digene® Female Swab Specimen Collection Kit











Intended Use

For collection and transport of cervical specimens to be tested only with digene® Hybrid Capture 2 CT/GC DNA Tests

Storage Instructions

Store kits at 15-30°C. Do not use after the expiration date indcated next to the symbol $\underline{\square}$ on the pouch label.

Kit Contents

2 Swab 1 ml STM

Warnings and Precautions

READ ALL INSTRUCTIONS FULLY AND CAREFULLY BEFORE USING THIS PRODUCT.

Use only with digene HC2 CT/GC DNA Tests. Specimens collected with this system cannot be used for culture.

Caution:

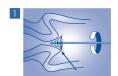
The United States Only: Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner.

For professional use only. Read these instructions carefully before taking the cervical specimen.

The collection and transport of cervical specimens is for single use only; reuse may cause a risk of infection and/or inaccurate results.

Some kit components contain 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.

Specimen Transport Medium: Warning! Causes mild skin irritation. Wear protective gloves/protective clothing/ eye protection/ face protection.





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Specimen Collection and Handling Note:

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 1 of the 2 specimen collection swabs provided. Discard the swab in accordance with local regulations.
- 2. Insert the second swab into the endocervical canal and rotate it through 5–180° turns, alternating in opposite directions (1).
- 3. Rub swab firmly over the entire area of the transformation zone (2).
- 4. Withdraw the swab carefully; avoid contact with vaginal mucosa.
- 5. Insert the swab to the bottom of the transport tube. Snap off the shaft at the score line (3), and cap the tube securely (4).

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 digene HC2 CT/GC DNA Test system instructions for use 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 with applicable State, Federal, and international regulations covering the transport of clinical specimens and infectious substances.

IVD	IVD marked Symbol	8	Do not reuse
•••	Manufacturer	STERILE R	Sterilized Using Radiation
LOT	Batch code	RX ONLY	For Prescription Use Only
	Do not use if package is damaged	\sum	Sufficient for "X" preparations
	Use by	Re)	Open here
REF	Catalog number	(3)	Do not re-sterilize
	Temperature Limitation	Each Pouch Contains	Each Pouch Contains
Ti	Consult instructions for use	NUM	Number
\triangle	Attention	COMP	Component
GTIN	Global Trade ID Number	CONT	Contains

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