

careBrush BRUSH

## Instructions for the collection of cervical specimens by 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. Cervical specimens may be collected by physicians or trained medical professionals, and vaginal specimens may be self-collected under the guidance of a medical professional.

**Important:** The instructions in this document are for specimens collected by physicians or trained medical professionals. For instructions on the collection of self-collected vaginal specimens under the guidance of a medical professional, refer to the document provided with each individual careBrush.

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

- 50 careBrushes
- 1 IFU

### 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.

### 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



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## 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.

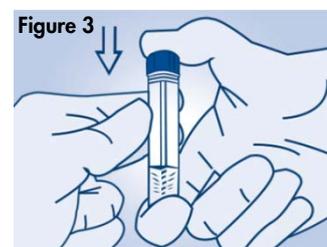
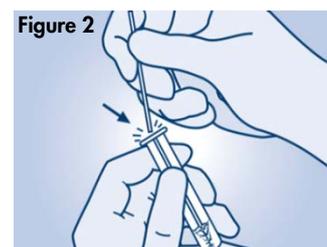
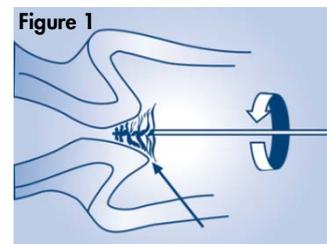
5. Gently rotate the *careBrush* 3 full turns in a counter-clockwise direction (Figure 1).
6. Gently remove the *careBrush* from the cervical canal. Make sure that no part of the *careBrush* remains in the cervical canal. Do not reinsert the *careBrush*.

**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 2).
9. Recap the *careHPV* Collection Medium tube securely (Figure 3).



## Specimen Handling and Storage

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 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](http://www.qiagen.com) or can be requested from QIAGEN Technical Services or your local distributor.

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