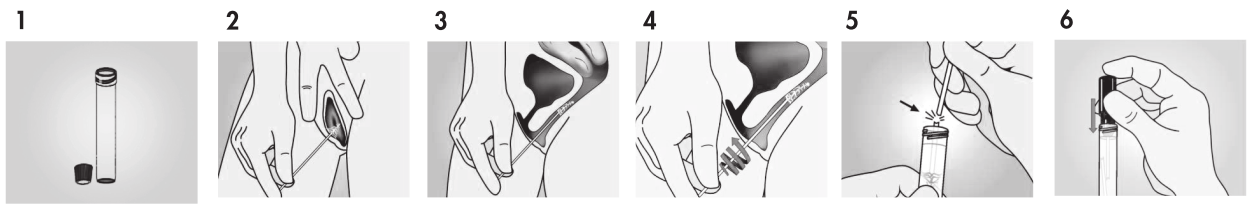
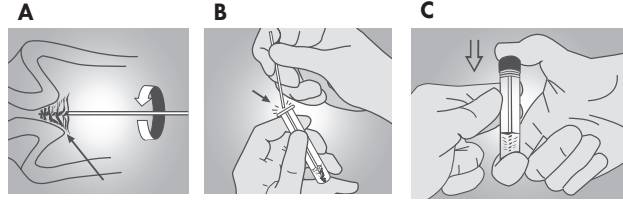


careBrush

Vaginal Self-Sampling Procedure



Cervical Physician-Sampling Procedure



Intended Use

The careBrush is intended for use with careHPV Collection Medium for the collection of specimens for subsequent testing with the careHPV® Test. Vaginal specimens may be self collected under the guidance of a medical professional, and cervical specimens may be collected by physicians or trained medical professionals.

Read these instructions for use (IFU) carefully before collecting a specimen.

Refer to *careHPV Test Kit Handbook* for additional information on specimen handling.

Please visit support.qiagen.com for your local QIAGEN Representative's contact information.

Use this contact information to attain technical support or to report a serious incident.

The CE marking indicates that this product meets the requirements of the European Union Medical Device Regulation 2017/745.

Materials Provided

- 1 careBrush **BRUSH**
- 1 IFU

Materials Required But Not Provided

1 careHPV® Collection Medium tube

Warnings and Precautions

- Do not use the careBrush on pregnant women.
- Do not use if package is damaged.
- Do not re-use.
- Do not collect a specimen if anti-fungal cream or high concentrations of blood, contraceptive jelly or douche are present.
- Do not use after the expiration date indicated next to the symbol on the package label.
- Specimens to be tested using the careHPV Test must be collected using a careBrush and stored in a careHPV Collection Medium tube containing careHPV Collection Medium.
- Specimens collected with a careBrush and stored in careHPV Collection Medium cannot be used for culture.
- Do not use collected specimens for testing if the careHPV Collection Medium spills before or after a vaginal sample is obtained. If a spill occurs, collect a new specimen and place the careBrush into a new careHPV Collection Medium vial.
- Consider all human specimens potentially infectious.
- Dispose of all specimens, reagents, and other potentially contaminated materials in accordance with national and local regulations.
- Do not touch the brush before or after specimen collection.
- Do not touch the brush to any surface outside of the collection tube.
- Do not put the careHPV Collection Medium in your mouth or ingest; if the liquid gets in your mouth or is ingested, immediately notify a medical professional.
- Do not inhale the careHPV Collection Medium; if inhaled, immediately notify a medical professional and get fresh air.

- Do not allow the careHPV Collection Medium to contact your eyes; if the liquid contacts your eyes, immediately notify a medical professional and keep your eye open while rinsing for several minutes under running water.

- Self-collection is intended for use under the guidance of a medical professional. Consult with your doctor or nurse if you need any advice or information on the device, if you have difficulties using the device or if you think that the device may have led to an undesirable side-effect not listed in these instructions for use.

Storage and Handling

Store unopened careBrushes at 15–30°C. Product stored as directed will retain the expiration date printed on the package label.

Vaginal Self-Sampling Procedure

Important: If at any time during this procedure you experience pain or major discomfort, stop and consult your medical professional.

1. Taking care not to spill the liquid in the tube, remove the cap from the careHPV Collection Medium tube and place the cap on a hard, flat surface with the inside of the cap pointing up (1).
2. Gently open the outside of your vagina and insert the brush into the opening (2).
3. Continue to insert the brush by gently rotating the brush to the left or to the right until you feel resistance (3).
4. Hold the brush in place and gently rotate the brush in a circle 5 times (4).
5. Remove the brush from your vagina and put the brush in to the careHPV Collection Medium tube so the brush touches the bottom of the tube and is immersed in the liquid.
6. Hold the tube firmly with one hand and use your other hand to grip the brush shaft. Break off the end of the shaft by snapping the shaft at the line (5). Only the lower portion, with the brush side down, should be in the liquid.
7. Discard the broken portion of the brush shaft. Leave the remainder of the careBrush in the careHPV Collection Medium.
8. Place the cap on the careHPV Collection Medium tube. Ensure the cap is pushed flush and the careHPV Collection Medium tube is tightly sealed (6).
9. Clearly label the tube with your first and last name and the collection date.

Cervical Physician-Sampling Procedure

Important: If a Pap smear specimen is to be collected, collect the Pap smear specimen before obtaining the specimen for the careHPV Test. Do not use the careBrush for Pap collection.

Important: If a colposcopy will be performed, collect the careHPV Test cervical specimen prior to application of acetic acid or iodine.

1. Obtain and open a careBrush package.

2. Obtain a careHPV Collection Medium tube. Remove the cap from the tube and place the tube upright in a rack. Keep the cap for future use.
3. Remove excess mucus from the cervical os and surrounding ectocervix using a cotton swab. Discard the swab.
4. Gently insert the careBrush 1–1.5 cm into the cervical os until the largest outer bristles of the careBrush touch the ectocervix. Important: Avoid touching other surfaces when inserting the careBrush. Do not insert the careBrush completely into the cervical canal.
5. Gently rotate the careBrush 3 full turns in a counter-clockwise direction (Figure A).
6. Gently remove the careBrush from the cervical canal. Make sure that no part of the careBrush remains in the cervical canal. Do not reinsert the careBrush. Important: Avoid touching other surfaces when removing the careBrush from the cervical canal.
7. Insert the careBrush to the bottom of the careHPV Collection Medium tube. Important: Avoid touching the bristles of the careBrush to the outside of the tube or any other object.
8. Snap off the shaft of the careBrush at the score line (Figure B).
9. Recap the careHPV Collection Medium tube securely (Figure C).

Specimen Handling and Storage

Give the vaginal specimen to a medical professional as soon as possible. Vaginal and Cervical Specimens collected with a careBrush and placed in careHPV Collection Medium tubes may be shipped and stored at room temperature (15–30°C) for 14 days or at 2–8°C for 35 days.

For domestic transport, package and label specimens in compliance with applicable national and local regulations covering the transport of clinical specimens and infectious substances.

Glossary of Symbols

	Temperature Limitation		Use-by
	CE Marking		Open here
	Do not use if package is damaged		Global Trade ID Number
	Consult instructions for use		Caution, consult accompanying documents
	Batch code		Medical Device
	Catalog number		Brush
	Manufacturer		Each Pouch Contains
	Do not reuse/Single use only		Component
	Sufficient for <n> tests		Number

