

visby medical™

Training: Visby Medical Sexual Health Test



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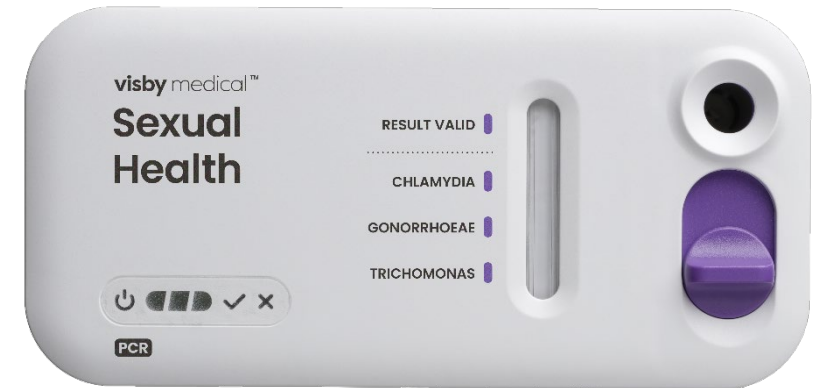
Product Overview

The Visby Sexual Health Test

1. No Call Backs

2. Informed Treatment

3. Reduce Patient Anxiety



Storage & Operating Conditions

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



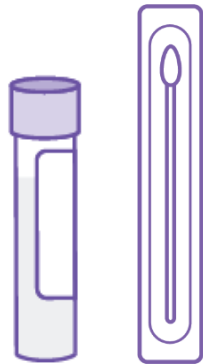
For best results, patient-collected samples should be tested as soon as possible.

Storage Conditions

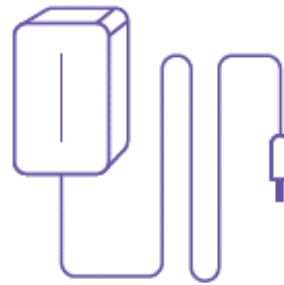
Visby Devices




Vaginal Specimen Collection Kit



Visby Power Adapter



TEMPERATURE

36°F (2°C)  86°F (30°C)

HUMIDITY

5%  80%

Do Not Freeze

Operating Conditions



TEMPERATURE
55°F - 91°F
(13°C - 33°C)



HUMIDITY
5% - 80%



PRESSURE
-300ft - 9500ft
(102.5 kPa - 71 kPa)

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

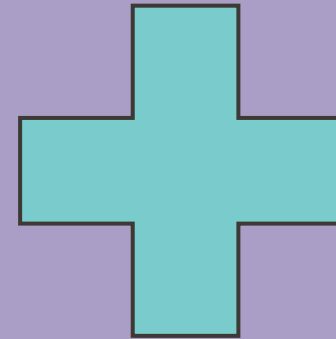
External Control Testing

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.



Catalog # NATCTNGTV-POS-IVD
Catalog # NATCTNGTV-NEG-IVD

How the Device Works

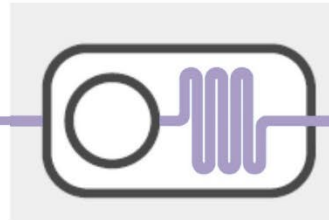
Load Sample

Sample rehydrates control organism



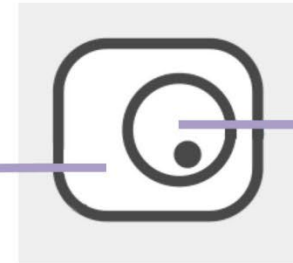
Sample Preparation

Sample is heat lysed



Mixing Chamber

Sample mixes with lyophilized PCR reagents



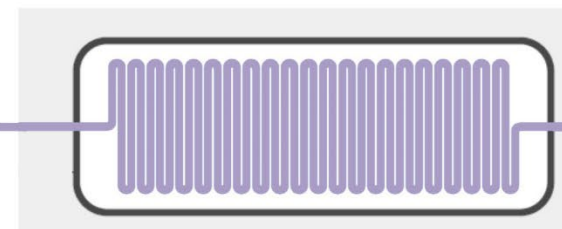
Detection

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



PCR

Sample goes through 40 cycles of PCR



Testing with the Visby Device

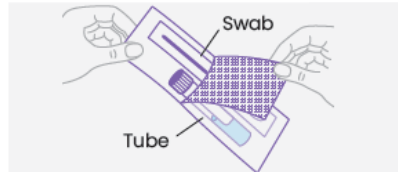
Vaginal Specimen Collection Instructions

Vaginal Specimen Collection Kit

Self-Collection Instructions

visby medical™

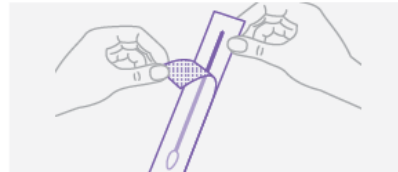
STEP 1 Open Kit



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.

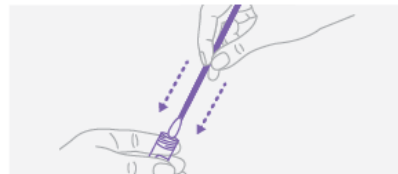
⚠ Remove the swab and **keep in your hand during Step 5.**

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.

Easy to Use



1

Plug in Device



2

Load Sample



3

Slide Port Closed

Setup: Prepare the Workspace

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



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.

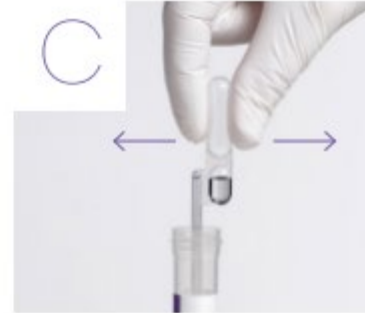
Step 1: Mix and Add Patient Sample



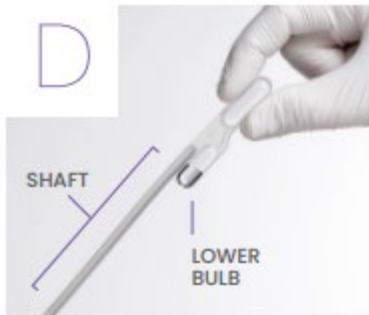
Mix the sample (or control) by **gently inverting** the tube **5 times**.



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.**

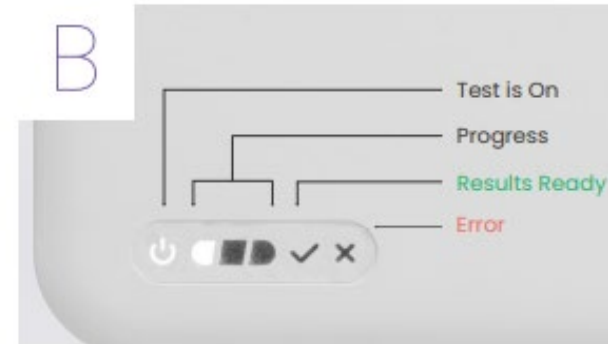
Step 2: Run the Test

 Do not move test while running.



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.

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



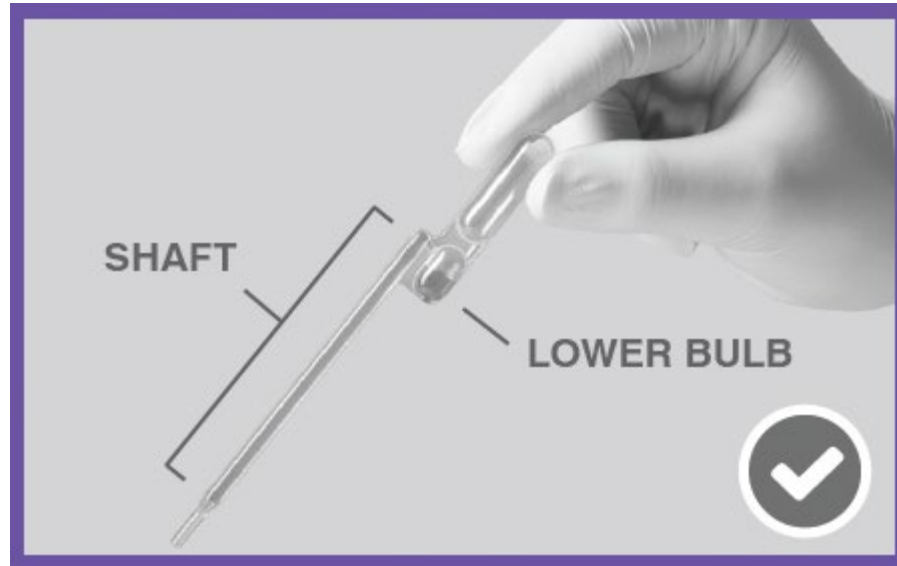
Check that the first progress **indicator light is blinking**. Lights will initially blink and then become stable as the test progresses.



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.

Using the Pipette

Using the Pipette



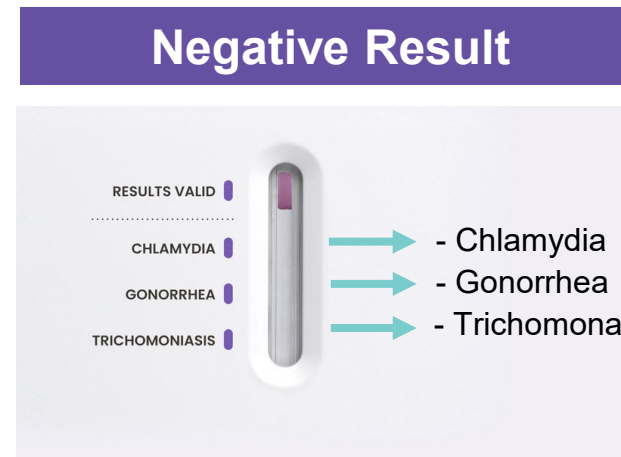
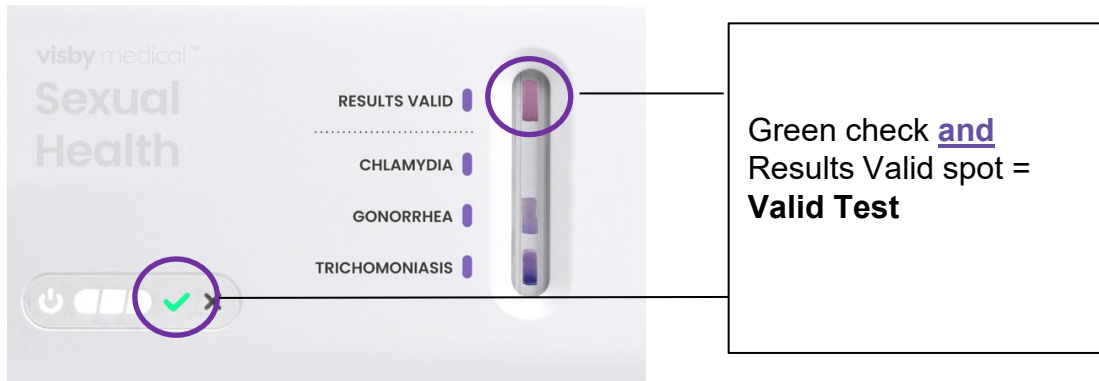
- Avoid bubbles
- Pipette is full
- Fluid in the lower bulb

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

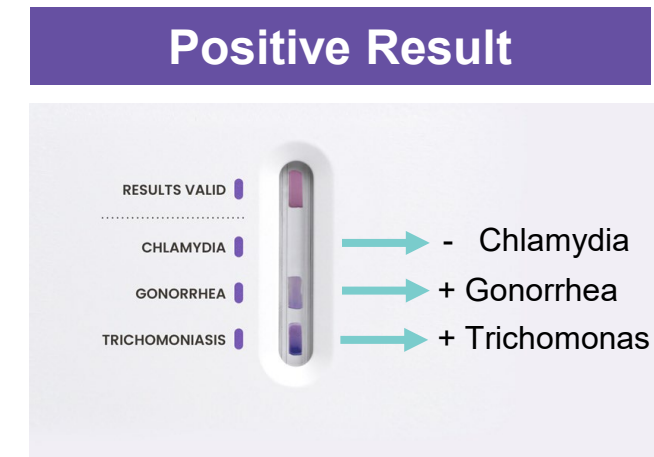
Interpreting Results

Step 3: Interpret Results

After 28 Minutes



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

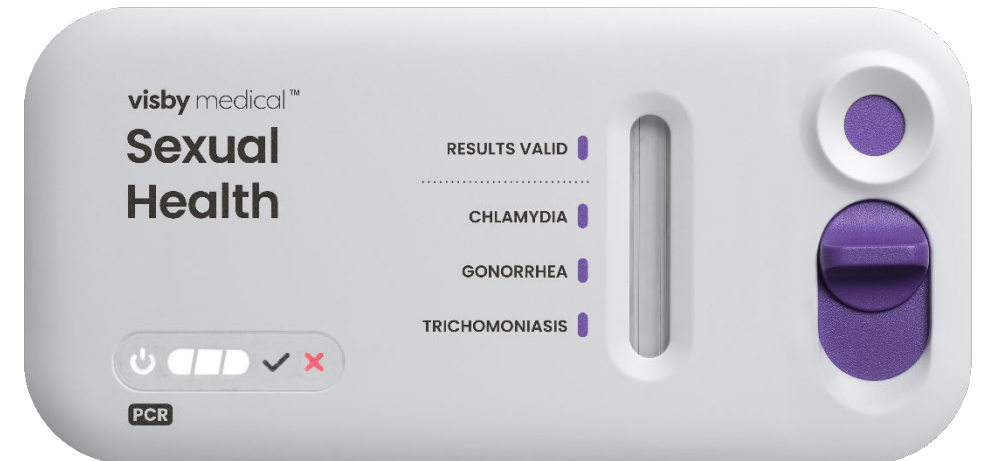
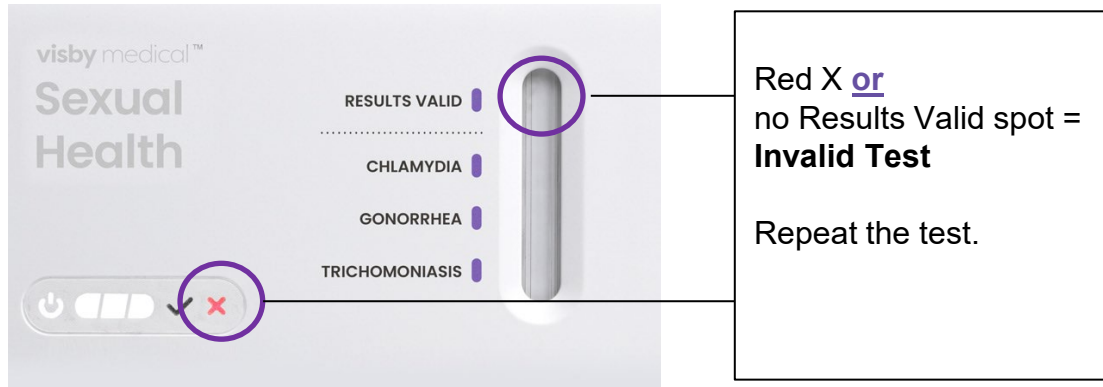


Positive: Any shade of purple with distinct edges next to the target is a positive result.

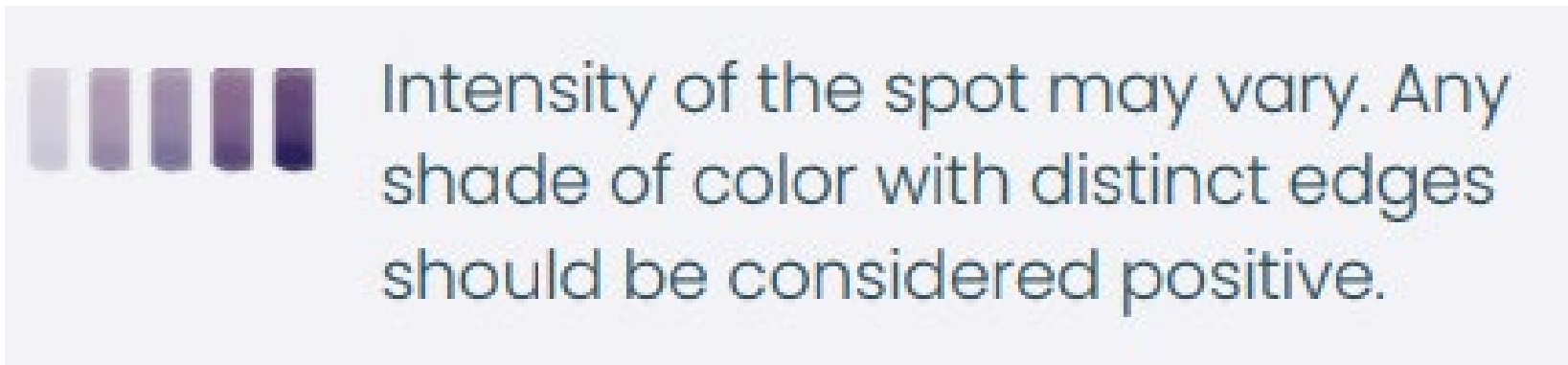
Interpret the results for **up to 2 hours**

Step 3: Interpret Results

Invalid Results

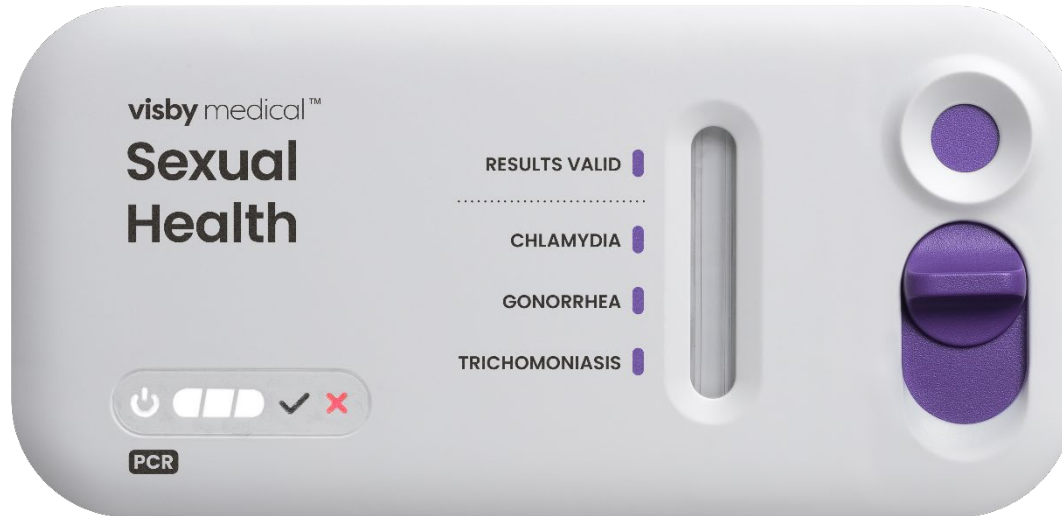


Variance in Spot Color



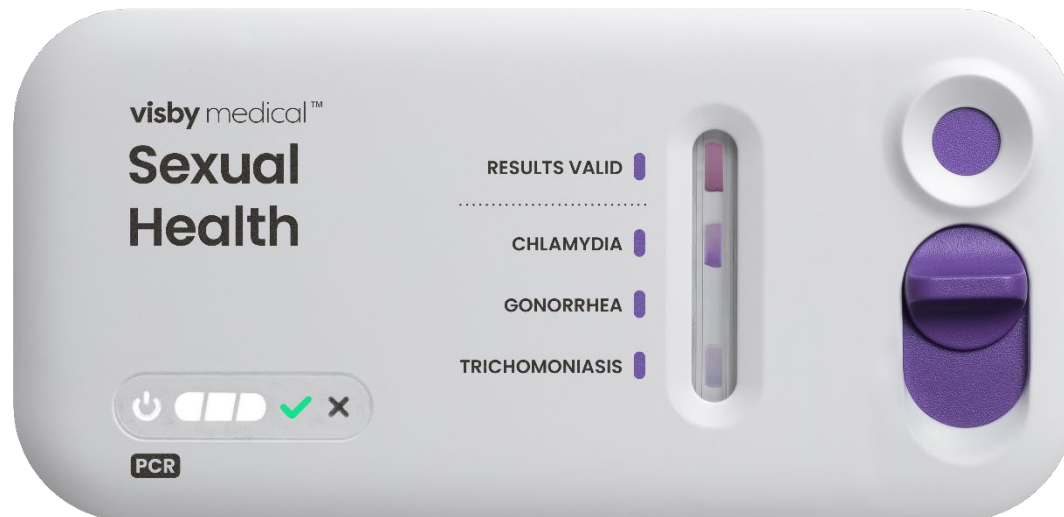
Results Interpretation

1



- +
 CT
 NG
 TV
 Invalid

2



- +
 CT
 NG
 TV
 Invalid

Causes of Invalid Results

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
- Loose connection between device and power adapter
- Unplugging/re-plugging in the device after slider is shut

Common Causes of No Results Valid Spot

1) Improper Sample Handling

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

2) Improper Use of the Visby Test

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

Invalid Retesting

Invalid Patient Sample:

Return to the patient sample and repeat using a new pipette and new Visby Medical Sexual Health Test.

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

Troubleshooting Tracker

Device Name: _____

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

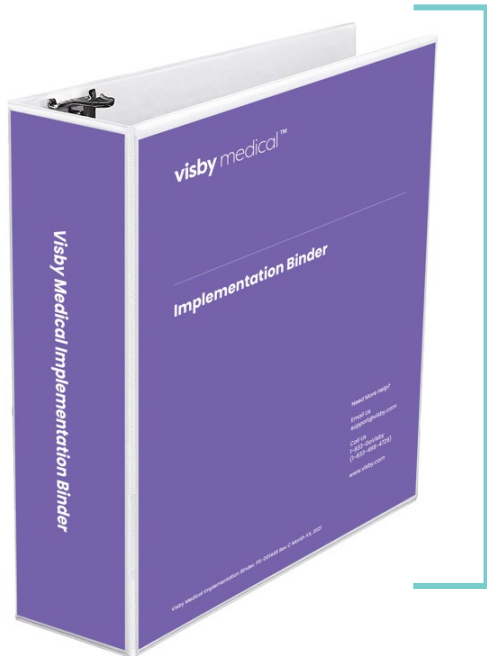
Our Customer Support Staff is trained on the Visby Test and is dedicated to help resolve your issues to the best of our ability. We may ask for an emailed/faxed copy of this log to help our support staff better understand your institution's exact problem.

Date, Time	Operator	Device Lot	Invalid Type	Issue
			<input type="checkbox"/> Red X <input type="checkbox"/> No Control/Valid Spot <input type="checkbox"/> Other	
			<input type="checkbox"/> Red X <input type="checkbox"/> No Control/Valid Spot <input type="checkbox"/> Other	
			<input type="checkbox"/> Red X <input type="checkbox"/> No Control/Valid Spot <input type="checkbox"/> Other	
			<input type="checkbox"/> Red X <input type="checkbox"/> No Control/Valid Spot <input type="checkbox"/> Other	
			<input type="checkbox"/> Red X <input type="checkbox"/> No Control/Valid Spot <input type="checkbox"/> Other	
			<input type="checkbox"/> Red X <input type="checkbox"/> No Control/Valid Spot <input type="checkbox"/> Other	
			<input type="checkbox"/> Red X <input type="checkbox"/> No Control/Valid Spot <input type="checkbox"/> Other	
			<input type="checkbox"/> Red X <input type="checkbox"/> No Control/Valid Spot <input type="checkbox"/> Other	
			<input type="checkbox"/> Red X <input type="checkbox"/> No Control/Valid Spot <input type="checkbox"/> Other	

Resources

Training Resources

The Visby Implementation Binder



- Training Checklist
- Training Quiz
- Results interpretation Quiz
- Certificate of Training
- Testing Personnel Training Assessment

Access Training Resources

www.visbymedical.com/visby-university

Password: Visby-POC

- Training Presentation
- STI Implementation Binder
- Virtual Training Quiz
- CLSI Template
- Demo video

Questions?



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@visby.com

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.'

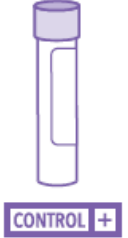
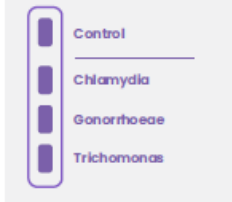
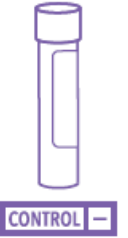
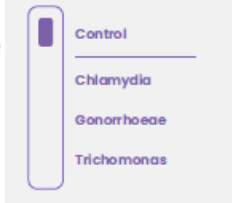
Organism	Limit of Detection
CT Serovar H (VR-879)	16.0 EB/mL
CT Serovar D (VR-885)	5.9 EB/mL
NG (ATCC 19424)	5.7 CFU/mL
NG (ATCC 49226)	6.2 CFU/mL
TV (ATCC 30001)	1.2 troph/mL
TV (ATCC 30238)	0.24 troph/mL

Part Numbers

10 Pack (1 Box)	10 Devices 12 Pipettes 12 Biohazard bags 1 Sexual Health Test QRG 1 Sexual Health Test IFU (available digitally)	PS-400372 (2 x 10 devices)
Required Accessories	Visby Power Adapter	PS-000288
	Vaginal Specimen Collection Kit <ul style="list-style-type: none"> • Swab + Visby Collection Media • Self Collection Instructions • Instructions for Use 	PS-000715
Required but not Supplied	ZeptoMetrix® External Controls	Pos Catalog # NATCTNGTV-POS-IVD Neg Catalog # NATCTNGTV-NEG-IVD

External Controls

ZeptoMetrix®

Product Code	Unit	Control Key
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 



Test external controls with the same procedure as patient samples

**For storage instructions refer to manufacturer's package insert*