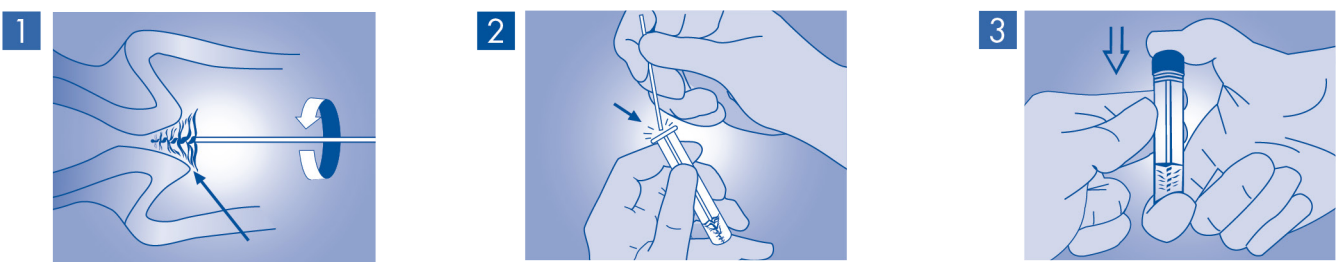


digene® HC2 DNA Collection Device



Name and Intended Use

The *digene*® HC2 DNA Collection Device is intended for the collection and transport of cervical specimens to be tested only with the *digene* Hybrid Capture 2 HPV and CT/GC DNA Tests. **IT IS NOT INTENDED FOR PAP COLLECTION.**

R only For the United States Only:

Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner.

Model No. A0040

Please visit www.qiagen.com for your local QIAGEN Representative’s contact information or call 1-800-344-3631 (for United States and Canada only) or 00800-22-44-6000 (for the rest of the world) for any technical inquiries.

Reagents and Materials Provided

- 1 x 1 BRUSH Brush
- 1 x 1 ml STM Specimen Transport Medium (contains 0.05% sodium azide)

Warnings and Precautions

- Do not reuse.
 - Do not use if package is damaged.
- For professional use only. Read all instructions fully and carefully before using this product.
- Do not use cervical brush with pregnant women.
 - Consider all human specimens potentially infectious.
 - Use only with *digene* HC2 HPV and CT/GC DNA Tests. Specimens collected with this system cannot be used for culture.
 - Specimen Transport Medium: Warning! Causes mild skin irritation. Wear protective gloves/ protective clothing/ eye protection/ face protection.
 - 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 to obtain Safety Data Sheets.

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

- 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.
- Remove excess mucus from the cervical os and surrounding ectocervix using a cotton swab. Discard the swab in accordance with local regulations.
- 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 (1). **DO NOT INSERT BRUSH COMPLETELY INTO THE CERVICAL CANAL.**
- Remove the brush from the canal. Avoid touching the bristles to the outside of the tube or to any other object.
- Insert the brush into the bottom of the transport tube. Snap off the shaft at score line (2), and cap the tube securely (3).

Cervical Biopsy (HPV Only):

Fresh cervical biopsies up to 5 mm in cross-section must be placed immediately into the Specimen Transport Medium and stored frozen at -20°C. Cervical biopsies processed with histological fixatives cannot be tested with *digene* HC2 DNA Tests.

Specimen Transport

Cervical 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 appropriate *digene* HC2 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. Store cervical biopsies at -20°C. Biopsy specimens may be shipped at 2–30°C for overnight delivery to the testing laboratory, and refrozen at -20°C upon receipt. 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. Parafilm® is a registered trademark of American Can Co.

Glossary of Symbols

	Temperature Limitation		Use-by
	Do not use if package is damaged		Global Trade ID Number
	Consult instructions for use		Caution, consult accompanying
	Batch code		Contains
	Catalog number		In Vitro Diagnostics Medical Device
	Manufacturer		Each Pouch Contains
	Do not reuse/Single use only		Component
	Sufficient for <n> tests		Number
	For prescription use only		Unique Device Identifier
For Collection and transport of cervical specimens to be tested only with the <i>digene</i> ® Hybrid Capture® 2 HPV and CT/GC DNA tests. NOT INTENDED FOR PAP COLLECTION. Do not use cervical brush with pregnant women.		For Collection and transport of cervical specimens to be tested only with the <i>digene</i> ® Hybrid Capture® 2 HPV and CT/GC DNA tests. NOT INTENDED FOR PAP COLLECTION. Do not use cervical brush with pregnant women.	

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