

Vaginal Specimen Collection Kit

Instructions for Use

For Use with the Visby Medical Sexual Health Click Test



Collection Kit Name

Visby Medical Sexual Health Vaginal Specimen Collection Kit

Common or Usual Name

Vaginal Specimen Collection Kit

Intended Use

The Visby Medical Sexual Health Vaginal Specimen Collection Kit is designed to collect, preserve, and transport *Chlamydia trachomatis* (CT), *Neisseria gonorrhoeae* (NG), and *Trichomonas vaginalis* (TV) in patient-collected vaginal specimens from symptomatic and asymptomatic women prior to analysis with the Visby Medical Sexual Health Click Test. The Vaginal Specimen Collection Kit is not for home use.

Summary and Explanation of the Procedure

 Consult Visby Medical Sexual Health Click Test Instructions for Use (<https://www.visbymedical.com/sti-click-ifu/>).

Principles of the Procedure

The Visby Medical Sexual Health Vaginal Specimen Collection Kit consists of a flocked swab and a tube containing collection media. After collection of a vaginal specimen, the swab is placed into the collection media tube and gently tapped against the bottom of the tube. The swab is then discarded and the tube returned to the health care provider.

Materials**Provided Materials**

Each 50 pack contains:

Component	Quantity	Description
Swab	50	Individually wrapped, sterile swab
Collection Media	50	Tube containing collection media (3.2 mL)
Self-Collection Instructions	50	Pack of self-collection instructions

Note: Safety Data Sheets (SDS) are available at Visby Medical Customer Support 1-833-468-4729 (1-833-GoVisby).

Materials Required but Not Supplied


- Patient Label
- Visby Medical Sexual Health Click Test

Warnings and Precautions

1. For in vitro diagnostic use. Rx only.
2. Do not apply the collection media directly onto the skin or mucous membranes or take internally.
3. Use the Visby Medical Sexual Health Vaginal Specimen Collection Kit only as directed.
4. Do not insert the swab into the vagina more than approximately 2 inches.
5. Treat all biological specimens, including used Vaginal Specimen Collection Kits, as if capable of transmitting infectious agents. Because it is often impossible to know which may be infectious, all biological specimens should be treated with standard precautions.

Sexual Health

Guidelines for specimen handling are available from the U.S. Center for Disease Control and Prevention and the Clinical Laboratory Standards Institute.^{1,2}

- Take care to avoid cross-contamination during the specimen handling steps. Specimens can contain extremely high levels of organisms.
- Maintain proper storage conditions during specimen shipping to ensure the integrity of the specimen. Specimen stability under shipping conditions other than those recommended has not been evaluated.
- Only patient-collected vaginal swab specimen taken with the Visby Medical Vaginal Specimen Collection Kit should be used with the Visby Medical Sexual Health Click Test.
- Do not collect the sample if the following products have been used within the last 48 hours: douches, washes, lubricants, vaginal wipes, vaginal moisturizers, antiperspirants, deodorants or feminine hygiene spray in the genital area.
- Do not use the Vaginal Specimen Collection Kit if it appears to be damaged or opened.
- The specimen collection media is a clear, colorless, and odorless solution. Do not use if the solution appears discolored or has a strong odor.
- Do not use the Vaginal Specimen Collection Kit past its expiration date.
- The Visby Medical Sexual Health Vaginal Specimen Collection Kit may contain irritants. Do not ingest the contents of the tube. If the contents of the tube are splashed in your eyes,  flush your eyes with water. If the contents splash onto your skin, wash with soap and water. If irritation persists, notify a health care provider.
- If a spill with the Vaginal Specimen Collection Kit occurs, soak up material with an absorbent. Spray the contaminated area and materials with 10% bleach. Wipe down the surface so that it is saturated with bleach and let rest for at least 10 minutes. Once a minimum of 10 minutes has passed, spray the area with 70% ethyl or isopropyl alcohol and wipe down the surface. Discard the Vaginal Specimen Collection Kit according to the Institution's standard practices. Use a new Visby Medical Sexual Health Vaginal Specimen Collection Kit to collect a new sample.
- Do not dilute patient samples.
- Women who have symptoms suggesting Pelvic Inflammatory Disease (PID) should not use the patient collected swab specimen as a replacement for a pelvic exam.

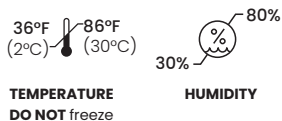
Specimen Collection and Handling

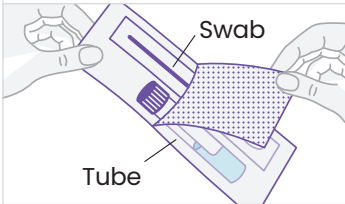
Specimen Collection

Note: Ensure that patients read and understand the Self-Collection Instructions before providing them with the Visby Medical Sexual Health Vaginal Specimen Collection Kit.

All specimens tested with the Visby Medical Sexual Health Click Test must be collected with the Visby Medical Vaginal Specimen Collection Kit and in accordance with the Self-Collection Instructions (provided below).

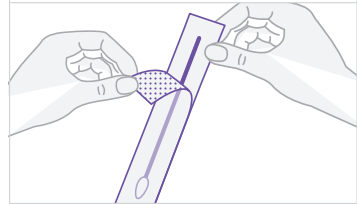
Vaginal Specimen Collection Kit and Sexual Health Click Test Storage Conditions



STEP 1 Open Kit

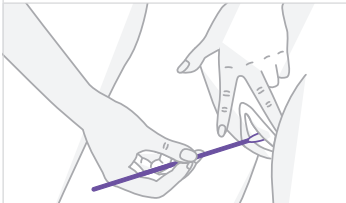
Wash your hands and undress from the waist down.

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

STEP 2 Unwrap Swab

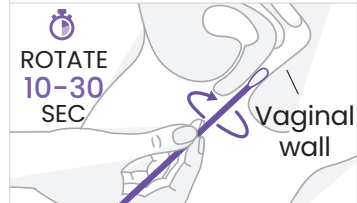
Unwrap the swab.

⚠ 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

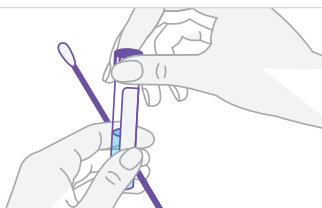
Hold the swab in your hand by placing it between your thumb and your forefinger.

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

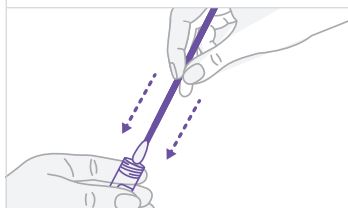
STEP 4 Collect Sample

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

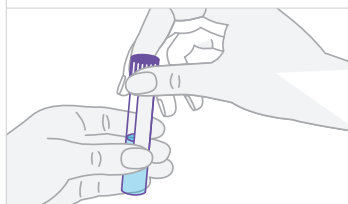
Carefully unscrew the cap ensuring the soft tip of the swab doesn't touch anything. Set the cap down.

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.

Specimen Transport and Storage*Vaginal Specimen Collection Kit*

Store the Vaginal Specimen Collection Kit between 36°F and 86°F (2°C and 30°C), 30% and 80% humidity. Do not freeze.

Specimen

Patient specimens collected with the Vaginal Specimen Collection Kit can be stored at room temperature up to 4 hours between 68°F and 86°F (20°C and 30°C), refrigerated up to 4 hours between 36°F and 46°F (2°C and 8°C), or frozen for up to 90 days at less than 5°F (-15°C).

For refrigerated specimens, ensure the cap is securely tightened. Invert specimen tube at least 5 times to re-suspend any settled specimen particulates or mucus before loading the Visby Medical Sexual Health Click Test.

For frozen specimens, allow the tube to thaw out on the bench top for 1-2 hours prior to use. Once thawed, ensure the cap is securely tightened. Invert specimen tube at least 5 times to re-suspend any settled specimen particulates or mucus before loading the Visby Medical Sexual Health Click Test.

Note: Specimens should be labeled and shipped in compliance with applicable state, federal, and international regulations covering the transport of clinical specimens and etiologic/infectious substances. Time and temperature conditions for storage must be maintained during transport.















Limitations

1. Use the Visby Medical Sexual Health Vaginal Specimen Collection Kit only with the Visby Medical Sexual Health Click Test. Performance has not been established with other products.
2. The performance of the Vaginal Specimen Collection Kit has not been evaluated in women less than 14 years of age.
3. The Vaginal Specimen Collection Kit application is limited to clinical settings where support and counseling are available to explain the procedures and precautions.

References

1. Centers for Disease Control and Prevention. Biosafety in microbiological and biomedical laboratories. 5th Edition.
2. CLSI Publication M29. Protection of laboratory workers from occupationally acquired infections; Approved Guideline. 4th Edition.

Index of Symbols

Symbol	Symbol Title (ISO 15223-1 Reference No.)
	Sterilized using ethylene oxide (5.2.4)
	Catalog Number (5.1.6)
	Do not reuse (5.4.2)
	Fragile, Handle with care (5.3.1)
	Batch code (5.1.5)
	Prescription Use Only (21 CFR 801.109)
	Caution (5.4.4)
	Consult instructions for use (5.4.3)
	Manufacturer (5.1.1)
	Use by date (5.1.4)
	Temperature limitation (5.3.7)
	Humidity limitation (5.3.8)
	In vitro diagnostic medical device (5.5.1)
	Do not use if package is damaged (5.2.8)



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