

visby medical™

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# Training: Visby Medical Respiratory Health Test



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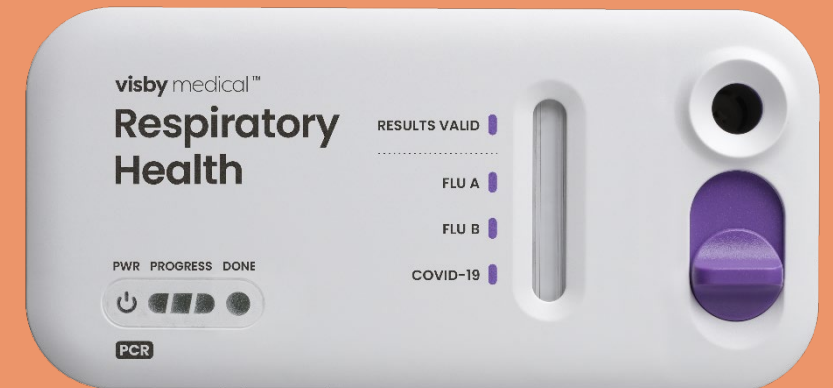
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# Product Overview

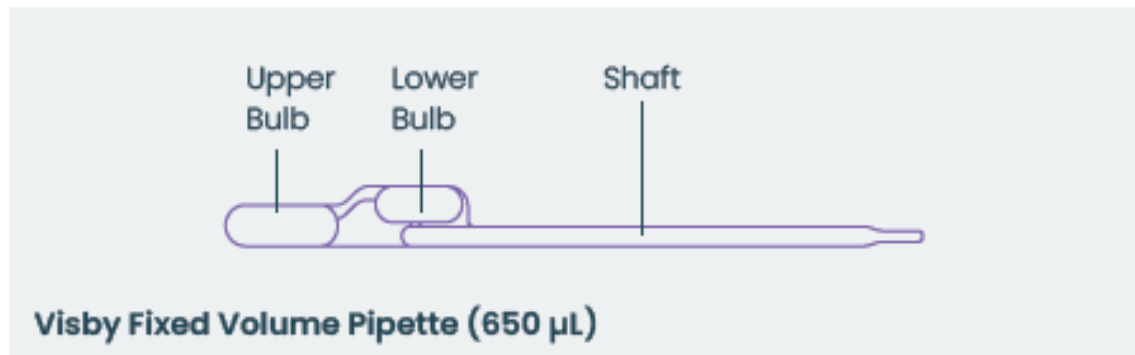
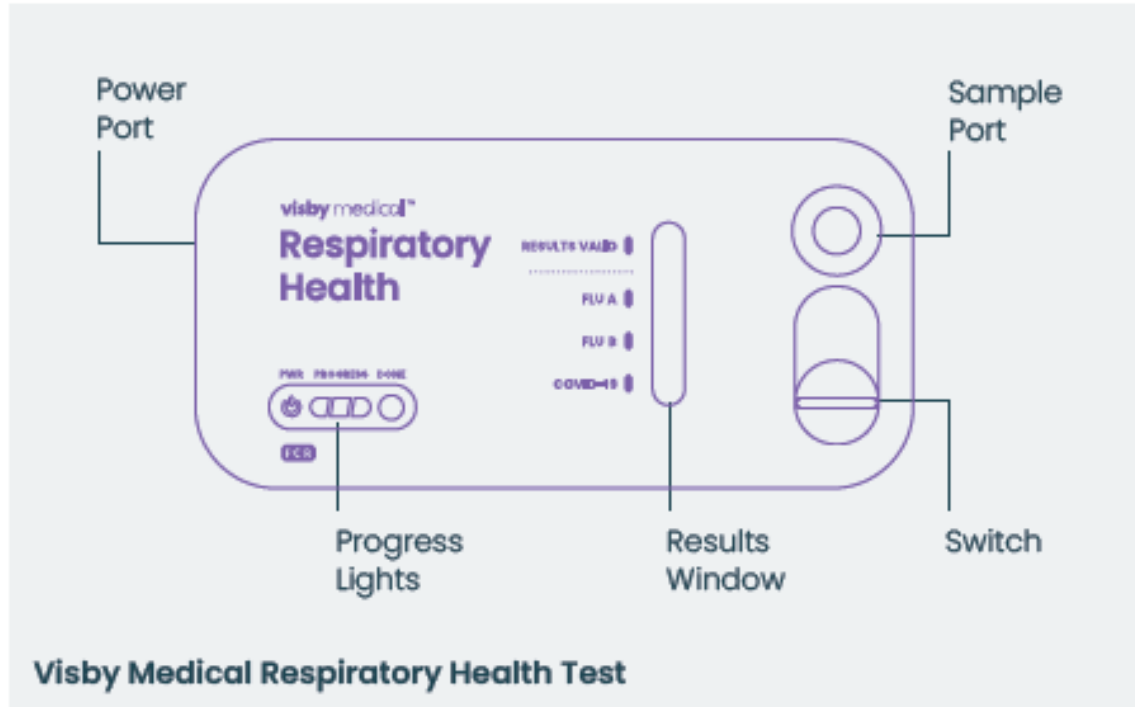
# The Visby Respiratory Health Test

1. No Call Backs
2. Informed Treatment
3. Reduce Patient Anxiety



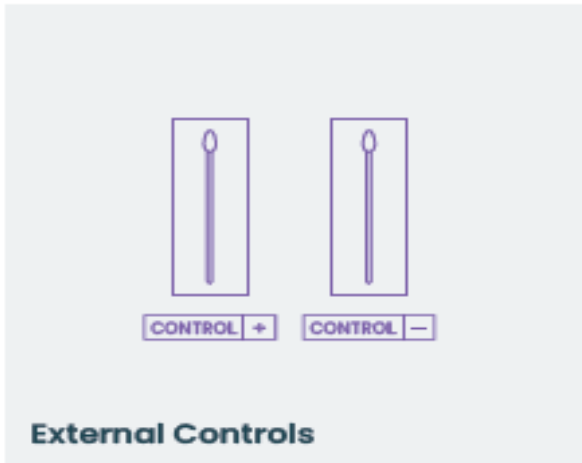
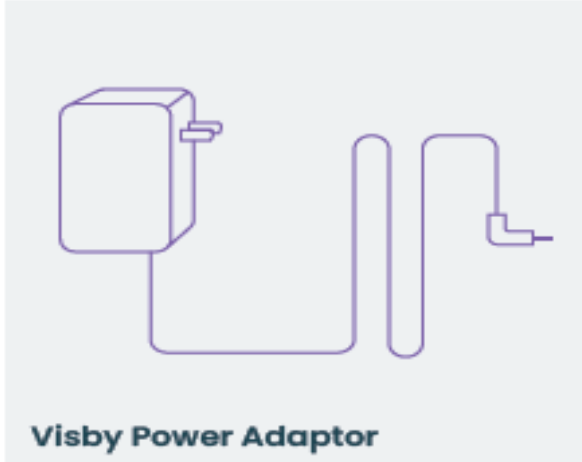


# Materials Provided and Required

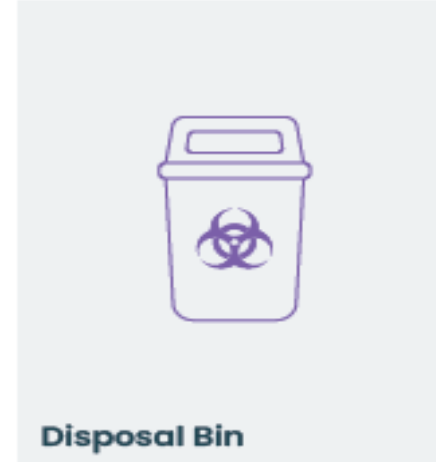
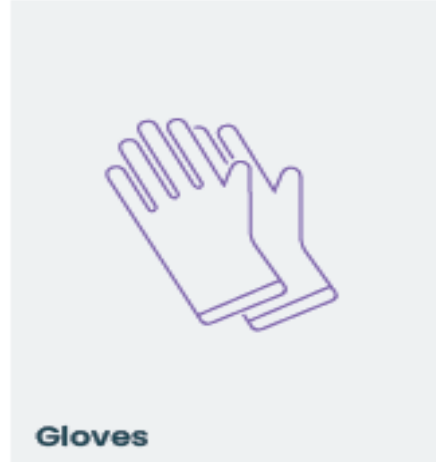


# Other Required Materials

## Available as Accessories



## Not Provided



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# Storage & Operating Conditions

# Sample Storage Conditions

Collected Sample in Visby Buffer



**2 hours at**  
**Room Temperature**

**59°F - 86°F**  
**(15°C - 30°C)**

or

**48 hours at**  
**Refrigerated Temperature**

**36°F - 46°F**  
**(2°C - 8°C)**

**DO NOT FREEZE**

To increase sample stability time: collect sample into the dry tube first, then transfer to Visby Buffer.



**Up to 1 hour at**  
**Room Temperature**  
**59°F - 86°F**  
**(15°C - 30°C)**

# Operating Conditions



TEMPERATURE  
**55°F - 88°F**  
(13°C - 31°C)



HUMIDITY  
**5% - 80%**

- Run on a clean, level surface
- Do not move the test once it is loaded or plugged in

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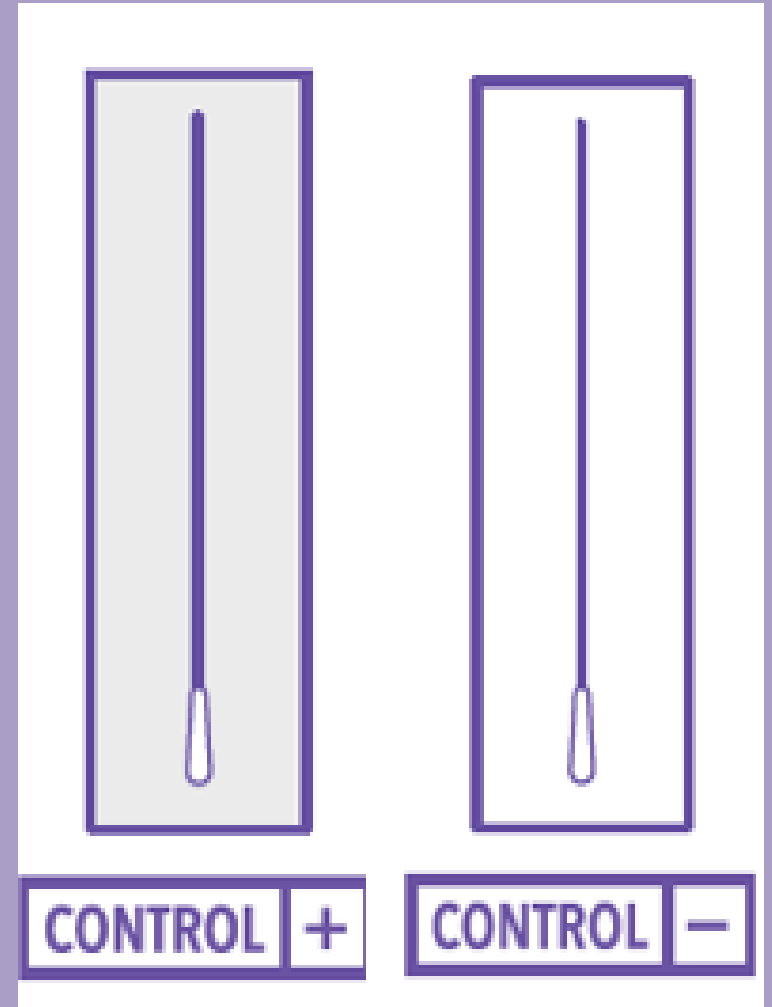
# External Control Testing

# Required External Control Testing

Test external controls with

- Each new shipment received
- Each untrained operator

Further controls may be tested in order to conform with local, state and/or federal regulations, accrediting groups, or your lab's standard Quality Control procedures.



Positive and Negative External Control Swabs (PS-400381)

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# How the Device Works



# Easy to Use



1

Plug in Device



2

Load Sample



3

Slide Port Closed

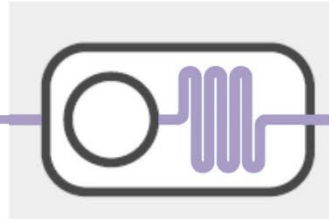
## Load Sample

Sample rehydrates  
lyophilized RT Reagents



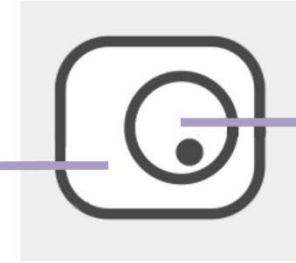
## Sample preparation

- Lysis of Flu A, Flu B, SARS-CoV-2
- Reverse Transcription: RNA converted to DNA



## Mixing chamber

Sample mixes with lyophilized  
PCR reagents



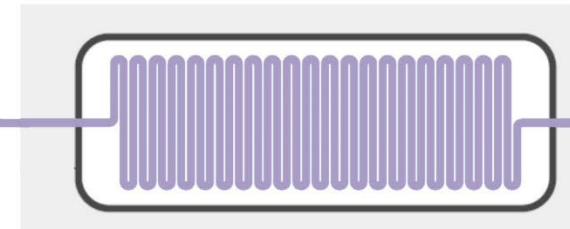
## Detection

- Amplicon binds to specific capture probes on the channel
- Enzyme/substrate reaction results in purple spot development



## PCR

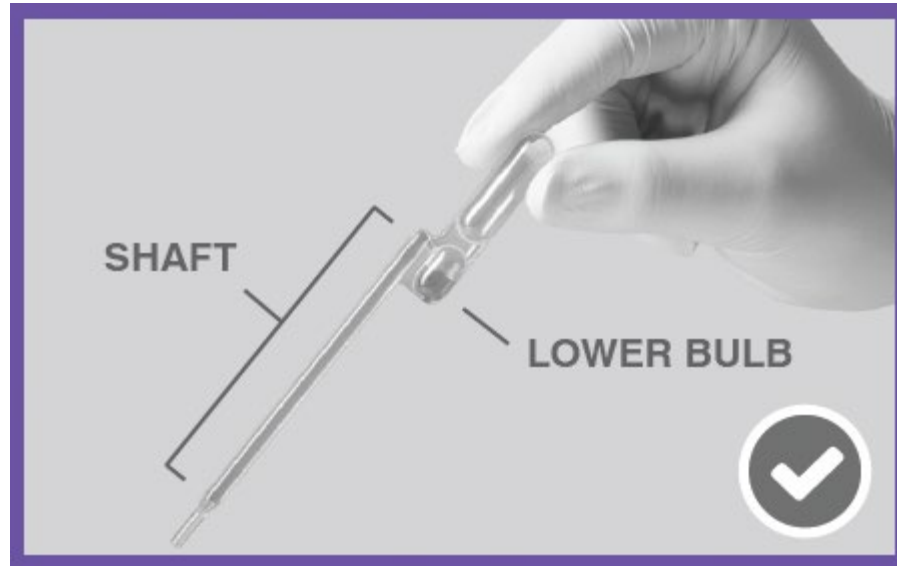
Sample goes through  
40 cycles of PCR



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# Using the Pipette

# Using the Pipette



- Avoid bubbles
- Pipette is full
- Fluid in the lower bulb

**Tip:** Pause and visually verify correct usage prior to loading the test

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# Testing with the Visby Device

# Setup: Prepare the Workspace

Operating Temperature:  
55°F (13°C) - 88°F (31°C)



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 Adapter** into the device power port. **Note:** If the power light blinks, refer to the Troubleshooting Section.



**Remove the sticker** over the sample part.

# Step 1: Add Patient Swab to Visby Respiratory Health Buffer Tube



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



**Take** the patient swab.



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 2: Mix and Add Patient Sample



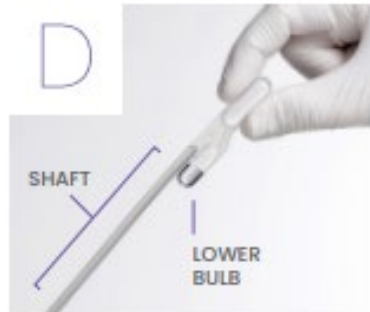
Mix the sample by **gently inverting** the tube **5 times**. **Note:** Failure to invert may lead to inaccurate results.



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.**



# 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.

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# Interpreting Results

# Variance in Spot Color

The color may range in different intensities and shades of blue, maroon or purple.



Clear, defined lines and rectangular shape is what constitutes a spot

Background Staining



Speckling and Bubbles



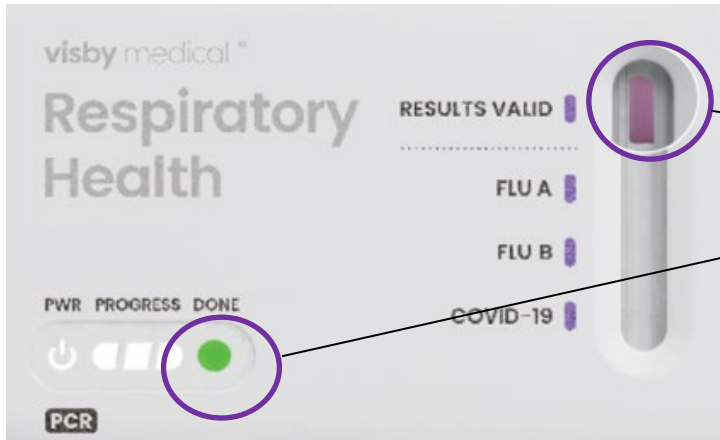
Spot Shadow



Background staining, Non-specific small flakes, bubbles, or extremely faint spots without distinct edges should NOT be considered a positive result.

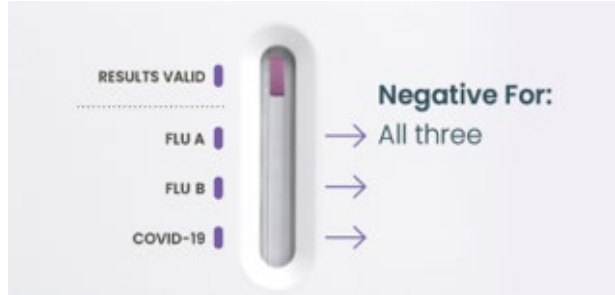
# Step 3: Interpret Results

## After 28 Minutes



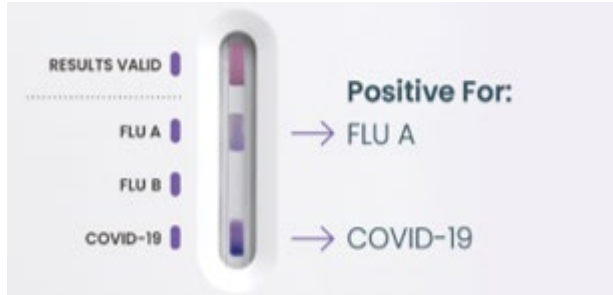
Green status light and Results Valid spot = **Valid Test**

### Negative Result



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

### Positive Result

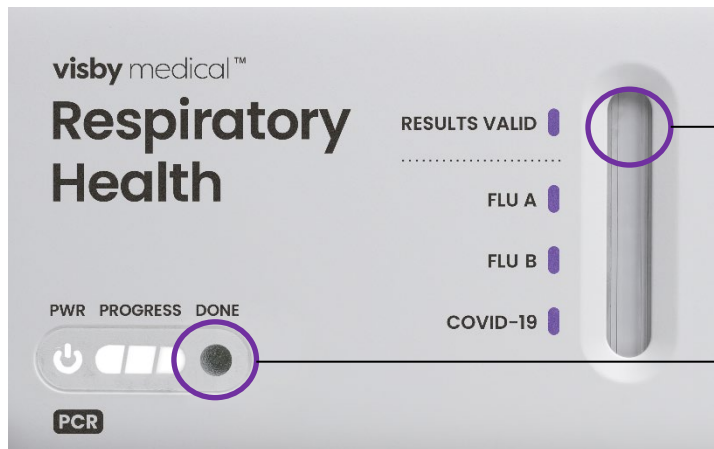


**Positive:** Any shade of purple with distinct edges next to the target is a positive result.

Interpret the results for **up to 2 hours**

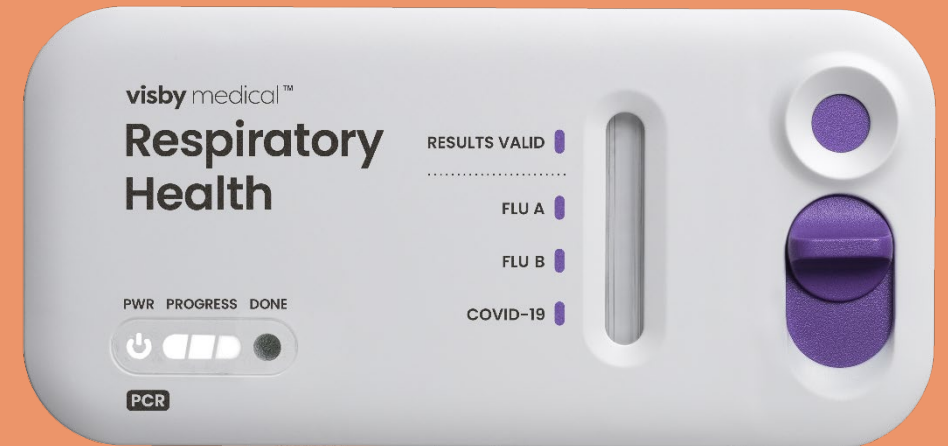
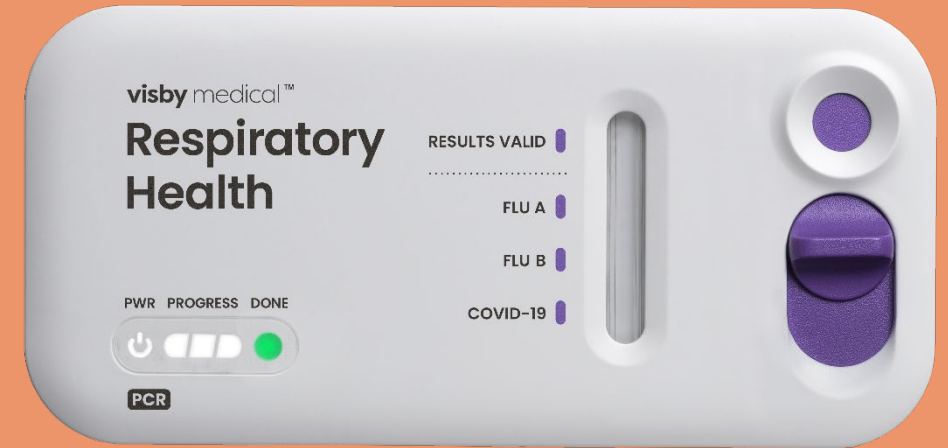
# Step 3: Interpret Results

## Invalid Results



No green "done" light  
OR no Results Valid  
spot = **Invalid Test**

Repeat the test.



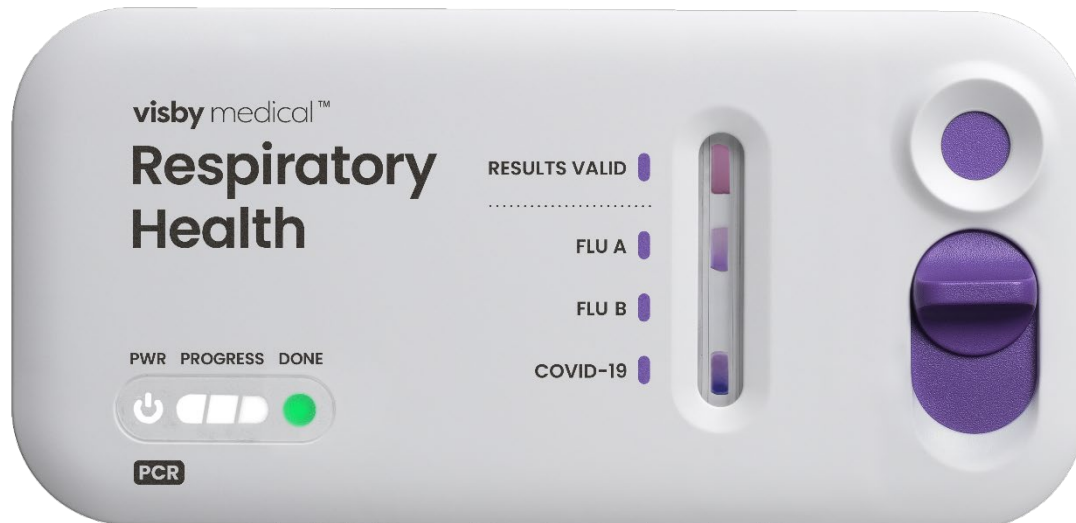
# Results Interpretation

1



- +
- Flu A
  - Flu B
  - Covid-19
  - Invalid

2



- +
- Flu A
  - Flu B
  - Covid-19
  - Invalid

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# Causes of Invalid Results

# Electronic Control

**If the power light is blinking:** Wait until the power light is stable before loading the sample

**Device operated outside of the temperature conditions**



**If the power light and progress lights are blinking together:** Retest with another device

**Interrupted power to the device**





# Common Causes of No Results Valid Spot

## 1) Improper Sample Handling

- Clinical samples can contain inhibitors that may generate invalid results
- Sample was collected in anything other than the Visby Buffer Collection Tube
  - i.e., Other collection kits, water, or other buffers
- Incorrect sample volume was loaded into the test

## 2) Improper Use of the Visby Test

- Improper storage of the Visby Test or Visby Collection Kits
- Use of expired Visby Devices or Visby Collection Kits

# Invalid Retesting

## Invalid Patient Sample:

Return to the patient sample and repeat using a new pipette and new Visby Medical Respiratory Health Test. Keep the invalid device in a provided biohazard bag in case Customer Support wants the device back for further investigation.

*If sample storage conditions are exceeded, obtain a new sample.*

### Troubleshooting Tracker

Device Name: \_\_\_\_\_

For help, contact Visby Medical Customer Support at 1-833-GoVisby (1-833-468-4729), fax: 408-608-2374 or email [support@visby.com](mailto:support@visby.com).

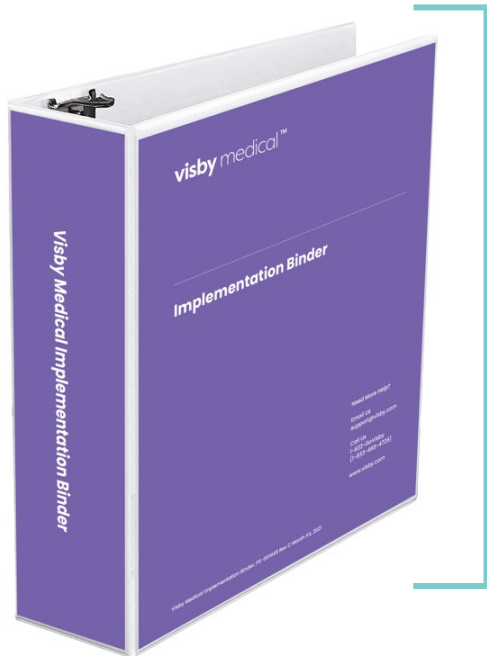
Date, Time	Operator	Device Lot	Invalid Type	Issue
			<input type="checkbox"/> No Results Valid <input type="checkbox"/> No Green Done Light <input type="checkbox"/> Other	
			<input type="checkbox"/> No Results Valid <input type="checkbox"/> No Green Done Light <input type="checkbox"/> Other	
			<input type="checkbox"/> No Results Valid <input type="checkbox"/> No Green Done Light <input type="checkbox"/> Other	
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# Resources

# Training Resources

## The Visby Implementation Binder



- Product Information
- Training Tips
- Results interpretation quiz
- Certificate of training
- Testing personnel training assessment
- Templates for documentation

## Access Training Resources

[www.visbymedical.com/visby-university](http://www.visbymedical.com/visby-university)

**Password:** Visby-POC

- Training presentation
- Implementation binder
- Virtual training quiz
- Demo video



# Questions?



Hours: Mon-Fri 8:00am – 4:00pm PST  
Call Us: 1-833-GoVisby  
(1-833-468-4729)  
Email Us: [support@visby.com](mailto:support@visby.com)

**Visby Medical**  
[training@visby.com](mailto:training@visby.com)

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# Appendix

# Clinical and Analytical Performance

Pathogen	PPA*	NPA*
Flu A	96.8 %	99.0%
Flu B	96.9%	100%
Covid-19	96.1%	98.2%

Virus	LoD Concentration
Influenza A/H1N1 2009, Brisbane/02/18	106 copies/swab
Influenza A/H3N2, Kansas/14/2017	125 copies/swab
Influenza B/Washington/02/19	728 copies/swab
Influenza B/Oklahoma/10/2018	778 copies/swab
SARS-CoV-2 (USA-WA1/2020)	100 copies/swab

\*Data is a combination of prospective fresh specimens (NP and AN), banked specimens (NP), and surrogate specimens (NP). For more information on the clinical and analytical performance of the Visby Respiratory Health Test, please refer to the Instructions for Use.

# Part Numbers

<b>10 Pack (1 Box)</b>	10 Devices 12 Pipettes 12 Visby Respiratory Health Buffer Tubes 12 Biohazard bags 1 Quick Reference Guide 1 Instructions for Use (available digitally)	PS-400380 (2 x 10 Packs)
<b>Required Accessories</b>	Visby Power Adapter	PS-000288
	External Control Swabs (1 kit= 2 Pos / 2 Neg)	PS-400381

