SIMPLI-COLLECT™ HPV COLLECTION KIT
PATIENT REFERENCE GUIDE

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.

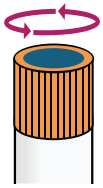
1. SETTING UP

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.



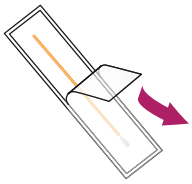
COUNTER CLOCKWISE TO UNCAP

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

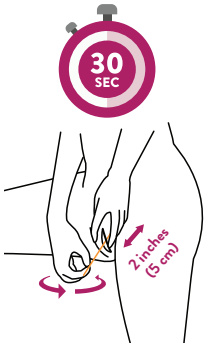
2B Find a comfortable position to easily access the opening of your vagina.

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).



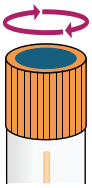
SNAP

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.

Warnings and precautions

- 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.
- 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 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.

Limitations of procedure

- 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.

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.

Reference: simpli-COLLECT™ HPV Collection Kit Package Insert: 53-608542/R02

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For *in vitro* diagnostic use. Rx Only.

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