



EN Name and Intended Use

The *digene*® HC2 DNA Collection Device is intended for the collection and transport of physician-collected cervical specimens and self-collected vaginal specimens (under the guidance of a medical professional) to be tested with the *digene* HC2 High-Risk HPV DNA Test. The *digene* HC2 DNA Collection Device is not intended for Pap collection.

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

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.

Reagents and Materials Provided

1x1 Brush

1x1ml Specimen Transport Medium (contains 0.05% sodium azide)

Warnings and Precautions

Specimen Transport Medium: Warning! Causes mild skin irritation. Wear protective gloves/ protective clothing/ eye protection/ face protection. Immediately wash affected area of skin with water and soap, and rinse thoroughly. Contact your local QIAGEN Representative to obtain Safety Data Sheets.

CHEMTREC USA & Canada 1-800-424-9300
Outside USA & Canada call +1 703-527-3887

Do not reuse

Do not use if package is damaged

•For best results, users must first read these instructions before beginning collection and then perform each step in the listed order.

•Do not use cervical brush on pregnant women. Please let your physician know if you think you may be pregnant.

•Do not put Specimen Transport Medium (tube liquid) in your mouth or ingest it. If you do put the tube liquid in your mouth or ingest the tube liquid, contact a physician immediately.

•Do not inhale (breathe in) Specimen Transport Medium (tube liquid). If you do inhale the tube liquid, get fresh air; consult a physician in case of complaints.

•If Specimen Transport Medium (tube liquid) comes in contact with eyes, rinse opened eye for several minutes under running water. Then consult a physician.

•Consider all human specimens potentially infectious.

•Physician-collected cervical specimens and self-collected vaginal specimens can only be used with the *digene* HC2 High-Risk HPV DNA Test. Specimens collected with this system cannot be used for culture.

•Do not collect self-collected vaginal specimens if antifungal cream or contraceptive jelly are present.

•Do not touch the brush before or after specimen collection.

•Do not touch the brush to any surface outside of the collection tube.

•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.

•Specimen Transport Medium contains sodium azide, which may react with lead or copper plumbing to form highly explosive metal azide compounds. Dispose of in accordance with local regulations. **Contact your local QIAGEN Representative or your local medical professional on how to dispose or clean spills. For contact information, please visit support.qiagen.com.**

Storage Instructions

Store kits at 15-30°C. Do not use after the expiration date indicated next to the symbol on the pouch label.

Specimen Collection and Handling Vaginal Self-Collection Procedure

1. Pull off the cap from the tube and place it down on a hard, flat surface with the inside of the cap pointing up. Be careful not to spill the Specimen Transport Medium (liquid in the tube).
2. Gently open the outside of your vagina and insert the brush into the opening (Graphic 1).
3. Continue to insert the brush by gently rotating it to the left or to the right until you meet resistance (Graphic 2). If you experience pain or major discomfort, stop and consult your nurse or physician.
4. Gently hold the brush in place. Count to 10 slowly before rotating. Rotate the brush 5 times in a circle to collect the sample (Graphic 3).
5. Remove the brush from your vagina and put it in the provided tube (brush facing down) until it

touches the bottom. Break the end of the handle by snapping it at the line on the handle while holding the tube firmly with one hand and placing the other hand near the end of the brush (Graphic 4). Upon breaking the handle, discard the broken portion.

6. Only the lower portion, with the brush side down, should be in the tube and immersed in the Specimen Transport Medium (liquid in the tube). Carefully secure the cap (Graphic 5), clearly label the tube, and then give the tube to a medical professional.

Specimen Collection and Handling Cervical Physician-Collection Procedure

Collect Pap smear specimen before obtaining specimen for DNA testing. Collect DNA specimen prior to application of acetic acid or iodine if a colposcopy will be performed.

1. Remove excess mucus from the cervical os and surrounding ectocervix using a cotton swab. Discard the swab in accordance with local regulations.

2. Insert the brush 1-1.5 cm into the os of the cervix until the largest outer bristles of the brush touch the ectocervix. Rotate it 3 full turns in a counter-clockwise direction. **DO NOT INSERT BRUSH COMPLETELY INTO THE CERVICAL CANAL.** (Graphic 6)

3. Remove the brush from the canal. Avoid touching the bristles to the outside of the tube or to any other object.

4. Insert the brush to the bottom of the transport tube. Snap off the shaft at score line (Graphic 7), and cap the tube securely (Graphic 8).

Specimen Transport

Specimens may be held for up to 2 weeks at room temperature and shipped without refrigeration to the testing site. At the testing laboratory, specimens can be stored an additional week at

2-8°C or 3 months at -20°C prior to testing. Refer to the *digene* HC2 High-Risk HPV DNA Test instructions for use for instructions on how to run the assays. To prevent caps from popping off specimen tubes that are shipped or stored frozen, cover caps with Parafilm® prior to shipment. For domestic and international shipments, specimens should be packaged and labeled in compliance to applicable State, Federal, and international regulations covering the transport of clinical specimens and infectious substances.

Glossary of Symbols

	Temperature Limitation		Manufacturer
	CE - IVD marked Symbol		Do not reuse
	Do not use if package is damaged		Caution, consult accompanying documents
	Consult instructions for use		EACH POUCH CONTAINS
	Batch code		UDI
	Catalog number		Cervical Brush
	Component		STM
	GTIN number		Medical device
	Authorized Representative		Material Number
	Contains		Expiration Date

For collection and transport of physician-collected cervical and self-collected vaginal specimens to be tested with the *digene*® Hybrid Capture® 2 High-Risk HPV DNA Test. NOT INTENDED FOR PAP COLLECTION. Do not use cervical brush with pregnant women.

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Trademarks

QIAGEN®, Sample to Insight®, *digene*®, Hybrid Capture®, (QIAGEN Group); Parafilm® (BEMIS Company, Inc.).

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