

visby medical™



Training: Visby Medical Sexual Health Test

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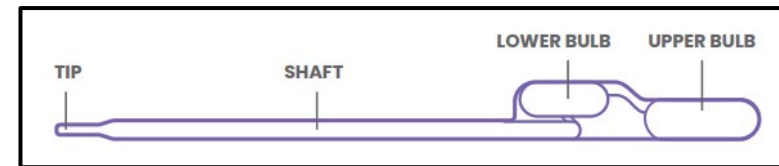
Product Overview

Materials Provided and Required for Testing

Visby Medical Sexual Health Test 20 devices per case

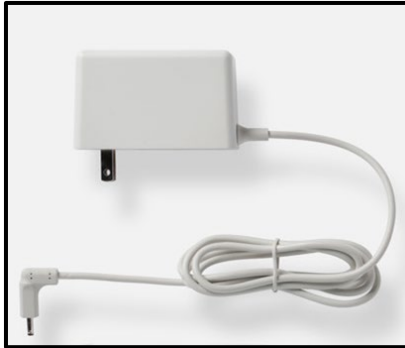


Visby Fixed Volume Pipette (650 μ L)



Materials Required: Available as Accessories

Visby Power Adapter



Visby Vaginal Specimen Collection Kit



Materials Required: Not Provided

External Controls Required Manufactured by **ZeptoMetrix®**



Gloves



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

- **No dilution step**
- **Use external control as if it were a refrigerated patient sample with a room temperature Visby device and Visby pipette.**



Six (6) x 1 mL Vials per Kit



CONTROL +

Valid Positive

RESULTS VALID ▶

CHLAMYDIA ▶

GONORRHEA ▶

TRICHOMONIASIS ▶



Control Run

Six (6) x 1 mL Vials per Kit



CONTROL -

Valid Negative

RESULTS VALID ▶

CHLAMYDIA ▶

GONORRHEA ▶

TRICHOMONIASIS ▶



Control Run

ZeptoMetrix®

Catalog # NATCTNGTV-POS-IVD

Catalog # NATCTNGTV-NEG-IVD

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

Patient Sample Collection

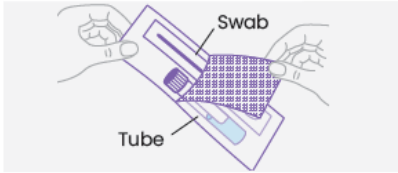
Vaginal Specimen Collection Instructions

Vaginal Specimen Collection Kit

Self-Collection Instructions

visby medical™

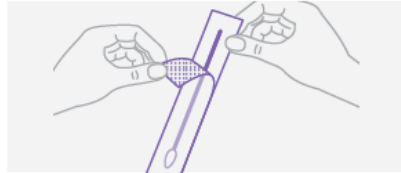
STEP 1 Open Kit



Wash your hands and undress from the waist down.

Open the Visby Vaginal Specimen Collection Kit, and set aside the tube.

STEP 2 Unwrap Swab



Unwrap the swab.

⚠ Do not touch the soft tip of the swab with your finger or on any surfaces. If you do or if the swab has no tip, discard it and start again with a new kit.

STEP 3 Hold Swab



Hold the swab in your hand by placing it between your thumb and your forefinger.

Carefully insert the soft tip of the swab about 2 inches into the opening of the vagina.

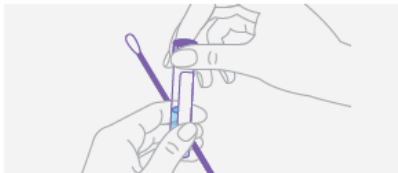
STEP 4 Collect Sample



Gently rotate the swab for 10-30 seconds, making sure that the swab touches the walls of the vagina.

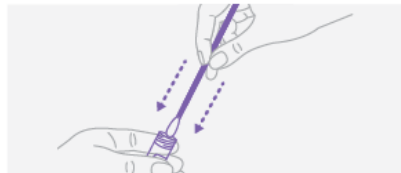
⚠ Remove the swab and **keep in your hand during Step 5.**

STEP 5 Open Tube



Carefully unscrew the cap ensuring the soft tip of the swab doesn't touch anything. Set the cap down.

STEP 6 Insert Swab



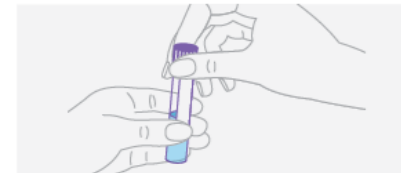
Hold the tube opening away from you and carefully insert the soft tip of the swab into the tube.

STEP 7 Tap Swab



Gently tap the swab against the bottom of the tube for 15 seconds. Avoid splashing. **Lift the swab out of the tube and discard appropriately.**

STEP 8 Return Tube



Tightly screw the cap on the tube.

Wash your hands with soap and water. Return the tube to your care-provider.

- [Vaginal Specimen Collection Instructions - Instructions for Use](#)
- [Vaginal Specimen Collection Instruction Card](#)

Self Collected Sample Storage Conditions

**4 hours at
Refrigerated - Room**

36°F - 86°F
(2°C - 30°C)

**90 days at
Frozen Temperature**

less than 5°F
(< - 15°C)

Collected Sample in Visby Buffer



For best results, patient-collected samples should be tested as soon as possible.

Testing and Interpreting Results

All testing instructions come from the Visby Medical Sexual 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) - 91°F (33°C)

Place device on a level surface



Clean your workspace and gather all the required materials, then **unwrap** the device.

Note: Use the device **immediately** after unwrapping. Use **new** gloves for each test.

Note: In case of refrigeration, ensure device comes to operating temperature prior to use.



Plug the **Visby Power Adaptor** into the device power port.



Remove the **sticker** over the sample port.

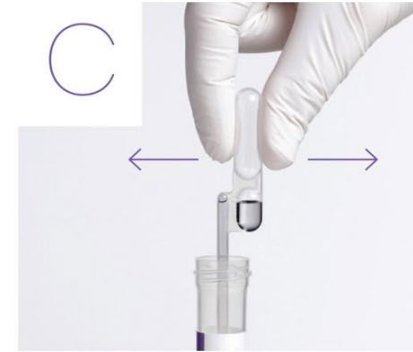
Step 1: Mix and Add Patient Sample (or External Control Vial)



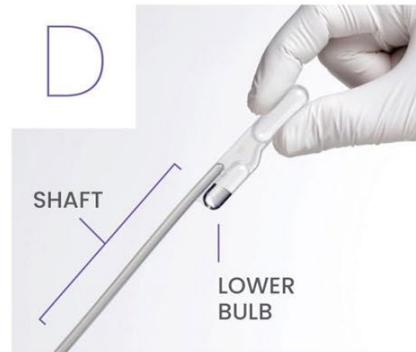
Mix the sample (or control) by **gently inverting** the tube **5 times**.



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.

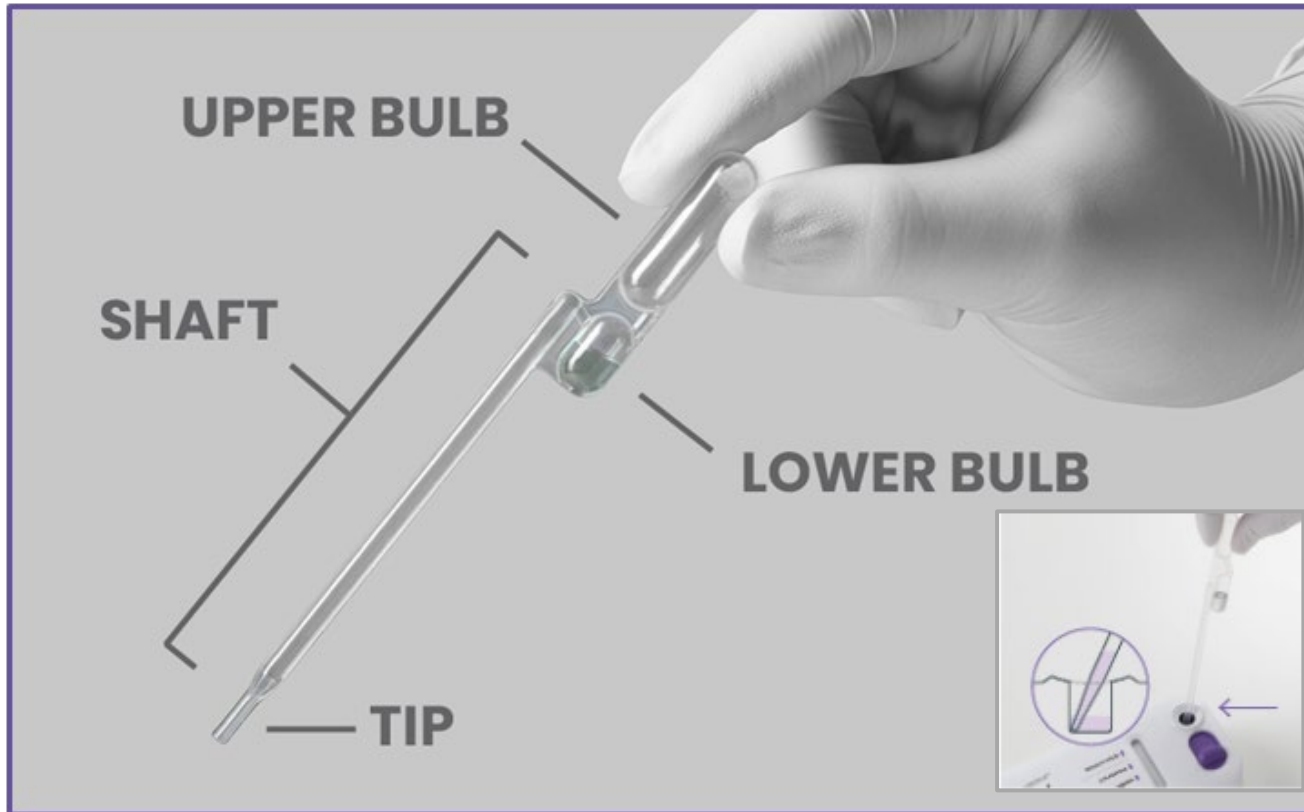


Place the tip at the **bottom** of the sample port and then squeeze the **upper bulb** of the pipette to release **all** of the sample.



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

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.

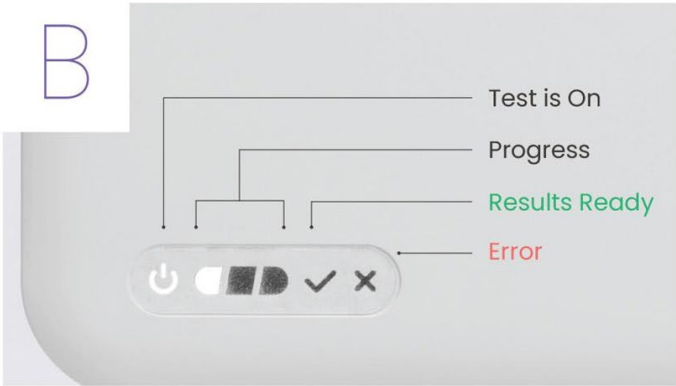
Step 2: Run the Test

 Do not move test while running.

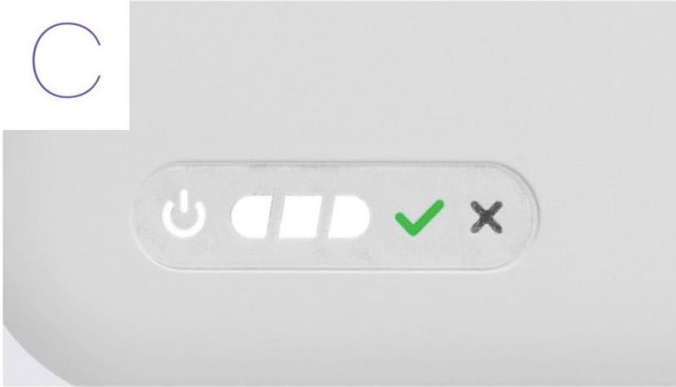
Note: Failure to operate device on a flat surface with the front of the device facing up may lead to invalid or inaccurate results.



Immediately after sample addition, slide the **switch upwards** in a firm, swift motion to fully close the sample port and ensure the test is started.



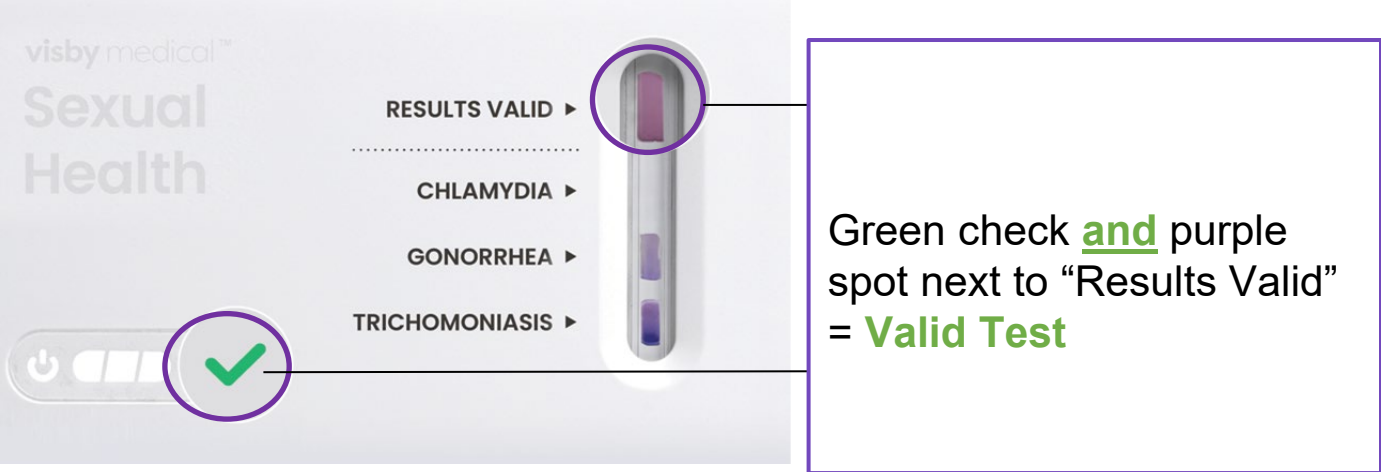
Check that the first progress **indicator light is blinking**. Lights will initially blink and then become stable as the test progresses.



Wait approximately **28 minutes** for a green check mark to appear indicating the test is finished running. **Note:** If a **red X** appears at any point, stop, do not read test results, and retest.

Step 3: Interpret Results

After approximately 28 Minutes, determine if test is valid.
If the test is valid, Read the Test Results:



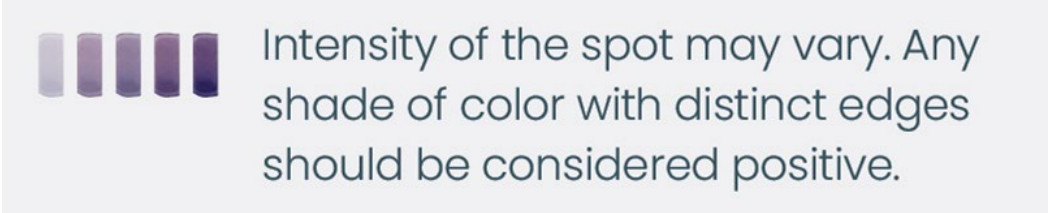
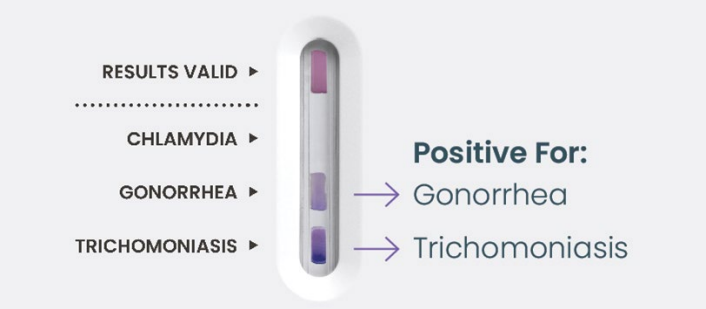
If test is not valid (missing green check or results valid spot), see next slide for information about invalid results.

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

Negative Result

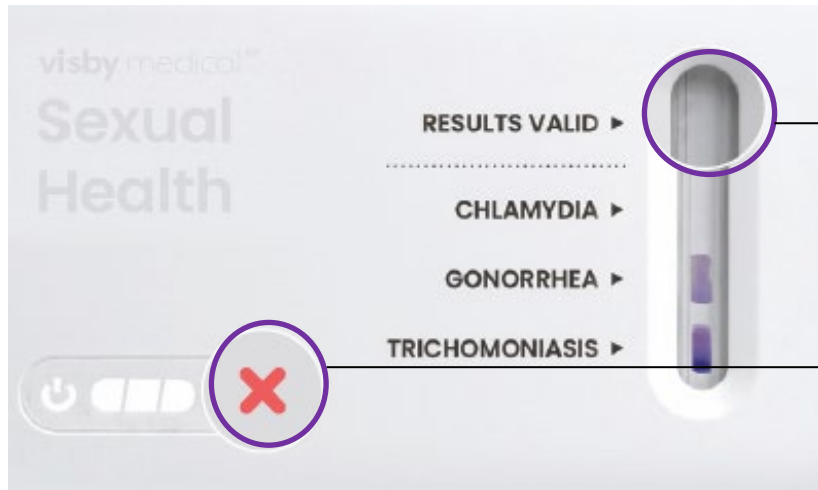


Positive Result



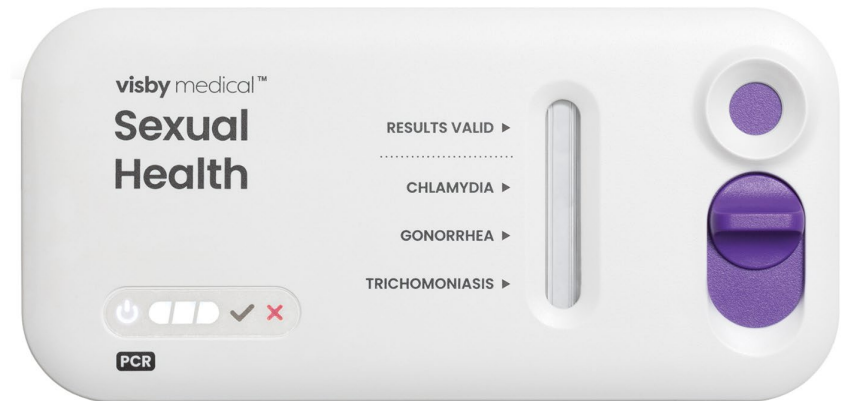
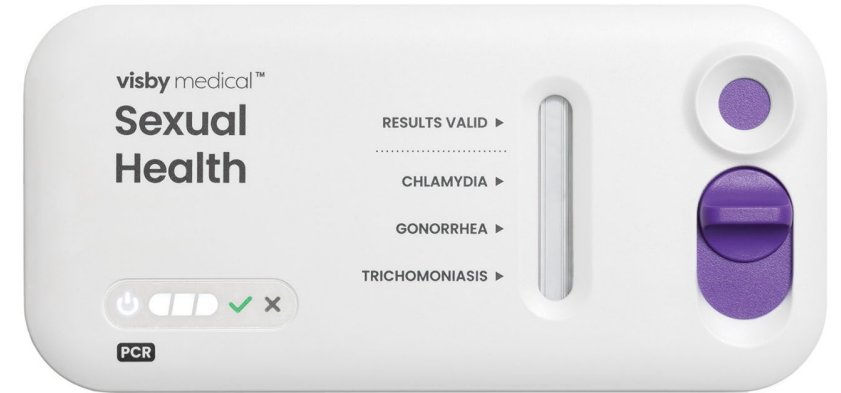
Interpret Results: Invalids

Invalid Results



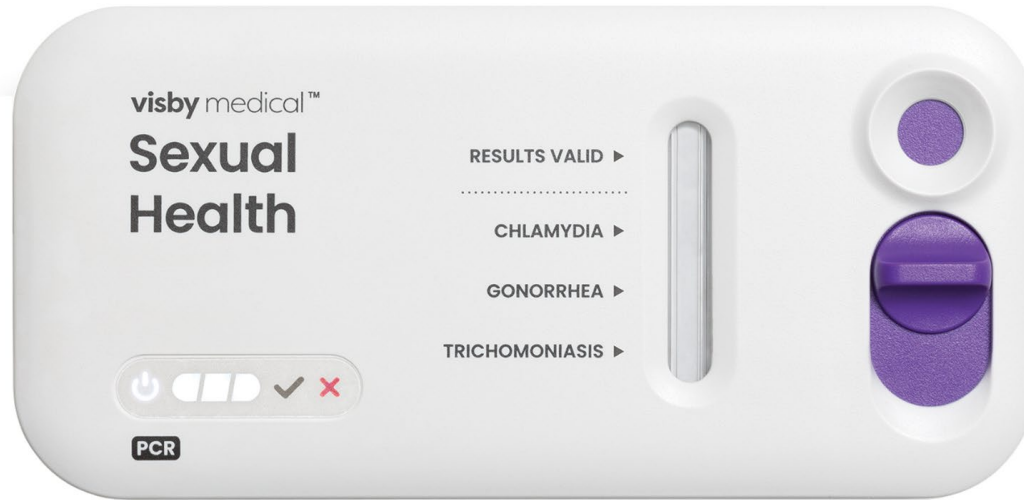
Red X or no Results
Valid spot = Invalid Test

Stop and Repeat the test.



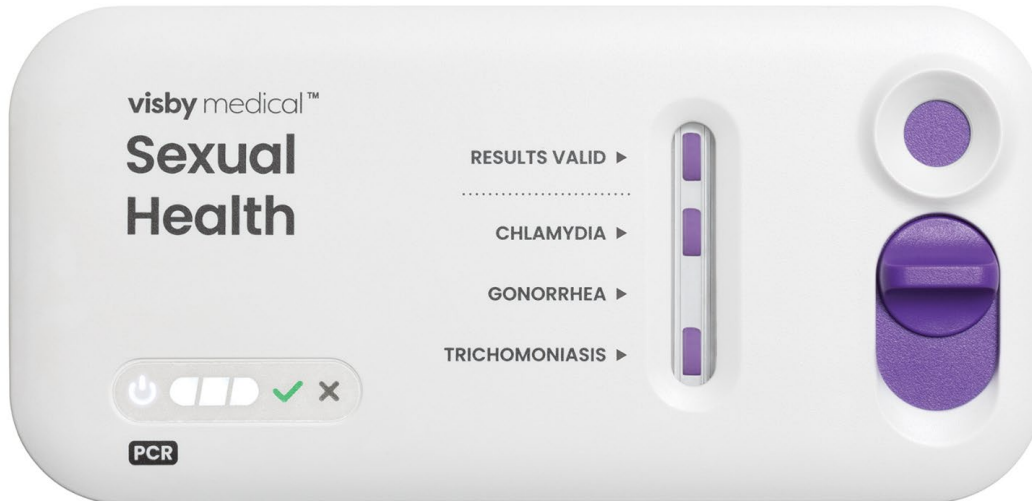
Results Interpretation

1



-	+		
■	■	CT	
■	■	NG	
■	■	TV	
X		Invalid	

2



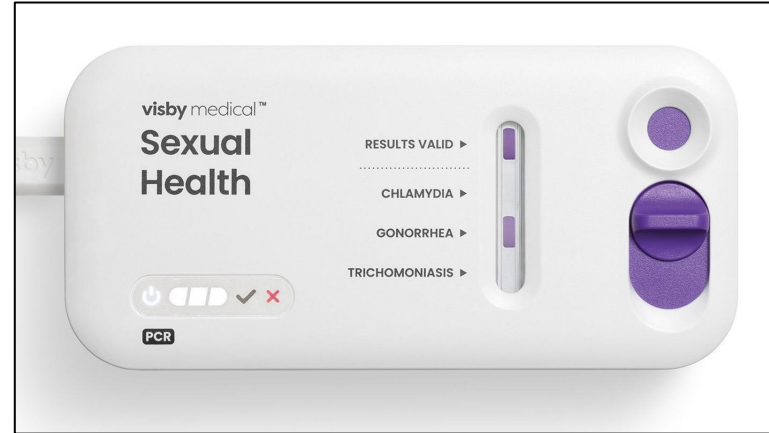
-	+		
■	X	CT	
X	■	NG	
■	X	TV	
■		Invalid	

Results Interpretation

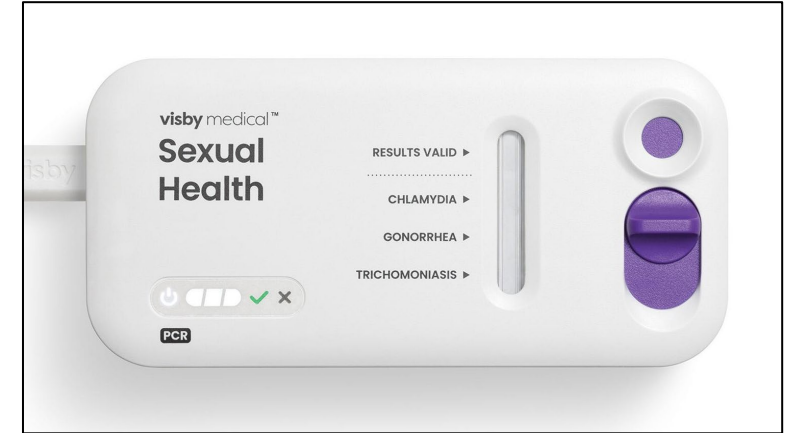
#1



#2



#3



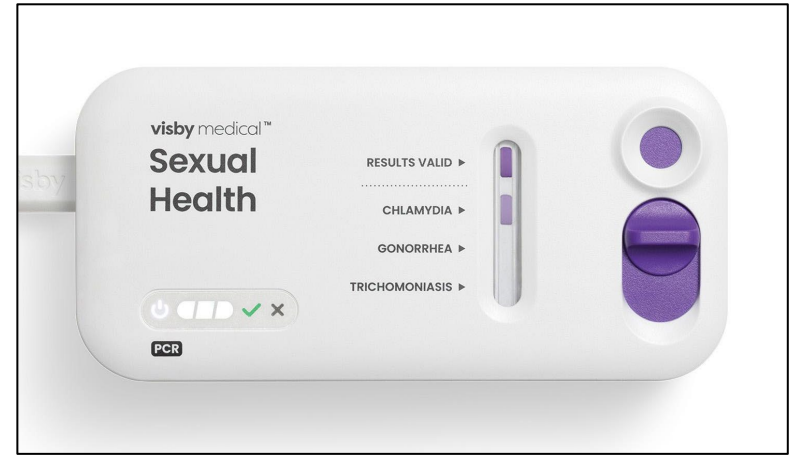
#4



#5



#6



Troubleshooting

Common Causes of a Red X

1) Device operated outside of the temperature conditions

- Temperature

Storage Conditions: 36°F- 86°F (2°C - 30°C)

Operating Conditions: 55°F- 91°F (13°C - 33°C)

2) Interrupted power to the device

- Loss of power
- Unplugging/replugging in the device after slider is shut

Common Causes of No Results Valid Spot

1) Improper Sample Handling

- Sample was collected after performing vaginal exam using lubricant
- Sample was collected in anything other than the Visby Vaginal Collection Kit (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)

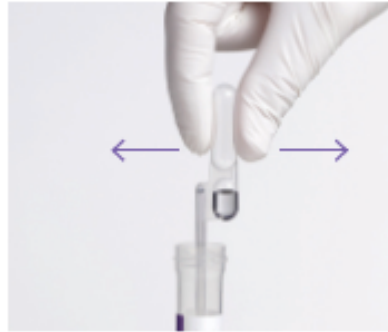
2) Improper Use of the Visby Test

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

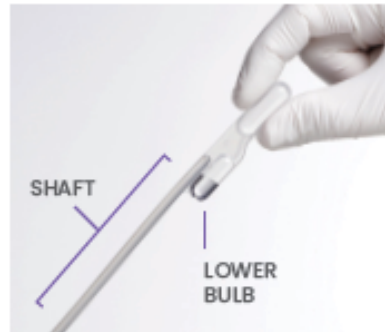
Using the Pipette



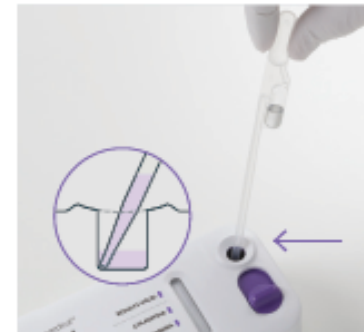
Squeeze the **upper bulb** of the provided pipette and submerge the tip to the **bottom** of the sample tube.



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.

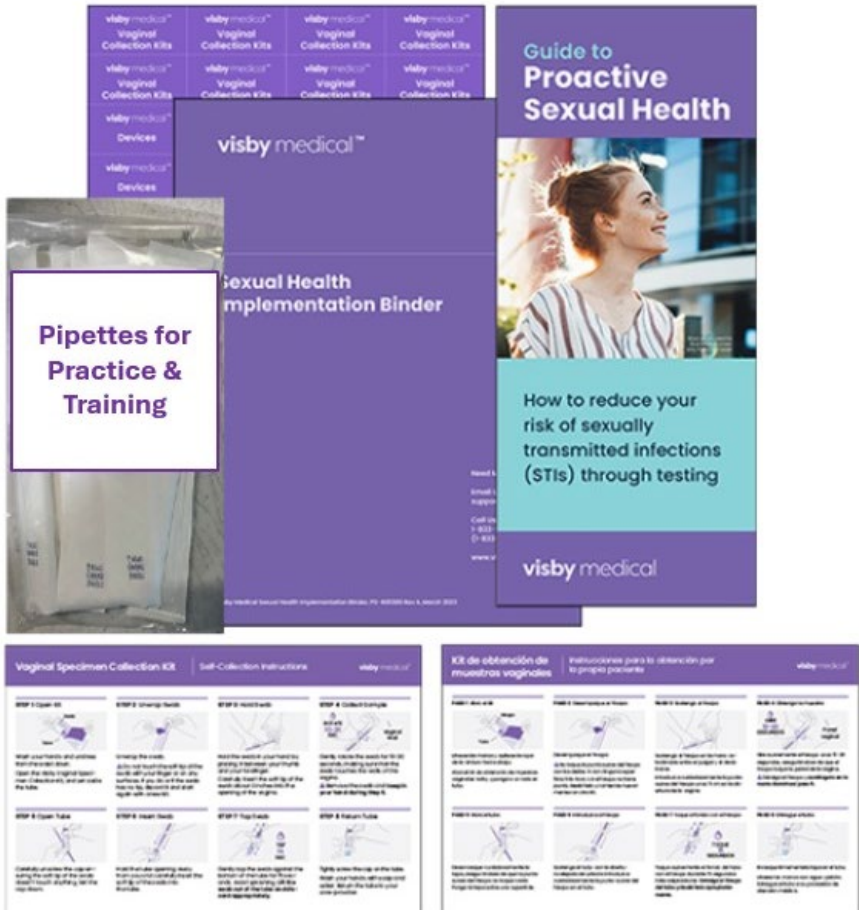
Scan to review video:
"Mastering the Pipette"



Resources

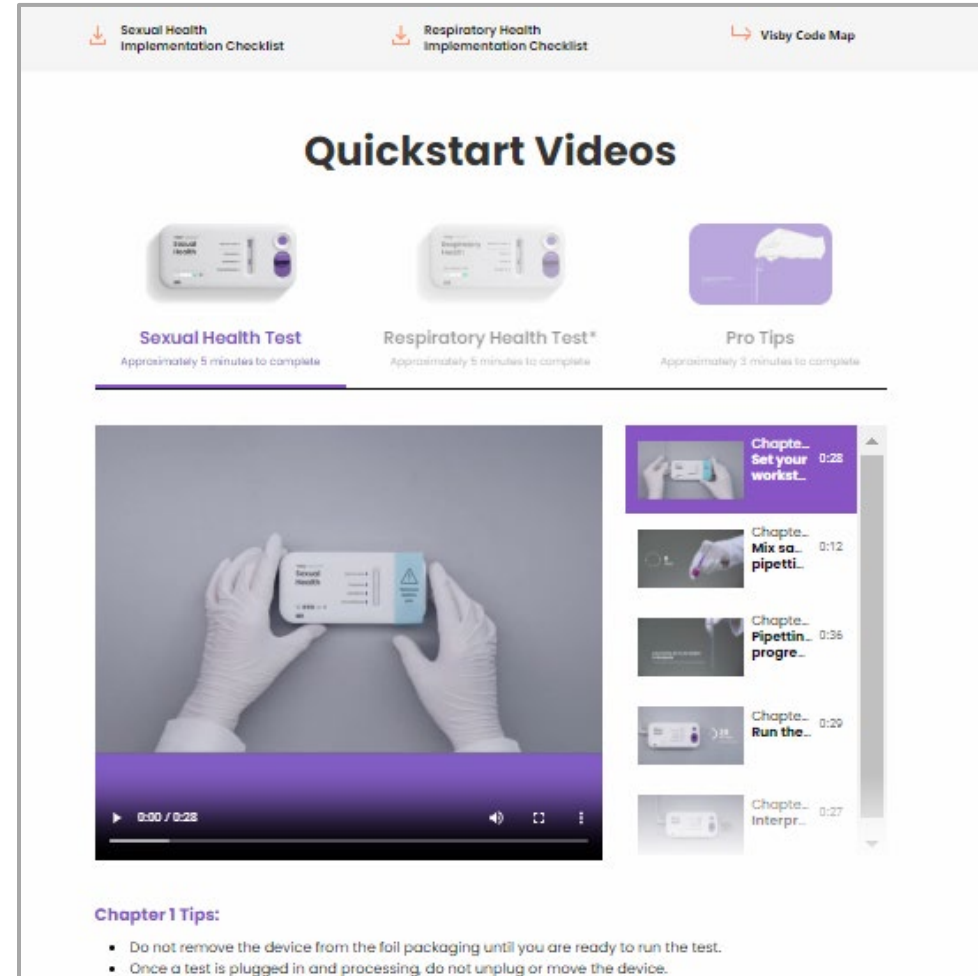
Training Resources

Complimentary Material:



- Sexual Health Implementation Binder (templates and information for policies and procedures)
- Sexual Health- Vaginal Specimen Collection Instructions Posters- English & Spanish
- Visby Lab Stickers (for supply organization in the lab)
- Sexual Health Patient Brochures
- Pipettes (for practice & training)

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 Sexual Health Test Information

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 (Visby Part Number PS-400372) *sold in cases. 1 case = 20 Test Devices	<ul style="list-style-type: none">• 10 Visby Medical Sexual Health Devices• 12 Pipettes• 1 Quick Reference Guide• Visby Medical Sexual Health Test Instructions for Use (available digitally)

Visby Sexual Health Test Information

<p>Materials Required and Available as Accessories</p>	<ul style="list-style-type: none"> • Visby Power Adapter (Visby Part Number PS-000288) • Visby Vaginal Specimen Collection Kit (Visby Part Number PS-000715)
<p>Vaginal Specimen Collection Kit (Visby Part Number PS-000715)</p>	<ul style="list-style-type: none"> • 50 Swabs • 50 Visby Collection Media Tubes • 50 Self-Collection Instructions • Vaginal Specimen Collection Kit Instructions for Use (available digitally)
<p>Required but Not Supplied</p>	<ul style="list-style-type: none"> • Medical Gloves • External Controls
<p>ZeptoMetrix® External Controls</p>	<p>NATrol™ Chlamydia trachomatis (CT), Neisseria gonorrhoeae (NG), Trichomonas vaginalis (TV) Controls by ZeptoMetrix® Corporation:</p> <ul style="list-style-type: none"> • Positive (1 order = 6 x 1.0 ml vials) ZeptoMetrix® Catalog # NATCTNGTV-POS-IVD • Negative (1 order = 6 x 1.0 ml vials) ZeptoMetrix® Catalog # NATCTNGTV-NEG-IVD
<p>Need Help?</p>	<p>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)</p>

Appendix

Clinical and Analytical Performance

Pathogen	PPA	NPA
Chlamydia (CT)	97.4 %	97.8%
Gonorrhoeae (NG)	97.8%	99.1%
Trichomonas (TV)	99.3% *	96.7% *

* Trichomonas is listed as sensitivity and specificity

For more information on the clinical and analytical performance of the Visby Medical Sexual Health Test, please refer to the 'Instructions for Use.'

Organism	Limit of Detection
CT Serovar H (VR-879)	16.0 EB/mL
CT Serovar D (VR-885)	5.9 EB/mL
NG (ATCC 19424)	5.7 CFU/mL
NG (ATCC 49226)	6.2 CFU/mL
TV (ATCC 30001)	1.2 troph/mL
TV (ATCC 30238)	0.24 troph/mL

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