (Benzocaine, Menthol)	2.5% (w/v)	3/3	3/3	3/3	3/3	3/3	3/3
Tobramycin	2.43 mg/mL	3/3	3/3	3/3	3/3	3/3	3/3
Zanamivir	5 mg/mL	3/3	3/3	3/3	3/3	3/3	3/3
Zicam (zinc) (Zincum aceticum 2X, Zincum gluconicum 1X)	5% (w/v)	3/3	3/3	3/3	3/3	2/3	3/3
	2.5% (w/v)	N/A	N/A	N/A	3/3	3/3	3/3

[1] One device returned an initial invalid result. The results were valid upon retesting.
[2] One device returned an initial invalid result. The retest returned an electronic control error. The results were valid upon the second retest.

4. Detection Limit:
   Two strains each of cultured influenza A and influenza B, and one inactivated strain of SARS-CoV-2 were evaluated to establish the limit of detection for the Visby Medical Flu and COVID-19 Test. Each virus was individually spiked into pooled, concentrated nasal sample matrix (CN-NSM) and tested in a range-finding study of five different concentrations with 3-fold dilutions between each concentration, with five swab replicates per

concentration. The lowest concentration with 100% detection was established as the estimated LoD. The estimated LoD was then confirmed by testing 20 swab replicates at the estimated LoD. The estimated LoD was confirmed if at least 19 of the 20 replicates returned positive results for the virus. If less than 19/20 replicates were positive, the concentration was increased until the acceptance criteria were met and the LoD was confirmed.

The LoD of the Visby Medical Flu and COVID-19 Test for influenza A, influenza B, and SARS-CoV-2 are summarized in **Table 8** below.

Table 8. Limit of Detection for the Visby Medical Flu and COVID-19 Test

Virus	Analytical Limit of Detection (LoD)	
	copies/swab	$TCID_{50}$/swab or FFU/swab
Influenza A 2009 H1N1, Brisbane/02/18	90	436 $TCID_{50}$/swab
Influenza A H3N2, Kansas/14/2017	270	4.2 FFU/swab
Influenza B Victoria, Washington/02/19	270	496 $TCID_{50}$/swab
Influenza B Yamagata, Oklahoma/10/2018	270	30.4 $TCID_{50}$/swab
SARS-CoV-2 (inactivated virus), USA-WA1/2020	20	N/A

A study demonstrated equivalent LoD of the Visby Medical Flu and COVID-19 Test for targets tested individually and co-formulated together.

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

a. Controls

i. Internal Procedural Controls:
The Visby Medical Flu and COVID-19 Test has built in electronic controls, an internal process control, and a sample adequacy control to ensure proper test execution. The electronic controls are driven by the device firmware which monitors the status of the device and communicates test progress and/or error states to the user via the LED status lights on the front of the device. The internal process control assay targets an RNA template (Bacteriophage MS2) that is contained in the device at a specific concentration. The internal process control assay is designed to ensure that all steps in the testing process are working properly. The sample adequacy control assay is designed to ensure that the sample used in the test is adequate. This control targets a human gene (RNaseP) and the template for the control is DNA from the human cells contained in the patient sample.

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

b. Unopened Kit Stability
A multi-lot kit stability study was conducted to determine the shelf-life of the Visby Medical Flu and COVID-19 Test kit. All test kits were preconditioned at 45-50°C for either two or four hours to mimic temperature excursions during shipping. Preconditioned kits were evaluated following storage at room temperature (18-22°C), an elevated room temperature (30°C), and at an elevated room temperature with elevated relative humidity (30°C and 75% RH). At two-month intervals, devices from each storage condition were

tested with a negative and a low positive sample. The data demonstrates that the unopened kit is stable up to 8 months when stored at 18-30°C.

c. Shipping Stability
A shipping stability study was conducted for a period of 80 hours to evaluate the stability of the Visby Medical Flu and COVID-19 Test under conditions representing extreme cold and hot temperatures for durations anticipated during a 72-hour shipping period. Samples for testing included an analyte negative pooled concentrated nasal sample matrix (CN-NSM), and a 3x LoD positive sample consisting of influenza A Brisbane/02/18 (H1N1), influenza B Washington/02/19, and inactivated SARS-CoV-2 USA-WA1/2020 in pooled CN-NSM. Ten devices per sample type (low positive or negative) were tested at baseline, and following the cold temperature profile, and the hot temperature profile. All devices returned the expected negative or triple positive result.

6. Assay Cut-Off:
Not applicable.

B Comparison Studies:

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

2. Matrix Comparison:
Not applicable.

C Clinical Studies:

1. Prospective Clinical Evaluation:
Clinical performance of the Visby Medical Flu and COVID-19 Test was established through a multi-center prospective study enrolling individuals with signs and symptoms of viral respiratory infection at fourteen (14) geographically diverse US testing sites in a simulated home setting. The study enrolled individuals 14 years or older (self-collected) or 2 to 13 years of age (collected by an adult) from February 2024 to May 2024.

Subjects 14 years of age and older were provided with a Visby Medical Flu and COVID-19 test kit and a smartphone that had the Visby Medical Application downloaded. The subjects were asked to follow the instructions provided in the test kit and/or Visby Medical Application to self-collect and test a dual nostril anterior nasal (AN) swab specimen. When the test was completed, the subject used the Visby Medical Application on a smartphone to take an image of the Visby device for automatic results interpretation. Subjects between the ages of 2 to 13 years of age were enrolled and tested by an accompanying adult (18 years or older). The testing process was the same as described above, with the exception that the accompanying adult collected and tested the dual nostril AN swab specimen. The subjects did not receive any training or coaching from the study staff when performing the sample collection or when performing the Visby Medical Flu and COVID-19 Test. An additional AN swab was collected by a healthcare provider (HCP) for comparator testing. The order of AN swab collection was randomized. The comparator sample was sent to a reference laboratory for comparator testing with an FDA-cleared molecular test.

A total of 1458 subjects were enrolled in the study. Of those, 55 study specimens were excluded from the performance analysis due to age below 2 years old (n=29), issues related to study procedures, inclusion criteria, or subject consent (n=16) or to lack of a valid Visby or comparator result (n=10). This left 1403 subjects for performance analysis of the Visby Medical Flu and COVID-19 Test, of which 1155 (82.3%) represented self-collected samples and 248 (17.7%) were adult-collected for a child. The demographics of the evaluable subjects are described in **Table 9**.

Table 9. Demographic Information

Age (years)	**N**	**%**
2-5	101	7.2%
6-21	270	19.2%
22-59	850	60.6%
≥60	182	13.0%
Total	1403	
Sex	N	%
Male	596	42.5%
Female	807	57.5%
Total	1403	
Self-reported subject race	**N**	**%**
White	999	71.2%
Black or African American	244	17.4%
Asian	58	4.1%
Multiracial	43	3.1%
Other	42	3.0%
American Indian or Alaskan Native	10	0.7%
Declined to state	3	0.2%
Native Hawaiian or other Pacific Islander	2	0.1%
Unknown	2	0.1%
Total	1403	
Self-reported highest level of education by subjects (14 years and older)	**N**	**%**
Declined to State	2	0.2%
Some Elementary School	0	0.0%

Some Middle School	26	2.3%
Some High School	117	10.1%
Graduated High School	331	28.7%
Some College	239	20.7%
Graduated College	352	30.5%
Postgraduate/Professional Degree	88	7.6%
Total	1155	

The positive percentage agreement (PPA) and negative percentage agreement (NPA) of influenza A, influenza B, and SARS-CoV-2 are shown in **Tables 10-12** below, separated by collection scenario (self or adult-collection).

Table 10. Clinical Performance for the Visby Medical Flu and COVID-19 Test for Influenza A

Scenario	N	TP	FP	TN	FN	PPA (95% CI)	NPA (95% CI)
Self-Collected and Tested	1155	34	7	1112	2	94.4% (81.9%-98.5%)	99.4% (98.7%-99.7%)
Adult-Collected and Tested for a Child	248	12	1	233	2	85.7% (60.1%-96.0%)	99.6% (97.6%-99.9%)
Overall	1403	46	8[a]	1345	4[b]	92.0% (81.2%-96.8%)	99.4% (98.8%-99.7%)

TP = True Positive; FP = False Positive; TN = True Negative; FN = False Negative. PPA = Positive Percent Agreement; NPA = Negative Percent Agreement.

[a] Influenza A nucleic acid was detected by an alternate molecular assay in all 8 samples tested by the Visby device.

[b] Influenza A nucleic acid was detected by an alternate molecular assay in all 4 samples tested by the Visby device.

Table 11. Clinical Performance for the Visby Medical Flu and COVID-19 Test for Influenza B

Scenario	N	TP	FP	TN	FN	PPA (95% CI)	NPA (95% CI)
Self-Collected and Tested	1155	19	2	1132	2	90.5% (71.1%-97.3%)	99.8% (99.4%-100%)
Adult-Collected and Tested for a Child	248	15	1	232	0	100.0% (79.6%-100%)	99.6% (97.6%-99.9%)
Overall	1403	34	3[a]	1364	2[b]	94.4% (81.9%-98.5%)	99.8% (99.4%-99.9%)

TP = True Positive; FP = False Positive; TN = True Negative; FN = False Negative. PPA = Positive Percent Agreement; NPA = Negative Percent Agreement.

[a] Influenza B nucleic acid was detected by an alternate molecular assay in 2 of the samples tested by the Visby device.

[b] Influenza B nucleic acid was not detected by an alternate molecular assay in the 2 samples tested by the Visby device.

Table 12. Clinical Performance for the Visby Medical Flu and COVID-19 Test for SARS-CoV-2

Scenario	N	TP	FP	TN	FN	PPA (95% CI)	NPA (95% CI)
Self-Collected and Tested	1155	97	11	1040	7	93.3% (86.8%-96.7%)	99.0% (98.1%-99.4%)
Adult-Collected and Tested for a Child	248	5	2	241	0	100.0% (56.6%-100%)	99.2% (97.1%-99.8)
Overall	1403	102	13 [a]	1281	7 [b]	93.6% (87.3%-96.9%)	99.0% (98.3%-99.4%)

TP = True Positive; FP = False Positive; TN = True Negative; FN = False Negative. PPA = Positive Percent Agreement; NPA = Negative Percent Agreement.

[a] SARS-CoV-2 nucleic acid was detected by an alternate molecular assay in 6 of the samples tested by the Visby device.

[b] SARS-CoV-2 nucleic acid was detected by an alternate molecular assay in 2 of the samples tested by the Visby device.

2. Clinical Cut-Off

Not applicable.

D Expected Values

The prospective clinical evaluation of the Visby Medical Flu and COVID-19 Test included 1,432 self-collected (or adult-collected for 2-13 years old) nasal swab specimens from fourteen (14) geographically diverse sites in the US. **Table 13** shows the positivity rate for influenza A, influenza B and SARS-CoV-2 for subjects enrolled at each site based on the Visby Medical Flu and COVID-19 Test result. **Table 14** shows the number and percentage of samples positive for influenza A, influenza B, and SARS-CoV-2, as determined by the Visby Medical Flu and COVID-19 Test stratified by age and sex categories.

Table 13. Positivity Rate of the Visby Medical Flu and COVID-19 Test for Detection of influenza A, influenza B and SARS-CoV-2

Site	% Positive (# positive / # tested)		
	Influenza A	Influenza B	SARS-CoV-2
1	6.1% (9/148)	2.0% (3/148)	8.8% (13/148)
2	0.0% (0/30)	3.3% (1/30)	10.0% (3/30)
3	0.6% (1/163)	0.6% (1/163)	12.3% (20/163)
4	1.5% (1/65)	0.0% (0/65)	3.1% (2/65)
5	4.5% (6/132)	5.3% (7/132)	9.1% (12/132)
6	2.2% (5/230)	3.0% (7/230)	4.8% (11/230)
7	4.1% (10/241)	0.4% (1/241)	5.0% (12/241)
8	0.0% (0/9)	0.0% (0/9)	0.0% (0/9)
9	12.5% (5/40)	17.5% (7/40)	15.0% (6/40)
10	3.3% (3/91)	0.0% (0/91)	6.6% (6/91)
11	0.0% (0/32)	0.0% (0/32)	3.1% (1/32)
12	2.2% (1/45)	8.9% (4/45)	6.7% (3/45)
13	11.1% (8/72)	1.4% (1/72)	33.3% (24/72)
14	4.8% (5/105)	4.8% (5/105)	1.9% (2/105)
Total	3.8% (54/1403)	2.6% (37/1403)	8.2% (115/1403)

Table 14. Positivity Rate by Age and Sex of the Visby Medical Flu and COVID-19 Test for Detection of influenza A, influenza B and SARS-CoV-2

Age	N (%)	% Positive (# Positive / # Tested)					
		Female			Male		
		Influenza A	Influenza B	SARS-COV-2	Influenza A	Influenza B	SARS-COV-2
2-5	101 (7.2%)	2.1% (1/48)	4.2% (2.48)	2.1% (1/48)	9.4% (5/53)	3.8% (2/53)	3.8% (2/53)
6-21	270 (19.2%)	2.4% (3/124)	3.2% (4/124)	4.8% (6/124)	5.5% (8/146)	8.2% (12/146)	2.7% (4/146)
22-59	850 (60.4%)	3.0% (16/524)	1.9% (10/524)	9.4% (49/524)	4.6% (15/326)	1.8% (6/326)	7.7% (25/326)
≥ 60	182 (13.0%)	1.8% (2/111)	0.9% (1/111)	18.0% (20/111)	5.6% (4/71)	0.0% (0/71)	11.3% (8/71)
Total	1403	2.7% (22/807)	2.1% (17/807)	9.4% (76/807)	5.4% (32/596)	3.4% (20/596)	6.5% (39/596)

There was one subject that tested positive for influenza B and COVID-19. There were no other subjects with co-infections of influenza A, influenza B and/or COVID-19 in the study.

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 45 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 the test results. An observer recorded successful scenario completion, user errors, close calls, and any observed difficulties. All thirty-eight (38) performance tasks and six (6) comprehension tasks were completed without use errors by over 93% of participants.

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 influenza A, influenza B, and 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 analysis of the Visby Medical Flu and COVID-19 Test was conducted in accordance with ISO 14971:2019. Risks associated with human factors, sample collection and handling, device operation, storage conditions, environmental factors, and result interpretation were evaluated through a systematic Task Analysis and Use-Related Risk Analysis (TAURRA). The hazard analysis included identification of potential use errors, potential hazards and hazardous situations, severity of potential harm, and risk control measures.

   A severity rating between 1 and 4 was assigned based on the potential harm, with lower values indicating lower severity: Negligible (1), Minor (2), Serious (4). Tasks associated with Serious (4) harm were designated as critical tasks and underwent mandatory Human Factors (HF) validation testing. A risk mitigation plan was developed and implemented for all identified risks. Mitigations were implemented via the following:

   - System design controls to eliminate or reduce use errors, including built-in electronic controls, internal process control assay, sample adequacy control assay, fixed-volume syringe, LED status lights, and automated result interpretation.
   - Fail-safes and failure alert mechanisms, including firmware-driven electronic controls that prevent test operation outside specified conditions (temperature, power, timing), control assays that generate invalid results when test processes fail, and Smart

Capture technology in the Visby Medical App that prevents poor-quality image capture.

- Labeling and instructional controls to alert users to potential errors, including comprehensive warnings and precautions, step-by-step illustrated User Instructions (paper and digital), video instructions via the Visby Medical Application, specific interference warnings, temperature and stability specifications, and troubleshooting guidance.

4. Failsafe Features

The Visby Medical Flu and COVID-19 device has been designed to minimize misuse by being simple to use and using workflows that are intuitive to the user. In the event of an error, the device has fail-safes and failure alert mechanisms that alert the user to the error and prevent erroneous results. These include:

- **Internal Process Control Assay-**Ensures all test steps (reverse transcription, PCR amplification, and detection) function properly; generates invalid result if process fails when no target is detected.
- **Sample Adequacy Control Assay-**Targets human DNA to confirm sufficient sample was collected and added; generates invalid result if inadequate sample detected (when no target present and process control passes).
- **Temperature monitoring-**Prevents test initiation outside operating range (13-31°C/55-88°F); displays specific LED error pattern with on-screen troubleshooting.
- **Power verification-**Prevents test operation with insufficient power (<5V, 3A); white power light will not illuminate if power adapter is incompatible.
- **2-hour timeout-**Prevents test initiation if device plugged in >120 minutes without starting; generates invalid result via electronic control error.
- **Fixed-volume syringe design-**Hard stop and fill line guide correct volume transfer; prevents under-filling or over-filling.
- **Slider actuation detection-**Test will not start unless purple switch fully closed; prevents operation with open sample port.
- **Power interruption detection-**Immediately stops test and generates invalid result if device unplugged during run; prevents restart after power loss.
- **Smart Capture technology-**Yellow-to-green corner guides ensure proper device alignment; shutter button only appears when device correctly positioned (15.2-19.0 cm distance, ≤13° angle).
- **Image Quality Assessment (IQA)-**Rejects poor quality images and prompts user to retake photo; prevents interpretation of blurry, misaligned, or poorly lit images.
- **Automated result interpretation-**Computer Vision/Machine Learning algorithm eliminates manual reading errors; prevents user misinterpretation of spot patterns.
- **Device state verification-**Detects if test is still in progress and displays "Test In Progress" error message; prevents premature result reading.
- **Green ready light detection-**Confirms test completion before allowing result interpretation.

5. Flex Studies

The operational limits of the device were evaluated in a series of studies simulating conditions of use outside of the intended use environment or in instances of user errors. Studies were run by trained operators using a testing panel of contrived positive samples consisting of influenza A, influenza B, and SARS-CoV-2 at 3x LoD, unless otherwise noted. Each study also contained a control condition in which tests were run within the specifications indicated by the instructions for use. For most of the test conditions, five replicates were tested per condition unless otherwise noted.

The Flex Study results in **Table 15** demonstrate that the test is robust to stresses of environmental conditions and potential user errors.

Table 15. Flex Studies

Test Case	Nominal	Conclusion
Delayed Testing	Unwrap device immediately before plugging in, load sample and close slider immediately to initiate test	System generated **expected valid results** when testing: • Delayed initiation of test by up to 105 minutes after sample addition • Delayed use of the device up to 4 hours after the device was removed from the protective foil wrap and placed under high humidity at 75% RH • Delayed use of the device up to 6 hours after the device was removed from the protective foil wrap and placed in direct sunlight under ambient conditions System generated **expected invalid** results when testing: • Delayed initiation of test by up to 135 minutes after sample addition System generated **expected valid and erroneous results** when testing: • Delayed use of the device 6 hours after the device was removed from the protective foil wrap **and** placed under high humidity at 75% RH (1 of 5 influenza A false negative) A labeling mitigation includes instructions that device should be used immediately after unwrapping and that users should add sample and close the slider without any delay.
Slider Actuation	Transfer sample to device, close slider completely, plug in device either before or after closing the slider	System generated **expected invalid results** for the following incorrect slider actuations: • Slider completely open (0% slider actuation) • Slider partially open (50% slider actuation) • Slider closed almost all the way (90% slider actuation)
Time of Reading Results[a]	Interpret results within 2 hours of test completion	System generated **expected valid results** when reading test results up to: • 24 hours after completion of the test

Test Case	Nominal	Conclusion
Interpretation using the Visby App from Varying Distances and Angles[b]	Hold phone horizontally directly above the Visby device at the same angle as the device	• Smart Capture would not allow the user to take a picture of the Visby device if the smartphone was <15.2 cm or >19.0 cm above the Visby device • When the smartphone is positioned between 15.2 – 19.0 cm, Smart Capture allows the user to take a picture of the Visby device at various angles and gives a valid expected result or error message to retake a picture. • No erroneous results were generated in any test cases regardless of the height or angle of the smartphone to the Visby device.
Sample Volume Loading Variability	500 µL is transferred to the device with a single-volume syringe provided in the test kit	System generated **expected valid results** when testing: • 375 µL to 1000 µL sample volume input System generated **expected invalid results** when testing: • No sample added System generated **expected valid and erroneous results or invalid results** when testing: • 250 µL sample volume input (1 of 5 false negative for influenza B, all 5 negatives were invalid) • 5850 µL sample volume input entire sample volume poured into the sample port (3 of 5 false negative for influenza A and influenza B, 4 of 5 false negative for COVID-19) As a mitigation, a fixed-volume syringe is included in the kit. Users fill the syringe with the collected specimen to the fill line.
Sample Dilution Volume Variability	Place swab in Visby Medical Flu and COVID-19 Collection Media (5.85 mL)	System generated **expected valid results** when eluting swab in: • 1 mL to 10 mL of Visby Medical Flu and COVID-19 Collection Media
Swab Elution	Place swab in buffer, recap buffer, mix by inverting 5 times Do not use any other swab	System generated **expected and valid results** when testing the following variations of swab elution and swab: • Swirl 5 seconds, no inversion • Swirl 10 seconds, no inversion • No inversion • 3 inversions • Vigorous shaking • Dip swab in and take out without swirling or inversion • Foam swab System generated **expected valid and erroneous results** when testing the following swab elution and swab: • Cotton swab (1 of 5 false negative for influenza A) A labeling mitigation has been included that instructs users to not use any other swab. Use of another swab can lead to incorrect results.

Test Case	Nominal	Conclusion
Specimen Stability	Sample in buffer tube is stable at 15-30°C for 2 hours (room temperature) and at 2-8°C (refrigerated) for 48 hours	System generated **expected valid results** when testing samples stored beyond the claimed specimen stability: • Dry swab stored at -20°C for one hour • Dry swab stored at 30°C for 2.5 hours • Swab eluted in Visby Buffer stored at -20°C for 1 hour • Swab eluted in Visby Buffer stored at 4°C for up to 1 week • Swab eluted in Visby Buffer stored at 30°C for up to 8 hours • Swab eluted in Visby Buffer stored at 40°C and 95% RH for one hour System generated **expected valid and erroneous results** when testing samples stored beyond the claimed specimen stability: • Dry swab stored at 40°C for one hour (1 of 5 false negative for influenza B) A labeling mitigation has been included that instructs users that swab must be immediately placed into tube after collection to avoid incorrect results.
Incorrect Sample Type	Specimen is a self-collected anterior swab sample that is eluted into the Visby Medical Flu and COVID-19 Collection Media prior to loading into the sample input port	System generated **expected valid results** when using the following incorrect specimen type and incorrect elution media: • Throat swab in Visby Collection Media • Tongue swab in Visby Collection Media System generated **invalid results** when using the following incorrect specimen type and incorrect elution media: • Saliva • UTM System generated **expected valid, erroneous results** or **invalid results** when using the following incorrect sample: • Sputum (9 of 10 tests invalid and 1 of 1 false positive for influenza B) System generated **expected valid and erroneous results** when using the following incorrect elution media: • Saline (2 of 5 false negative results for influenza A, 5 of 5 for influenza B, and 4 of 5 for COVID-19) • Water (2 of 5 false negative for influenza B and 1 of 5 for COVID-19) A labeling mitigation has been included that instructs users that the device is for use only with nasal swab specimens collected in the Visby Medical Flu and COVID-19 Collection Media.
Incorrect Swab Handling	Do not touch the tip of swab Insert swab and rotate against the nasal walls 5 times in both nostrils using the same swab	System generated **expected valid results** when testing: • Coat sample onto a swab, touch the swab, then elute swab in Visby Medical Flu and COVID-19 Collection Media • Coat 60 µL of sample on a swab – as opposed to 120 µL – to simulate swabbing one nostril
Visibility of Results (Lighting	Standard room lighting (30-95 foot candles	When using a **non-white background**, the Visby App **correctly interpreted** the results with all three phone models

Test Case	Nominal	Conclusion
Conditions)[c]	(fc)), using a non-white background and avoiding overhead light	(iPhone X, iPhone 12, and Pixel 6) under the following conditions: • Low lighting (≤ 15 fc) • Standard room lighting (25-30 fc) • High lighting (95-100 fc) When using **a glossy white background**, the Visby App **correctly interpreted** the results according to the following: • iPhone X at all lighting conditions • iPhone 12 at standard and high lighting conditions When using a **glossy white background**, the Visby App was unable to detect the device to capture an image for digital interpretation for the following: • iPhone 12 at low lighting conditions • Pixel 6 at all lighting conditions A labeling mitigation has been included that instructs users to avoid placing the device directly under an overhead light to prevent glare.
Device Agitation	Do not move the test while it is running	The system generated **expected valid results** when devices were run with the following manipulations: • Inverted during RT/Lysis (~ 2 min after test initiation) • Inverted during PCR (~ 10 min after test initiation) • Inverted during Detection (~ 25 min after test initiation) • With vibration • Dropped from 1 meter before use The system generated **expected valid or invalid results** when devices were run with the following manipulations**:** • Dropped from 30 inches (max height) during run
Device Positioning	Test on a level surface, facing upwards	System generated **expected valid results** when devices were run with the following orientations: • +10° from level during run • -10° from level during run System generated **invalid results** when devices were run with the following orientations: • 90° rotation on horizontal edge – "Lights Down" (Words on top housing are in the correct orientation to be read) • 90° rotation on vertical edge (plug end is up) • Upside down (top housing is face-down on the flat surface System generated **expected valid, erroneous or invalid results** when devices were run with the following orientation: • 90° rotation on horizontal edge – "Lights Up" (Words on top housing are in an upside-down orientation, 9 of 10 invalid and 1 of 1 false negative for COVID-19) A labeling mitigation has been included that instructs users

Test Case	Nominal	Conclusion
		that the device should be placed and operated on a flat surface with the front of the device facing up. Placing the device at 90° angle on its side can result in invalid results.
Functionality after Freezing	Do not freeze the device	The system generated **expected valid or invalid results:** • After being stored in a freezer (<-15°C) for 24 hours A labeling mitigation has been included that states do not freeze.
Temperature, Humidity, and Altitude[d]	Device operates in the following range: • 13° to 31°C • 5 to 80% RH • -98 ft to 9500 ft altitude	The system generated **expected valid results** when operated: • Within temperature operating conditions (13°C to 31°C) as well as low and high (11°C, 32°C) temperatures at both high (95% RH) and low (5% RH) humidity • At all altitudes (-60 m to 2970 m, -197 ft to 9744 ft) The system generated **expected invalid results** due to electronic control errors when operated: • Outside of the operating temperature range (≥34°C and ≤9°C) at both high (95% RH) and low (5% RH) humidity No impact due to changes in humidity or altitude, including the combination of temperature and humidity.
Power Fluctuation	USB-C power adapter should be a minimum of 5 volts and 3 amps minimum Do not unplug the device during operation. Device may be unplugged prior to initiating the test.	System generated **expected valid results** when: • The device was unplugged before test initiation, plugged back in, then the test initiated System generated **expected invalid results** when: • The device was unplugged and plugged back in during a test run System generated **expected error message(s)** when: • The device was plugged in with a USB-C with less than the minimum power of 5 volts and 3 amps ("Device Is Not Powered") • The device was plugged in with a USB-C with a minimum power of 5 volts and 3 amps ("Test In Progress")

[a] The study was performed with 8 different unique samples prepared with viruses spiked into negative clinical matrix at 3x LoD concentration and tested. The 8 unique samples represented all possible permutations of valid results: one negative, 3 unique single positive, 3 unique double positive, and 1 unique triple positive sample. Each unique sample was tested in triplicate at 0, 2, 6, and 24 hours using 3 different phone models (iPhone X, iPhone 12, and Pixel 6).

[b] Three distances between the phone and the Visby device were evaluated (≤15 cm, 15.2–25 cm, and ≥26 cm), with five different angles tested at each distance: flat, low, high, left, and right using 3 different phone models (iPhone X, iPhone 12, and Pixel 6). One (1) replicate negative clinical matrix and one (1) replicate triple-spiked low positive at 3x LoD was tested per condition with each phone model.

[c] The study was performed with 8 different unique samples prepared with viruses spiked into negative clinical matrix at 3x LoD concentration and tested. The 8 unique samples represented all possible permutations of valid results: one negative, 3 unique single positive, 3 unique double positive, and 1 unique triple positive sample. Each unique sample was tested in triplicate at each condition using 3 different phone models (iPhone X, iPhone 12, and Pixel 6).

[d] Three negative samples and 3 triple-spiked low positive samples at 3x LoD were evaluated for temperature and humidity per condition. Six negative samples and 6 triple-spiked low positive samples at 3x LoD were evaluated for altitude conditions. Due to restrictions at the environmental testing vendor, inactivated virus was used diluted into Visby buffer rather than natural clinical matrix.

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

7. Software documentation was reviewed and found to be acceptable.

8. 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.