simpli-COLLECT™ HPV Collection Kit

REF 09R16-001
53-608542/R02

Revised December 2025

REF 09R16-001
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℞ ONLY

NOTE: Changes Highlighted

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 up to a total (including shipping time) of 14 days or at 15°C to 30°C for up to 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.

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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
Rx ONLY	Prescription Use Only
MD	Medical Device
PRODUCED BY	Produced By
UNIT	Unit
SAMPLE TUBE	Sample Tube
SWAB	Swab
SPECIMEN COLLECTION SWAB	Specimen Collection Swab
	Do Not Use if Package is Damaged and Consult Instructions for Use
	Peel Open Here
	Do Not Reuse
STERILE R	Sterilized Using Irradiation
	Temperature Limit
	Use By Date
	Consult Instructions for Use or Electronic Instructions for Use
	Date of Manufacture
	Manufacturer
EC REP	Authorized Representative in the European Community/European Union

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.
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Des Plaines, IL 60018 USA

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Appendix A: Self-Collected Vaginal Swab Specimen Instructions

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.

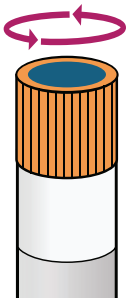
1. SETTING UP

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.

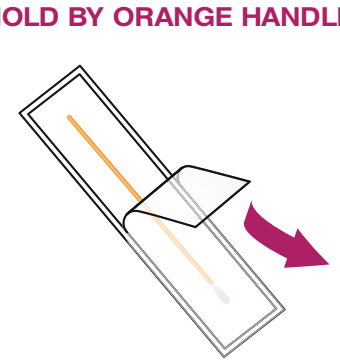


2. COLLECTING YOUR SAMPLE

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.



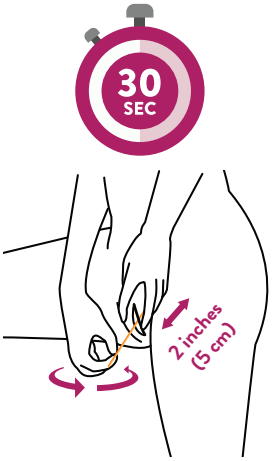
2B Find a comfortable position to easily access the opening of your vagina.

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).

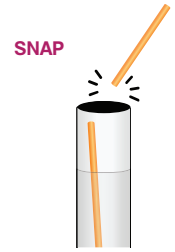
Carefully remove swab. **Do not set swab down!**



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).

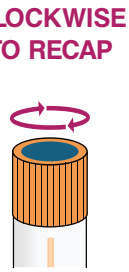


3B Throw this top piece of the swab handle away!

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.



3D Return the transport tube containing the swab to your healthcare provider.

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Revisado en diciembre de 2025

NOTA: consulte las modificaciones marcadas

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Apéndice A: Instrucciones para la recogida de frotis vaginales por la paciente

Sólo para uso en diagnóstico *in vitro*

Su kit contiene lo siguiente:

- Un Alinity m Sample Tube (tubo de muestra)
- Un hisopo estéril para la recogida del espécimen

PRECAUCIÓN: NO toque la punta blanca del hisopo ni lo apoye en ninguna superficie. Si toca la punta blanca o si el hisopo se apoya sobre alguna superficie o se cae, los resultados obtenidos podrían no ser exactos. Tiene que pedir un nuevo simpli-COLLECT HPV Collection Kit.

1. PREPARACIÓN

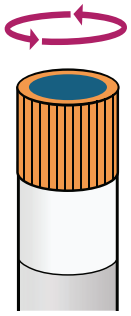
1A Lávese y séquese las manos



1B Abra el kit que contiene el tubo. Retire el tubo. Coloque el envase en una superficie lisa.

Sostenga el tubo en posición vertical y quite el tapón. Vuelva a meter el tubo abierto y el tapón en el envase.

GIRE EN SENTIDO ANTIHORARIO PARA ABRIR EL TAPÓN



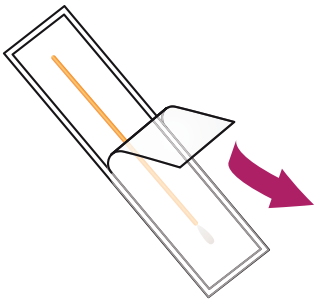
2. RECOGIDA DE LA MUESTRA

2A Abra el envase del hisopo y sosténgalo por la varilla naranja.

- No toque la punta blanca.

Mientras utiliza el hisopo, procure no tocar nada con la punta blanca, excepto el interior de la vagina.

SUJÉTELO POR LA VARILLA NARANJA



2B Adopte una postura cómoda para acceder fácilmente a la abertura de la vagina.

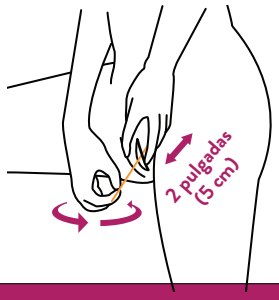
Sostenga el hisopo con una mano. Con la otra mano, separe los pliegues de piel para acceder a la abertura de la vagina.

Introduzca con cuidado en la vagina la punta blanca del hisopo aproximadamente 5 cm (2 pulgadas).

Gire suavemente el hisopo durante 15 a 30 segundos (asegúrese de que el hisopo toca las paredes vaginales).

Extraiga el hisopo con cuidado. **¡No apoye el hisopo en ninguna superficie!**

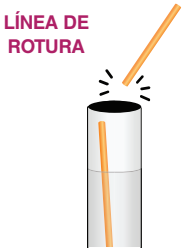




3. TRANSFERENCIA DEL HISOPO

3A Sostenga el tubo en posición vertical. Con la punta blanca apuntando hacia abajo, introduzca el hisopo en el tubo.

Rompa la varilla naranja del hisopo doblándola contra el tubo por la línea de rotura.
(Es posible que deba elevar ligeramente el hisopo para encontrar la línea de rotura).



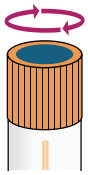
3B ¡Deseche la parte superior del hisopo!

La parte inferior del hisopo permanecerá dentro del tubo.



3C Sostenga el tubo en posición vertical y ciérrelo girando el tapón en sentido horario. **Cuando note resistencia,** siga girando el tapón otro cuarto de vuelta hasta que no gire más.

GIRE EN SENTIDO HORARIO PARA CERRAR EL TAPÓN



3D Lleve el tubo de transporte que contiene el hisopo a su profesional sanitario.

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