

WARNINGS AND PRECAUTIONS

IVD

- For In Vitro Diagnostic Use
- FOLLOW ALL INSTRUCTIONS in the Instructions for Use. If you do not follow the instructions, your result could be incorrect.
- Keep out of reach of children under 14 years old.
- DO NOT USE the simpli-COLLECT™ Swab Collection Kit if the kit is damaged, the kit box is open, or if the kit is leaking. **DISCARD UNUSED, DAMAGED, OR LEAKING KITS** in accordance with local, state, and federal regulations.
- DO NOT USE the simpli-COLLECT Swab Collection Kit if the kit is beyond its **EXPIRATION DATE**. Use of expired kits can lead to incorrect results.
- PREGNANT WOMEN should not use the simpli-COLLECT Swab Collection Kit without first discussing with their healthcare provider.
- The sample tube with liquid buffer contains detergent. The liquid in the tube may cause skin or eye irritation. If the liquid comes in contact with your skin or eyes, rinse with water for several minutes. Remove contact lenses, if present and easy to do, and continue rinsing. If irritation continues, seek medical advice.
- Protective eyewear is recommended while using this kit.
- Wash hands thoroughly after handling.
- Do not ingest.
- Avoid contact with skin and eyes.
- Only use the swab provided with the simpli-COLLECT Swab Collection Kit.
- A negative test result does not preclude the possibility of infection with other pathogens.
- The test system is not a substitute for visits to a healthcare provider. The information provided by the product should not be used to start, stop, or change any course of treatment unless advised by a healthcare provider.
- Anyone with recent sexual contact with a person known to have a sexually transmitted infection should visit a healthcare provider for treatment and evaluation as soon as possible (refer to the CDC website at www.cdc.gov/std/).
- Contact a healthcare provider prior to collecting the sample if the user has a condition that makes it difficult to use the test (e.g., problems with vision, handling the test components, or understanding test instructions or results).
- Accurate results are dependent on adequate product storage and adherence to the specimen collection and testing procedures.
- Failure to follow test procedures can lead to incorrect results.

KEY TO SYMBOLS	
	Reference Number
	Do Not Re-use
	Temperature Limit
	Expiration Date
	Consult Instructions for Use or Consult Electronic Instructions For Use
	Peel Open Here
	Do Not Use If Package Is Damaged and Consult Instructions For Use
	Important Information
	Produced By
	Lot Number
	Recyclable
	Polyethylene Terephthalate
	Sterilized Using Irradiation
	Specimen Collection Swab
	Do Not Pre-Wet Swab
	Biological Risks
	Store At
	Unique Kit Identifier
	Authorized Representative in the European Community/European Union
	Manufacturer

KEY TO SYMBOLS	
	In Vitro Diagnostic Medical Device
	In Vitro Test
	For In Vitro Diagnostic Use
	For Prescription Use Only
	Information For USA Only

SAFETY PRECAUTIONS	
The following warnings and precautions apply to: Sample Tube with Liquid Buffer	
H320	Causes eye irritation.
Prevention	
P264	Wash hands thoroughly after handling.
Response	
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337+P313	If eye irritation persists: Get medical advice/attention.

Items with the recyclable symbol can be recycled. All other components should be disposed of in household trash.

Safety Data Sheets are available at: <https://www.abbott.com/msds.html>

LIMITATIONS OF THE PROCEDURE

- This kit should only be used to collect vaginal swab specimens.
- Pregnant women should not use the simpli-COLLECT Swab Collection Kit without first discussing with their healthcare provider.
- Vaginal swab sampling is not designed to replace cervical exams for diagnosis of female urogenital infections. Patients may have cervicitis, urethritis, urinary tract infections, or vaginal infections due to other causes or concurrent infections with other agents.
- Women who have symptoms suggesting pelvic inflammatory disease (PID) should not use the self-collected vaginal swab specimen as a replacement for a pelvic exam.
- Assay interference may be observed in the presence of gel-based hand sanitizers at concentrations greater than 0.1% in simpli-COLLECT vaginal swab specimens.

SUMMARY AND EXPLANATION OF THE TEST

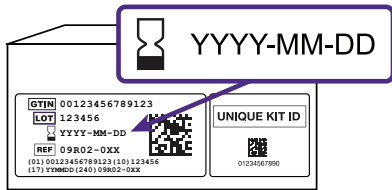
The simpli-COLLECT Swab Collection Kit allows you to self-collect vaginal swab samples (e.g., at home or other setting outside a clinical setting). You will collect your sample and send it to a laboratory that will test for sexually transmitted infections.

This kit is a prescription item. You should contact your healthcare provider for any questions you may have about this kit or about the sexually transmitted infections being tested. For additional information on sexually transmitted infections, refer to the following CDC websites:

- Sexually Transmitted Infections (STI): www.cdc.gov/std/
- Fact Sheets on STIs: www.cdc.gov/sti/communication-resources/index.html

EXPIRATION DATE

DO NOT USE the simpli-COLLECT Swab Collection Kit if the kit is beyond its **EXPIRATION DATE**.



TECHNICAL ASSISTANCE

Contact your healthcare provider with questions regarding test results/diagnosis or assistance with obtaining a new kit. Contact your healthcare provider or testing laboratory with questions regarding return shipping.

Refer to the complete simpli-COLLECT STI Test package insert for additional information, available at:

www.molecular.abbott/us/en/home/simpli-collect

TEST PERFORMANCE

In clinical studies, the Alinity m STI Assay demonstrated 98.5% sensitivity (the test's ability to correctly identify an individual with a disease) and 99.3% specificity (the test's ability to correctly identify an individual who does not have a disease) for detection of *Chlamydia trachomatis* (CT), 100.0% sensitivity and 99.7% specificity for detection of *Neisseria gonorrhoeae* (NG), 99.4% sensitivity and 97.8% specificity for detection of *Trichomonas vaginalis* (TV), and 95.4% sensitivity and 98.6% specificity for detection of *Mycoplasma genitalium* (MG).

INTENDED USE

The simpli-COLLECT™ STI Test is a test system intended for in vitro detection and identification of *Chlamydia trachomatis* (CT), *Neisseria gonorrhoeae* (NG), *Trichomonas vaginalis* (TV), and *Mycoplasma genitalium* (MG) in home-collected specimens. The specimens are shipped to a clinical laboratory for testing using the Alinity m STI Assay with the automated Alinity m System for the direct, qualitative detection and differentiation of ribosomal RNA from CT, DNA from NG, ribosomal RNA from TV, and ribosomal RNA from MG to aid in the diagnosis of disease(s) caused by infection from these organisms. The assay may be used to test the following self-collected specimens from symptomatic and asymptomatic individuals for the following analytes:

- CT: vaginal swabs, female urine, and male urine
- NG: vaginal swabs, female urine, and male urine
- TV: vaginal swabs, female urine, and male urine
- MG: vaginal swabs and male urine

The simpli-COLLECT STI Test contains all the necessary components for the self-collection and transport of urine from male and female patients (simpli-COLLECT Urine Collection Kit) or vaginal swabs from female patients (simpli-COLLECT Swab Collection Kit) in their home, or in similar environments. The simpli-COLLECT Collection Kits may also be used to self-collect specimens in a clinic.

STORAGE

Store kit at room temperature (between 59°F to 86°F or 15°C to 30°C). Ensure all test components are at room temperature before use.

After collection, keep sample at room temperature (between 59°F to 86°F or 15°C to 30°C).

Abbott Swab Collection is manufactured for Abbott Molecular Inc. by MML Diagnostics Packaging, Inc., Troutdale, OR 97060 USA.

Abbott Molecular Inc. is the legal manufacturer of the simpli-COLLECT Swab Collection Kit.

Abbott Molecular Inc. is the legal manufacturer of the simpli-COLLECT STI Test.

simpli-COLLECT is a trademark of Abbott. All other trademarks are property of their respective owners.

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simpli-COLLECT™

Swab Collection Kit
Instructions for Use

Need help? Scan here:



www.molecular.abbott/us/en/home/simpli-collect

Read all instructions before you start.

Keep the box. You will use it to send back your sample.

YOU AND YOUR HEALTH COME FIRST,
SO LET'S GET STARTED!

More information on other side of page


Need help? Scan here.
www.molecular.abbott/us/en/home/simpli-collect

UNPACKING YOUR KIT


- Store kit at room temperature (between 59°F to 86°F or 15°C to 30°C) before and after sample collection. Contact your healthcare provider for a new kit if your kit or sample was not stored properly.
- Do not use if box arrived unsealed or if parts are missing or damaged.** Contact your healthcare provider for a new kit.
- Unpack kit on a clean, dry surface.
- If the liquid in the sample tube comes in contact with your skin or eyes, rinse with water for several minutes. Remove contact lenses, if present and easy to do, and continue rinsing. If irritation continues, seek medical advice.

- Locate the return mailing label in the mailing pouch your kit arrived in. Please contact the return mailing service to arrange a pickup, or find a drop off point before you collect your sample so that you can **mail your sample to the laboratory within 24 hours.**


KIT CONTENTS




SAMPLE TUBE WITH LIQUID BUFFER




SWAB
Do not open until instructed




TUBE AND CAP HOLDER



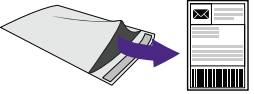
BIOHAZARD BAG



TUBE AND BAG LABEL SHEET




RETURN BOX
(Same box your kit arrived in)




RETURN MAILING LABEL
(Provided in mailing pouch your kit arrived in)

BEFORE STARTING


Read and understand the instructions before using the kit.
If you do not follow the instructions, your result could be incorrect.



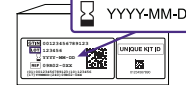
Make sure you can mail your sample within 24 hours.



Do not use if you are pregnant without first discussing with your healthcare provider.




Do not clean genital area immediately before collecting sample.



DO NOT use the kit after the **Expiration Date**. If expired, contact your healthcare provider for a new kit.

1 SETTING UP

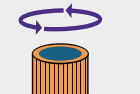
- For this step, you will need:
- Tube (Sample Tube with Liquid Buffer)
 - Tube and Cap Holder



1A

Wash your hands with soap and water. Dry your hands thoroughly.

Do not use hand sanitizer. Hand sanitizer may interfere with the test result.



1B

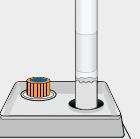
Hold tube upright and unscrew the cap.

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- The tube contains liquid! **Do not remove any liquid from this tube.**
- If your tube has leaked or spilled, contact your healthcare provider for a new kit.

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If the liquid in the tube comes in contact with your skin or eyes, rinse with water for several minutes. Remove contact lenses, if present and easy to do, and continue rinsing. If irritation continues, seek medical advice.



1C

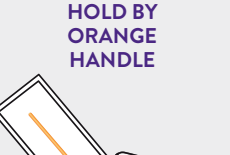
Find the tube and cap holder.

Put the cap within the raised circle and the tube upright in the hole.

2 COLLECTING YOUR SAMPLE

Let's begin! Don't worry, it's easy!
For this step, you will need:

- Swab



2A

Remove the swab from the wrapper with your clean hands. Hold by the orange handle with the white tip up.

HOLD BY ORANGE HANDLE

DO NOT SET SWAB DOWN

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- Do not touch white tip of the swab to anything.
- Do not pre-wet swab with the liquid in the tube before collecting.
- Do not set swab down.

If the white tip is touched or the swab is laid down or dropped, your results may not be accurate.

If this happens, contact your healthcare provider for a new kit.



2B

Undress from the waist down. Find a comfortable position to easily access the opening of your vagina.

Holding the swab with one hand, gently spread the vaginal labia with your other hand.

Insert the white tip of the swab about **2 inches (5 cm)** into the opening of your vagina. Rotate the swab for **15 to 30 seconds**.

Make sure the swab touches the sides of your vagina. Remove the swab from your vagina being careful not to touch your skin.


Do not set the swab down.

DO NOT SET SWAB DOWN AFTER COLLECTION

3 TRANSFER SWAB

For this step, you will need:

- Tube (upright in Tube and Cap Holder)
- Swab



3A

BREAK LINE

With the white tip pointed down, put the swab into the tube.

Snap the orange swab handle by bending the handle against the tube at the break line.


You may need to lift the swab slightly to find the break line.



3B

Throw this top piece of the swab handle away!

The bottom of the swab will remain in the tube.




3C

SCREW ON CAP TIGHTLY

Hold tube upright and recap the tube by screwing the cap clockwise.

When you feel resistance, keep turning about another quarter turn until cap no longer moves.

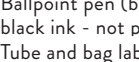


3D

Wash and dry your hands.

4 COMPLETING LABEL INFORMATION

For this step, you will need:



4A


- Ballpoint pen (blue or black ink - not provided)
- Tube (containing swab)
- Biohazard bag
- Tube and bag label sheet

Locate the sample tube label and biohazard bag label in your language.

Use a ballpoint pen to **print** on both labels. Fill out **both labels** with:

- First Name**
- Last Name**
- Date of Birth**
- Date of Collection**

It is important that your writing is legible.

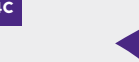


4B

Peel the **sample tube label** off the label sheet and stick it on the **sample tube**.

It is okay to place the label over the existing tube label.

The label **must** be applied to the sample tube or you will not receive a result.



4C

Peel the **biohazard bag label** off the label sheet and stick it on the **biohazard bag**.

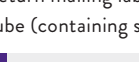
Do not cover the biohazard symbol.

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You will not receive your results if the labels are not filled out correctly!

5 RETURNING SAMPLE

For this step, you will need:




5A

- Return mailing label (provided in mailing pouch)
- Tube (containing swab)
- Biohazard bag
- Return box


Put the tube in the biohazard bag.

Seal the bag completely.




5B

Put the biohazard bag (containing your tube) into the return box.




5C

Peel the self-adhesive tape on box and close the lid to seal the box.



5D

Flip the box over.




5E

Find the return mailing label in the mailing pouch your kit arrived in.

Stick the return mailing label on the bottom of the return box — **do not cover UN3373 label!**

Mail your sample to the laboratory within 24 hours.



5F

Now your sample will travel to the laboratory and be tested.

Talk to your healthcare provider about your results.