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Respiratory Health Implementation Binder

Need More Help?

Email Us
support@visby.com

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

www.visby.com

Visby Medical Respiratory Health Implementation Binder, PS-400385 Rev B, July 2023

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Respiratory Health Implementation Binder

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Product

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	1 hour at room temperature: 59°F -86°F (15°C - 30°C)
Visby Respiratory Health Test 10 Pack	• 10 Visby Medical Respiratory Health Devices • 12 Pipettes • 12 Visby Respiratory Health Buffer Tubes • 12 Disposal Bags • 1 Quick Reference Guide
Materials Required and Available as Accessories	• Visby Power Adapter • External Controls
Materials Required but Not Supplied	• Gloves • Disposal Bin • Swabs
External Controls	Respiratory Health Control Swab Kit: • 2 Positive Swabs • 2 Negative Swabs
Need Help?	Email us: support@visby.com Call us: 1-833-468-4729 (1-833-GoVisby)

Reordering Materials From Visby Medical

Product Name	Quantity	Part Number
Visby Medical Respiratory Health Test	20	PS-400380
Power Adaptor	1	PS-000288
External Control (2 positive, 2 negative swabs)	1	PS-400381

1. To order more materials from Visby Medical, contact your sales representative or Visby customer support at support@visby.com or 1-833-GoVisby (1-833-468-4729).
2. Please have the part numbers and quantity ready when contacting Visby Medical.

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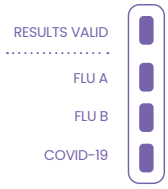
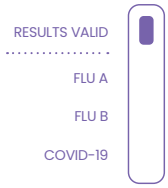
Visby Respiratory Health Test External Controls

Product Code	Units in Kit	Control Kit
Respiratory Health Positive Control Swab	2 Swabs	Valid Positive Control Run 
Respiratory Health Negative Control Swab	2 Swabs	Valid Negative Control Run 

Ordering External Controls

To purchase external controls please contact Visby Medical Customer Support at 1-833-468-4729 (1-833-GoVisby).

Testing External Controls

Test a set of external controls with each new shipment received and once for 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.

Procedure to Run External Controls

External controls should be run using the same procedure as patient samples.

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.

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5 tips for success

1. To avoid contamination, change gloves and absorbent pads after every test. Also, dispose of the pipette immediately after use. Do not place the pipette down on any surface after unwrapping.

2. Always invert the capped sample tube prior to loading the Visby Device.

3. Always operate the device between 55°F – 88°F (13°C – 31°C). If the test is stored outside of the operating conditions allow the test to come up to the operating conditions prior to use.

4. Use only the Visby provided pipette to transfer 1 pipette full of volume into the sample port. Avoid bubbles and air gaps in the pipette shaft.

5. Once the device has finished processing, the results can be read for up to 2 hours.

For help, contact Visby Medical Customer Support at **1-833-GoVisby** (1-833-468-4729) or email **support@visby.com**.

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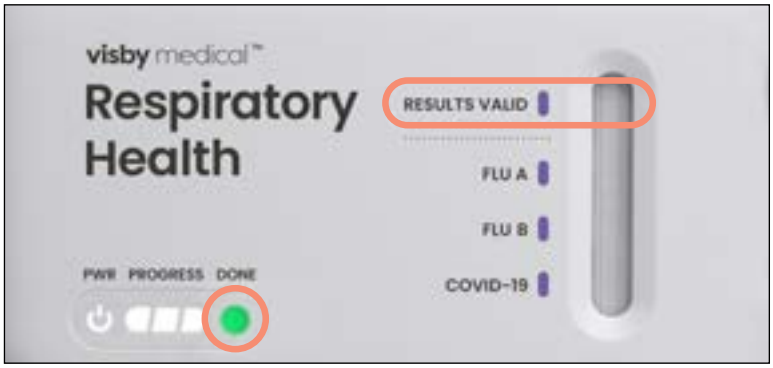
Troubleshooting Invalid Results



Operating Conditions

- Ensure the device is operated between 55°F - 88°F (13°C - 31°C).
- If the device is stored outside of the operating conditions, ensure the device has been given enough time to reach the operating conditions prior to testing
- Ensure you are not testing near a radiator or air conditioning vent which can create a pocket of cold or warm air outside of the operating conditions

Power Supply

- Ensure the device has a constant power supply while the test is processing

No "Results Valid" Spot

Improper Sample Handling

- Only collect samples into the Respiratory Health Buffer Tube provided by Visby
- Ensure the sample has been stored correctly:
  - In Visby Buffer: Up to 48 hours at refrigerated temperature 36°F - 46°F (2°C - 8°C)
  - In Visby Buffer: 2 hours at room temperature 59°F - 86°F (15°C – 30°C)
  - In Dry Tube: Up to 1 hour at room temperature 59°F - 86°F (15°C - 30°C)
- Always invert the capped sample tube prior to loading into the Visby device
- Only load 1 full pipette of sample volume into the Visby device
  - Ensure the pipette shaft is full of liquid, does not have any bubbles or air gaps in the shaft, and some overflow fluid has entered the lower bulb
  - Pause and visually verify correct usage before loading the test
  - Do not add extra sample to the test

Improper Device Usage

- Ensure all materials are within their expiration date
- Only open the foil packaging of the Visby Test when the sample is ready to be loaded
- Ensure the sample port is fully closed once the sample is loaded

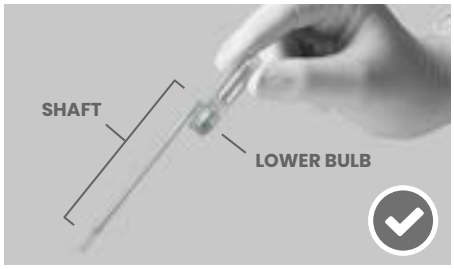
Using the Pipette

1 Each pipette is single use. Unwrap the pipette from the top. Only touch the upper bulb of the pipette and never set the open pipette down on your work surface or touch the tip. Immediately dispose of the pipette after use.

---

2 To Use the pipette:

- **a.** Squeeze the upper bulb
- **b.** Submerge the pipette tip to the bottom of the sample tube
- **c.** Release the upper bulb
- **d.** Pause to verify that the pipette is:
  - Full of liquid
  - Free of bubbles or air gaps
  - Overflow fluid has entered the lower bulb
- **e.** Dispense the sample into the sample port of the Visby Test by squeezing the upper bulb. Bubbles the sample port of the test are okay. Some overflow fluid will remain in the lower bulb



Tip: If the pipette has bubbles or an air gap, dispense the sample back into the sample tube and try aspirating again by slowly releasing the upper bulb.

---

3 When dispensing, some overflow fluid will remain in the lower bulb. Add only 1 pipette full of sample into the Visby Test. Do not add more or less volume.

---

4 Only use the Visby provided pipettes to load the Visby Device. Additional pipettes are provided if needed.

Contamination Prevention

Background:

The Visby device is a single-use (disposable), fully integrated, rapid, automated in vitro diagnostic test that utilizes PCR technology to amplify and detect nucleic acid targets.

A Polymerase Chain Reaction (PCR) is the process of making millions of copies of a specific DNA segment of interest. If the starting genetic material is RNA, the RNA is first converted to DNA in a process called reverse transcription. PCR utilizes reagents and temperature cycling to duplicate each copy of DNA per cycle. At the end of 35 to 40 cycles the reaction has made almost half a billion copies. The amplified DNA segment of interest is called amplicon.

PCR is an invaluable diagnostic tool because it amplifies genetic targets from organisms making them easier to find at very low levels. When paired with detection methods, PCR helps determine the presence or absence of the organism of interest in a patient sample. Since PCR is a highly sensitive diagnostic tool, the reaction is susceptible to contamination.

Contamination occurs when a pathogen or amplicon is introduced by the user to a sample or test accidentally. The introduction of contaminants can result in a false positive. Unlike pathogen contamination, amplicon are harmless, very small, and very difficult to clean. It is best practice to avoid all potential causes of contamination by following good lab practices and the following guidelines:

Tips for Avoiding Contamination

- Implement daily decontamination of each workstation
- Change gloves between testing each patient sample
- Once a pipette is opened, it should never be placed down on the work surface
- Never touch the tip or the shaft of the pipette
- All single use materials such as the Visby Device and pipettes should be disposed of immediately after use
- Once a device has finished processing and the results have been recorded, always place the used device in the provided disposal bag and dispose of per your institution's standard practices
- Never disassemble the Visby device

If a Spill or Drip Occurs:

1. Drop a disposable towel to trap and soak up the spill.
2. Saturate a new disposable towel with the 1:10 bleach solution or alternative equivalent (bleach wipes or bleach spray) and wipe the surface of the workstation until it is visibly wet with bleach.
3. Let the bleach rest at least 10 minutes on the work surface.
4. Saturate a new disposable paper towel with 70% ethanol or sanitizing wipes to wipe the bleach residue off the work surface.
5. Dispose of affected single use materials according to your Institution’s standard practices.

Note: If a spill occurs on the Visby Power Adapter, unplug the unit and wipe it down vigorously with 70% ethanol. Allow the power adapter to completely dry before use.

If a Suspected False Positive Occurs:

1. Test a Negative external control on the Visby device.
2. If the result is positive, thoroughly decontaminate the workstation and common touch points including cabinet handles, door handles, and pens. Decontamination instructions are listed in the following pages.
3. Once decontamination is complete, test a negative external control again on the Visby Device. If the result is positive contact Visby Medical Customer Support.

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Decontamination Procedure

What is Bleach?

Bleach is the common name for sodium hypochlorite. Most over the counter bleach contains about 6% sodium hypochlorite. Bleach is used to not only disinfect your workstation but to degrade amplicon and protect your site from contamination.

Directions for Decontaminating Your Workstation

1 Gather your bleach and ethanol

- **a.** Create a 1:10 bleach solution by diluting standard bleach (6% sodium hypochlorite) 1:10 with water. Add 1/4 cup bleach per gallon of water.

  Note: Diluted bleach is stable for 24 hours.

- **b.** If your institution prefers to use an option that does not require diluting bleach daily, please follow these guidelines.

Do	Ensure the product contains sodium hypochlorite (bleach). *Look for the Active Ingredients on the label.
Don't	Don't use any products that contain substitutes for bleach (Alcohol or Dimethyl Benzyl Ammonium Chloride).

- **c.** Obtain 70% ethanol.

---

2 Saturate a disposable towel with the 1:10 bleach solution or alternative equivalent (bleach wipes or bleach spray). Wipe the surface of the workstation until it is visibly wet with bleach.

Tip: Ensure that any touch points such as pens and door handles are bleached.

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3 Let the bleach rest at least 10 minutes on the work surface.

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4 Saturate a new disposable paper towel with 70% ethanol and wipe the bleach residue off the work surface.

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5 Fill out applicable decontamination logs. Visby recommends daily decontamination of workstations.

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Training Materials

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Training Checklist

Institution: _____ **Device Name:** _____

Name: _____ **Date:** _____

Visby Test Overview	**Initials**
User has found, identified, and reviewed: **a.** Visby Instructions for Use and Quick Reference Guide **b.** Visby Test storage conditions **c.** Visby Test operating conditions **d.** Visby power adapter **e.** Visby Test lot number and expiration date **f.** Proper external control testing requirements	
Sample Collection Overview	
User has found and identified: **a.** Sample collection materials (swab and collection tube) **b.** Patient sample storage conditions and stability **c.** User demonstrated an understanding of the collection instructions	
Patient Sample Testing	
a. User demonstrated proper glove changing protocol between handling each sample **b.** User understood the importance of inverting the specimen prior to testing **c.** User demonstrated correct pipette usage and acknowledged potential common user errors **d.** User demonstrated correct plugging in of the Visby Device **e.** User understood how to reduce potential contamination	
Results Interpretation	
a. User identified the internal controls (results valid spot) and confirmed result validity **b.** User demonstrated proper result interpretation **c.** User understood to retest the patient sample if an invalid result occurs	

User Signature: _____ **Date:** _____

Trainer Signature: _____ **Date:** _____

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Training Quiz

Name: _____ **Device Name** _____

Date: _____ **Score:** _____

Read each question carefully. Write T (true) or F (false) on the line next to the question.

---

1 Patient samples should only be collected into the Visby Respiratory Health Buffer. _____

2 There are two additional pipettes in each 10 pack of Visby tests. _____

3 Operators should always change gloves between handling patient specimen. _____

4 The Visby Test should be operated between 55°F - 88°F (13°C - 31°C). _____

5 To properly decontaminate the workspace, saturate a disposable towel with 10% bleach and wipe the surface of the workspace until it is visibly wet with the bleach solution. Let the bleach solution rest at least ten minutes on the work surface. Saturate a new disposable towel with 70% ethanol to clean the bleach residue off of the works surface. _____

6 Bubbles and air gaps are acceptable in the pipette when transferring the sample. _____

7 A patient sample can be stored for up to 48 hours at refrigerated temperature 36°F - 46°F (2°C - 8°C) or 2 hours at room temperature 59°F - 86°F (15°C - 30°C) _____

8 Once the Visby Device is finished processing, results can be read for up to two hours. _____

9 A set of external controls should be tested in accordance with local, state, and federal accrediting organizations as applicable. _____

Training Quiz: Answers

1. **True**. The Visby Medical Sexual Health Test requires vaginal samples to be collected in the Visby vaginal specimen collection kit which includes a swab and collection media.

2. **True**. Each 10 pack of Visby tests has two additional pipettes to account for testing external controls.

3. **True**. To avoid the risk of contamination, always change gloves between handling different patient samples.

4. **True**. The Visby Test should be operated between 55°F - 88°F (13°C - 31°C). Operating instructions can be found in the Quick Reference Guide and the Instructions for Use.

5. **True**. Letting bleach rest on your work surface for at least ten minutes will effectively decontaminate your station. Make sure to use products with sodium hypochlorite as an active ingredient because bleach substitutes will not fully protect your site from contamination. Wiping down the surface with 70% ethanol will clean any bleach residue off of the surface.

6. **False**. Bubbles and air gaps should always be avoided in the shaft of the pipette when transferring the sample. This causes the incorrect volume to be transferred and may result in an invalid error.

7. **True**. A patient sample can be stored for up to 48 hours at refrigerated temperature 36°F - 46°F (2°C - 8°C) or 2 hours at room temperature 59°F - 86°F (15°C – 30°C).

8. **True**. If the Visby Device stays plugged in, the green done status light will stay illuminated for 2 hours signaling that the results can still be interpreted.

9. **True**. A set of external controls should be tested in accordance with local, state, and federal accrediting organizations as applicable. The Visby Medical Respiratory Health Test also requires external controls to be tested with each new shipment and once per each untrained operator.

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Visby Medical Respiratory Health Test Results Interpretation Quiz

1 Invalid ____

	Neg	Pos
Flu A	____	____
Flu B	____	____
COVID-19	____	____

2 Invalid ____

	Neg	Pos
Flu A	____	____
Flu B	____	____
COVID-19	____	____

3 Invalid ____

	Neg	Pos
Flu A	____	____
Flu B	____	____
COVID-19	____	____

4 Invalid ____

	Neg	Pos
Flu A	____	____
Flu B	____	____
COVID-19	____	____

5 Invalid ____

	Neg	Pos
Flu A	____	____
Flu B	____	____
COVID-19	____	____

6 Invalid ____

	Neg	Pos
Flu A	____	____
Flu B	____	____
COVID-19	____	____

7 Invalid ____

	Neg	Pos
Flu A	____	____
Flu B	____	____
COVID-19	____	____

8 Invalid ____

	Neg	Pos
Flu A	____	____
Flu B	____	____
COVID-19	____	____

9 Invalid ____

	Neg	Pos
Flu A	____	____
Flu B	____	____
COVID-19	____	____

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Visby Medical Respiratory Health Test Results Interpretation Quiz: Answers

1. Positive for All

2. Flu A Neg
   Flu B Pos
   COVID-19 Pos

3. Flu A Pos
   Flu B Neg
   COVID-19 Neg

4. Flu A Neg
   Flu B Neg
   COVID-19 Pos

5. Flu A Pos
   Flu B Neg
   COVID-19 Pos

6. Invalid

7. Flu A Neg
   Flu B Pos
   COVID-19 Neg

8. Invalid

9. Flu A Pos
   Flu B Pos
   COVID-19 Neg

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Certificate of Training

Institution: _____

Device Name: _____

This is to verify that personnel responsible for running the Visby Test have been thoroughly trained on the Test and the Test procedure. This has included:

- **Review of the instructions for use**
- **Successful operation of the Visby Test**
- **Successful interpretation of the Visby Test results**

Names of the personnel who have been trained with the Visby Test and are responsible for reporting patient results:

Print Name	Signature	Date

Signature of Laboratory Director(s) responsible for personnel and testing:

_____ _____

Signature **Date**

_____ _____

Signature **Date**

_____ _____

Trainer **Date**

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Testing Personnel Training Assessment

Device Name: _____

Procedure	Satisfactory	Unsatisfactory	Not Applicable	Comments/Corrective Actions
External Control Sample Preparation				
Specimen Handling/ Processing				
Operation of the Visby Test				
Interpretation of Results				
Applicable Documentation				

Review of Records	Satisfactory	Unsatisfactory	Not Applicable	Comments/Corrective Actions
Patient/Quality Control Log Sheet Records				
Proficiency Testing Records				
Assessment of Problem Solving Skills				
(Attach all supporting documents)				

Additional Observations: _____

_____

_____

Evaluator: _____ **Date:** _____

Operator: _____

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Documentation

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Visby Test External Quality Control

Device Name: _____

For the Visby Respiratory Health Test, test external controls once with each new shipment received and once for 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 procedure.

Date	Operator's Initials	Test Lot #	Control Type (circle)	Control Lot/Exp	Results	Comments/Reason for testing
			Pos Neg			
			Pos Neg			
			Pos Neg			
			Pos Neg			
			Pos Neg			
			Pos Neg			
			Pos Neg			
			Pos Neg			
			Pos Neg			
			Pos Neg			
			Pos Neg			
			Pos Neg			
			Pos Neg			

Reviewed by: _____ **Date:** _____

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Workspace Decontamination Log

Visby recommends daily decontamination of workspaces and immediate decontamination when a spill occurs or a suspected contamination event occurs.

To properly decontaminate the workspace, saturate a disposable paper towel with 1:10 diluted bleach (or equivalent) and wipe the surface of the workspace until it is visibly wet with the bleach solution. Let the bleach solution rest at least ten minutes on the work surface. Saturate a new paper towel with 70% ethanol to clean the bleach residue off of the work surface.

Workspace:					
Date	**Initials**	**Comments**	**Date**	**Initials**	**Comments**

Reviewed by: _____ **Date:** _____

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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**.

Date, Time	Operator	Device Lot	Invalid Type	Issue
			☐ No Results Valid ☐ No Green Done Light ☐ Other	
			☐ No Results Valid ☐ No Green Done Light ☐ Other	
			☐ No Results Valid ☐ No Green Done Light ☐ Other	
			☐ No Results Valid ☐ No Green Done Light ☐ Other	
			☐ No Results Valid ☐ No Green Done Light ☐ Other	
			☐ No Results Valid ☐ No Green Done Light ☐ Other	
			☐ No Results Valid ☐ No Green Done Light ☐ Other	
			☐ No Results Valid ☐ No Green Done Light ☐ Other	
			☐ No Results Valid ☐ No Green Done Light ☐ Other	
			☐ No Results Valid ☐ No Green Done Light ☐ Other	

Quality Assessment Review Form and Checklist

These forms are used for periodical review of the patient testing process. These should be filed with the quality assessment records.

Device Name: _____

Quality Assessment Activity	Comments	Date	Initials
Patient Test Management: Evaluate criteria for specimen submission, handling, and rejection; test results requisitions and reporting, accuracy and reliability of reports.			
Quality Control: Assess control data, errors in reporting results, and corrective actions taken with appropriate documentation records.			
Proficiency Testing: Review the effectiveness of corrective actions taken for unsatisfactory performance or failures.			
Comparison of Test Results: At least twice a year, review the comparative results for multiple methods, instruments, or site correlations when more than one procedure exists.			
Relationship of Patient Test Information to Test Results: Evaluate patient test reports for accuracy of patient information, test results, and normal ranges. Identify and evaluate results inconsistent with patient's age, sex, diagnosis, and other test parameters.			
Personnel: Evaluate the effectiveness of policies and procedures for assuring employees' competence in performing testing and reporting test results.			
Communications: If applicable, evaluate documented problems and corrective actions that occur between the laboratory and the authorized individual who orders or receives the test result.			
Complaint Investigation: Evaluate documented complaints and corrective actions.			
Quality Assessment Reviews with Staff: Document discussion with Staff regarding identified problems and corrective actions during the QA review.			

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