

careBrush **BRUSH**

Instructions for self-collection of vaginal specimens under the guidance of a medical professional

Intended Use

For use with the careHPV® Test

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.

Important: The instructions in this document are for the self-collection of vaginal specimens under the guidance of a medical professional. For instructions on the collection of cervical specimens by a medical professional, refer to the document provided with each package of careBrushes.

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

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


Materials Provided

- 1 careBrush
- 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 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.
- 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.

Storage and Handling

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



619024



QIAGEN
QIAGEN Strasse 1
40724 Hilden
GERMANY



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.
2. Gently open the outside of your vagina and insert the brush into the opening (Figure 1).
3. Continue to insert the brush by gently rotating the brush to the left or to the right until you feel resistance (Figure 2).
4. Hold the brush in place and count from 1 to 10. Rotate the brush in a circle 5 times (Figure 3).
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 (Figure 4). Only the lower portion, with the brush side down, should be in the liquid.
7. Discard the broken portion of the brush shaft.
8. Place the cap on the *careHPV* Collection Medium tube (Figure 5).
9. Clearly label the tube with your first and last name and the collection date.

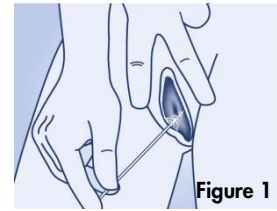


Figure 1

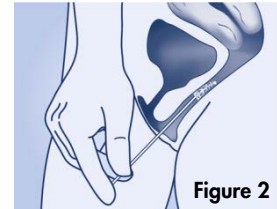


Figure 2

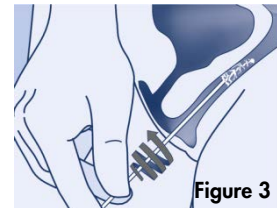


Figure 3

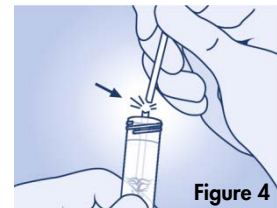


Figure 4

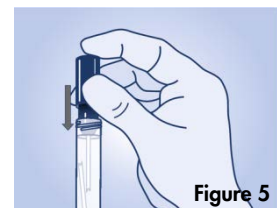


Figure 5

Specimen Handling and Storage

Give the specimen to a medical professional as soon as possible.

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 30 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.

Ordering Information

Product	Contents	Cat. no.
<i>careBrush</i>	50 pre-scored cervical brushes	619024
<i>careHPV</i> Collection Medium	50 tubes containing 1 ml of <i>careHPV</i> Collection Medium	619025
<i>careHPV</i> Test	For 96 reactions; kit for detection of 14 high-risk HPV genotypes	614015

For up-to-date licensing information and product-specific disclaimers, see the respective QIAGEN kit handbook or user manual. QIAGEN kit handbooks and user manuals are available at www.qiagen.com or can be requested from QIAGEN Technical Services or your local distributor.

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