visby medical™

Sexual Health

QUICK REFERENCE GUIDE

CLIA Waived for Vaginal Samples

CLIA waived labs must follow the manufacturer's instructions for performing the test. 42 CFR 493.15(e)(1).

Need Help?

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

Email Us
support@visby.com

Visby Medical, Inc.
3010 North First Street
San Jose, CA 95134

Visit Us Online
visby.com

For additional information, refer to the Visby Medical Sexual Health Test Instructions for Use (www.visby.com/sti-ifu/). A printed copy can be requested from Visby Medical Customer Support at 1-833-468-4729 (1-833-GoVisby) or support@visby.com.

IVD Rx Only

Setup | Prepare the Workspace | Operating Temperature: 55°F (13°C)—91°F (33°C) | ⚠ Place device on a level surface.

A

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.

B

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

C

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

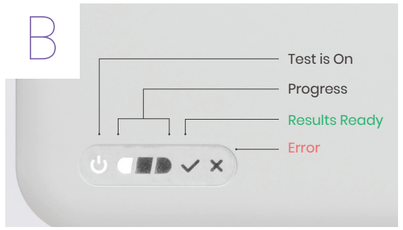
Step 2 | Run the Test | ⚠ Do not move test while running.

A

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.

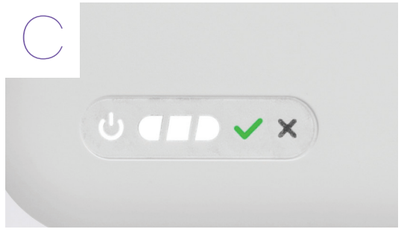
Note: Failure to operate device on a flat surface with the front of the device facing up may lead to invalid or inaccurate results.

B



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

C



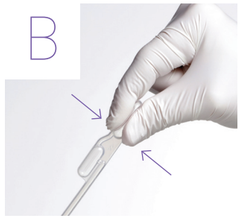
Wait approximately **28 minutes** for a green check mark to appear indicating the test is finished running. **Note:** If a **red X** appears at any point, stop, do not read test results, and retest.

Step 1 | Mix and Add Patient Sample

A

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

B

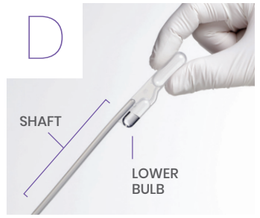


Squeeze the **upper bulb** of the provided pipette and submerge the tip to the **bottom** of the sample tube.

C

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

D



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

E

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.

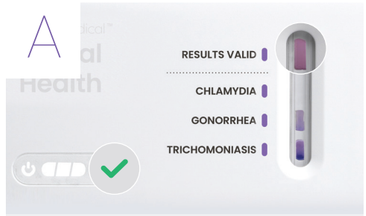
F

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

Step 3 | Interpret Results | ⚠ If the test is invalid, stop, and retest!

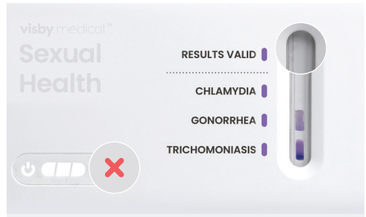
Determine if the test is valid.

A



Green check **and** purple spot next to "Results Valid" = **Valid Test**

Read Results

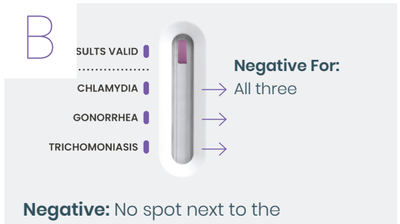


Red X **or** no purple spot next to "Results Valid" = **Invalid Test**

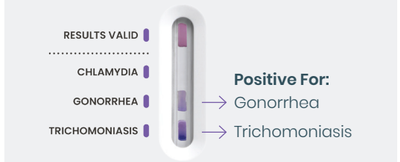
Stop and Retest

Read the test results.

B



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.

Intensity of the spot may vary. Any shade of color with distinct edges should be considered positive.

Note: Results may be read up to 2 hours after the test is completed. Do not read results if test is invalid.

Important Information

The Visby Medical Sexual Health Test is for the qualitative detection of *Chlamydia trachomatis* (CT), *Neisseria gonorrhoeae* (NG), and *Trichomonas vaginalis* (TV). It should only be used with the **Visby Medical Sexual Health Vaginal Specimen Collection Kit** (sold separately). Please refer to the Self-Collection Instructions and Instructions for Use for more information.

Users should read the complete test procedure and recommended quality control procedure before performing the test. Please refer to the Instructions for Use for more information.

Color-blind individuals may be unable to differentiate between status light colors. They may consult the light location and shape of the light to determine test status.

Retest

1. Confirm patient sample has not exceeded the 4 hour stability window at room temperature or refrigerated. If more than 4 hours has elapsed, collect a new sample.
2. Repeat test with a new device and pipette beginning with the Setup step.
3. If the retest continues to return an invalid result, collect a new sample and repeat the test with a new device and pipette beginning with the Setup step. If the repeat test fails, please contact Visby Medical Customer Support at **1-833-468-4729 (1-833-GoVisby)**.

Storage Specifications

Patient Samples*

ROOM TEMPERATURE	REFRIGERATED
up to **4 hours** between **64°F - 86°F** (18°C - 30°C)	up to **4 hours** between **36°F - 46°F** (2°C - 8°C)

*See the Instructions for Use for preparation of refrigerated samples

Visby Medical Sexual Health Tests & Vaginal Specimen Collection Kits (unused and in original packaging)

TEMPERATURE	HUMIDITY
36°F (2°C) – 86°F (30°C)	5% – 80%

Do Not Freeze

Operating Conditions

Run the test on a clean, level surface. Test samples within four hours of collection.

TEMPERATURE	HUMIDITY	PRESSURE
55°F (13°C) – 91°F (33°C)	5% – 80%	-300ft 102.5kPa – 9500ft 71kPa

Disposal

Dispose the device, pipette, and specimen collection kit according to your institution's standard practices.

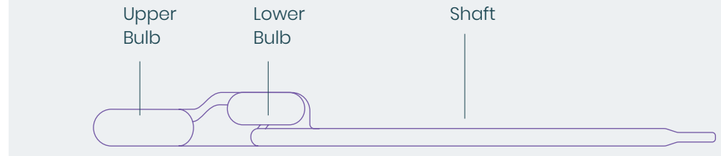
Quality Control

External controls should be run using the same step-by-step instructions provided in this guide. The controls must be tested once with each new shipment received and once for each untrained operator. Please refer to the Instructions for Use for more information on running external quality controls.

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).**

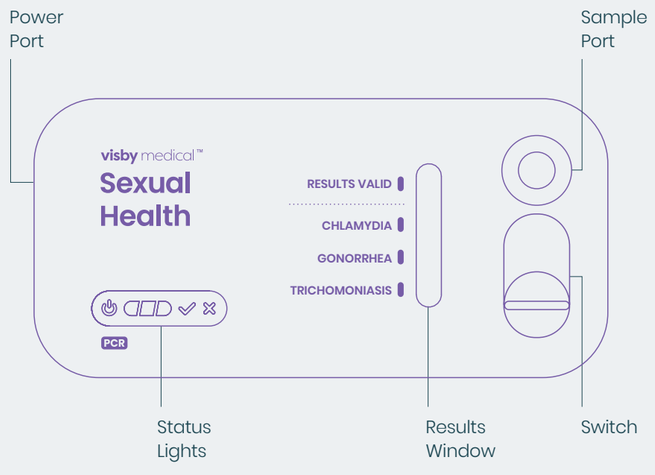
EXTERNAL POSITIVE AND NEGATIVE CONTROLS
NATtrol™ *Chlamydia trachomatis* (CT), *Neisseria gonorrhoeae* (NG), *Trichomonas vaginalis* (TV) Controls by ZeptoMetrix Corporation.

Product Code	Unit	Control Key
NATtrol™ CT/NG/TV Positive Control SKU: NATCTNGTV-POS-IVD	**Six (6) x** 1 mL Vials per Kit	Valid Positive Control Run
NATtrol™ CT/NG/TV Negative Control SKU: NATCTNGTV-NEG-IVD	**Six (6) x** 1 mL Vials per Kit	Valid Negative Control Run



Materials Provided and Required

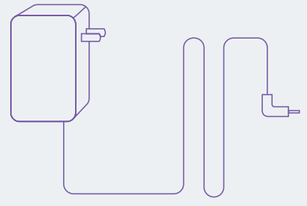
Materials Provided



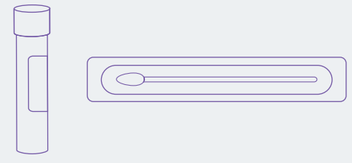
Visby Medical Sexual Health Test

Visby Fixed Volume Pipette (650 µL)

Available as Accessories

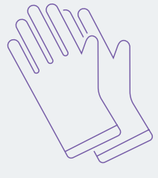


Visby Power Adaptor

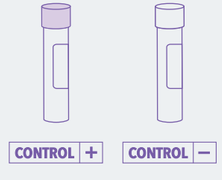


Visby Medical Sexual Health Vaginal Specimen Collection Kit

Not Provided



Gloves



External Controls

IVD Rx Only