

Laboratory Name:	
Laboratory Address:	
Date:	

Visby Medical Sexual Health Test - CLSI Procedure

This CLSI test procedure template is intended to provide an outline reference for the procedure and performance of the Visby Medical Sexual Health Test. This document is not intended to replace the complete Instructions for Use. Any modifications to this document are the sole responsibility of the Organization described in the table above.

1. Intended Use

The Visby Medical Sexual Health Test is a single-use (disposable), fully-integrated, automated Polymerase Chain Reaction (PCR) in vitro diagnostic test intended for use in point-of-care or clinical laboratory settings for the rapid detection and differentiation of DNA from *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, and *Trichomonas vaginalis* in self-collected female vaginal swab specimens using the Visby Medical Sexual Health Vaginal Specimen Collection Kit in a health care setting. The test results are to aid in the diagnosis of symptomatic or asymptomatic infections with *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, and *Trichomonas vaginalis*.

2. Principles of the Procedure

The Visby Medical Sexual Health Test is a single-use (disposable), fully integrated, rapid, compact device containing a PCR-based assay for direct qualitative detection and differentiation of DNA from CT, NG, and TV. The test system includes the Visby Medical Sexual Health device, the Visby Medical power supply, the Visby Medical Vaginal Collection kit, and fixed-volume transfer pipettes. The device processes a vaginal swab sample by automatically performing all steps required to complete lysis, polymerase chain reaction, and amplicon detection. The patient uses the Visby Medical Vaginal Collection Kit to self-collect a vaginal specimen with the provided flocked swab, and then the patient elutes the specimen into the Visby Medical Collection Media. The test operator transfers the collection media containing the patient specimen into the sample port of the device using the provided fixed-volume pipette where it rehydrates a lyophilized internal process control. The sample enters a lysis module, where the DNA of the sample and the internal process control are extracted using a combination of chemical lysis and high temperature. The extracted DNA enters a mixing chamber where it rehydrates lyophilized PCR reagents, followed by thermocycling to amplify target DNA. If present, the amplified pathogen target (CT, NG, and/or TV) and internal process control hybridize to specific probes located on a flow channel. Detection of the target-specific PCR product is accomplished via an enzyme-linked colorimetric assay using streptavidin bound horseradish peroxidase (HRP) and a colorimetric substrate that forms a purple precipitate. Test results can be expected in approximately 30 minutes: a green check mark will appear, and a purple color will appear in the "Control" spot, indicating a valid test. A purple spot adjacent to "Chlamydia," "Gonorrhoeae," and/or "Trichomonas" signifies the presence of amplified CT, NG, and/or TV DNA in the sample.

3. Specimen Collection and Handling

Specimen Type	Female vaginal swab specimens self-collected in clinical settings, using the Visby Medical Sexual Health Vaginal Specimen Collection Kit
Patient Sample Storage Specifications	For best results, patient collected samples should be tested as soon as possible. If storage is required, specimens can be held at: 4 hours at refrigerated to room temperature 36°F - 86°F (2°C-30°C) or 90 days at frozen temperature at less than 5°F (-15°C)

4. Materials

Materials Provided in 10 pack Test Kit	10 Visby Medical Sexual Health Devices 12 Visby Pipettes (650 µL) 1 Quick Reference Guide 1 Instructions for Use (digital)
Materials Required and Available as Accessories	Visby Power Adapter Visby Medical Sexual Health Vaginal Specimen Collection Kit
Required but Not Supplied	<ul style="list-style-type: none">- NATrol™ Chlamydia trachomatis (CT), Neisseria gonorrhoeae (NG), Trichomonas vaginalis (TV) controls by ZeptoMetrix Corporation:<ul style="list-style-type: none">● Positive Control Packs: Catalog # NATCTNGTV-POS-IVD● Negative Control Packs: Catalog # NATCTNGTV-NEG-IVD- Absorbent Pads- Hazardous Waste Disposal Bin

5. Test Kit Storage

Store the Visby Medical Sexual Health Test kit between 36°F and 86°F (2°C and 30°C), and 5% and 80% humidity. Do not freeze. If exposed to cold temperatures, ensure that the Visby Medical Sexual Health device is allowed to come to room temperature (at least 55°F [13°C]) prior to use.

6. Quality Control

Internal Procedural Controls

The Visby Medical Sexual Health Test has built-in procedural controls. The results of the procedural controls are displayed in the results window and status areas with each test result.

The Visby Medical Sexual Health device contains an internal process control. If all elements in the device are functioning properly, then the Control spot will produce color. The internal process control monitors effective sample preparation, PCR amplification, and detection. Additionally, there is an electronic control mechanism that detects hardware, software, and various user error failures. If this electronic control passes, a green check mark status light appears. If this electronic control fails, a red “X” status light appears. A valid test requires a green check mark status light AND a purple spot next to the “Control” in the Results window.

At a very low frequency, patient samples can contain inhibitors that may generate invalid results.

External Positive and Negative Controls

External Controls are available separately from ZeptoMetrix. These controls must be run once with each new shipment of kits and once for each new 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.

7. Test Procedure

Please follow these instructions carefully. This test is designed for use by health care professionals.

Operating Conditions

TEMPERATURE 55°F - 91°F (13° - 33°C)	HUMIDITY 5%-80%	PRESSURE - 300ft - 9500ft 102.5 kPa – 71 kPa	Run the test on a clean, level surface. Test samples within four hours of collection.
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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

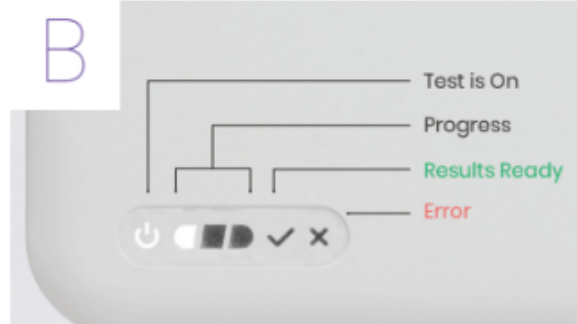
Run
the Test

⚠ 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.

Step 3

Interpret Results

⚠ If the test is invalid, stop, and retest!

Determine if the test is valid.

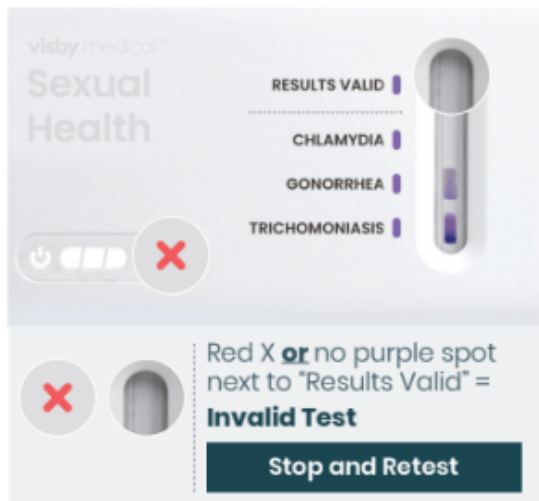


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Sexual Health

RESULTS VALID | [Purple Spot] ✓
CHLAMYDIA | [Purple Spot]
GONORRHEA | [Purple Spot]
TRICHOMONIASIS | [Purple Spot]

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

Read Results



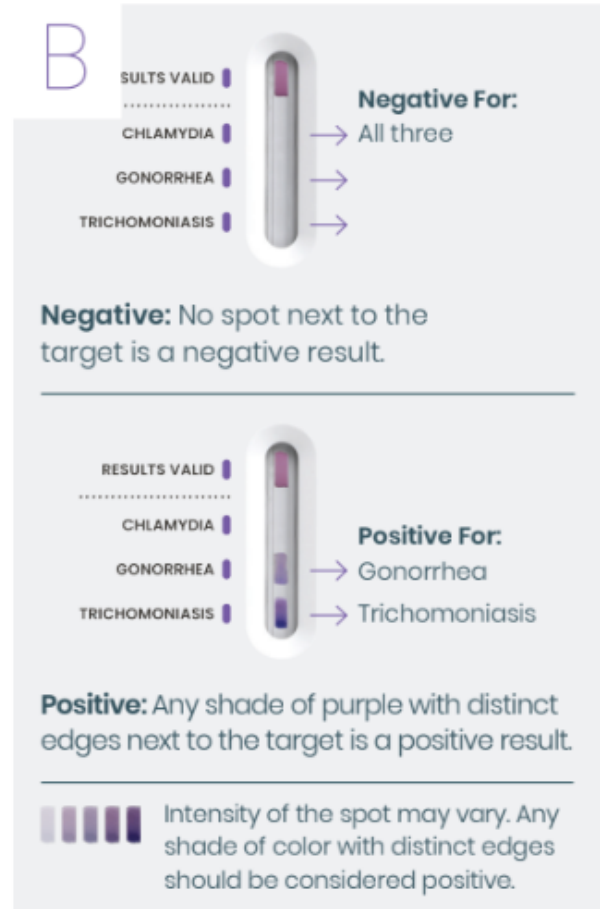
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RESULTS VALID | [No Spot] ✗
CHLAMYDIA | [Purple Spot]
GONORRHEA | [Purple Spot]
TRICHOMONIASIS | [Purple Spot]

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

Stop and Retest

Read the test results.



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RESULTS VALID | [Purple Spot] ✓
CHLAMYDIA | [Purple Spot] →
GONORRHEA | [Purple Spot] →
TRICHOMONIASIS | [Purple Spot] →

Negative For: All three

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

RESULTS VALID | [Purple Spot] ✓
CHLAMYDIA | [Purple Spot] →
GONORRHEA | [Purple Spot] →
TRICHOMONIASIS | [Purple Spot] →

Positive For: Gonorrhea, Trichomoniasis

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.

The Visby Medical Sexual Health device, pipette, and Vaginal Specimen Collection Kit should be disposed of in accordance with local regulations.

8. Retest Procedure

The Visby collection media tube includes enough sample volume to perform two retests. If a retest is required, obtain the leftover sample from the Visby collection media tube. Repeat the test with a new Visby Medical Sexual Health device. If the leftover sample has exceeded the storage recommendations (4 hours at room temperature or under refrigeration), or if the sample volume is insufficient, collect a new sample and repeat the test with a new Visby Medical Sexual Health Test.

If the retest continues to return an invalid or red "X" 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 Test. If the repeat test fails, please contact Visby Medical Customer Support at 1-833-468-4729 (1-833-GoVisby).

9. References/Related Documents

Visby Medical Sexual Health Instructions for Use, PS-300648
Visby Medical Sexual Health Quick Reference Guide, PS-000901