

visby medical™ Respiratory Health

QUICK REFERENCE GUIDE



This test is only for anterior nasal and nasopharyngeal swab specimens. Labs with a Certificate of Waiver may use this test.

IVD Rx Only

For additional information, please find the full Visby Medical Respiratory Health Test Instructions for Use at visby.com/respiratory-health-test/. A printed copy can be requested at no additional cost from Visby Medical Customer Support at 1-833-468-4729 (1-833-GoVisby) or support@visby.com.

Step 2 | Mix and Add Patient Sample



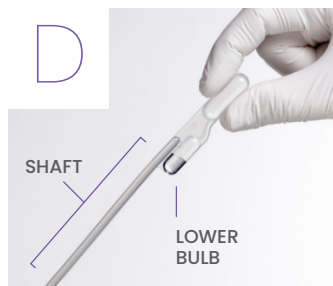
Mix the sample by **gently inverting** the tube **5 times**. **Note:** Failure to invert may lead to inaccurate results.



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



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



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



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.



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

Setup | Prepare the Workspace | Operating Temperature: 55°F (13°C)–88°F (31°C) | Place device on a level surface.



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. **Use the device immediately after unwrapping** to ensure accurate results.

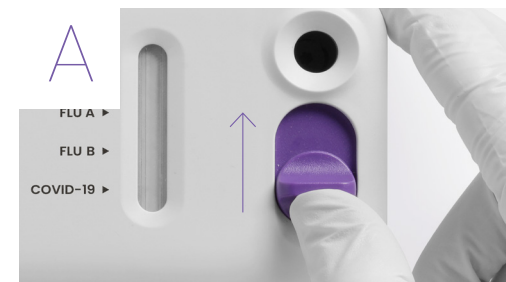


Plug the **Visby Power Adaptor** into the device power port. **Note:** If the power light blinks, refer to the Troubleshooting Section.



Remove the sticker over the sample port.

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



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.



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.



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

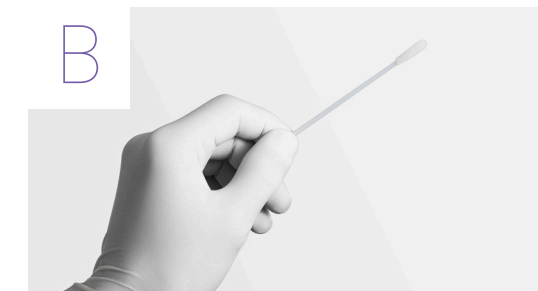


Wait approximately **30 minutes** for a green light to appear indicating the test is finished running.

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



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



Take the patient swab.

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



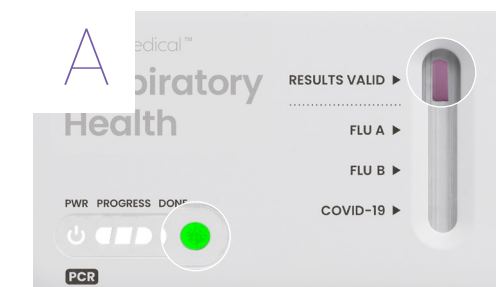
Place the patient swab into Visby Respiratory Health Buffer Tube. **Note:** **Break the handle** of the swab.



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

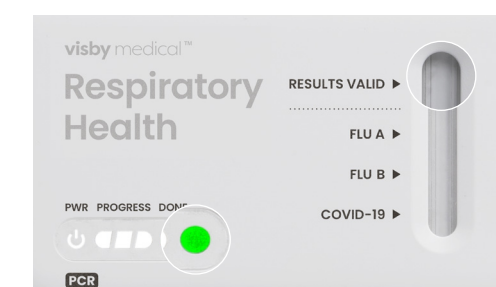
Step 4 | Interpret Results | If the test is invalid, stop, and retest!

Determine if the test is valid.



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

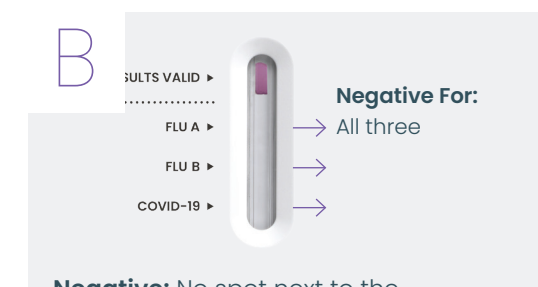
Read Results



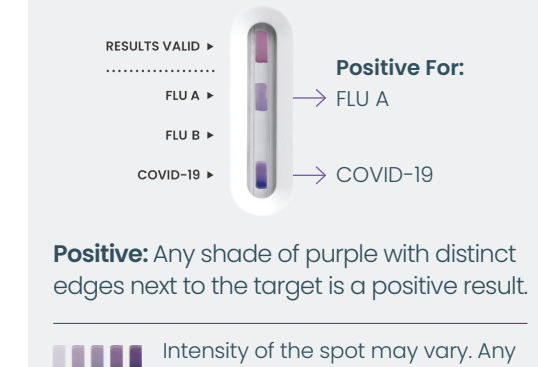
Green light + No Results Valid spot = **Invalid Test**

Stop and Retest

Read the test results.



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.

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

Important Information

The **Visby Medical Respiratory Health Test** is for the qualitative detection and differentiation of influenza A, influenza B, and SARS-CoV-2. Collect patient samples using nasopharyngeal or dual nostril anterior nasal swabs. Please refer to Sample Collection Instructions and Instructions for Use for more information.

 Users should read the complete test procedure and recommended quality control procedure before performing the test. Please refer to the instructions for use for more information.

Color-blind individuals may be unable to differentiate between status light colors. They may consult the light location and shape of the light to determine test status.

A Certificate of Waiver is required to perform this test in a CLIA Waived setting. Failure to follow the instructions or any modifications to the test will result in the test no longer meeting the requirements for waived classification.

Retest

The patient sample is stable in the Visby Respiratory Health Buffer at room temperature for **2 hours** or at refrigerated temperature for **48 hours**.

1. Confirm patient sample storage specifications have not been exceeded. **If conditions were exceeded**, collect a new sample.
2. Repeat test with a new device and pipette beginning with the Setup step. **If the repeat test fails**, please contact Visby Medical Customer Support.

Disposal

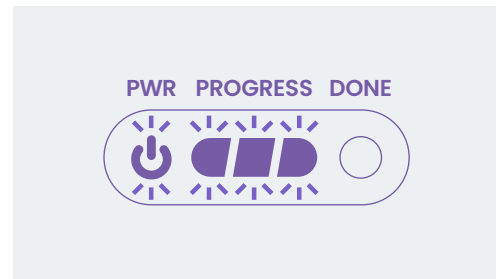
 Dispose the device, pipette and respiratory health buffer tube according to your institution's standard practices.

Troubleshooting



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 above.
- For a detailed Troubleshooting Guide, refer to the Instructions for Use (IFU).

Sample Handling



Testing samples beyond these conditions can lead to inaccurate results

IN BUFFER TUBE up to **2 hours** at room temperature **59°F–86°F** (15°C–30°C)

IN BUFFER TUBE up to **48 hours** at refrigerated temperature **36°F–46°F** (2°C–8°C)


Storage Conditions

(unused and in original packaging)

TEMPERATURE

36°F (2°C)  86°F (30°C)

HUMIDITY

5%  80%

Store in a cool and dry environment (36°F–86°F). **Do not freeze.**


Operating Conditions

Run the test on a clean, level surface.

TEMPERATURE

55°F (13°C)  88°F (31°C)

HUMIDITY

5%  80%

Quality Control

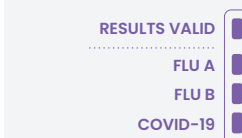
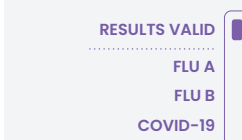
INSTRUCTIONS TO RUN EXTERNAL CONTROLS

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

Proceed to Step 2 of the Quick Reference Guide. The controls must be tested once with each new shipment received and once for each untrained operator. Please refer to the Instructions for Use for more information on running external quality controls.

EXTERNAL POSITIVE AND NEGATIVE CONTROLS

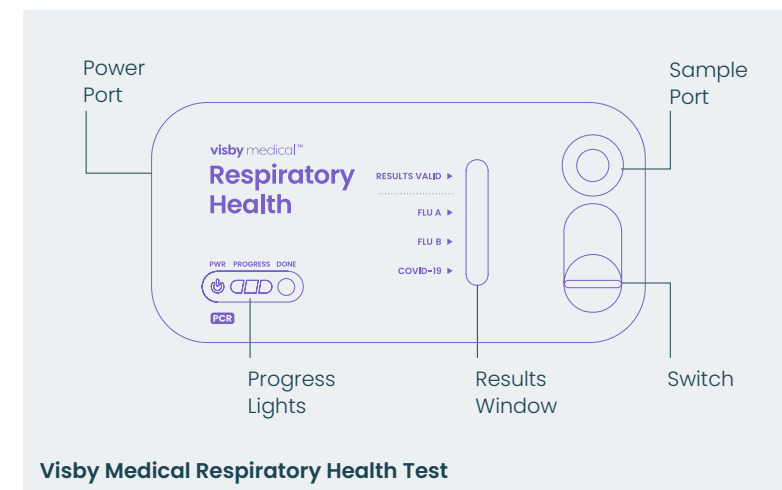
Flu A/Flu B/SARS-CoV-2 Control Panel (CL00016, Microbiologics, Inc.)

External Controls	Units in Kit	Control Key
Flu A/Flu B/SARSCoV-2 Control Panel (positive)	2 Swabs	Valid Positive Control Run 
Flu A/Flu B/SARSCoV-2 Control Panel (negative)	2 Swabs	Valid Negative Control Run 

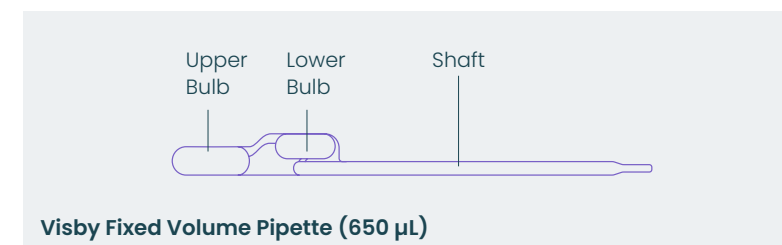
If the positive or negative external controls fail, repeat with new external control and a new Visby Respiratory Health Test. If the repeat test fails, please contact **Visby Medical Customer Support** at **1-833-468-4729 (1-833-GoVisby)**.

Materials Provided and Required

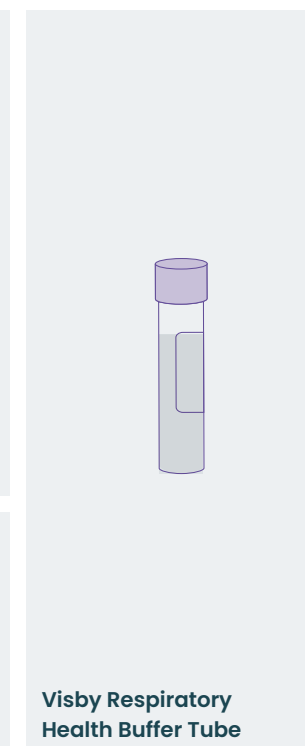
Materials Provided



Visby Medical Respiratory Health Test

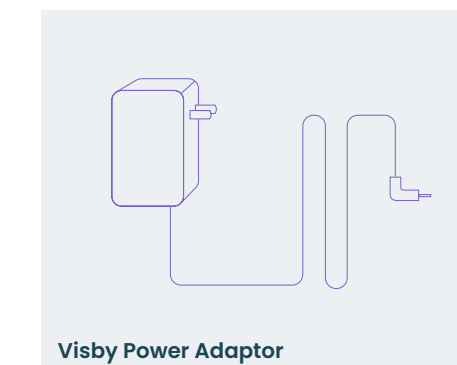


Visby Fixed Volume Pipette (650 µL)

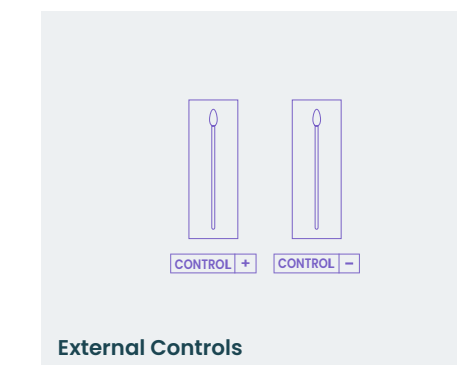


Visby Respiratory Health Buffer Tube

Available as Accessories



Visby Power Adaptor



External Controls

Not Provided



Gloves



Swab