visby medical™

IVD Rx Only

Respiratory Health

Instructions for Use

This test is only for anterior nasal and nasopharyngeal swab specimens

For qualitative detection and differentiation of influenza A, influenza B, and SARS-CoV-2 nucleic acid. For Rx Only.

PS-400005

Device Name

Visby Medical Respiratory Health Test

Common or Usual Name

Visby Respiratory Health Test

CLIA Waived

A Certificate of Waiver is required to perform this test in a CLIA Waived setting. To obtain CLIA waiver information and a Certificate of Waiver, please contact your state health department. Additional CLIA waiver information is available at the Centers for Medicare and Medicaid website at www.cms.hhs.gov/CLIA. Failure to follow the instructions or any modifications to the test will result in the test no longer meeting the requirements for waived classification.

Intended Use

The Visby Medical Respiratory Health Test is a single-use (disposable), fully integrated, automated Reverse Transcription Polymerase Chain Reaction (RT-PCR) *in vitro* diagnostic test intended for the simultaneous qualitative detection and differentiation of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), influenza A, and influenza B RNA in nasopharyngeal swab and anterior nasal swab specimens from individuals with signs and symptoms of respiratory tract infection. Clinical signs and symptoms of respiratory tract infection due to SARS-CoV-2, influenza A, and influenza B can be similar.

The Visby Medical Respiratory Health Test is intended for use as an aid in the differential diagnosis of SARS-CoV-2, influenza A, and influenza B infection if used in conjunction with other clinical and epidemiological information, and laboratory findings. SARS-CoV-2, influenza A, and influenza B viral RNA are generally detectable in nasopharyngeal swab and anterior nasal swab specimens during the acute phase of infection. This test is not intended to detect influenza C virus infections.

Positive results are indicative of the presence of the identified virus, but do not rule out bacterial infection or co-infection with other organisms not detected by the test. The agent(s) detected by the Visby Medical Respiratory Health Test may not be the definitive cause of disease. Negative results do not preclude SARS-CoV-2, influenza A, or influenza B infection. The results of this test should not be used as the sole basis for diagnosis, treatment, or other patient management decisions.

Summary and Explanation of the Procedure

Influenza (flu) and COVID-19 are both contagious respiratory illnesses that are caused by different viruses. COVID-19 is caused by infection with a coronavirus (called SARS-CoV-2) and flu is caused by infection with influenza viruses. Symptoms of flu and COVID-19 are similar, so it is not possible to differentiate infections caused by these viruses based on symptoms alone.[1]

Influenza viruses can cause mild to severe illness. Serious outcomes of flu infection can result in hospitalization or death. Older patients, young children, and patients with certain health conditions are at high risk of serious flu complications. There are two main types of influenza virus: types A and B. Influenza A and B viruses primarily circulate during the winter months in temperate climates.[2] Patients with influenza may experience fever, chills, cough, sore throat, runny or stuffy nose, muscle or body aches,

headaches, fatigue, and some patients may have vomiting and diarrhea, though this is more common in children than adults.[3]

Coronaviruses are a large family of viruses which may cause illness in animals or humans. In humans, several coronaviruses are known to cause respiratory infections ranging from the common cold to more severe diseases such as Middle East Respiratory Syndrome (MERS) and Severe Acute Respiratory Syndrome (SARS). The most recently discovered coronavirus, SARS-CoV-2, causes COVID-19, which was characterized as a pandemic by the World Health Organization (WHO) from March 2020 to May 2023.

Patients with COVID-19 can have a wide range of symptoms, ranging from mild symptoms to severe illness. Symptoms may appear 2-14 days after exposure to the virus. Patients with COVID-19 may exhibit fever, chills, cough, shortness of breath, difficulty breathing, fatigue, muscle or body aches, headache, new loss of taste or smell, sore throat, congestion, nausea, vomiting, and/or diarrhea.[4] The virus that causes COVID-19 is easily spread from person to person.[4]

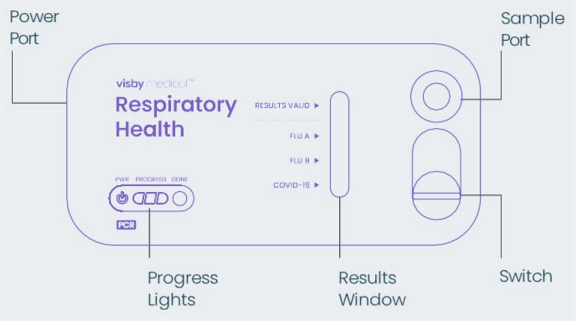
Principles of the Procedure

The Visby Medical Respiratory Health Test is a single-use (disposable), fully integrated, compact device containing a reverse transcription polymerase chain reaction (RT-PCR) based assay for qualitative detection of influenza A, influenza B, and/or SARS-CoV-2 viral RNA in upper respiratory tract specimens. The device automatically performs all steps required to complete lysis, reverse transcription (RT), PCR amplification, and detection.

Specimen collected using nasopharyngeal (NP) or anterior nasal (AN) swabs (without transport media) are placed in the Visby Medical Respiratory Health Buffer and then transferred into the sample port of the device using the provided fixed volume pipette. The sample enters a lysis module and rehydrates the RT enzyme and RT primers. The mixture then moves through a sample preparation module where viruses and human cells are simultaneously lysed, and RNA is reverse transcribed. The resulting fluid (containing cDNA) is then mixed with lyophilized PCR reagents containing the DNA polymerase enzyme and PCR primers. The PCR mixture (containing cDNA template and reagents) is then thermal cycled to amplify the targets, including human beta-2 microglobulin (B2M) RNA, which serves as a process control. After PCR, the biotinylated product is hybridized to covalently bound capture probes at specific locations along a flow channel. The flow channel is configured to facilitate an enzymatic reaction that uses streptavidin bound horseradish peroxidase (HRP) and a colorimetric substrate that forms a purple precipitate. The operator observes a color change at the specific locations indicating the presence of an amplified target. Test results can be expected in approximately 30 minutes: illumination of a “DONE” status light on the front of the device and a purple color in the “RESULTS VALID” spot, indicate a successful test. A purple spot adjacent to “Flu A”, “Flu B”, and/or “COVID-19” signifies the presence of, influenza A, influenza B, and/or SARS-CoV-2 viral RNA.

Materials Required

Materials Provided in 10 Pack Test Kit

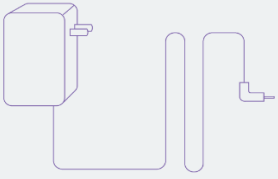


Visby Medical Respiratory Health Test – Quantity 10

Visby Fixed Volume Pipette (650 µl) – Quantity 12

Visby Respiratory Health Buffer Tube with Visby Respiratory Health Buffer (5.85 mL)– Quantity 10

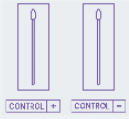
Materials Required and Available as Accessories



Visby Power Adapter*†

Visby Power Adapter

(PS-000855 or PS-000288)



External Controls

Flu A/Flu B/SARS-CoV-2 Control Panel (CL00016, Microbiologics)

Materials Required but Not Provided

Gloves

Swab

Use sterile nylon, foam, or polyester flocked flexible shaft swabs, only. Cotton and rayon swabs are not compatible with the Visby Respiratory Health Test.

Warnings and Precautions

General

1. For *in vitro* diagnostic use. Rx only.
2. This product is for single use only; do not reuse the Visby Medical Respiratory Health Test.
3. Federal Law restricts this device for sale by or on the order of a licensed practitioner (US only).
4. Color-blind users may be unable to differentiate between green and white status lights. However, they can consult the light location and shape of the light to determine test status. When interpreting results, the purple shade may appear as a dark shade for some users.
5. Results from the Visby Medical Respiratory Health device must be interpreted in accordance with these instructions for use.

Safety and Contamination Prevention

1. Follow your Institution's safety procedures for working with chemicals and handling biological samples.
2. Visby Respiratory Health Buffer may contain irritants. Do not ingest the contents of the tube. If the contents of the tube are splashed in your eyes, flush your eyes with water. If the contents splash onto your skin, wash with soap and water. If irritation persists, notify a health care provider (HCP).
3. Wear gloves while handling samples. If the gloves come in contact with specimen or appear to be wet, change gloves to avoid contaminating other specimens. Change gloves between the processing of each specimen and before leaving the work area and upon entry into work areas.
4. Keep the work area clean to prevent contamination.
5. Do not try to disassemble the Visby Respiratory Health device.
6. Treat all biological specimens, including used Visby Medical Respiratory Health devices, as if capable of transmitting infectious agents. All biological specimens should be treated with standard precautions. Guidelines for specimen handling are available from the U.S. Centers for Disease Control and Prevention and the Clinical Laboratory Standards Institute.[5]
7. If a spill occurs with Visby Medical Respiratory Health Test and/or Visby Respiratory Health Buffer Tube, soak up the spill with an absorbent material. Spray the contaminated area and materials with 10% bleach. Wipe down the surface so that it is saturated with bleach and let rest for at least 10 minutes. Once 10 minutes have passed, wipe the area down with an absorbent material, such as paper towels, followed by rinsing the area with water. Discard the Visby Medical Respiratory Health device according to your institution's standard practices.
8. If a spill occurs on the Visby power adapter, unplug, and wipe it down vigorously with 70% ethyl or isopropyl alcohol. Allow the power adapter to completely dry before using it again.
9. Safety Data Sheets (SDS) are available at Visby Medical Customer Support 1-833-GoVisby (1-833-468-4729).
10. Viral culture should not be attempted in cases of positive results for SARS-CoV-2 and/or any similar microbial agents, unless a facility with an appropriate level of laboratory biosafety (e.g., BSL 3 and BSL 3+, etc.) is available to receive and culture specimens.
11. If infection with a novel Influenza A virus is suspected based on current clinical and

epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent influenza viruses and sent to state or local health departments for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.

Electromagnetic Compatibility (EMC) Safety

1. Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
2. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Visby Medical Respiratory Health Test, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Visby Medical Respiratory Health Device and Accessories

1. The Visby Medical Respiratory Health device will not run at temperatures outside of the operating conditions and the power light will blink. If this occurs, place the device at the proper temperature and wait for the power light to give a stable white light. Refer to the troubleshooting section of the Quick Reference Guide for additional information.
2. Do not use the Visby Medical Respiratory Health device if it appears broken, has been dropped, or is past its expiration date.
3. The Visby Medical Respiratory Health Buffer is a clear, colorless, and odorless solution. Do not use if the solution appears discolored or has a strong odor.
4. Do not use the Visby Respiratory Health Buffer Tube if it appears to be leaking, damaged, opened, or is past its expiration date.
5. Do not shake or tilt the Visby Medical Respiratory Health device after adding a sample.
6. Store the Visby Medical Respiratory Health device sealed in a pouch prior to use. Do not unwrap until ready to use; storage of the unwrapped device for an extended time prior to use may result in invalid or false negative results.
7. Do not move or unplug the power cable, adapter, or Visby Medical Respiratory Health device while the test is running.
8. The Visby power adapter should be replaced if an increased number of errors are observed. Failure to do so may result in invalid results.
9. Only use the supplied Visby power adapter (9 V, 3.5 A DC) to power the Visby Medical Respiratory Health device. Using other power adapters will void the safety protection of the device and could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
10. The Visby Medical Respiratory Health device is best used in a room with adequate lighting and away from glare.
11. Testing samples stored in Visby Medical Respiratory Health Buffer for more than 120 minutes (2 hours) at room temperature or 48 hours under refrigeration can result in invalid or false negative test results.
12. The results of Visby Medical Respiratory Health Test must be read within 120 minutes (2 hours) after the "Done" Green status light appears.
13. The purple switch on the Visby Respiratory Health device must be fully closed to start the test. Failure to completely close the switch will result in failure to start the test and will cause invalid test results.

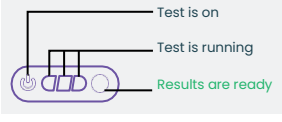
14. The Visby Medical Respiratory Health device should be operated on a flat surface, placing the device at 90° can result in invalid or false negative test results.
15. The Visby Medical Respiratory Health Test should be disposed of in the appropriate specimen waste containers according to your Institution's standard practices.
    Note: Dispose of the power adapter per your local, federal, and institutional guidelines.

Specimen

1. Follow your institution's and CDC Interim Guidelines for Biosafety and COVID-19.[5]
2. Visby Medical Respiratory Health Test is intended for testing NP or AN swabs collected in Visby Respiratory Health Buffer.
3. Collect the NP or AN swab specimens only with the recommended swab types (i.e., sterile nylon, foam, or polyester flocked flexible shaft swabs). Cotton and rayon swabs are not compatible with the Visby Respiratory Health Test.
4. Always process patient specimens with the Visby Respiratory Health Buffer in accordance with the instructions for use.
5. Do not place the swab in viral transport media, saline, water, or alternate media prior to testing.
6. The Visby Respiratory Health Buffer Tube is used to process a single specimen only. If a retest is required, refer to the retesting procedure section.
7. Failure to add sufficient specimen volume to the test can lead to invalid results.
8. The Visby Medical Respiratory Health device requires a specific volume of specimen. Use the provided fixed-volume pipette to transfer specimen to the device.
9. Clinical specimens can contain inhibitors that may generate invalid results.
10. Ensure tube caps are tightened prior to inverting the Visby Respiratory Health Buffer Tube containing the patient specimen. Inverting the Visby Buffer Tube with a patient specimen less than 5 times can result in inaccurate results.

Color Blindness Precaution

While colorblind users may be unable to differentiate green and white status lights, they can consult the light location and shape of the light to determine test status.



Test Kit and Device Storage

Store Visby Medical Respiratory Health Test kit between 36°F-86°F (2°C-30°C), and between 5% and 80% humidity. Do not freeze. In case of refrigeration or other exposure to cold temperatures, ensure that the Visby Medical Respiratory Health device is allowed to come to at least its minimum operating temperature of 55°F (13°C) prior to use.

Specimen Collection and Storage

The Visby Respiratory Health Test is intended for testing NP or dual-nostril AN swabs collected without transport media. Patient samples should be collected using an NP or AN swab (without transport media) according to the provided recommended collection instructions or your institution's standard practices. Use sterile nylon, foam, or polyester flocked flexible shaft swabs, only.

For best results, patient samples should be tested as soon as possible. If the sample cannot be immediately tested, it can be stored as shown in the following table.

WARNING: Testing samples beyond these conditions can lead to invalid or inaccurate results.

Patient Sample Storage Specifications

IN VISBY BUFFER Up to 120 minutes (2 hours) at room temperature **59°F - 86°F** (15°C – 30°C)	IN VISBY BUFFER Up to 48 hours at refrigerated temperature **36°F - 46°F** (2°C - 8°C)

Visby Medical Respiratory Health Test Procedure

Follow these instructions carefully. This test is designed for use by health care professionals.

Operating Conditions

TEMPERATURE
55°F - 88°F
(13°C - 31°C)

HUMIDITY
5% - 80%

Setup | Prepare the Workspace Place device on a level surface.

A. Clean your workspace and gather all the required materials, then **unwrap** the device. **Wear gloves** while handling samples and **change gloves** between testing each specimen.
Note: Use the device **immediately after unwrapping** to ensure accurate results.

B. Plug the **Visby Power Adaptor** into the device power port.
Note: If the power light blinks, refer to the Troubleshooting Section.

C. Remove the sticker over the sample port.

Step 1 | Ensure Patient Swab is Collected per Collection Instructions and Swab is in Visby Health Buffer Tube as Shown

A. Open the Visby Respiratory Health Buffer Tube and **place it** in tube holder.

B. Take the patient swab.

Note: Do not use rayon or cotton swabs with this test

C. Place the patient swab into Visby Respiratory Health Buffer Tube.
Note: Break the handle of the swab.

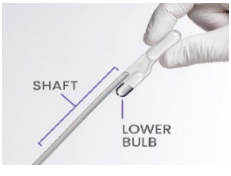
D. With the swab in the tube, screw cap back onto the Visby Respiratory Health Buffer Tube. Label the tube. **Note the time.**

Step 2 | Mix and Add Patient Sample

A. Mix the sample by **gently inverting** the tube **5 times**.
Note: Failure to invert may lead to inaccurate results.

B. Squeeze the **upper bulb** of the provided pipette and submerge the tip to the **bottom** of the sample tube.

C. Release the upper bulb **slowly** to fill the shaft. **Keep pipette tip submerged** until shaft is full. Extra fluid should enter the lower bulb.

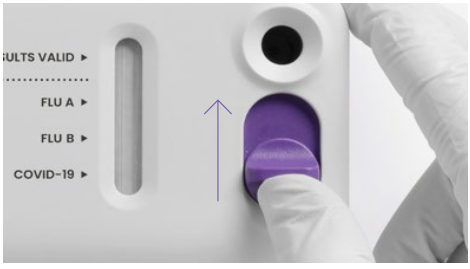


D. Ensure the shaft is filled with liquid sample.
Note: Do not squeeze lower bulb or invert the pipette.

E. Place the tip at the **bottom** of the sample port and then squeeze the **upper bulb** of the pipette to release **all** of the sample.

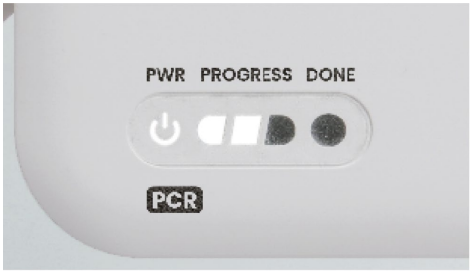
F. Some fluid will remain in the lower bulb. Discard the pipette according to your institution's guidelines immediately. **Do not set down.**

Step 3 | Run the Test Do not move test while running. Run the test immediately after adding patient sample.

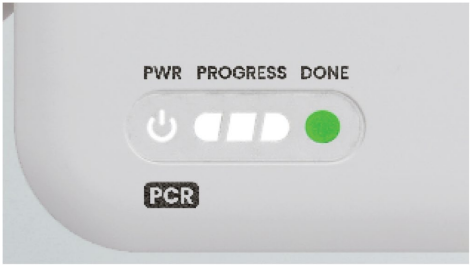


A. Slide the **switch upwards** in a firm, swift motion to close the sample port to start the test. **Do not move test while running.** **Note:** Make sure the switch is pushed all the way up.

B. Check that the first **progress indicator light is blinking**. Lights will initially blink and then become stable as the test progresses. **Note:** If something different happens to the lights, please refer to the Troubleshooting Section.



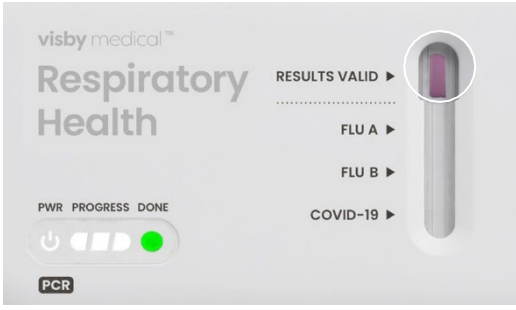
C. The second progress indicator light should become stable within **20 minutes**.



D. Wait approximately **30 minutes** for a green light to appear indicating the test is finished running.

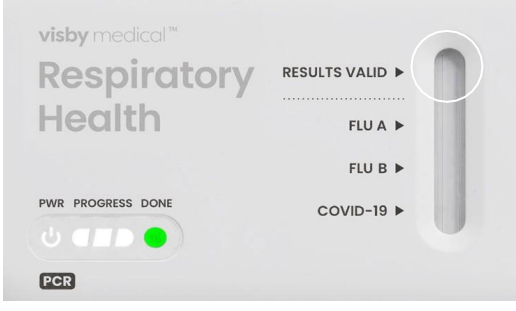
Step 4 | Interpret Results If the test is invalid, stop, and retest!

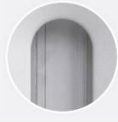
A. Determine if the test is valid.



Green light + Results Valid spot = **Valid Test**

Read Results

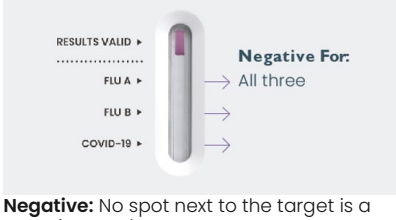




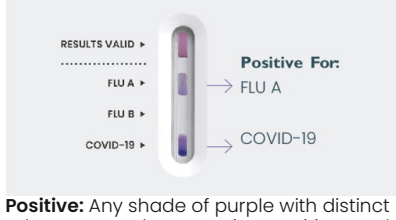
Green light + No Results Valid spot = **Invalid Test**

Stop and Retest

B. Read the test results.
Note: Results may be read up to 2 hours after the test is completed. **Do not read** results if test is invalid.



Negative: No spot next to the target is a negative result.



Positive: Any shade of purple with distinct edges next to the target is a positive result.

Intensity of the spot may vary. Any shade of color with distinct edges should be considered positive.

Result Interpretation and Action Table

The following table provides guidance on test interpretation and result reporting. Refer to the Appendix for more information on test interpretation.

Indicator Lights	"RESULTS VALID" Spot	Flu A Spot	Flu B Spot	COVID-19 Spot	Result Interpretation	Action Step
Green Done Light does not Illuminate	N/A	N/A	N/A	N/A	Invalid See Troubleshooting Section in the Appendix	
N/A	Absent	N/A	N/A	N/A	Invalid	Retest
Green Done Light	**Present**	**Present**	Absent	Absent	**Flu A Detected** Flu B Not Detected COVID-19 Not Detected	Report results
Green Done Light	**Present**	Absent	**Present**	Absent	Flu A Not Detected **Flu B Detected** COVID-19 Not Detected	Report results
Green Done Light	**Present**	Absent	Absent	**Present**	Flu A Not Detected Flu B Not Detected **COVID-19 Detected**	Report results
Green Done Light	**Present**	**Present**	**Present**	Absent	**Flu A Detected** **Flu B Detected** COVID-19 Not Detected	Report results
Green Done Light	**Present**	**Present**	Absent	**Present**	**Flu A Detected** Flu B Not Detected **COVID-19 Detected**	Report results
Green Done Light	**Present**	Absent	**Present**	**Present**	Flu A Not Detected **Flu B Detected** **COVID-19 Detected**	Report results
Green Done Light	**Present**	**Present**	**Present**	**Present**	**Flu A Detected**, **Flu B Detected** **COVID-19 Detected**	Report results
Green Done Light	**Present**	Absent	Absent	Absent	Flu A Not Detected Flu B Not Detected COVID-19 Not Detected	Report results

Retest Procedure

If a retest is required, obtain the leftover sample from the Visby Respiratory Health Buffer tube. If the leftover sample has been stored for ≤ 120 minutes at room temperature or for ≤ 48 hours at refrigerated temperature, then it can be re-tested with a new device. If the leftover sample has exceeded the storage recommendations, and/or if the sample volume is insufficient, collect a new sample and repeat the test with a new Visby Medical Respiratory Health Test.

If a repeat test with a patient sample fails, collect a new sample for testing or contact Visby Medical Customer Support at 1-833-468-4729 (1-833-GoVisby).

Quality Control

The Visby Medical Respiratory Health Test has built-in procedural controls. These include an internal process control and built-in electronic control. The result of the process control is displayed in the results window while the results of the electronic controls are displayed using the status lights.

Internal Process Control

The Visby Medical Respiratory Health device contains an internal process control assay that targets human beta-2 microglobulin (B2M) RNA. The internal process control monitors lysis, reverse transcription, PCR amplification, and detection. If these steps are completed successfully, then a purple spot will develop next to "Results Valid" in the results window. If the purple spot does not appear, the test result is Invalid, and the test must be repeated with a new Visby Medical Respiratory Health device.

Electronic Control

The electronic controls monitor the device to ensure proper operation. If the electronic control passes, a green done status light appears. If this control fails, the white status light will fail to illuminate or will flash, as shown below. See the Additional Troubleshooting section in the Appendix for additional information.

If the power light is blinking:

- The device is outside operating temperature (55°F–88°F or 13°C–31°C).
- If the room is in the right temperature range, wait for the device to reach operating temperature. The power light will become stable when that happens.
- If the room is too cold or too hot, move to a different location within the operating temperature range.
- Wait until the power light is stable before loading the sample.

If the power light and progress lights are blinking together:

- The device has encountered an error and is no longer functional.
- Refer to the Retesting Instructions.

External Positive and Negative Controls

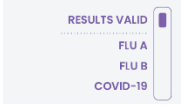
Good laboratory practice suggests the use of external positive and negative controls to ensure that the test is working properly and that the test is correctly performed.

The external control must be run once with each new shipment of test kits and once for each untrained operator. Further controls may be tested to conform with local, state and/or federal regulations, accrediting groups, or your laboratory's standard Quality Control procedures.

Procedure to Run External Controls

1. To run external control swabs, unwrap the swab, place it into the Visby Respiratory Health Buffer Tube, and tap the swab against the bottom of the tube 5 times.
2. Discard the swab according to your institution's guidelines and screw the cap back onto the Visby Respiratory Health Buffer Tube. Proceed to Step 2 of the procedure to run the test.

Flu A/Flu B/SARS-CoV-2 Control Panel (Microbiologics, (CL00016)

External Controls	Control Key
Flu A/Flu B/ SARS-CoV-2 Control Panel (Positive)	Valid Positive Control Run 
Flu A/Flu B/ SARS-CoV-2 Control Panel (Negative)	Valid Negative Control Run 

If the positive or negative external controls fail, repeat the test with a new control swab with a new Visby Medical Respiratory Health device. If a repeat test fails, contact Visby Medical Customer Support at 1-833-468-4729 (1-833-GoVisby).

Limitations

1. The performance of the Visby Medical Respiratory Health Test was established using NP and AN swab specimens.
2. The test is a qualitative test and does not provide the quantitative value of detected organism present.
3. Cross-reactivity with respiratory tract organisms other than those tested in the Analytical Specificity Study may lead to erroneous results.
4. Careful compliance with the instructions in this insert and the Quick Reference Guide Instructions are necessary to avoid inaccurate results.
5. Because the detection of influenza A, influenza B, and SARS-CoV-2 is dependent on the viral load present in the sample, reliable results are dependent on proper sample collection, sample processing, handling, and storage. Failure to observe proper procedures in any one of these steps can lead to incorrect results.
6. Performance with this test has only been evaluated with human specimens from individuals with signs and symptoms of respiratory infections. Performance has not

been established for specimens collected from individuals not identified in the intended use population.

7. The effect of interfering substances has been evaluated only for those listed in the interfering substances section of this document.
8. Mutations within the target region of influenza A, influenza B, and SARS-CoV-2 could affect primer and/or probe binding, resulting in failure to detect the presence of virus.
9. This test cannot rule out diseases caused by other bacterial or viral pathogens.
10. Viral nucleic acid may persist in vivo, independent of virus viability. Detection of influenza A, influenza B, and SARS-CoV-2 nucleic acid does not imply that the corresponding virus is infectious or is the causative agents for clinical symptoms.
11. Clinical performance has not been established with all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of influenza A, influenza B, and SARS-CoV-2 and their prevalence, which change over time.
12. The Visby Medical Respiratory Health Test is predicted to have decreased ability to detect some strains of non-H1N1 or non-H3N2 influenza A strains of zoonotic origin that are not currently known to be widely circulating in humans (e.g., H5N1, H5N6, H5N8, H9N2).
13. This test is not intended to differentiate influenza A subtypes or influenza B lineages. If differentiation of influenza subtypes and strains is needed, additional testing, in consultation with state or local public health departments, is required.
14. Positive and negative predictive values are dependent upon prevalence. False negative results are more likely during peak activity when disease prevalence is high and false positive results are more likely during periods of low activity.
15. Negative results do not preclude SARS-CoV-2, influenza A, or influenza B infection.
16. The test results should be interpreted in conjunction with other clinical and laboratory data available to the clinician.
17. Recent patient exposure to FluMist® or other live attenuated influenza vaccines may cause false positive results.
18. Use sterile nylon, foam, or polyester flocked flexible shaft swabs, only. Cotton and rayon swabs are not compatible with the Visby Respiratory Health Test.
19. The Visby Medical Respiratory Health Test has not been validated for the testing of pooled specimens or the screening of specimens from asymptomatic individuals.
20. The performance of the Visby Medical Respiratory Health Test has not been specifically evaluated for NP swab or AN swab specimens from immunocompromised individuals.
21. The performance of the Visby Medical Respiratory Health Test has not been specifically evaluated in a population known to be vaccinated against illnesses caused by SARS-CoV-2 (COVID-19).
22. The performance of the Visby Medical Respiratory Health Test has not been established for monitoring treatment of infection with SARS-CoV-2.
23. The performance of the Visby Medical Respiratory Health Test has not been established for screening of blood or blood products.
24. Performance characteristics for flu A were established when flu A/H1 and A/H3 were predominant. When other flu A viruses are emerging, performance characteristics may differ.

Expected Values

The performance of the Visby Medical Respiratory Health Test included 1,501 prospectively collected respiratory (NP and AN) swab specimens. The number and percentage of cases positive for influenza A, influenza B, and SARS-CoV-2, as determined by the Visby Medical Respiratory Health Test, are shown by age and sex categories in Table 1 below.

Table 1 Positivity Rate by Age and Sex of the Visby Medical Respiratory Health Test for Detection of influenza A, influenza B and SARS-CoV-2 in Respiratory Swab Specimens (NP and AN) During the Prospective Clinical Study (Enrollment from May 2022-March 2023)

Age	N (%)	% Positive (# Positive / # Tested)					
		Female			Male		
		Influenza A	Influenza B	SARS-COV-2	Influenza A	Influenza B	SARS-COV-2
0-5	72 (6.5%)	0.0% (0/35)	0.0% (0/35)	8.6% (3/35)	0.0% (0/37)	0.0% (0/37)	8.1% (3/37)
6-21	247 (22.2%)	6.0% (8/134)	0.0% (0/134)	9.0% (12/134)	12.4% (14/113)	0.0% (0/113)	7.1% (8/113)
22-59	649 (58.2%)	4.5% (19/418)	0.0% (0/418)	19.9% (83/418)	5.2% (12/231)	0.4% (1/231)	21.6% (50/231)
≥ 60	147 (13.2%)	0.0% (0/92)	0.0% (0/92)	21.7% (20/92)	1.8% (1/55)	0.0% (0/55)	32.7% (18/55)
Total	**1115**	**4.0% (27/679)**	**0.0% (0/679)**	**17.4% (118/679)**	**6.2% (27/436)**	**0.2% (1/436)**	**18.1% (79/436)**

Table 2 Positivity Rate by Age and Sex of the Visby Medical Respiratory Health Test for Detection of influenza A, influenza B and SARS-CoV-2 in Respiratory Swab Specimens (NP and AN) During the Prospective Clinical Study (Enrollment from November 2023-February 2024)

Age	N (%)	% Positive (# Positive / # Tested)					
		Female			Male		
		Influenza A	Influenza B	SARS-COV-2	Influenza A	Influenza B	SARS-COV-2
0-5	13 (3.4%)	0.0% (0/6)	16.7% (1/6)	0.0% (0/6)	28.6% (2/7)	0.0% (0/7)	0.0% (0/7)
6-21	78 (20.1%)	17.1% (7/41)	14.6% (6/41)	14.6% (6/41)	21.6% (8/37)	10.8% (4/37)	2.7% (1/37)
22-59	234 (60.6%)	11.8% (19/161)	7.5% (12/161)	16.1% (26/161)	11.0% (8/73)	12.3% (9/73)	16.4% (12/73)
≥ 60	61 (15.8%)	2.4% (1/41)	0.0% (0/41)	22.0% (9/41)	20.0% (4/20)	0.0% (0/20)	35.0% (7/20)
Total	**386**	**10.8% (27/249)**	**7.6% (19/249)**	**16.5% (41/249)**	**16.1% (22/137)**	**9.5% (13/137)**	**14.6% (20/137)**

Performance Characteristics

Clinical Evaluation

Performance characteristics of the Visby Medical Respiratory Health Test were established in a clinical study that included testing of prospectively collected fresh specimens. The objective of this study was to establish the clinical performance of the Visby Medical Respiratory Health Test for the detection and differentiation of SARS-CoV-2, influenza A, and influenza B viral RNA in clinical specimens when in the intended use setting. This study was conducted at five CLIA Waived testing settings in the US. All study specimens were tested with the Visby Medical Respiratory Health Test by typical CLIA Waived operators according to the Quick Reference Guide (QRG) and Instructions for Use (IFU). Specimens were collected and tested between May 2022 and Feb 2024.

Prospective Sample Testing

Subjects presenting with signs and symptoms of a viral respiratory infection were prospectively enrolled at five CLIA Waived sites in the US including urgent care and family care clinics. One NP or dual nostril AN swab specimen was placed directly in Visby Respiratory Health Buffer and tested with the Visby device. The samples were also tested with an FDA-cleared influenza molecular test and an FDA-EUA authorized SARS-CoV-2 RT-PCR test as a comparator.

A total of 1,592 subjects were enrolled in the study. Ninety one (91) study specimens were excluded from the performance analysis due to of lack of a valid comparator result (n=53), lack of a valid Visby test result (n=21), the subject did not meet inclusion criteria (n=10), or for protocol deviations (n=6). One subject withdrew from the study. This left 1,501 subjects for performance analysis of the Visby Medical Respiratory Health Test.

A total of 1,575 Visby tests were performed on subjects that met the inclusion criteria, did not experience a protocol deviation, did not withdraw from the study. Of these 79 (5.0%) had an initial invalid test result of which 21 (1.3%) were invalid when retested. Of the 840 NP swab specimens tested, 30 (3.6%) had an initial invalid test result of which 5 (0.6%) were invalid when retested. Of the 735 AN swab specimens tested, 49 (6.7%) had an initial invalid test result of which 16 (2.2%) were invalid when retested.

The positive percentage agreement (PPA) and negative percentage agreement (NPA) of influenza A, influenza B, and SARS-CoV-2 are shown in Table 3 below.

Table 3 Prospective Fresh NP and AN Swab Specimen Performance – Enrollment from May 2022 to Feb 2024 (Visby vs. Comparator Assays)

	Specimen Type (NP/AN)	TP	FP	TN	FN	PPA (95% CI)	NPA (95% CI)
Influenza A	NP	33	4[a]	791	1[c]	97.1% (85.1-99.5%)	99.5% (98.7-99.8%)
	AN	61	5[b]	604	2[d]	96.8% (89.1-99.1%)	99.2% (98.1-99.7%)
	NP+AN	94	9	1395	3	96.9% (91.3-98.9%)	99.4% (98.8-99.7%)
Influenza B	NP	15	2[e]	812	0	100% (79.6-100%)	99.8% (99.1-99.9%)
	AN	15	1[f]	656	0	100% (79.6-100%)	99.9% (99.1-100%)
	NP+AN	30	3	1468	0	100% (88.7-100%)	99.8% (99.4-99.9%)
SARS-CoV-2	NP	130	7[g]	687	5[i]	96.3% (91.6-98.4%)	99.0% (97.9-99.5%)
	AN	116	5[h]	549	2[j]	98.3% (94.0-99.5%)	99.1% (97.9-99.6%)
	NP+AN	246	12	1236	7	97.2% (94.4-98.7%)	99.0% (98.3-99.5%)

[a] 3 of 4 false positive NP specimens tested positive and one tested negative with an alternate molecular assay
[b] 5 of 5 false positive AN specimens tested positive with an alternate molecular assay
[c] 1 false negative NP specimen tested positive with an alternate molecular assay
[d] 2 false negative AN specimen tested positive with an alternate molecular assay
[e] 2 of 2 false positive NP specimens tested positive with an alternate molecular assay
[f] 1 of 1 false positive AN specimens tested positive with an alternate molecular assay
[g] 5 of 7 false positive NP specimens tested positive and 2 tested negative with an alternate molecular assay
[h] 4 of 5 false positive AN specimens tested positive, and 1 tested negative with an alternate molecular assay
[i] 3 of 5 false negative NP specimens tested negative and 2 tested positive with an alternate molecular assay
[j] 1 of 2 false negative AN specimen tested negative and 1 tested positive with an alternate molecular assay

Reproducibility

A study was performed to evaluate the reproducibility of the Visby Medical Respiratory Health Test when used by untrained users in CLIA Waived settings. The operators performing the testing were non-laboratorians representing healthcare professionals that may be encountered at such sites. The study evaluated a seven (7) member panel composed of NP swabs seeded with unspiked clinical matrix (negative) and NP swabs seeded with clinical matrix individually spiked with low (1x LoD) or moderate (3-5x LoD) concentrations of the three target viruses.

A total of six (6) study operators (2 operators at each site) tested the panel three (3) times each testing day, over six (6) non-consecutive days. Three reagent lots were used in the study. Each lot was used for two (2) days of testing. The composition of the panel members along with a summary of results (correct count / total count) and percent agreement with the expected results for each panel member is presented in Table 4 below.

Table 4 Summary of Reproducibility Results with the Visby Medical Respiratory Health Test

Panel Member	Site 1	Site 2	Site 3	Overall Agreement	
	% Agreement (count)	% Agreement (count)	% Agreement (count)	% Agreement (count)	95% CI
Influenza A Moderate Positive	100.0% (36/36)	100.0% (36/36)	100.0% (36/36)	100.0% (108/108)	96.6%-100.0%
Influenza A Low Positive	94.4% (34/36)	100.0% (36/36) [a]	88.9% (32/36)	94.4% (102/108) [a]	88.4%-97.4%
Influenza B Moderate Positive	97.2% (35/36)	100.0% (36/36)	100.0% (36/36)	99.1% (107/108)	94.9%-99.8%
Influenza B Low Positive	97.2% (35/36)	100.0% (36/36)	91.7% (33/36)	96.3% (104/108)	90.9%-98.6%
SARS-CoV-2 Moderate Positive	100.0% (36/36)	100.0% (36/36)	100.0% (36/36)	100.0% (108/108)	96.6%-100.0%
SARS-CoV-2 Low Positive	97.2% (35/36)	100.0% (36/36)	88.9% (32/36)	95.4% (103/108)	89.6%-98.0%
Negative	100.0% (36/36)	100.0% (36/36)	100.0% (36/36)	100.0% (108/108)	96.6%-100.0%

[a] One sample was positive for influenza A, but unexpectedly positive for SARS-CoV-2

Analytical Evaluation

Limit of Detection

The limit of detection (LoD) is the lowest concentration of viral nucleic acid that is reliably detected by the Visby Respiratory Health Test. Influenza A, influenza B, and SARS-CoV-2 were tested in a range-finding study of 3-fold dilutions in negative clinical matrix, and the lowest concentration with 100% detection was established as the estimated LoD. The estimated LoD was confirmed by testing 20 replicates, where confirmation of the LoD was achieved when at least 19 of the 20 replicates returned a positive result for the virus tested. All viruses were tested individually in single-positive samples. The LoD of the Visby Medical Respiratory Health Test for influenza A, influenza B, and SARS-CoV-2 are summarized in Table 5 below.

Table 5 Limit of Detection (LoD) for the Visby Medical Respiratory Health Test Analytes

Virus	LoD Concentration
Influenza A/H1N1 2009, Brisbane/02/18	**106 copies/swab** 4.89 $TCID_{50}$/swab
Influenza A/H3N2, Kansas/14/2017	**125 copies/swab** 2.01 FFU[a]/swab
Influenza B/Washington/02/19	**728 copies/swab** 9.20 $TCID_{50}$/swab
Influenza B/Oklahoma/10/2018	**778 copies/swab** 88.37 $TCID_{50}$/swab
SARS-CoV-2 (USA-WA1/2020)	**100 copies/swab**

[a] FFU: Fluorescent Focus Units. Titer by Fluorescent Focus Assay in MDCK-SIAT1 Cells.

WHO 1st International Standard for SARS-CoV-2

The established analytical sensitivity or LoD of the Visby Medical Respiratory Health Test when tested with the World Health Organization (WHO) 1st International Standard for SARS-CoV-2 RNA (NIBSC code: 20/146) is 2.2 x 10^5 IU/mL of RNA in the sample tested.

Inclusivity

The ability of the Visby Medical Respiratory Health Test to detect 10 H1N1 (pandemic 2009) strains, 13 H3N2 strains, 12 influenza B strains (5 each of Victoria and Yamagata lineages and 2 additional strains), 6 SARS-CoV-2 strains, and 6 avian influenza A strains (RNA only, representing H5N1, H7N9, and H9N2). Each virus was individually spiked into negative clinical matrix at or near 3x LoD (unless otherwise noted) and tested in triplicate. All strains were successfully detected within 3x LoD, with the exception of the Omicron (BA.2.3) Isolate USA/MD-HP24556/2022 (detected at 6x LoD) and A/Egypt/321/2007 (H5N1).

Table 6 Analytical Reactivity (Inclusivity) of the Visby Respiratory Health Test

Virus	Strain	Tested Concentration
Influenza A H1N1 (pdm2009)	A/Brownsville/39H/2009	318 copies/swab
	A/Hong Kong/H090-761-V1(0)/2009	318 copies/swab
	A/Netherlands/2629/2009	318 copies/swab
	A/Massachusetts/15/2013	318 copies/swab
	A/Bangladesh/3002/2015	318 copies/swab
	A/Michigan/45/2015	318 copies/swab
	A/St. Petersburg/61/2015	318 copies/swab
	A/Hawaii/66/2019	318 copies/swab
	A/Wisconsin/588/2019	318 copies/swab
	A/Indiana/02/2020	318 copies/swab
Influenza A H3N2	A/Netherlands/22/2003	393 copies/swab
	A/New York/55/2004	393 copies/swab
	A/Brisbane/10/2007	393 copies/swab
	A/Uruguay/716/2007	393 copies/swab
	A/Hong Kong/H090-756-V1(0)/2009	393 copies/swab
	A/Perth/16/2009	393 copies/swab
	A/Victoria/361/2011	393 copies/swab
	A/Texas/50/2012	393 copies/swab
	A/Switzerland/9715293/2013	393 copies/swab
	A/Alaska/232/2015	393 copies/swab
	A/California/55/2020	393 copies/swab
	A/Hong Kong/2671/2019	393 copies/swab
	A/Wisconsin/04/2018	393 copies/swab
Avian Influenza A[1]	A/duck/Hunan/795/2002 (H5N1)	1500 pg/mL
	A/chicken/Yunnan/1251/2003 (H5N1)	1500 pg/mL
	A/Vietnam/1194/2004 (H5N1)	1500 pg/mL
	A/Egypt/321/2007 (H5N1)	Not Detected[2]
	A/Anhui/1/2013 (H7N9)	1500 pg/mL
	A/chicken/Hong Kong/G9/1997 (H9N2)	1500 pg/mL
Influenza B	B/Lee/1940	2334 copies/swab
	B/Maryland/1/1959	2334 copies/swab
Influenza B Victoria Lineage	B/Malaysia/2506/2004	2184 copies/swab
	B/St. Petersburg/14/2006	2184 copies/swab
	B/Brisbane/60/2008	2184 copies/swab
	B/Nevada/03/2011	2184 copies/swab
	B/New Jersey/1/2012	2184 copies/swab
Influenza B Yamagata Lineage	B/New York/1061/2004	2334 copies/swab
	B/Florida/4/2006	2334 copies/swab
	B/Texas/06/2011	2334 copies/swab
	B/Phuket/3073/2013	2334 copies/swab
	B/Guangdong-Liwan/1133/2014	2334 copies/swab
SARS-CoV-2	Alpha (B.1.1.7) England/204820464/2020	300 copies/swab
	Beta (B.1.351) South Africa/ KRISP-K005325/2020	100 copies/swab
	Gamma (P.1) Japan/TY7-503/2021	300 copies/swab
	Delta (B.1.617.2) USA/PHC658/2021	300 copies/swab
	B.1.1.529 BA.1 Isolate: USA/MD-HP20874/2021	300 copies/swab
	Omicron (BA.2.3) Isolate: USA/MD-HP24556/2022	600 copies/swab

[1] Purified RNA was tested due to biosafety regulations.

[2] The Visby Medical Respiratory Health Test returned influenza A positive results in 2/3 replicates at 1500 pg/mL for the A/Egypt/321/2007 (H5N1) strain RNA.

In silico analysis of sequences from GISAID are conducted routinely to assess the ability of the Visby Medical Respiratory Health Test to detect the most recent COVID-19 strains. The results of these analyses of 16,856,233 total sequences, as of August 2024, show that the Visby Medical Respiratory Health Test will detect all variants in circulation.

Cross-Reactivity and Microbial Interference

The potential for cross-reactivity from microorganisms that may be found in an upper respiratory sample other than the target respiratory viruses (influenza A, influenza B, and SARS-CoV-2) on the performance of the Visby Medical Respiratory Health Test was evaluated. Forty-three (43) microorganisms were tested in triplicate at high concentrations (>10^5 units/mL for viruses and >10^6 units/mL for bacteria and yeast) in negative samples (negative clinical matrix). No cross-reactivity was observed with any of the organisms at the concentrations tested.

Microbial Interference was evaluated by testing the same 43 microorganisms in triplicate in negative clinical matrix in the presence of low concentrations of the target organisms (3X LoD for influenza A, influenza B, and SARS-CoV-2). No microbial interference was observed with any of the microorganisms at the concentrations tested.

Table 7 Microorganisms Evaluated for Cross-Reactivity and Microbial Interference on Visby Respiratory Health Test

Viruses (ATCC Number)	Bacteria and Yeast (ATCC Number)
Human Coronavirus 229E (VR-740)	*Bordetella parapertussis* (15311)
	Bordetella pertussis (9340)
Human Coronavirus OC43 (VR-1558)	*Candida albicans* (18804)
Human coronavirus HKU1 (VR-3262SD) *	*Chlamydia pneumoniae* (53592)
Human Coronavirus NL63 (VR-3263SD) *	*Corynebacterium xerosis* (373)
SARS-Coronavirus (VR-3280SD) *	*Escherichia coli* (25922)
MERS-Coronavirus (VR-3248SD) *	*Haemophilus influenzae* (49247)
Adenovirus strain 1, C1 Ad 71 (VR-1)	*Lactobacillus brevis* (14869)
Adenovirus strain 7 (VR-7)	*Legionella pneumophila* (33152)
Cytomegalovirus (VR-977)	*Moraxella (Branhamella) catarrhalis* (25238)
Epstein Barr virus (B95-8, ZeptoMetrix)	*Mycobacterium tuberculosis* (25177)
Enterovirus 68 (NR-51430, BEI)	*Mycoplasma genitalium* (49123)
	Mycoplasma pneumoniae (15531)
Human metapneumovirus (hMPV) (NR-22232, BEI)	*Neisseria meningitidis* serogroup a (13077)
Human parainfluenza virus 1 (NR-48681, BEI)	*Neisseria mucosa* (19695)
Human parainfluenza virus 2 (VR-92)	*Pneumocystis jirovecii* also called Pneumocystis carinii Delanoe and Delanoe (PRA-159)
	Pseudomonas aeruginosa (0801519, ZeptoMetrix)
Human parainfluenza virus 3 (VR-93)	*Staphylococcus aureus* (12600)
Human parainfluenza virus 4b (NR-3238, BEI)	*Staphylococcus epidermidis* (12228)
Measles (VR-24)	*Streptococcus pneumoniae* (49619)
Mumps (VR-106DQ) *	*Streptococcus pyogenes* (19615)
Respiratory syncytial virus (Strain B) (VR-1400)	*Streptococcus salivarius* (9759)
Human rhinovirus 1A (strain 2060) (VR-1559)	Pooled human nasal wash

* Purified RNA was tested for these viruses.

Competitive Interference

The potential for high concentrations of one target organism to interfere with detection of low concentrations of another target organism was evaluated. Influenza A, influenza B, and SARS-CoV-2 viruses were spiked into negative clinical matrix 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 ≥10^5 copies/swab. No competitive interference was observed for any of the three target viruses at the concentrations tested.

Table 8 Competitive Interference for each Target Virus

Viral Targets in Sample			Detection Rate (# Positive / # Tests)		
Influenza A	**Influenza B**	**SARS-CoV-2**	**Influenza A**	**Influenza B**	**SARS-CoV-2**
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	3/3	0/3	3/3
Neg	Low	High	0/3	3/3	3/3

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. The potential interfering substances were spiked in negative clinical matrix and tested in the presence and absence of low concentrations (3x LoD) of influenza A, influenza B, and SARS-CoV-2 viruses. All samples were tested in triplicate. As shown in Table 9 below, all of the negative samples returned valid results that were negative for influenza A, influenza B, and SARS-CoV-2. All the positive samples returned valid results that were positive for influenza A, influenza B, and SARS-CoV-2. None of the tested substances were found to interfere with test accuracy at the concentrations tested.

Table 9 Potentially Interfering Substances

Substance	Concentration	Negative Samples (# Negative / # Tests)	Low Positive Samples (3x LoD) (# Positive / # Tests)
Afrin	25% (v/v)	3/3	3/3
Biotin	3.5 µg/mL	3/3	3/3
Flonase	25% (v/v)	3/3	3/3
Fresh Whole Blood Pooled Human Donors	5% (v/v)	3/3	3/3
Human lotion	5% (w/v)	3/3	3/3
Hand sanitizer	5% (w/v)	3/3	3/3
Purified mucin protein	1% (w/v)	3/3	3/3
Method all purpose cleaner	5% (v/v)	3/3	3/3
Mupirocin	12 mg/mL	3/3	3/3
Nasacort	25% (v/v)	3/3	3/3
Nasal Saline Spray	25% (v/v)	3/3	3/3
NeoSynephrine Cold & Sinus Extra Strength Spray	25% (v/v)	3/3	3/3
Seventh generation disinfectant	5% (v/v)	3/3	3/3
Softsoap moisturizing hand soap	5% (w/v)	3/3	3/3
Tobramycin	2.43 mg/mL	3/3	3/3
Zanamivir (Relenza)	5 mg/mL	3/3	3/3
Zicam Allergy Relief	25% (v/v)	3/3	3/3

References

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5. Interim Guidelines for Biosafety and COVID-19 https://www.cdc.gov/covid/php/lab/index.html

Index of Symbols

Symbol	Meaning	ISO 15223-1 Ref. Number
	Power supply	N/A
	Catalog number	5.1.6
	Do not reuse	5.4.2
	Handle with care	5.3.1
	Batch code	5.1.5
	Caution	5.4.4
	Consult instructions for use	5.4.3
	Manufacturer	5.1.1
	Expiration date	5.1.4
	Temperature limitation	5.3.7
	Humidity limitation	5.3.8
	Biological risk	5.4.1
	*In vitro* diagnostic medical device	5.5.1
	Do not use if package is damaged	5.2.8
	Nemko 61010	N/A
	Prescription Use Only	N/A

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Appendix

More Information on Result Interpretation

The following are occasionally observed:

Background Staining	Speckling and Bubbles	Spot Shadow
		
The background color in the results window may turn a light shade of blue or purple over time. This is a normal feature of chemistry. This should not be considered a positive result.	Non-specific small flakes in the results window should not be interpreted to be a positive result. It is also normal for bubbles to appear in the results window during test processing.	An extremely faint spot without distinct edges may be seen in the results window. This should not be interpreted to be a positive result.

Additional Troubleshooting

Status Light Behavior	Cause of error	User instructions
None of the white lights illuminate 	The device is not receiving power or there was a power interruption during the run	• If the error occurs prior to the start of the run, the user can ensure the device is properly plugged in and proceed with testing • If a power interruption occurred after the run starts, the test will not progress. The sample must be tested with a new device.
The white power light is blinking 	The device is being operated outside of its temperature range	The device can be allowed to reach operating temperature or moved to a more appropriate location prior to the start of the run
The white power light is on, but the progress lights do not turn on 	The purple slider was not completely closed or did not activate the test	Confirm the slider is completely closed. If it is, the test will not progress, and the sample must be tested with a new device.
All of the white lights blink 	The device has experienced an error	The test will not complete, and the sample must be tested with a new device.

If you are unsure how to interpret a result, please contact **Visby Medical Customer Support** at 1-833-GoVisby (1-833-468-4729).