

simpli-COLLECT™ HPV Collection Kit

REF 09R16-001

53-608542/R1

Created September 2025

REF 09R16-001

53-608542/R1



CUSTOMER SERVICE: 1-800-553-7042

CUSTOMER SERVICE INTERNATIONAL: CALL YOUR ABBOTT REPRESENTATIVE

Instructions must be carefully followed. Reliability of results cannot be guaranteed if there are any deviations from these instructions.

NAME

simpli-COLLECT™ HPV Collection Kit

INTENDED USE

The simpli-COLLECT HPV Collection Kit is intended for the self-collection and transportation of vaginal swab specimens for testing with the Alinity m HR HPV assay.

Refer to the Alinity m HR HPV assay package insert for additional information.

The simpli-COLLECT HPV Collection Kit is not intended for home use.

SUMMARY AND EXPLANATION OF THE TEST

The simpli-COLLECT HPV Collection Kit allows patients to self-collect vaginal swab specimens in a clinical setting. The kit contains an Alinity m Sample Tube and an individually packaged sterile specimen collection swab. The patient collects the vaginal swab specimen and transfers the specimen to the Alinity m Sample Tube. The simpli-COLLECT HPV Collection Kit can only be used to self-collect a vaginal swab specimen.

CONTENTS

Kit Contents

simpli-COLLECT HPV Collection Kit

List No. 09R16-001

Each non-reusable simpli-COLLECT HPV Collection Kit contains the following:

- One Alinity m Sample Tube
- One Sterile Specimen Collection Swab

Component	Quantity
simpli-COLLECT HPV Collection Kit	50 individually-wrapped simpli-COLLECT HPV Collection Kits per box, 10 boxes per case

WARNINGS AND PRECAUTIONS

IVD

- **For In Vitro Diagnostic Use Only**
- Follow all instructions in this package insert.
- Do not use the simpli-COLLECT HPV Collection Kit if the package is damaged or if the seal is broken. Discard unused or damaged kits in accordance with local, state, and federal regulations.
- Do not use the simpli-COLLECT HPV Collection Kit beyond its expiration date.
- Wear disposable gloves while handling specimens and wash hands thoroughly afterward. Use of protective eyewear is recommended.
- Optimal performance of the Alinity m HR HPV assay requires adequate specimen collection and handling. Ensure the outside of the transport tube and cap are not contaminated. Refer to the Alinity m HR HPV assay package insert for additional information.
- Use only the orange shaft swab provided in the simpli-COLLECT HPV Collection Kit for collecting swab specimens. The swab must remain in the Alinity m Sample Tube after specimen collection. Do not place multiple swabs in the Alinity m Sample Tube.
- The effects of factors such as vaginal discharge, use of tampons, douching, or specimen collection variables have not been determined.

- Decontaminate and dispose of all specimens, reagents, and other potentially contaminated materials in accordance with local, state, and federal regulations.^{1,2}
- The simpli-COLLECT HPV Collection Kit is a single use device. Reuse of the device or patient contact with a previously used swab could potentially expose the patient to infectious organisms.
- Avoid touching the blue top of the Alinity m Pierceable Cap to prevent potential contamination.
- Ensure that the Alinity m Pierceable Cap seals tightly to prevent potential contamination.
- Follow the specimen collection procedures. Remove the cap before placement of the specimen collection swab into the transport tube. Do not push a specimen collection swab through the cap.

Safety Precautions

The following warnings and precautions apply to: simpli-COLLECT HPV Collection Kit.

CAUTION: This product requires the handling of human specimens. It is recommended that all human sourced materials be considered potentially infectious and handled with appropriate biosafety practices. This product is not considered hazardous by the criteria in 29 CFR 1910.1200 or the General Classification guideline for preparations of the EU.

Storage

	Storage Temperature	Maximum Storage Time
Unopened	15°C to 30°C	Until expiration date

PROCEDURE

Materials Provided

50 individually-wrapped simpli-COLLECT HPV Collection Kits per box, 10 boxes per case (List No. 09R16-001).

Other Materials Required But Not Provided

- Adhesive labels for sample identification information

SPECIMEN COLLECTION PROCEDURES

Self-Collected Vaginal Swab Specimen Collection

Instructions for self-collected vaginal swab specimens are provided in Appendix A.

Specimen Storage

After collection, store transport tube at 2°C to 8°C for up to 14 days or at 15°C to 30°C for up to 8 days.

Specimen Shipping

Vaginal specimens collected using the simpli-COLLECT HPV Collection Kit may be shipped (up to 7 days) and then stored at 2°C to 8°C for a total (including shipping time) of 14 days or at 15°C to 30°C for a total (including shipping time) of 8 days before resuspension in specimen buffer. Specimens must not exceed the maximum storage time listed in the **Specimen Storage** section prior to testing. For domestic or international shipments, specimens should be packaged and labeled in compliance with applicable state, federal, and international regulations covering the transport of clinical, diagnostic, or biological specimens.

LIMITATIONS OF THE PROCEDURE

- **FOR IN VITRO DIAGNOSTIC USE**
- Optimal performance of this kit requires appropriate specimen collection, handling, preparation, and storage (refer to the **SPECIMEN COLLECTION PROCEDURES** and **Appendix A** sections of this package insert).
- This kit should only be used to self-collect vaginal swab specimens. Refer to the Alinity m HR HPV assay package insert for more information.
- The self-collected vaginal swab specimen application is limited to health care facilities where support and counseling is available to explain the procedures and precautions.
- Pregnant women should not use the simpli-COLLECT HPV Collection Kit.

BIBLIOGRAPHY

1. Clinical and Laboratory Standards Institute (CLSI). *Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline—Fourth Edition*. CLSI Document M29-A4. Wayne, PA: CLSI; 2014.
2. US Environmental Protection Agency. *EPA Guide for Infectious Waste Management*. US Environmental Protection Agency, 1986:1-1–5-5, R1-R3, A1-A24. Publication No. EPA/530-SW-86-014.

KEY TO SYMBOLS

REF	Reference Number
LOT	Lot Number
IVD	In Vitro Diagnostic Medical Device
In Vitro Test	In Vitro Test
For In Vitro Diagnostic Use	For In Vitro Diagnostic Use
R_x ONLY	Prescription Use Only
PRODUCED BY	Produced By
UNIT	Unit
SAMPLE TUBE	Sample Tube
SWAB	Swab
	Do Not Use if Package is Damaged
	Peel Open Here
	Do Not Reuse
STERILE R	Sterilized Using Irradiation
	Temperature Limit
	Use By
	Consult Instructions for Use or Electronic Instructions for Use
	Manufacturer

TECHNICAL ASSISTANCE

For technical assistance, call Abbott Technical Services at 1-800-553-7042 (within the US), or +49-6122-580 (outside the US) or visit the Abbott website at www.molecular.abbott.

The simpli-COLLECT HPV Collection Kit 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 HPV Collection Kit.

MML Diagnostics Packaging, Inc. is the legal manufacturer of the Specimen Collection Swab.



Abbott Molecular Inc.
1300 East Touhy Avenue
Des Plaines, IL 60018 USA

©2025 Abbott. All Rights Reserved.

Alinity is a trademark of Abbott. simpli-COLLECT is a trademark of Abbott. All other trademarks are property of their respective owners.
53-608542/R1

simpli-COLLECT™ HPV Collection Kit

Appendix A: Self-Collected Vaginal Swab Specimen Instructions

REF 09R16-001

53-608542/R1

For In Vitro Diagnostic Use Only

Your kit contains the following:

- One Alinity m Sample Tube
- One Sterile Specimen Collection Swab

CAUTION: DO NOT touch the white tip of the swab or lay the swab down. If the white tip is touched or the swab is laid down or dropped, your results may not be accurate. You need to request a new simpli-COLLECT HPV Collection Kit.

1. SETTING UP

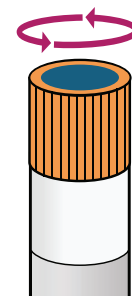
- 1A** Wash and dry your hands



- 1B** Open kit containing tube. Remove tube. Place packaging on a flat surface.

Hold tube upright and remove cap. Place open tube and cap back into packaging.

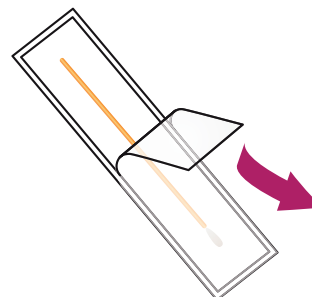
COUNTER CLOCKWISE TO UNCAP



2. COLLECTING YOUR SAMPLE

- 2A** Peel open swab packet and hold by orange swab handle.
- Do not touch white tip.
- While using the swab, try not to touch the white tip of the swab to anything except the inside of your vagina.

HOLD BY ORANGE HANDLE



- 2B** 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 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!**

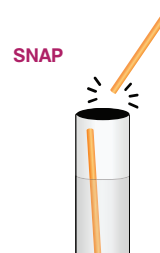


3. TRANSFER SWAB

3A

Hold tube upright. 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

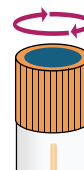
Throw this top piece of the swab handle away!
The bottom of the swab will remain in the tube.



3C

Hold tube upright and recap the tube by turning the cap clockwise. When you feel resistance, **keep turning** about another quarter turn until cap no longer moves.

CLOCKWISE
TO RECAP



3D

Return the transport tube containing the swab to your healthcare provider.

Instructions for use with Alinity m HR HPV assay



The Evalyn® Brush is to be used for the collection of vaginal specimens for use with the Alinity m HR HPV assay. Users should read and carefully follow these instructions. If you have any questions or difficulties with the collection process described below, please ask your healthcare provider for more information. Should unexpected events not described in these instructions occur during self-collection, inform your healthcare provider.

Warnings:

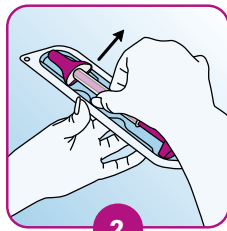
- Inform your healthcare provider if you have used any substances such as vaginal creams, gels, lubricants, etc. within 48 hours prior to collection.
- The brush should not touch any other surface prior to inserting into vagina.
- For single use only.

Do not use:

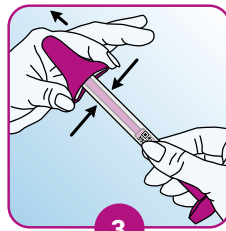
- If the packaging is damaged or if the expiry date has passed
- During menstruation
- During pregnancy or within three months after giving birth
- If you have recently undergone gynecological surgery
- In case of unusual bleeding or pelvic pain



1
Wash your hands before usage.



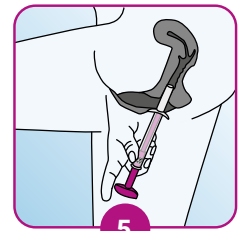
2
Remove the Evalyn Brush from the packaging. Do not throw the packaging away.



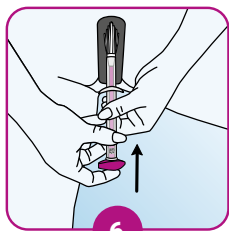
3
Press the sides of the pink cap with your thumb and index finger to remove the pink cap from the Evalyn Brush. Ensure that you do not touch the white brush of the Evalyn Brush with your hands!



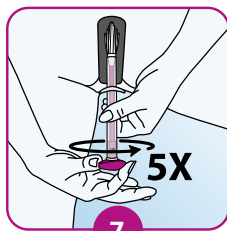
4
Obtain the sample whilst in a standing position. Assume a comfortable stance (e.g. as if you were about to insert a tampon).



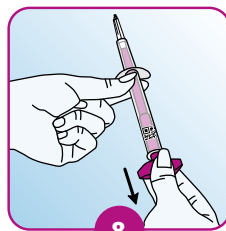
5
Spread your labia with one hand, and with the other, insert the Evalyn Brush into your vagina until the wings touch your labia.



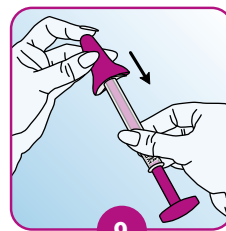
6
Hold the transparent casing with one hand, and with your other hand, push the pink plunger in the direction of the transparent casing. You will hear and feel a click when the brush is in the right position with the pink plunger directly against the casing.



7
Turn the pink plunger five rotations in the same direction. After each rotation, you will hear a click. This helps you count the rotations. After turning the plunger five times, carefully remove the Evalyn Brush.



8
Hold the transparent casing with one hand, and with your other hand, pull on the pink plunger until the white brush disappears into the casing. When doing so, do not touch the top part of the Evalyn Brush above the wings.



9
Hold the transparent end to ensure the white brush does not extend again. Place the pink cap back on the Evalyn Brush using your thumb and index finger. You will hear a click when it is properly in place.



10
Put the Evalyn Brush back inside the packaging. After collection, hand over the brush for processing.



Rovers Medical Devices B.V.
Lekstraat 10, 5347 KV Oss
The Netherlands
T +31 (0)412 648 870
info@roversmedicaldevices.com
www.roversmedicaldevices.com

Rovers® Evalyn®Brush is a patented product and a registered design.

Rovers® and Evalyn®Brush are registered trademarks of Rovers Medical Devices B.V. based in Oss, the Netherlands. Alinity is a registered trademark of Abbott. All rights reserved.

REF 380500131

Abbott p/n : 09R25-001

Version EC-AB-2025-08-US





El cepillo Evalyn® Brush se utiliza para la recogida de muestras vaginales para el uso con las pruebas Alinity m HR HPV. Los usuarios deben leer y seguir atentamente estas instrucciones. Si tiene alguna pregunta o dificultad con el proceso de recogida descrito a continuación, solicite más información a su proveedor de asistencia sanitaria. Si se produce un suceso inesperado no descrito en estas instrucciones durante la toma de muestras, informe a su proveedor de asistencia sanitaria.

Advertencias:

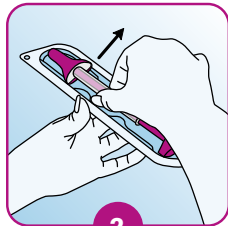
- Informe a su proveedor de asistencia sanitaria si ha utilizado alguna sustancia, como cremas vaginales, geles, lubricantes, etc., en las 48 horas previas a la recogida.
- El cepillo no debe tocar ninguna otra superficie antes de la inserción en la vagina.
- De un solo uso.

No utilizar:

- Si el envase está dañado o si ha pasado la fecha de caducidad
- Durante la menstruación
- Durante el embarazo o en los tres primeros meses tras el parto
- Si se ha sometido recientemente a una cirugía ginecológica
- En caso de hemorragia inusual o dolor pélvico



1
Lávese las manos antes de utilizarlo.



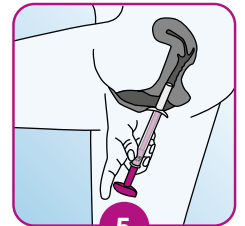
2
Saque el Evalyn Brush del envase. No tire el embalaje.



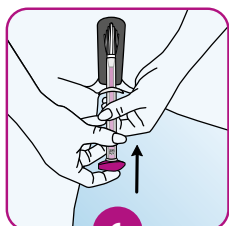
3
Presione los laterales del tapón rosa con el pulgar y el índice para retirarlo del Evalyn Brush. ¡Asegúrese de no tocar las cerdas blancas del Evalyn Brush con las manos!



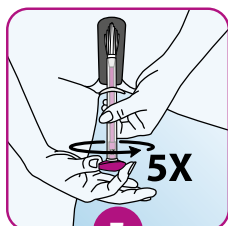
4
Póngase de pie para tomar la muestra. Adopte una postura cómoda (por ejemplo, como si fuera a colocarse un tampón).



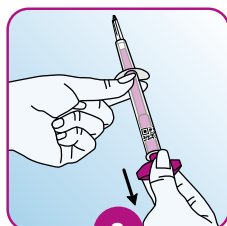
5
Abra los labios de la vulva con una mano, y con la otra, inserte el Evalyn Brush en la vagina hasta que las alas toquen los labios.



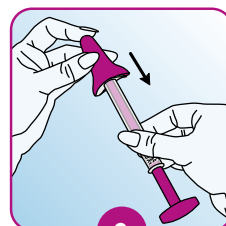
6
Sostenga la envoltura exterior transparente con una mano, y con la otra mano, empuje el émbolo de color rosa en la dirección de la envoltura transparente. Escuchará y notará un clic cuando el cepillo se encuentre en la posición correcta con el émbolo rosa en contacto directo con la envoltura exterior.



7
Gire el émbolo rosa cinco veces en la misma dirección. Después de cada rotación, escuchará un clic. Esto le ayudará a contar las rotaciones. Después de girar el émbolo cinco veces, retire el Evalyn Brush con cuidado.



8
Sostenga la envoltura exterior transparente con una mano, y con la otra mano, tire del émbolo de color rosa hasta que el cepillo blanco desaparezca en la envoltura transparente. Al hacer esto, no toque la parte superior por encima de las alas.



9
Sujételo por el extremo transparente para garantizar que el cepillo blanco no vuelve a salir. Vuelva a colocar el tapón rosa en el Evalyn Brush utilizando el pulgar y el índice. Escuchará un clic cuando encaje correctamente en su sitio.



10
Coloque de nuevo el cepillo Evalyn Brush en el envase. Tras la recogida, entregue el cepillo para el procesamiento.



Rovers Medical Devices B.V.
Lekstraat 10, 5347 KV Oss
The Netherlands
T +31 (0)412 648 870
info@roversmedicaldevices.com
www.roversmedicaldevices.com

El Evalyn®Brush de Rovers® es un producto patentado y un diseño registrado.

Rovers® y Evalyn® son marcas registradas de Rovers Medical Devices B.V. Oss, Países Bajos. Alinity es una marca registrada de Abbott. Todos los derechos reservados.

REF 380500131

Abbott p/n : 09R25-001

Version EC-AB-2025-08-US

