May 27, 2026

Visby Medical, Inc.
Jennifer Albrecht
Director of Regulatory Affairs
3010 N. First St.
San Jose, California 95134

Re: K253971
Trade/Device Name: Visby Medical Flu and COVID-19 Test
Regulation Number: 21 CFR 866.3984
Regulation Name: Over-the-counter test to detect SARS-CoV-2 from clinical specimens
Regulatory Class: Class II
Product Code: SIA
Dated: December 11, 2025
Received: December 11, 2025

Dear Jennifer Albrecht:

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

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

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

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

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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

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

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

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

Sincerely,

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K253971

Device Name
Visby Medical Flu and COVID-19 Test

Indications for Use *(Describe)*
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.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(k) Summary

A. Submitter

Name: Visby Medical, Inc.
Address: 3010 N. First Street
San Jose, CA 95134
Phone: 1-833-468-4729

Contact: Jennifer Albrecht
Date Prepared: April 21, 2026

B. Device

Name of Device: Visby Medical Flu and COVID-19 Test
Common Name: Visby Flu and COVID-19 Test
Classification Name: Over-the-counter test to detect SARS-CoV-2 from clinical specimens
Regulatory Classification: Class II
Regulation: 21 CFR 866.3984
Primary Product Code: SIA

C. Predicate Device

Cue COVID-19 Molecular Test (DEN220028)

D. 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 dependents 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. As suggested by the name, 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.

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 (Flu A, Flu B and/or COVID-19), 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.

E. Intended 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.

F. Substantial Equivalence

The Visby Medical Flu and COVID-19 Test is substantially equivalent to Cue COVID-19 Molecular Test, DEN220028.

The following table compares the Flu and COVID-19 Test Cue COVID-19 Molecular Test and outlines the similarities and differences between the two tests.

Characteristic	**Predicate Device:** **Cue COVID-19 Molecular Test**	**Subject Device:** **Visby Medical** **Flu and COVID-19**
510(k) Number	DEN220028	K253971
Regulation	21 CFR 866.3984	Same
Product Code	QWB	SIA
Device Class	Class II	Same
Technology/ Detection	Isothermal nucleic acid amplification	Reverse Transcription Polymerase Chain Reaction (RT-PCR) system, qualitative

Characteristic	Predicate Device: Cue COVID-19 Molecular Test	Subject Device: Visby Medical Flu and COVID-19
Intended Use	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 SARSCoV-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.	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.
Indications for Use	Symptomatic subjects; Over-the-Counter Use	Same
Target	SARS-CoV-2	SARS-CoV-2, influenza A, and influenza B

Characteristic	Predicate Device: Cue COVID-19 Molecular Test	Subject Device: Visby Medical Flu and COVID-19
Specimen Types	Anterior Nasal Swabs	Same
Assay Results	Qualitative	Same
Instrument System	Cue Health Monitoring System and Cue Health App	N/A, self-contained assay and instrument system and Visby Medical App

G. Summary of Performance Data

Clinical Method Comparison

The primary objective of the study was to establish the clinical performance of the Visby Medical Flu and COVID-19 Test for the 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 when tested by lay users in an at-home setting.

This multi-center prospective clinical study was an observational and method comparison study where eligible study subjects collected nasal swabs in a simulated home environment and then tested their samples on the Visby Medical Flu and COVID-19 Test without oversight by a medical professional.

This study was conducted at fourteen (14) geographically diverse US clinical sites in simulated at-home settings. The study sites included but were not limited to POC settings such as primary care clinics, urgent care clinics, and research institutions with access to subjects with signs and symptoms of respiratory infections. Individuals with symptoms of a respiratory infection were invited to enroll in the study. After obtaining consent (or asset as appropriate), subjects performed one of the following study procedures.

1. **Self-collection and testing** - 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 AN swab specimen. When the test was completed, the subject used the Visby Medical Application to take an image of the Visby device for automatic results interpretation. The subjects did not receive any training or coaching from the study staff when performing the sample collection or when performing the Visby test.

2. **Adult collection and testing of a child** - Subjects between the ages of 6-month and 13 years of age could be enrolled and tested by an accompanying adult (18 years or older). The testing process is the same as described above, with the exception that the accompanying adult collected and tested the dual nostril AN swab specimen. Note: subjects < 2 years old were later excluded from the intended use.

In both scenarios, an additional AN swab was collected by a healthcare provider (HCP) for comparator testing. The order of specimen collection (specimen in transport media used for comparator testing or the sample collected in Visby Collection Media used for testing with the Visby device) was randomized. The comparator sample was sent to the reference laboratory for comparator testing with an FDA-cleared molecular test. The Visby test results were compared to the results of the comparator test, which was considered to be the correct result. Specimens were collected and tested between February 2024 to May 2024.

A total of 1,458 subjects were enrolled in the study. Fifty-five subjects were excluded from the performance analysis due to lack of a valid Visby or comparator result (n=10), issues related to study procedures, inclusion criteria, or subject consent (n=16), or age below intended use (n=29 between 6-23 months old). This left 1,403 subjects for performance analysis of the Visby Medical Flu and COVID-19 Test. The demographics of the evaluable subjects are described in Table 1.

Table 1. 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%
Post Graduate/Professional Degree	88	7.6%
Total	1155	

From the 1,458 subjects participated in this study, 45 subjects were excluded from the evaluation of the invalid rate because subjects were excluded from further data analysis due to issues related to study procedures, inclusion criteria, subject consent, or age. Of the remaining 1,413 subjects, 1,342 (95.0%) had an initial valid Visby test result, 56 (4.0%) had an invalid (aka 'test did not work') test result, and 15 (1.1%) did not get a final test result. Of the 71 subjects that did not obtain an initial valid test result, 65 conducted a retest of which 62 received a valid test result. Only 3 (0.2% of subjects that conducted an initial test) had a second invalid test result.

The positive percentage agreement (PPA) and negative percentage agreement (NPA) of influenza A, influenza B, and SARS-CoV-2 are shown in Tables 2-4 below.

Table 2. AN Swab Specimen Performance (Visby vs. Comparator Assays) - 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%)

[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 3. AN Swab Specimen Performance (Visby vs. Comparator Assays) - 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%)

[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 4. AN Swab Specimen Performance (Visby vs. Comparator Assays) - 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%)

[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.

Expected Values

The performance of the Visby Medical Flu and COVID-19 Test included 1,403 self-collected (or adult-collected for 2-13 years old) nasal swab specimens from fourteen (14) geographically diverse sites in the US. Table 5 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 6 shows the number and percentage of cases 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 5. 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 6. 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 (60.6%)	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.

Analytical Evaluation

Limit of Detection

The purpose of this study was to establish the lowest level of influenza A, influenza B, and SARS-CoV-2 that is reliably detected by the Visby Medical Flu and COVID-19 Test.

Two strains each of influenza A and influenza B, and one strain of SARS-CoV-2 were tested in the study. Each virus was individually spiked into a 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, and 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 a positive result for the virus. If < 19/20 replicates were positive, the concentration was increased until the acceptance criteria were met and the LoD was confirmed.

The LoD performance of the Visby Medical Flu and COVID-19 Test for influenza A, influenza B, and SARS-CoV-2 is summarized in Table 7 below.

Table 7. Limit of Detection (LoD) for the Visby Medical Flu and COVID-19 Test Analytes

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 was conducted to demonstrate equivalent performance of the Visby Medical Flu and COVID-19 Test for targets tested individually and co-formulated together.

Inclusivity

The purpose of this study was to assess the ability of the Visby Medical Flu and COVID-19 Test to perform as intended when tested with different influenza A, influenza B, and SARS-CoV-2 strains. 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. Each strain was successfully detected in 3/3 devices for the expected virus (influenza A, influenza B, or SARS-CoV-2) on the Visby Medical Flu and COVID-19 Test.

- For influenza A (including avian influenza), 23 of the 24 strains were detected at the initial test concentration. One strain (A/Hong Kong/H090-761-V1(0)/2009) had a detectable minimum concentration of 6x LoD (540 copies/swab).
- For influenza B, 12 of the 12 strains were detected at 3x LoD (810 copies/swab).
- For inactivated SARS-CoV-2, 1 of the 6 strains (Delta (B.1.617.2) USA/PHC658/2021) was detected at 3x LoD (60 copies/swab). The minimum detectable concentrations for the remaining strains were as follows:
    - 6x LoD (120 copies/swab)
        - Alpha (B.1.1.7) England/204820464/2020
        - Beta (B.1.351) South Africa/ KRISP-K005325/2020
        - Gamma (P.1) Japan/TY7-503/2021
    - 12x LoD (240 copies/swab)
        - Omicron (Lineage B.1.1.529) USA/MD-HP20874/2021
        - Omicron (Lineage BA.2.3) USA/MD-HP24556/2022

The results from this study demonstrate that the Visby Medical Flu and COVID-19 Test can detect multiple strains of influenza A, influenza B, and SARS-CoV-2 that are

circulating in humans. Performance of the Visby Medical Flu and COVID-19 Test for each inclusivity strain is summarized below (Table 8 through Table 10).

Table 8. Analytical Reactivity (Inclusivity) of the Visby Medical Flu and COVID-19 Test - Influenza A Strains

Influenza A Virus	Strain	Concentration (copies/swab)	Detection Rate (# Positive for FLU A / # Valid Tests)
Influenza A H1N1 (pandemic 2009)	A/Brownsville/39H/2009	270 (3x LoD)	3/3
	A/Hong Kong/H090-761-V1(0)/2009	270 (3x LoD)	2/3
		540 (6x LoD)	3/3
	A/Netherlands/2629/2009	270 (3x LoD)	3/3
	A/Massachusetts/15/2013	270 (3x LoD)	3/3
	A/Bangladesh/3002/2015	270 (3x LoD)	3/3
	A/Michigan/45/2015	270 (3x LoD)	3/3
	A/St. Petersburg/61/2015	270 (3x LoD)	3/3
	A/Hawaii/66/2019	270 (3x LoD)	3/3
	A/Indiana/02/2020	270 (3x LoD)	3/3
	A/Wisconsin/588/2019	270 (3x LoD)	3/3
Influenza A H3N2	A/Netherlands/22/2003	810 (3x LoD)	3/3
	A/New York/55/2004	810 (3x LoD)	3/3
	A/Brisbane/10/2007	810 (3x LoD)	3/3
	A/Uruguay/716/2007	810 (3x LoD)	3/3
	A/Hong Kong/H090-756-V1(0)/2009	810 (3x LoD)	3/3
	A/Perth/16/2009	810 (3x LoD)	3/3
	A/Victoria/361/2011	810 (3x LoD)	3/3
	A/Texas/50/2012	810 (3x LoD)	3/3
	A/Switzerland/9715293/2013	810 (3x LoD)	3/3 [1]
	A/Alaska/232/2015	810 (3x LoD)	3/3
Influenza A Avian [2]	A/bovine/Ohio/B24OSU-439/2024 (H5N1)	810 (3x LoD)	3/3
	A/Vietnam/1194/2004 (H5N1)	1.5 ng/mL	3/3
	A/Anhui/1/2013 (H7N9)	1.5 ng/mL	3/3 [3]
	A/chicken/Hong Kong/G9/1997 (H9N2)	1.5 ng/mL	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 FLU B positive result.

Table 9. Analytical Reactivity (Inclusivity) of the Visby Medical Flu and COVID-19 Test - Influenza B Strains

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

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

Table 10. Analytical Reactivity (Inclusivity) of the Visby Medical Flu and COVID-19 Test - SARS-CoV-2 strains

SARS-CoV-2 Virus	Strain	Concentration (copies/swab)	Detection Rate (# Positive for SARS-CoV-2 / # Valid Tests)
SARS-CoV-2	Alpha (B.1.1.7) England/204820464/2020	60 (3x LoD)	1/3
		120 (6x LoD)	3/3
	Beta (B.1.351) South Africa/ KRISP-K005325/2020	60 (3x LoD)	2/3
		120 (6x LoD)	3/3
	Gamma (P.1) Japan/TY7-503/2021	60 (3x LoD)	2/3
		120 (6x LoD)	3/3
	Delta (B.1.617.2) USA/PHC658/2021	60 (3x LoD)	3/3
	Omicron (Lineage B.1.1.529) USA/MD-HP20874/2021	60 (3x LoD)	0/3 [1]
		120 (6x LoD)	1/3
		240 (12x LoD)	3/3
	Omicron (Lineage BA.2.3) [1] USA/MD-HP24556/2022	60 (3x LoD)	1/3
		120 (6x LoD)	1/3
		240 (12x LoD)	3/3

[1] One valid device returned an unexpected FLU 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 COVID-19 strains. As of June 2025, analysis of 7,937,280 total sequences demonstrates that the Visby Medical Flu and COVID-19 Test detects all variants currently in circulation.

Cross-Reactivity and Microbial Interference

The purpose of these studies was to demonstrate that the Visby Medical Flu and COVID-19 Test does not return false positive or false negative results when microorganisms other than the target viruses (influenza A, influenza B, and SARS-CoV-2) are present in a sample.

These studies evaluated a total of 42 microorganisms. To evaluate whether cross-reactivity would be detected, 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 provide the expected negative results and confirm that the microorganism did not cause the device to report a false positive result.

To evaluate whether microbial interference would be detected, 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 B, and SARS-CoV-2 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 microorganism did not cause the device to report a false negative result.

All tests for both cross-reactivity and microbial interference returned 3/3 devices with the expected results (negative in the cross-reactivity study and positive in the microbial interference study). This demonstrates that these microorganisms do not cause cross-reactivity or microbial interference at the concentrations tested using the Visby Medical Flu and COVID-19 Test, as shown in Table 11.

Table 11. Microorganisms Evaluated for Cross-Reactivity and Microbial Interference on 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 $TCID_{50}$/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 $TCID_{50}$/mL	3/3	3/3	3/3	3/3	3/3	3/3
MERS-Coronavirus*	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 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 [2]	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 $TCID_{50}$/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
Measles [2]	1.1 x 10^4 $TCID_{50}$/mL	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 [3]	1.1 x 10^6 genomic copies/mL	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 [3]	1.1 x 10^6 genomic copies/mL	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 [3]	1.1 x 10^6 genomic copies/mL	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
Neisseria mucosa [3]	1.1 x 10^6 genomic copies/mL	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 [3]	1.1 x 10^6 genomic copies/mL	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 [3]	1.1 x 10^6 genomic copies/mL	3/3	3/3	3/3	3/3	3/3	3/3

[1] One device returned an initial invalid result and had valid result 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 was extracted and purified, and nucleic acid was quantified in genomic copies/mL.
* Purified RNA was tested for these organisms.

Competitive Interference

The purpose of this study was to evaluate the performance of the Visby Medical Flu and COVID-19 Test when influenza A, influenza B, and SARS-CoV-2 are present in samples at varying concentrations and combinations to simulate mixed infection conditions (presence of multiple target viruses). The potential for high concentrations of one target virus to interfere with detection of low concentrations of another target virus or cause false positive result for the virus that was not included in the sample was evaluated.

Each of the target viruses (influenza A, influenza B, and SARS-CoV-2) were spiked into a 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 12 (below), all 6 mixed infection combinations returned 3/3 devices with the 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. This data supports that there is no competitive interference between targets at the concentrations tested on the Visby Medical Flu and COVID-19 Test.

Table 12. Competitive Interference for Each Target Virus on Visby Medical Flu and COVID-19 Test

Virus and Concentration			Detection Rate (# Positive / # Tested)		
FLU A	**FLU B**	**COVID-19**	**FLU A**	**FLU B**	**COVID-19**
High	Low	Neg	3/3	3/3	0/3
High	Neg	Low	3/3	0/3	3/3
Low	High	Neg	3/3	3/3	0/3
Neg	High	Low	0/3	3/3	3/3
Low	Neg	High [1]	3/3	0/3	3/3
Neg	Low	High [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 x 10^4 copies/swab.

Endogenous/Exogenous Interfering Substances

The purpose of this study was to evaluate the performance of the Visby Medical Flu and COVID-19 Test in the presence of potentially interfering endogenous and exogenous substances that may be present in a clinical sample.

This study tested 26 potentially interfering substances in triplicate in both negative and positive samples at prespecified concentrations to confirm that the substance does not cause the device to report a false positive or false negative result, respectively, and also to understand if the substances cause invalid results. Negative samples were pooled,

concentrated nasal sample matrix (CN-NSM). Low positive samples were created by triple spiking influenza A, influenza B, and SARS-CoV-2 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 13 below lists the substances tested and the performance of the test at each concentration, separated by virus.

Table 13. 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)		
		FLU A	FLU B	COVID-19	FLU A	FLU B	COVID-19
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
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% (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.

Specimen Stability

The purpose of this study was to establish the stability of dual-nostril anterior nasal specimens collected in the Visby Medical Flu and COVID-19 Collection Media when stored at room temperature (15 - 30°C) or refrigerated (2 - 8°C) conditions.

To create low positive samples, influenza A, influenza B, and SARS-CoV-2 were spiked at a 2x LoD concentration of each virus into pooled, concentrated nasal sample matrix (CN-NSM). A total of 20 low positive samples were tested at the baseline and at each storage time-point. To blind the reader to the expected test results, an additional 5 negative (CN-NSM) samples were interspersed and tested randomly at each time-point. The device results were interpreted by the Visby App, which is unbiased as to the sample input information.

Table 14 summarizes the results for each time point. All devices tested with both low positive and negative samples at all time-points returned the expected results. The acceptance criteria were met at all tested storage conditions. The claimed specimen stability for nasal specimens in the Visby Medical Flu and COVID-19 Collection Media is 2 hours at room temperature (15 – 30°C) or 2 days in the refrigerator (2 – 8°C), which includes successful time points at least 10% beyond those times.

All low positive devices returned the expected triple positive results at all time-points tested. Based on the results, the following specimen stability in Visby Medical Flu and COVID-19 Collection Media is claimed:

- Room temperature (15 – 30°C) storage up to 120 minutes (2 hours)
- Refrigerated (2 – 8°C) storage up to 48 hours (2 days)

Table 14: **Summary of the Device Performance for Each Storage Condition and Time-Point**

Storage Condition	Time-point	# Expected Results / # Valid Devices					
		Negative Samples			Low Positive Samples (2x LoD)		
		FLU A	FLU B	COVID-19	FLU A	FLU B	COVID-19
N/A	T_0	5/5	5/5	5/5	20/20 [1]	20/20 [1]	20/20 [1]
Room Temperature (30°C)	120 - 130 minutes	5/5	5/5	5/5	20/20 [2]	20/20 [2]	20/20 [2]
	150 - 160 minutes	5/5	5/5	5/5	20/20	20/20	20/20
Refrigerated (4°C)	5 - 6 hours	5/5 [2]	5/5 [2]	5/5 [2]	21/21 [3]	21/21 [3]	21/21 [3]
	24 - 25 hours	5/5	5/5	5/5	20/20	19/20	20/20
	26 - 27 hours	5/5	5/5	5/5	20/20	20/20	20/20
	48 - 49 hours	5/5	5/5	5/5	20/20 [1]	20/20 [1]	20/20 [1]
	52 - 54 hours	5/5	5/5	5/5	20/20	20/20	20/20

[1] Two devices returned an initial invalid result. The results for both samples were valid upon retesting.
[2] One device returned an initial invalid result. The result was valid upon retesting.
[3] An additional device was inadvertently tested.

Precision

The purpose of this study was to evaluate the repeatability of the Visby Medical Flu and COVID-19 Test. This study evaluated within-lab precision using three panel members 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 LoD) or moderate (5x LoD) concentrations of the three target viruses.

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 15, below. The overall agreement rate was 99.4%, and the Visby Test demonstrated reproducible results across operators, device lots, days of testing, within days, and within runs.

Table 15: Summary of the Device 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 Flu A, Flu B, COVID-19	Flu A	100.0% (32/32)	100.0% (32/32)	100.0% (32/32)	100.0% (96/96)	96.2%-100.0%
	Flu B	100.0% (32/32)	100.0% (32/32)	100.0% (32/32)	100.0% (96/96)	96.2%-100.0%
	COVID-19	100.0% (32/32)	100.0% (32/32)	100.0% (32/32)	100.0% (96/96)	96.2%-100.0%
Low Positive 2x LoD Flu A, Flu B, COVID-19	Flu A	100.0% (32/32)	100.0% (32/32)	100.0% (32/32)	100.0% (96/96)	96.2%-100.0%
	Flu B	100.0% (32/32)	100.0% (32/32)	100.0% (32/32)	100.0% (96/96)	96.2%-100.0%
	COVID-19	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%

Flex Studies

Flex studies were conducted to evaluate the robustness of the Visby Medical Flu and COVID-19 Test for use in over-the-counter (OTC) settings. OTC devices (test systems) require a higher level of robustness as their testing environment is outside the conventional laboratory where operator expertise and environmental conditions may be less standardized.

The flex studies evaluated procedural miscues. All flex testing was conducted using the primary strains of influenza A, influenza B, and SARS-CoV-2 that were tested throughout the analytic studies. Negative samples were composed of pooled, concentrated nasal sample matrix (CN-NSM). To prepare the positive test samples, each virus was spiked into CN-NSM at a 3x LoD concentration to make a triple positive sample.

For each flex study, the condition was deemed to be adequately controlled if the device did not produce erroneous results (false positive or false negative). Conditions that resulted in an invalid (aka 'test did not work') test result due to a failure of the internal process control assay or the built-in electronic control were considered to have effective engineering controls (failure alerts and fail safes). Test conditions that produced erroneous results were evaluated to ensure that proper warning and precautions were provided to the end user. The results demonstrate that the test is robust to stresses of environmental conditions and potential user errors.

H. Human Factors Studies

The purpose of these studies was to evaluate if the Visby Medical Flu and COVID-19 Test was safe and effective for the intended users, uses, and use environments with acceptable residual risk. This determination is based on application of the human factors and usability engineering processes throughout the development of the system.

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 testing process, from 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. The results of the usability study demonstrated that the Visby Medical Flu and COVID-19 Test can be used by lay users safely and effectively.