

June 2020

# *careHPV*<sup>®</sup> Collection Medium Instructions for Use (Handbook)

For use with *careHPV* Test

IVD

CE

REF



R5 MAT

619025

QIAGEN GmbH, QIAGEN Strasse 1, D-40724 Hilden

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# Intended Use

For use with *careHPV* Test

The *careHPV* Collection Medium is intended to be used with a *careBrush* 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.

Read this Instructions for Use (IFU) carefully before collecting a cervical or vaginal specimen.


Please visit **[support.qiagen.com](https://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.

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## Materials Provided

- 50 tubes, each containing 1 ml of *careHPV* Collection Medium
- 1 Instructions for Use

# Warnings and Precautions

- 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.
- All human specimens should be considered potentially infectious.
- Dispose of all specimens, reagents, and other potentially contaminated materials in accordance with national and local regulations.
- careHPV Collection Medium contains sodium azide which may react with lead or copper plumbing to form highly explosive metal azide compounds. Upon disposal, flush with large amounts of water.

## careHPV Collection Medium

<p><b>CAUTION</b></p> 	<p>Warning! Causes mild skin irritation. (W1)</p> <p>If skin irritation occurs: Get medical advice/attention.</p>
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# Reagent Storage and Handling

Store unopened tubes of *careHPV* Collection Medium at 15–30°C. Product stored as directed will retain the expiration date printed on the package label.

## Specimen Handling

A patient should immediately give self-collected specimens to a medical professional. If a medical professional is not available, store the specimens accordingly and transfer to a medical professional as soon as possible.

## Specimen Storage

Store specimens in *careHPV* Collection Medium between 15°C and 30°C for 14 days or between 2°C and 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.

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# Procedure

















Refer to the applicable IFU provided with the *careBrush* for instructions on specimen collection.

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

# Symbols

The following symbols may appear on the packaging and labeling:

Symbol	Symbol definition
	Use by
	In vitro diagnostic medical device
	Catalog number
	Lot number
	Material number
	Components
	Contains
	Global Trade Item Number
	Temperature limitation
	Manufacturer
	Consult instructions for use
	Caution
	careHPV Collection Medium
	Do not reuse





Do not use if package is damaged

# Ordering Information

<b>Product</b>	<b>Contents</b>	<b>Cat. no.</b>
<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 (96)	Assay reagent 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.

# Document Revision History

Date	Changes
R5, June 2020	Layout changes Revised Intended Use section to add sentence about contact information Updated Specimen Storage section for 2°C and 8°C to 35 days from 30 days. Added Symbols section

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### Limited License Agreement for *careHPV* Collection Medium

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