

visby medical™



Training: Visby Medical Respiratory Health Test

*This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories. This product has been authorized only for the detection and differentiation of nucleic acid from SARS-CoV-2, influenza A, and influenza B, not for any other viruses or pathogens; and the emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

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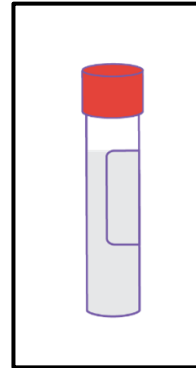
Product Overview

Materials Required for Testing

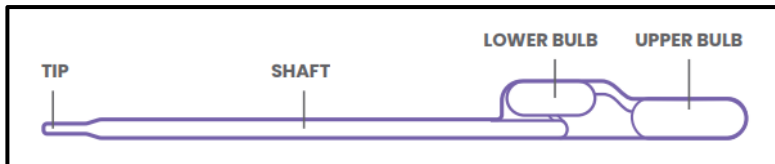
Materials Provided in Visby Medical Respiratory Health Test -20 devices per case



Visby Respiratory Health Buffer Tube



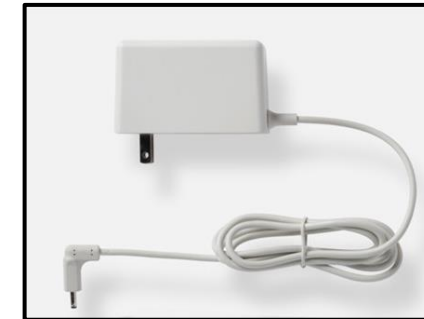
Biohazard Bags



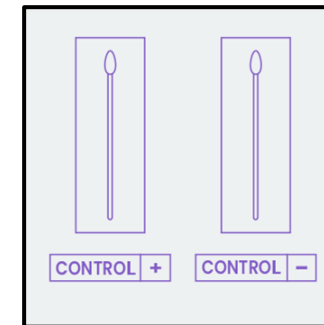
Visby Fixed Volume Pipette (650µL)

Materials Required and Available as Accessories

Visby Power Adapter



Visby External Control Swabs

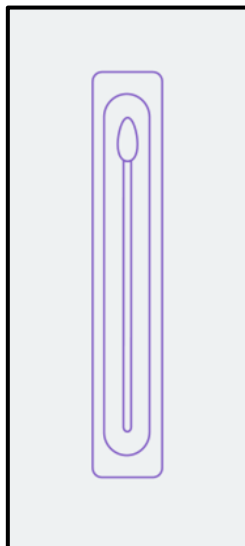


Materials Required and Not Provided

Gloves



Anterior Nasal or
Nasopharyngeal Swab*



Disposal Bin



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

External Control Testing

Required External Control Testing

Test external controls with

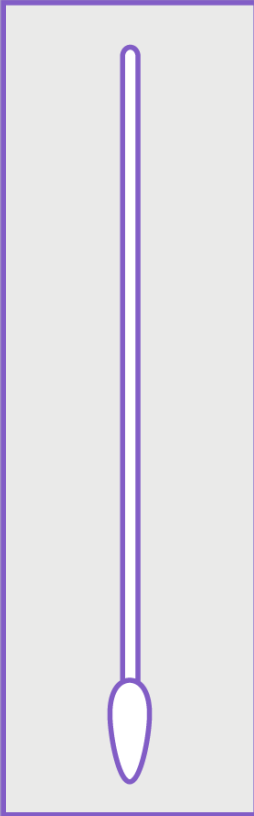
- Each new shipment received
- Each untrained operator

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.

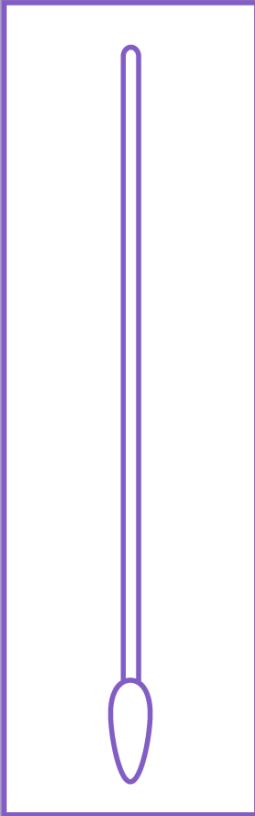
To run external control swabs, unwrap the swab, place it into the Visby Respiratory Health Buffer Tube, and gently tap the swab against the bottom of the tube 5 times. Discard the swab according to your institution's guidelines and screw the cap back onto the tube.



(Complete testing instructions available in the Visby Medical Respiratory Health Quick Reference Guide)



CONTROL +



CONTROL -

Positive and Negative External Control Swabs (PS-400381)

Sample Collection

Collect patient samples using nasopharyngeal or anterior nasal swabs. Please refer to Sample Collection Instructions and Instructions for Use for more information:







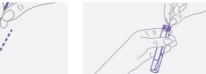


- [Anterior Nasal Specimen Collection Instructions](#)
- [Nasopharyngeal Specimen Collection Instructions](#)

Recommended Self-Collection Instructions in Health Care Settings
 DUAL NOSTRIL ANTERIOR NASAL SPECIMEN

IVD For in vitro diagnostic use
Rx Only For prescription use only For use under Emergency Use Authorization (EUA) only

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NOTE: Please swab **both nostrils** with the same swab.

<p>STEP 1 Prepare Materials</p>  <p>Wash your hands. Identify your dry tube and swab.</p>	<p>STEP 2 Unwrap the Swab</p>  <p>Hold the swab handle in your hand, by placing it between your thumb and your index finger. ⚠ Do not touch the soft tip of the swab with your finger or on any surfaces. If you do, start again with a new kit.</p>	<p>STEP 3 Insert the Swab</p>  <p>Place your index finger above the rim of your nostril and gently insert the soft tip of the swab into one nostril just until the soft tip is no longer visible (½ to ¾ inch or 1 to 1.5 cm). ⚠ If you experience pain, stop immediately.</p>	<p>STEP 4 Collect First Nostril</p>  <p>Rotate the swab slowly in your left nostril, making at least four sweeping circles around the inside wall of your nostril. This should take approximately 10-15 seconds per nostril. Withdraw the swab slowly. ⚠ Ensure the soft tip does not touch anything after removing it from the nostril.</p>	
<p>STEP 5 Collect Second Nostril</p>  <p>Use the same swab and repeat Steps 3 & 4 in your right nostril. ⚠ Keep the swab in your hand during Step 5 and make sure the soft tip does not touch anything after removing the swab from your nostril.</p>	<p>STEP 6 Open the Tube</p>  <p>Carefully unscrew the cap ensuring the soft tip of the swab doesn't touch anything. Set the cap down.</p>	<p>STEP 7 Insert the Swab</p>  <p>Hold the tube opening away from you and carefully insert the soft tip of the swab into the tube.</p>	<p>STEP 8 Store the Swab</p>  <p>Once the tip is near the bottom, break the swab handle at the swab breakpoint by bending back and forth. The swab should sit in the tube comfortably so that the cap can be screwed on. Discard the swab handle immediately.</p>	<p>STEP 9 Return Tube</p>  <p>Screw the cap back on tightly to prevent contamination. Wash your hands with soap and water.</p>

Recommended Health Care Provider Collection Instructions
 NASOPHARYNGEAL SPECIMEN

IVD For in vitro diagnostic use
Rx Only For prescription use only For use under Emergency Use Authorization (EUA) only

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<p>STEP 1 Wash your Hands</p>  <p>Wash your hands. Put on a new pair of gloves.</p>	<p>STEP 2 Unwrap the Swab</p>  <p>Hold the swab handle in your hand, by placing it between your thumb and your index finger. ⚠ Do not touch the soft tip of the swab with your finger or on any surfaces. If you do, start again with a new kit.</p>	<p>STEP 3 Insert the Swab</p>  <p>Tilt patient's head back 70 degrees. Gently and slowly insert a minitip swab with a flexible shaft through the nostril parallel to the palate until resistance is encountered. The distance is equivalent to that from the nostril to the ear of the patient, indicating contact with the nasopharynx.</p>	<p>STEP 4 Collect a Sample</p>  <p>Gently rub and roll the swab, leaving it in place for several seconds to absorb secretions. Slowly remove swab while rotating it.</p>
<p>STEP 5 Open the Tube</p>  <p>Carefully unscrew the cap ensuring the soft tip of the swab doesn't touch anything. Set the cap down.</p>	<p>STEP 6 Insert the Swab</p>  <p>Carefully place swab, tip first, into the tube provided.</p>	<p>STEP 7 Store the Swab</p>  <p>Once the tip is near the bottom, break the swab handle at the swab breakpoint by bending back and forth or cut it with sterile scissors. The swab should sit in the tube comfortably so that the cap can be screwed on. Discard the swab handle immediately.</p>	<p>STEP 8 Secure the Tube</p>  <p>Screw the cap back on tightly to prevent contamination.</p>

This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §2635, that meet the requirements to perform high, moderate, or waived complexity tests. The test is authorized for use at the level of Core (POC), Lab, in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation. The product has been authorized only for the detection and differentiation of nucleic acid from SARS-CoV-2, Influenza A, and Influenza B, not for any other viruses or pathogens. The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(5) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bb-5(b)(5), unless the declaration is terminated or authorization is revoked sooner.

IMPORTANT INFORMATION
 ⚠ Users should read the complete collection procedure before performing specimen collection. Do not over-insert the swab. www.visbymedical.com PS-400393 Rev C 03/23

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



In Dry Tube
Up to 1 hour at
Room Temperature

59°F - 86°F
(15°C - 30°C)

Testing and Interpreting Results

All testing instructions come from the Visby Medical Respiratory Health Quick Reference Guide

Easy to Use - The Three P's



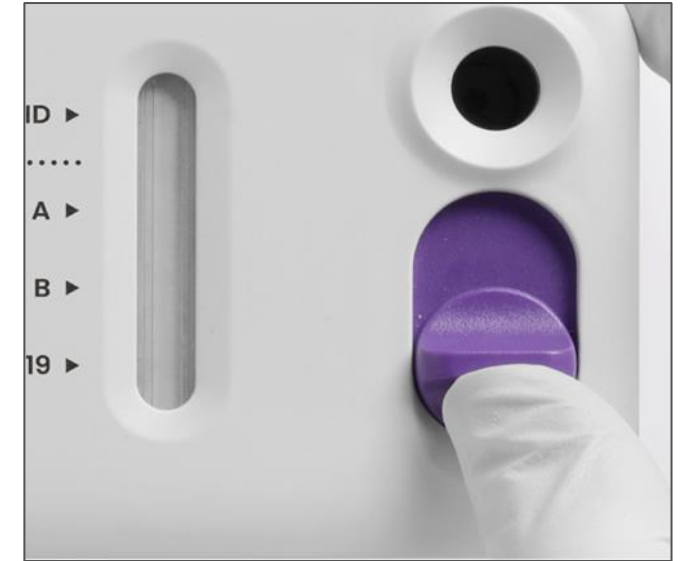
1

Plug in Device



2

Pipette Sample



3

Push Port Closed

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 1: Add Patient Swab to Visby Respiratory Health Buffer Tube



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

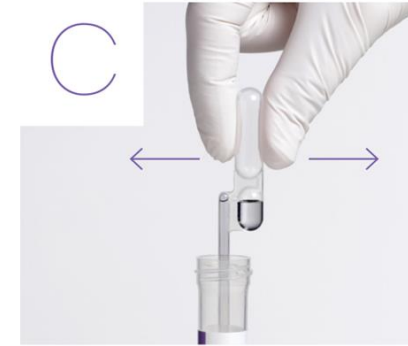
Step 2: Mix and Add Patient Sample



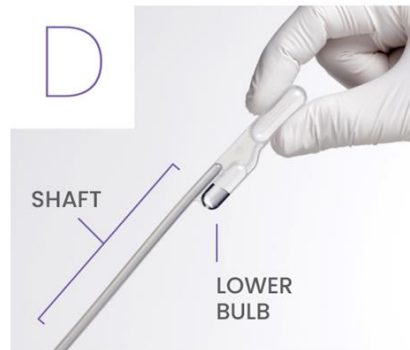
Mix the sample by **gently inverting** the tube **5 times**.
Note: Failure to invert may lead to inaccurate results.



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.

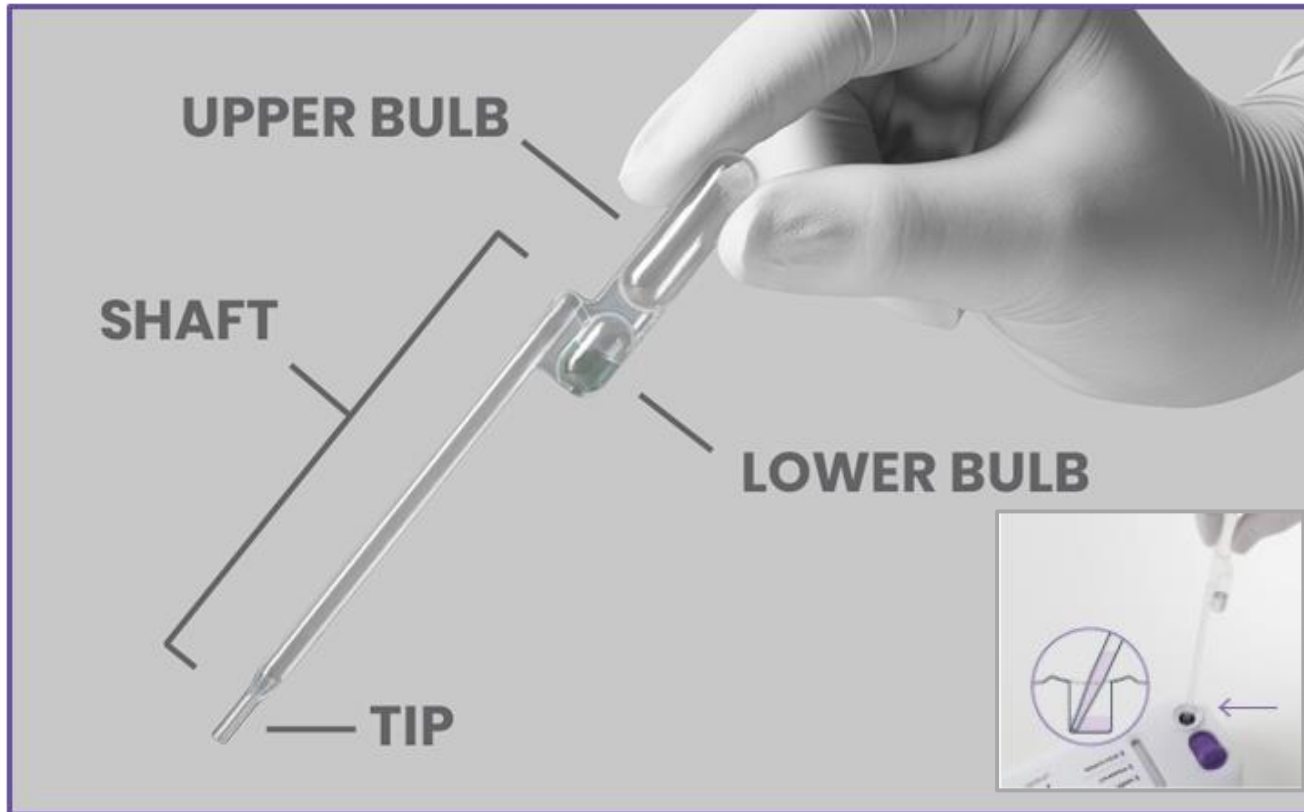


Place the tip at the **bottom** of the sample port and then squeeze the **upper bulb** of the pipette to release **all** of the sample.



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

Using the Pipette



- **Avoid bubbles**
Pause and visually verify the entire shaft of pipette is filled with liquid prior to loading the test
- **Fluid will remain in the lower bulb**
Once the sample is loaded into the pipette, do not invert the pipette. Doing so may create air bubbles in the shaft.

Step 3: Run the Test



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.

⚠ Do not move test while running. ⚠ Run the test immediately after adding patient sample.



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.



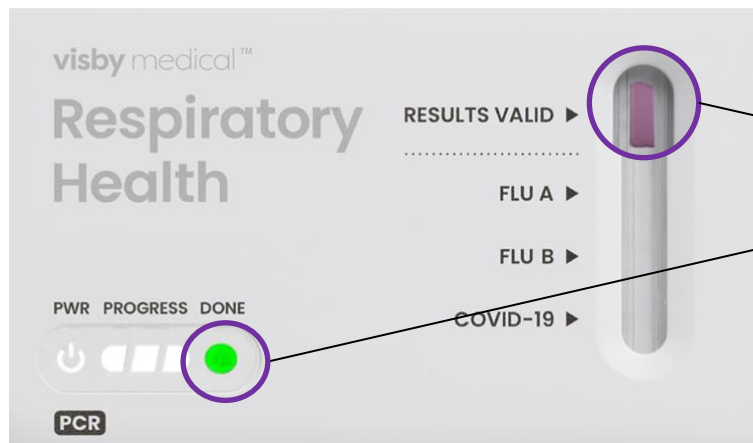
The second progress indicator light should become stable within **20 minutes**.



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

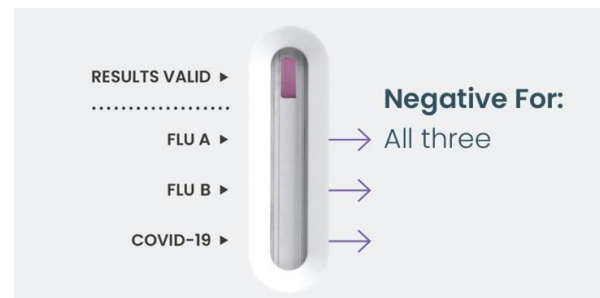
Step 4: Interpret Results

After 30 minutes, determine if test is valid. If the test is valid, read the test results:



Green light and
Results Valid spot =
Valid Test

Negative Result

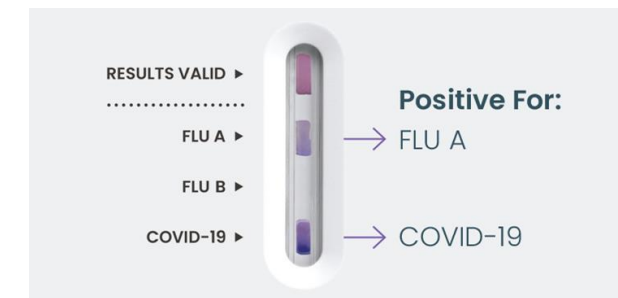


Negative For:

All three

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

Positive Result



Positive For:

FLU A

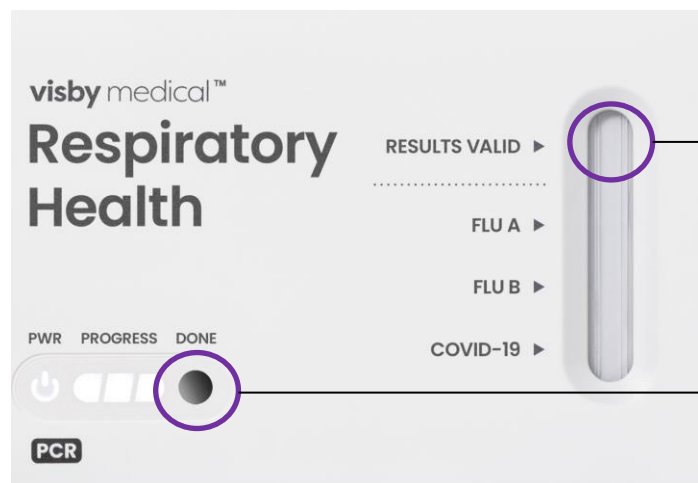
COVID-19

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

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

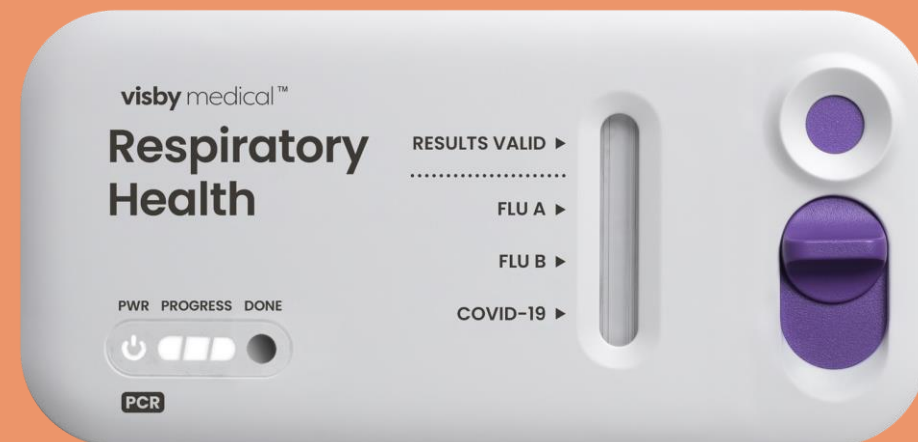
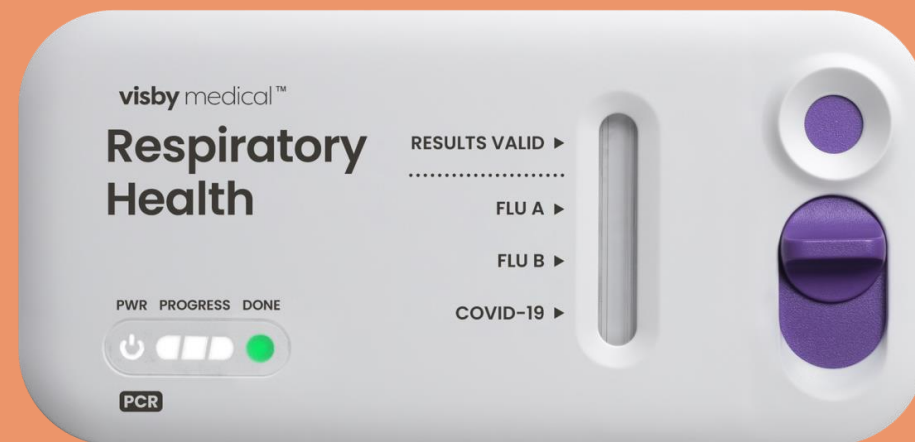
Interpret Results: Invalids

Invalid Results



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

Stop and Repeat the Test



Variance in Spot Color

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



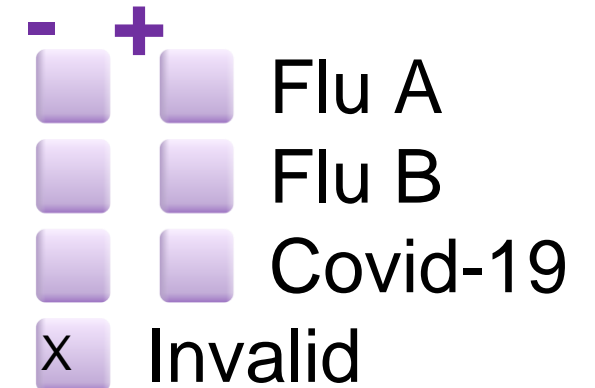
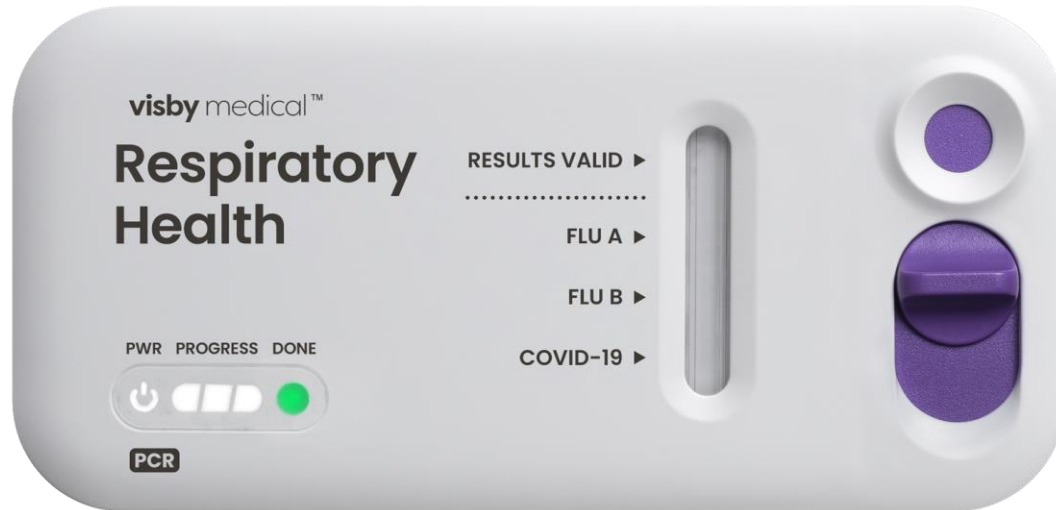
Clear, defined lines and rectangular shape is what constitutes a spot



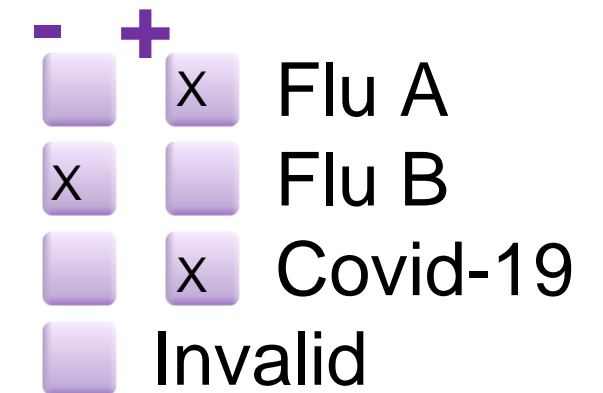
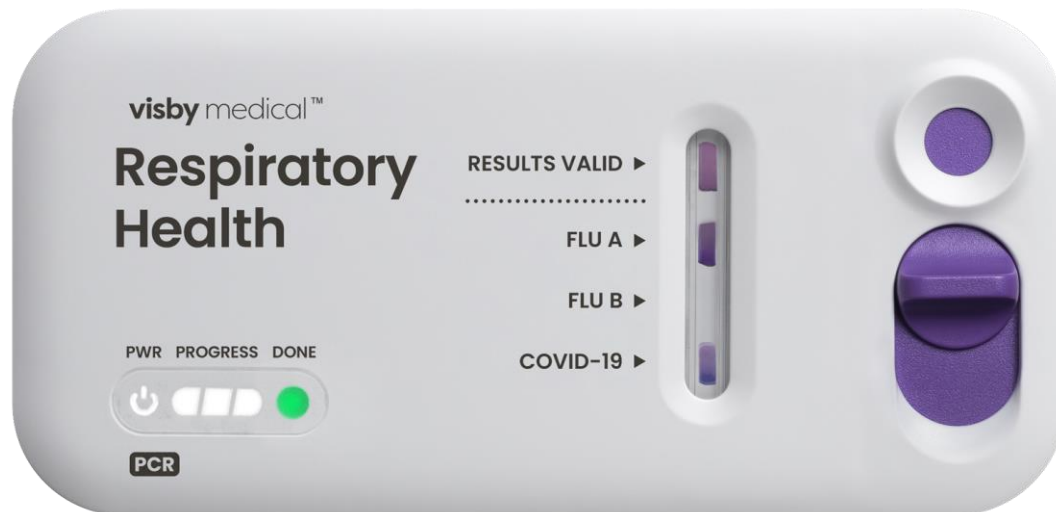
Background staining, Non-specific small flakes, bubbles, or extremely faint spots without distinct edges should NOT be considered a positive result.

Results Interpretation

1

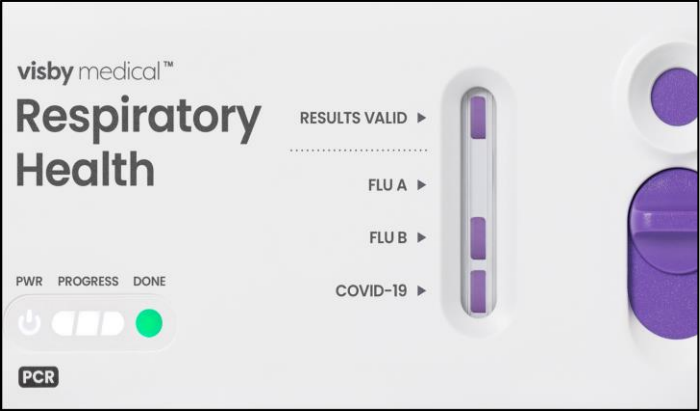


2

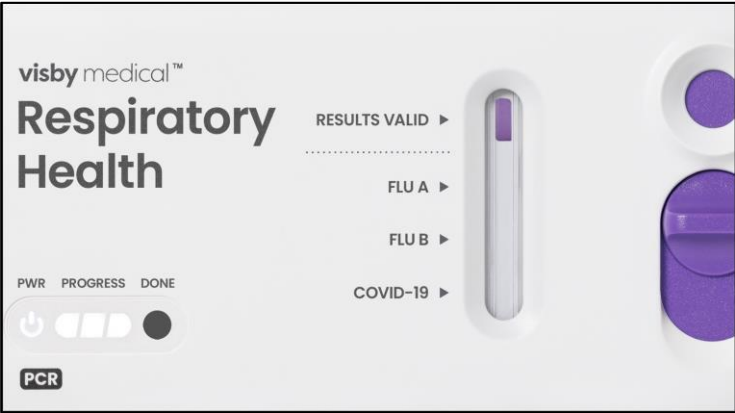


Results Interpretation

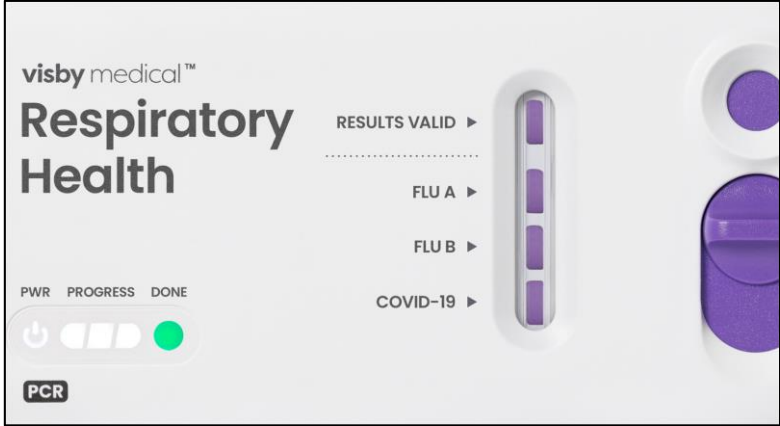
#1



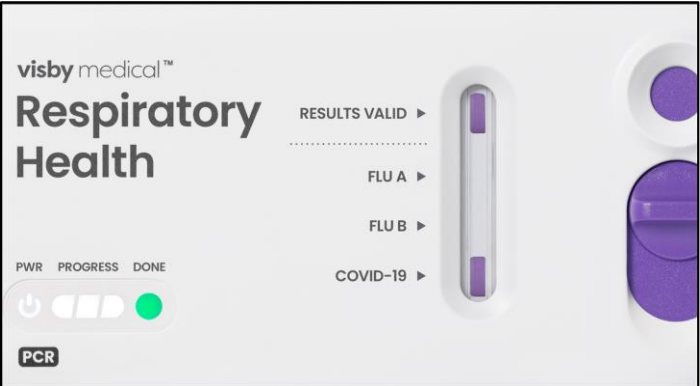
#2



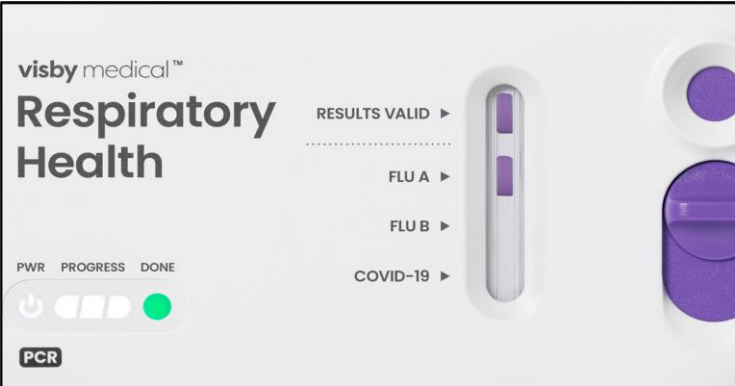
#3



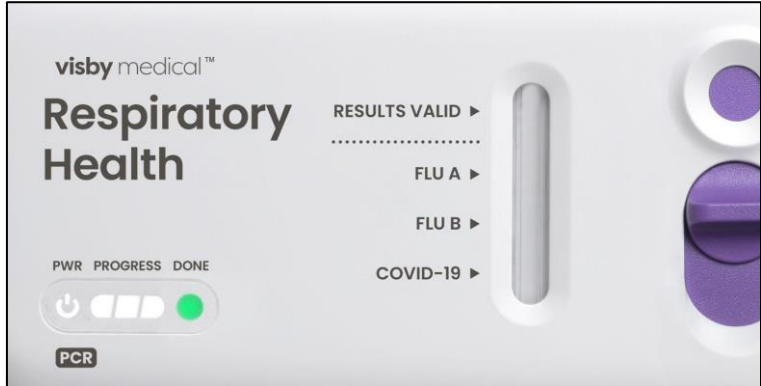
#4



#5





#6





Troubleshooting

Electronic Control

Status Light Behavior	Cause of error	User instructions
<p>None of the white lights illuminate</p> 	<p>The device is not receiving power or there was a power interruption during the run</p>	<ul style="list-style-type: none"> • 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.
<p>The white power light is blinking</p> 	<p>The device is being operated outside of its temperature range</p>	<p>The device can be allowed to reach operating temperature or moved to a more appropriate location prior to the start of the run</p>

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

Electronic Control Continued

<p>The white power light is on, but the progress lights do not turn on</p>  <p>The diagram shows a purple control panel with three indicators labeled 'PWR', 'PROGRESS', and 'DONE'. The 'PWR' indicator is a power button icon that is lit. The 'PROGRESS' indicator consists of three bars that are not lit. The 'DONE' indicator is a solid circle that is not lit.</p>	<p>The purple slider was not completely closed or did not activate the test</p>	<p>Confirm the slider is completely closed. If it is, the test will not progress, and the sample must be tested with a new device.</p>
<p>All of the white lights blink</p>  <p>The diagram shows the same purple control panel. The 'PWR', 'PROGRESS', and 'DONE' indicators are all shown with radiating lines around them, indicating they are blinking.</p>	<p>The device has experienced an error</p>	<p>The test will not complete, and the sample must be tested with a new device.</p>

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

Common Causes of No Results Valid Spot

1) Improper Sample Handling

- 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 (i.e., incorrect pipetting, using pipette other than Visby pipette)

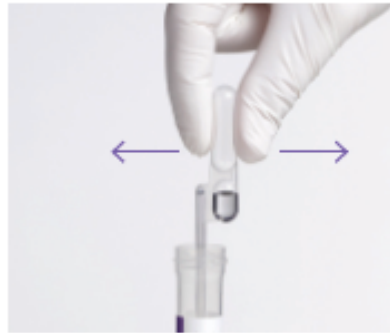
2) Improper Use of the Visby Test

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

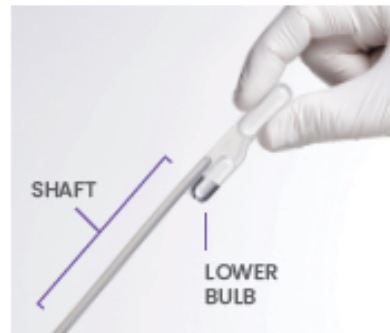
Using the Pipette



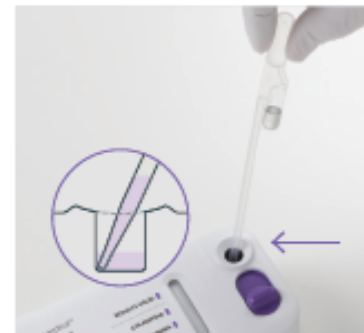
Squeeze the **upper bulb** of the provided pipette and submerge the tip to the **bottom** of the sample tube.



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



Check that there are **no air bubbles** in the shaft. **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.



Discard the pipette according to your institution's guidelines immediately. **Do not set down.**

Tips:

- **Pause and visually verify the entire shaft of pipette is filled with liquid prior to loading the test**
- **Once the sample is loaded into the pipette, do not invert the pipette. Doing so may create air bubbles in the shaft.**

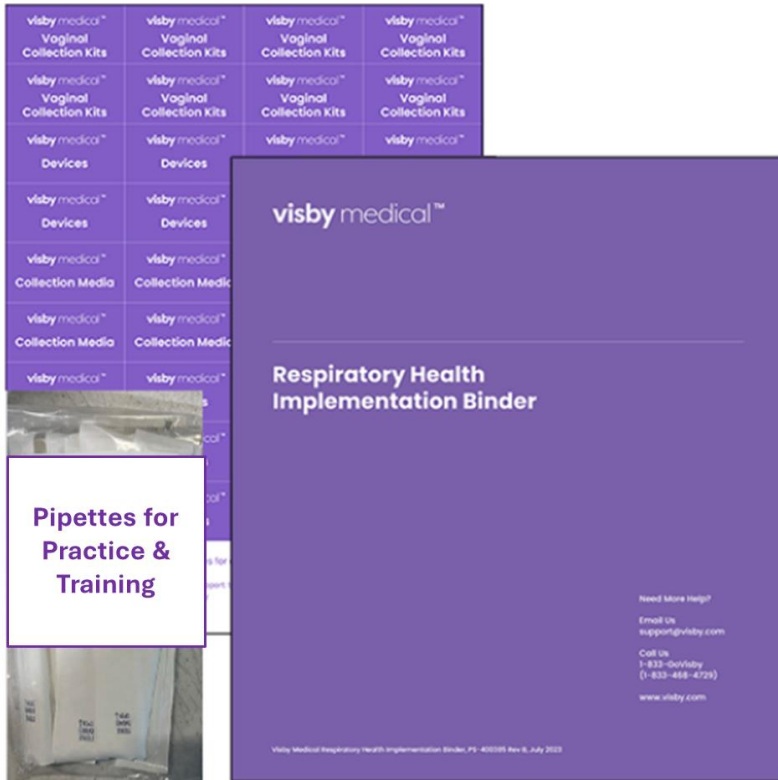
Scan to review video:
"Mastering the Pipette"



Resources

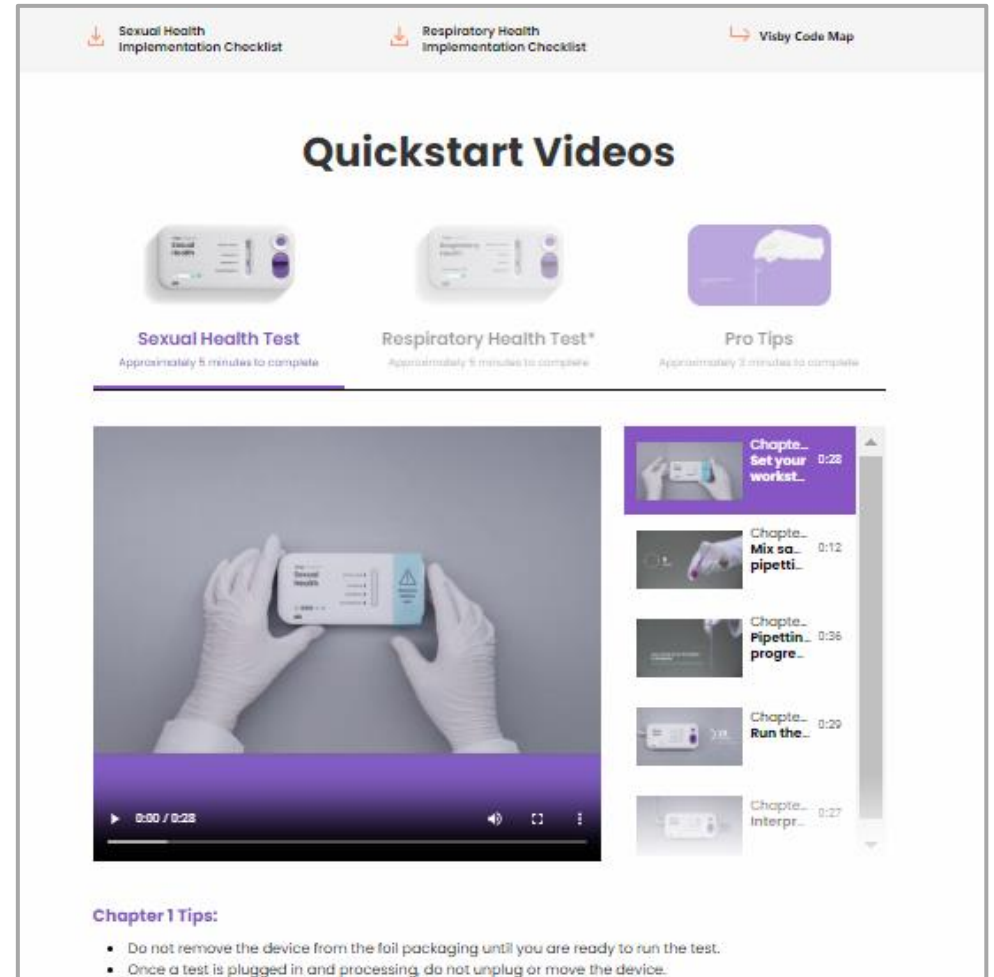
Training Resources

Complimentary Material:



- Respiratory Implementation Binder
- Lab Stickers (for organization)
- Pipettes (for training and practice)

Access to On-Demand Training Resources: visby.com/start



Are you ready for a surge?

Order additional power adapters to manage high testing volumes and improve workflow. Please contact Visby Customer Support to place an order: salesorders@visby.com



Visby Respiratory Health Test Information

Test Time	Approximately 30 minutes
Test Storage	Temperature: 36°F - 86°F (2°C - 30°C) Humidity: 5% - 80% DO NOT freeze
Operating Conditions	Temperature: 55°F - 88°F (13°C - 31°C) Humidity: 5% - 80%
Sample Type	Anterior swab (self or Health Care Provider collected) Nasopharyngeal swab, (HCP collected)
Patient Sample Storage	In dry tube up to 1 hour at room temperature 59°F–86°F (15°C–30°C) 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) Do not freeze

Visby Respiratory Health Test Information

Visby Respiratory Health Test 10 Pack (Visby Part Number PS-400380) *sold in cases. 1 case = 20 Test Devices	<ul style="list-style-type: none">• 10 Visby Medical Respiratory Health Devices• 12 Pipettes• 12 Visby Respiratory Health Buffer Tubes• 12 Disposal Bags• 1 Quick Reference Guide• Visby Medical Respiratory Health Test Instructions for Use (available digitally)
Materials Required and Available as Accessories	<ul style="list-style-type: none">• Visby Power Adapter (Visby Part Number PS-000288)
Materials Required but Not Supplied	<ul style="list-style-type: none">• Gloves• Disposal Bin• Swabs
External Controls (Visby Part Number PS-400381)	Respiratory Health Control Swab Kit: <ul style="list-style-type: none">• 2 Positive Swabs• 2 Negative Swabs
Need Help?	For Training: visby.training@visby.com For Orders: salesorders@visby.com For Customer Support: support@visby.com Call us: 1-833-468-4729 (1-833-GoVisby)

Appendix

Clinical and Analytical Performance

Pathogen	PPA	NPA
Flu A	97.9 %	99.3%
Flu B*	96.9% *	100% *
Covid-19	97.4%	98.8%

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.

Questions?



Customer Support

Email Us: support@visby.com

Call Us: 1-833-GoVisby
(1-833-468-4729)

Hours: Mon-Fri 8:00am – 4:00pm PST

Visby Medical

Training Support

Email Us: visby.training@visby.com

Visit Us: visby.com/start