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Sexual Health Implementation Binder

Need More Help?
Email Us:
visby.training@visby.com

go.visbymedical.com/training

Customer Support
Email Us:
support@visby.com

Call Us
1-833-GoVisby
(1-833-468-4729)
www.visby.com

Visby Medical Sexual Health Implementation Binder, PS-400386 Rev B, June 2024

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Sexual Health Implementation Binder

Table of Contents

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Product

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Visby Sexual Health Test Information

go.visbymedical.com/training

Test Time	28 minutes
Test Storage	Temperature: 36°F - 86°F (2°C - 30°C) Humidity: 5% - 80% DO NOT freeze
Operating Conditions	Temperature: 55°F - 91°F (13°C - 33°C) Humidity: 5% - 80% Atmospheric Pressure: 300ft - 9500ft
Sample Type	Self Collected Vaginal Swab
Patient Sample Storage	4 hours at refrigerated to room temperature 36°F -86°F (2°C – 30°C) 90 days at frozen temperature less than 5°F (-15°C)
Visby Sexual Health Test 10 Pack	• 10 Visby Medical Sexual Health Devices • 12 Pipettes • 1 Quick Reference Guide • Visby Medical Sexual Health Test Instructions for Use (available digitally)
Materials Required and Available as Accessories	• Visby Power Adapter • Visby Vaginal Specimen Collection Kit
Vaginal Specimen Collection Kit	• 50 Swabs • 50 Visby Collection Media Tubes • 50 Self-Collection Instructions • Vaginal Specimen Collection Kit Instructions for Use (available digitally)
Required but Not Supplied	• Medical Gloves • External Controls
External Controls	NATrol™ Chlamydia trachomatis (CT), Neisseria gonorrhoeae (NG), Trichomonas vaginalis (TV) Controls by ZeptoMetrix Corporation • Positive Control Packs: Catalog # NATCTNGTV-POS-IVD • Negative Control Packs: Catalog # NATCTNGTV-NEG-IVD
Need Help?	For Training: visby.training@visby.com For Customer Support: support@visby.com Call us: 1-833-468-4729 (1-833-GoVisby)

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Reordering Materials From Visby Medical

Product Name	Quantities Sold	Part Number
Visby Medical Sexual Health Test	20 tests	PS-400372
Visby Medical Vaginal Specimen Collection Kit (Individually wrapped)	50 count	PS-000715
Power Adapter	1 count per order	PS-000288

1. To order more materials from Visby Medical, contact your sales representative or Visby customer support at salesorders@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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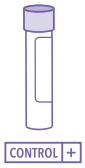
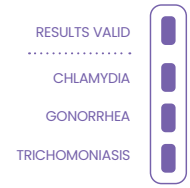
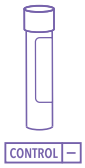
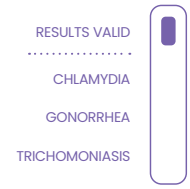
Visby Sexual Health Test
External Controls

Vendor	Product Code	Unit	Control Key
ZeptoMetrix®	**NATtrol CT/NG/TV Positive Control** Catalog # NATCTNGTV-POS-IVD	Six (6) x 1ml Vials per Kit 	Valid Positive Control Run 
	NATtrol CT/NG/TV Negative Control Catalog # NATCTNGTV-NEG-IVD	Six (6) x 1ml Vials per Kit 	Valid Negative Control Run 

Ordering External Controls

To purchase external controls please visit https://www.zeptometrix.com/ or call 1-800-274-5487

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. Mix the control by gently inverting the tube 5 times before testing.
2. Follow step 1 of the Quick Reference Guide to add the liquid external control into the sample port using the fixed volume pipette provided by Visby as if the external control was a patient sample.
3. Proceed with steps 2-3 of the Quick Reference Guide to run the test and get your results.

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5 Tips for Success

1. To avoid contamination, change gloves 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 5 times prior to loading the Visby Device.

3. Always operate the device between 55ºF - 91ºF (13ºC - 33ºC). 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. Once the sample is loaded into the pipette, do not invert the pipette. Doing so may cause air gaps in the pipette shaft.

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

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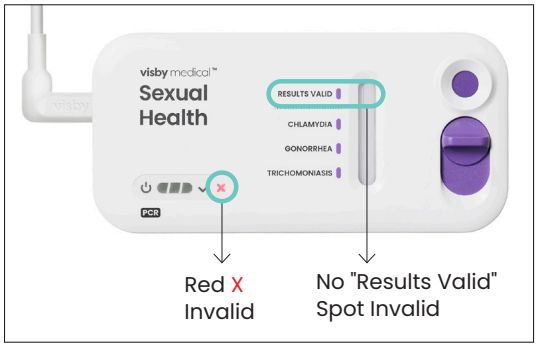
Troubleshooting Invalid Results



Red X Error

Operating Conditions

- Ensure the device is operated between 55°F - 91°F (13°C - 33°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

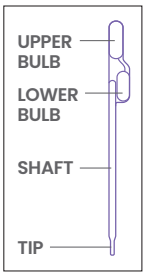
Power Supply

- 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 vaginal specimen collection kit provided by Visby
- Ensure the sample has been stored correctly:
  - -4 hours at refrigerated to room temperature (36°F - 86°F)
  - -90 days at frozen temperature (less than 5°F)
- Always invert the capped sample tube 5 times 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
- Once the sample is loaded into the pipette, do not invert the pipette. Doing so may cause air gaps in the pipette shaft
- 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

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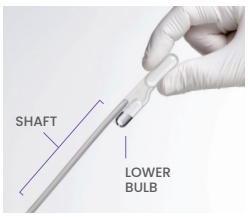
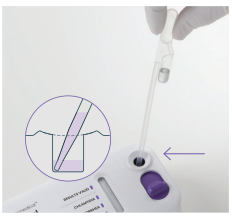
Using the Pipette

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

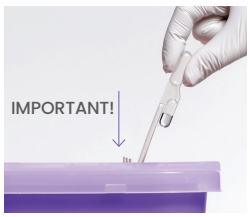
Release the upper bulb **slowly** to fill the shaft. Keep pipette tip submerged until shaft is full. Extra fluid should enter the lower bulb.



Check that there are **no air bubbles** in the shaft. **Note:** Do not squeeze lower bulb or invert the pipette.



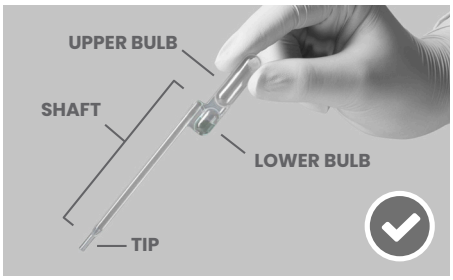
Place the tip at the **bottom** of the sample port and then squeeze the **upper bulb** of the pipette to release **all** of the sample.



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

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:
  - Free of air pockets and bubbles in the shaft
  - Shaft is full of fluid
  - Overflow fluid is in lower bulb
- **e.** Dispense the sample into the sample port of the Visby Test by inserting the pipette tip in the port hole and squeezing the upper bulb. Some overflow fluid will remain in the lower bulb. Do not add more or less volume.

Tips: 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.

Once the sample is loaded into the pipette, do not invert the pipette. Doing so may cause air gaps in the pipette shaft.

3 Only use the Visby provided pipettes to load the Visby Device. Additional pipettes are provided if needed. Contact training.visby@visby.com if you require additional pipettes.

For training support please email: **visby.training@visby.com**

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, all waste items should be disposed 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 at 1-833-GoVisby (1-833-468-4729) or email support@visby.com.

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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.

---

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

---

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:** Visby Medical - Sexual Health Test

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 (green check and 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:** Visby Medical - Sexual Health Test

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 Vaginal Specimen Collection Kit. _____

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 (13°C) - 91°F (33°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. The self collected vaginal sample can be stored for 4 hours at refrigerated to room temperature (36°F - 86°F) and/or 90 days at frozen temperature (less than 5°F) _____

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 (13°C) - 91°F (33°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**. The self collected vaginal sample can be stored for 4 hours at refrigerated to room temperature (36°F - 86°F) and/or 90 days at frozen temperature (less than 5°F)

8. **True**. If the Visby Device stays plugged in, the green check mark 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 Sexual 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 Sexual Health Test Results Interpretation Quiz

1 Invalid ____

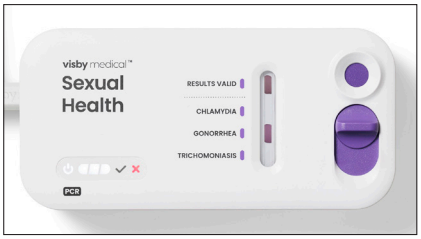
	Neg	Pos
CT	____	____
NG	____	____
TV	____	____

2 Invalid ____

	Neg	Pos
CT	____	____
NG	____	____
TV	____	____

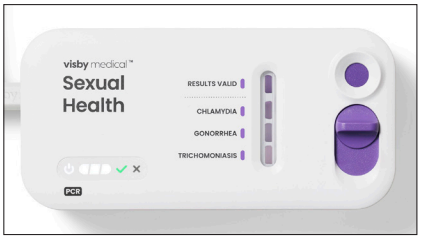
3 Invalid ____

	Neg	Pos
CT	____	____
NG	____	____
TV	____	____



4 Invalid ____

	Neg	Pos
CT	____	____
NG	____	____
TV	____	____

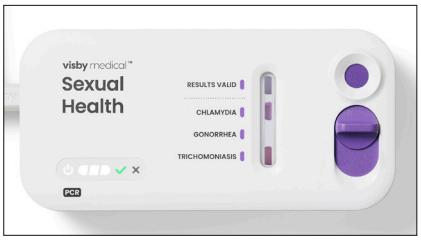


5 Invalid ____

	Neg	Pos
CT	____	____
NG	____	____
TV	____	____

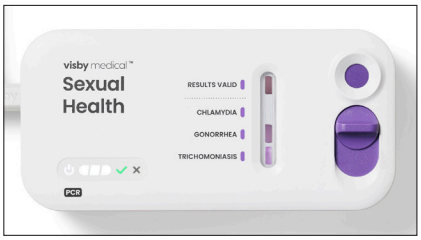
6 Invalid ____

	Neg	Pos
CT	____	____
NG	____	____
TV	____	____



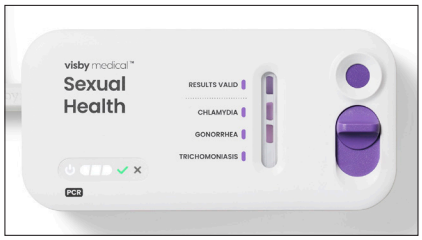
7 Invalid ____

	Neg	Pos
CT	____	____
NG	____	____
TV	____	____



8 Invalid ____

	Neg	Pos
CT	____	____
NG	____	____
TV	____	____



9 Invalid ____

	Neg	Pos
CT	____	____
NG	____	____
TV	____	____

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Visby Medical Sexual Health Test Results Interpretation Quiz: Answers

1. Invalid

2. CT Neg
   NG Neg
   TV Pos

3. CT Pos
   NG Neg
   TV Neg

4. Invalid

5. CT Pos
   NG Pos
   TV Pos

6. Invalid

7. CT Pos
   NG Neg
   TV Pos

8. CT Neg
   NG Pos
   TV Pos

9. CT Pos
   NG Pos
   TV Neg

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Certificate of Training

Institution: _____

Device Name: Visby Medical - Sexual Health Test

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	Job Title	Signature	Email	Date

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

_____ _____

Signature **Date**

_____ _____

Signature **Date**

_____ _____

Trainer **Date**

Certificate of Training

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Institution: _____

Device Name: Visby Medical - Sexual Health Test

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Print Name	Job Title	Signature	Email	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: Visby Medical - Sexual Health Test

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 Medical Sexual Health Test - External Control Log

Clinical Site Name: _____

Device Name: Visby Medical - Sexual Health Test

For the Visby Medical Sexual 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:** _____

For training support please email: **visby.training@visby.com**

Visby Medical Sexual Health Test - Detailed External Control Log

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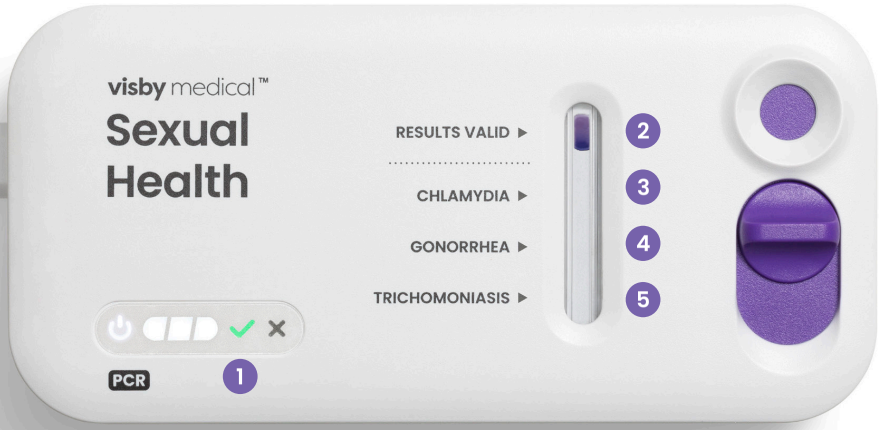

Test a set of external controls with each new shipment received and once for each untrained operator. Further controls may be tested in order to conform with local, state and/or federal regulations, accrediting groups, or your lab's standard Quality Control procedures. An operator should confirm a valid test prior to interpreting results. A valid test is a green check mark present as well as the presence of a results valid purple spot. For more information, please review Instructions for Use and Quick Reference Guide.

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

	Device Information		Control Information		Internal Controls				External Controls		
Date	**Lot #**	**Exp Date**	**Lot #**	**Exp Date**	**#1 Valid Electronic Control (Green Check Mark-Present or Absent)**		**#2- Results Valid Spot (Spot Development- Present or Absent)**		**#3-5 Valid Positive Control? (Spot development for all pathogens present)**	**#3-5- Valid Negative Control (No spot development for pathogens present)**	**Tech Initials**
/ /		/ /		/ /	Present	Absent	Present	Absent	Present	Absent	
/ /		/ /		/ /	Present	Absent	Present	Absent	Present	Absent	
/ /		/ /		/ /	Present	Absent	Present	Absent	Present	Absent	
/ /		/ /		/ /	Present	Absent	Present	Absent	Present	Absent	

Comments

Continued - Detailed External Control Log

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	Device Information		Control Information		Internal Controls				External Controls		
Date	Lot #	Exp Date	Lot #	Exp Date	#1 Valid Electronic Control (Green Check Mark-Present or Absent)		#2- Results Valid Spot (Spot Development-Present or Absent)		#3-5 Valid Positive Control? (Spot development for all pathogens present)	#3-5- Valid Negative Control (No spot development for pathogens present)	Tech Initials
/ /		/ /		/ /	Present	Absent	Present	Absent	Present	Absent	
/ /		/ /		/ /	Present	Absent	Present	Absent	Present	Absent	
/ /		/ /		/ /	Present	Absent	Present	Absent	Present	Absent	
/ /		/ /		/ /	Present	Absent	Present	Absent	Present	Absent	
/ /		/ /		/ /	Present	Absent	Present	Absent	Present	Absent	
/ /		/ /		/ /	Present	Absent	Present	Absent	Present	Absent	
/ /		/ /		/ /	Present	Absent	Present	Absent	Present	Absent	
/ /		/ /		/ /	Present	Absent	Present	Absent	Present	Absent	
/ /		/ /		/ /	Present	Absent	Present	Absent	Present	Absent	
/ /		/ /		/ /	Present	Absent	Present	Absent	Present	Absent	

Comments

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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:** _____

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

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Troubleshooting Tracker

Clinical Site Name: _____

Device Name: Visby Medical - Sexual Health Test

If a retest is required, obtain the leftover sample from the Visby collection media tube. If the leftover sample has been stored for ≤ 4 hours, then repeat the test with a new Visby Medical Sexual Health device. If the leftover sample has exceeded the storage recommendations (four hours at room temperature or under refrigeration), and/or if the sample volume is insufficient, collect a new sample and repeat the test with a new Visby Medical Sexual Health Test. If a retest continues to return an invalid result, collect a new sample and repeat the test with a new Visby Medical Sexual Health Test. If the positive or negative external controls fail, repeat the test with a new Visby Medical Sexual Health device. If a repeat test fails, please contact **Visby Medical Customer Support at 1-833-4684729 (1-833-GoVisby) or email support@visby.com.**

Date, Time	Operator	Device Lot	Invalid Type	Issue
			☐ Red X ☐ No Results Valid Spot ☐ Other	
			☐ Red X ☐ No Results Valid Spot ☐ Other	
			☐ Red X ☐ No Results Valid Spot ☐ Other	
			☐ Red X ☐ No Results Valid Spot ☐ Other	
			☐ Red X ☐ No Results Valid Spot ☐ Other	
			☐ Red X ☐ No Control/Valid Spot ☐ Other	
			☐ Red X ☐ No Results Valid Spot ☐ Other	
			☐ Red X ☐ No Results Valid Spot ☐ Other	

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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: Visby Medical - Sexual Health Test

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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Customer Support
Email Us:
support@visby.com

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(1-833-468-4729)
www.visby.com