

INTENDED USE

The simpli-COLLECT™ Swab Collection Kit is intended for the self-collection and transport of vaginal swabs for in vitro diagnostic testing. Swabs may be collected and prepared for transport in a healthcare or non-healthcare environment by a lay user.

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.
- 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.

WASTE COLLECTION GUIDELINES: PAPER COLLECTION AND PLASTIC COLLECTION		
Packaging Material	Symbol	Definition
Return Box Outer Wrap	21 PAP	Mixed Paper
Tube and Cap Holder	1 PETE	Polyethylene terephthalate
Sample Tube Packaging	22 PAP 7 OTHER	Plain Paper and Ethylene-vinyl acetate (EVA)
Swab Packaging	22 PAP	Plain Paper
Instructions for Use	22 PAP	Plain Paper
Mailing Pouch	4 LDPE	Low-density polyethylene
Tube and Bag Label Sheet	22 PAP	Plain Paper

Items with the recyclable symbol can be recycled. Follow your national, regional, and local ordinances accordingly for waste disposal regulations.

KEY TO SYMBOLS	
	Exclamation Mark
	In Vitro Diagnostic Medical Device
	In Vitro Test
	Reference Number
	Do Not Re-use
	Temperature Limit
	Expiration Date
	Consult Instructions for Use
	Peel Open Here
	Do Not Use If Package Is Damaged and Consult Instructions for Use
	Important Information
	Swab
	Sample Tube with Liquid Buffer
	Global Trade Item Number
	Produced By
	Lot Number
	Sterilized Using Irradiation
	Specimen Collection Swab
	Biological Risks
	Store At
	Unique Kit Identifier
	Authorized Representative in the European Community/European Union
	Manufacturer

SUMMARY AND EXPLANATION OF THE TEST

The simpli-COLLECT™ Swab Collection Kit allows you to self-collect vaginal swab specimens without supervision (e.g., home or other setting outside a clinical setting).

You will collect and transfer the specimen to the sample tube and return it to the laboratory for analysis.

WARNINGS AND PRECAUTIONS

- FOLLOW ALL INSTRUCTIONS** in the Instructions for Use. If you do not follow the instructions, your result may 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 seal on the kit is broken, or if the kit is leaking. **DISCARD UNUSED, DAMAGED, OR LEAKING KITS** in accordance with national, regional and local ordinances.
- DO NOT USE** the simpli-COLLECT Swab Collection Kit if the kit is beyond its **EXPIRATION DATE**
- DO NOT USE** the simpli-COLLECT Swab Collection Kit if **PREGNANT**.
- Only use the swab provided in the simpli-COLLECT Swab Collection Kit.
- The sample tube with liquid buffer contains detergent.** The liquid in the tube may cause serious eye irritation and mild skin irritation. If the liquid comes in contact with your eyes or skin, rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do, and continue rinsing. If irritation continues, seek medical advice. **WARNING:** Causes mild skin irritation. Causes serious eye irritation.
- Do not ingest.
- Avoid contact with skin and eyes.

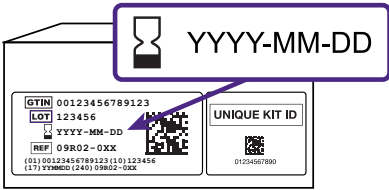
STORAGE

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

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

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 return shipping, test results/diagnosis, or assistance with obtaining a new kit.

If you need support on how to use or store this product please visit:

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



SAFETY PRECAUTIONS

IVD For In Vitro Diagnostic Use

The following warnings and precautions apply to: Sample Tube with Liquid Buffer	
Warning	
H319	Causes serious eye irritation.
H316	Causes mild skin 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.
P332+P313	If skin irritation occurs: Get medical advice/attention.*
P337+P313	If eye irritation persists: Get medical advice/attention.

*Not applicable where regulation EC 1272/2008 (CLP) has been implemented.

Safety Data Sheets are available at:
www.molecular.abbott/int/en/home/simpli-collect

Abbott Sample 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.

The simpli-COLLECT™ Swab Collection Kit is imported into the European Union by Abbott Diagnostics GmbH, located at Max-Planck-Ring 2, 65205 Wiesbaden, Germany.

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EC REP Abbott GmbH
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simpli-COLLECT™

Swab Collection Kit
Instructions for Use

Need help? Scan here:



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

Read all instructions before you start.
Keep the box. You will use it to send back your sample.



en
REF 09R02-005
and higher
53-608481/R2

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

More information on other side of page



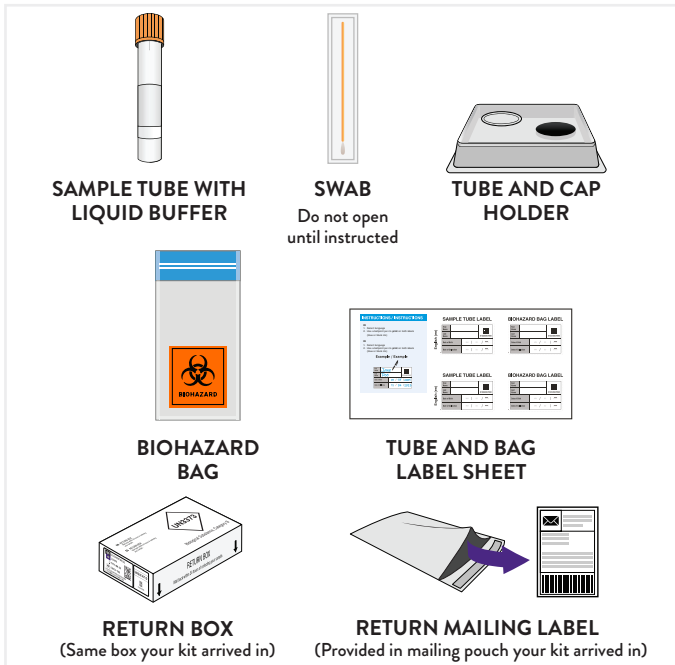
Need help? Scan here.

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

UNPACKING YOUR KIT

- Read and understand the instructions before using the kit. **If you do not follow the instructions, your result may be incorrect.**
- Store kit at room temperature (between 15°C to 30°C or 59°F to 86°F) before and after sample collection.
- 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.
- The liquid in the tube can cause irritation if it comes into contact with your eyes or skin. Read the warning section on the back of these instructions.
- For questions about this kit, refer to the Technical Assistance section on the back of these instructions.

KIT CONTENTS



BEFORE STARTING

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



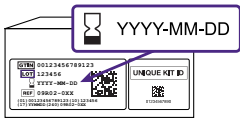
Make sure you can mail your sample within 24 hours.



Do not use if you are pregnant.



Do not clean genital area immediately before collecting sample.



Make sure you use the kit before the **Expiration Date**.

1 SETTING UP

For this step, you will need:

- Tube (Sample Tube with Liquid Buffer)
- Tube and Cap Holder

1A

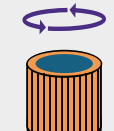


Wash and dry your hands.

Do not use hand sanitizer.

1B

UNSCREW CAP

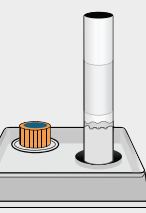


Hold tube upright and unscrew the cap.

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- The tube contains liquid! **Do not remove any liquid from this tube.**
- If your tube has leaked, shows signs of leaking (such as dried powder around the cap), or liquid is spilled, contact your healthcare provider to order a new kit.

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

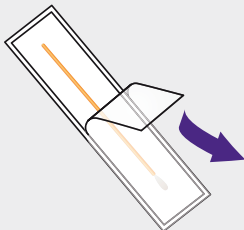
Let's begin! Don't worry, it's easy!

For this step, you will need:

- Swab

2A

HOLD BY ORANGE HANDLE



Peel open swab packet and hold by orange swab handle.

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- Do not touch white tip.
- Do not pre-wet swab.
- Do not set swab down.

DO NOT SET SWAB DOWN

While using the swab, try not to touch the white tip of the swab to anything except the inside of your vagina.

2B



DO NOT SET SWAB DOWN AFTER COLLECTION

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Do not clean genital area immediately before swabbing.

Find a comfortable position to easily access the opening of your vagina.

Hold swab with one hand. With the other hand, move the folds of skin (labia) out of the way to access the opening of your vagina.

Gently insert white tip of swab about 2 inches (5 cm) into your vagina.

Gently rotate swab for **15-30 seconds** (make sure swab touches the walls of your vagina).

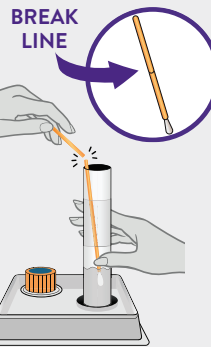
Carefully remove swab.
Do not set swab down.

3 TRANSFER SWAB

For this step, you will need:

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

3A

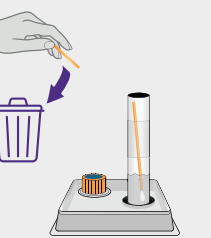


With the white tip pointed down, put the swab into the tube.

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.

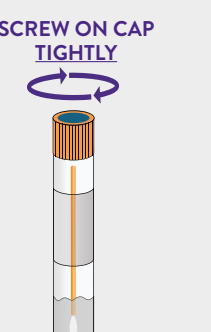
3B



Throw this top piece of the swab handle away!

The bottom of the swab will remain in the tube.

3C



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



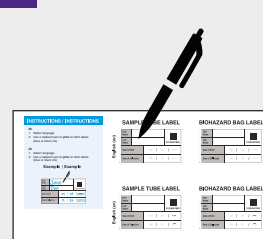
Wash and dry your hands.

4 COMPLETING LABEL INFORMATION

For this step, you will need:

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

4A

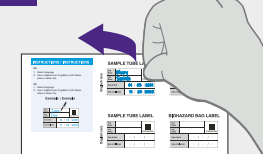


Locate the sample tube label and biohazard bag label in your language.

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

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

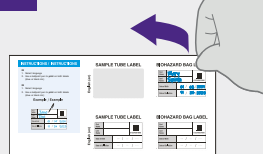
4B



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.

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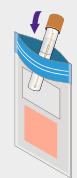
You may not receive your results if the labels are not filled out correctly!

5 RETURNING SAMPLE

For this step, you will need:

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

5A



Put the tube in the biohazard bag.

Seal the bag completely.

5B



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

5C



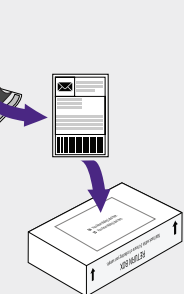
Peel the self-adhesive tape on box and close the lid to seal the box.

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.

CONGRATULATIONS! You've finished your part. Now your sample will travel to the laboratory and be tested. Talk to your healthcare provider about your results.

