

# Xpert<sup>®</sup> Vaginal/Endocervical Specimen Collection Kit

**REF** SWAB/A-50

Instructions for Use

**IVD** CE

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See Section 15, Revision History for a description of changes.

# Xpert® Vaginal/Endocervical Specimen Collection Kit

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*In Vitro* Diagnostic Medical Device



## 1 Proprietary Name

The Xpert® Vaginal/Endocervical Specimen Collection Kit

## 2 Common or Usual Name

Xpert Vaginal/Endocervical Specimen Collection Kit

## 3 Intended Purpose

### 3.1 Intended Use

The Xpert® Vaginal/Endocervical Specimen Collection Kit is designed to collect, preserve, and transport *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, and *Trichomonas vaginalis* DNA in endocervical swab specimens (collected by a clinician) and patient-collected vaginal swab specimens (collected in a clinical setting) from symptomatic and asymptomatic women prior to analysis with the Xpert CT/NG test or the Xpert TV test.

### 3.2 Intended User/Environment

The Xpert® Vaginal/Endocervical Specimen Collection Kit is intended to be used by trained users.

## 4 Summary and Explanation

Refer to the Instructions for Use for the Xpert CT/NG test or the Xpert TV test (as appropriate).

## 5 Principles of Procedure

The Xpert Vaginal/Endocervical Specimen Collection Kit allows for an extended range of time and temperature conditions for specimen storage and transport when testing for the presence of *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, and *Trichomonas vaginalis* in vaginal and endocervical swab specimens using the Cepheid Xpert CT/NG test or the Xpert TV test (as appropriate).

Vaginal and endocervical specimens are collected from patients using flocked swabs included in the specimen collection kit. Swabs are broken off into the transport reagent tubes to elute organisms and stabilize DNA. Swab specimens are then transported to the laboratory for testing on the GeneXpert Instrument Systems.

## 6 Reagents

### 6.1 Materials Provided

Xpert Vaginal/Endocervical Specimen Collection Kits: (quantity: 50)

Each kit contains a sealed package containing:

- 1 individually wrapped sterile large cleaning swab
- 1 package containing:
  - 1 tube containing Xpert Swab Transport Reagent (pink cap)
  - 1 individually wrapped sterile flocked collection swab
- Instructions for collection of patient-collected vaginal swabs (quantity 50)
- Instructions for collection of endocervical swabs (quantity: 1)

### 6.2 Materials Required but Not Provided

- Disposable Gloves
- Adhesive labels or sample identification information

## 7 Swab Specimens Appropriate for Use

Table 1 below identifies swab specimen types and assay targets that are acceptable for use with the Xpert CT/NG test and the Xpert TV test.

**Table 1. Swab Specimen Types**

Xpert Test	Test Target	Endocervical Swab Clinician-Collected Specimen	Vaginal Swab Patient-Collected Specimen
Xpert CT/NG test	Chlamydia, Trachomatis, and Neisseria Gonorrhoeae	Yes	Yes
Xpert TV test	Trichomonas vaginalis	Yes	Yes

## 8 Warnings and Precautions

- For prescription use only.
- Treat all biological specimens, including used cartridges, as if capable of transmitting infectious agents. Because it is often impossible to know which might be infectious, all biological specimens should be treated with standard precautions. Guidelines for specimen handling are available from the U.S. Center for Disease Control and Prevention and the Clinical and Laboratory Standards Institute.<sup>1,2</sup>
- Avoid cross contamination during sample handling steps.
- Do not use kit if opened or damaged.
- Spilled or leaking transport reagent tubes should be discarded and not be used.
- Use this collection kit only with the Xpert CT/NG test or the Xpert TV test.
- Follow your institution's safety procedures for working with chemicals and handling biological samples.
- With vaginal/endocervical specimens tested with the Xpert CT/NG tests, assay interference may be observed in the presence of blood (>1% v/v) or mucin (>0.8% w/v).
- With vaginal/endocervical specimens tested with the Xpert TV test, assay interference may be observed in the presence of blood (>60% v/v).

## 9 Kit Storage Requirements

Store the Xpert Vaginal/Endocervical Specimen Collection Kit at 2 °C – 30 °C.

The XperVaginal/Endocervical Specimen Collection Kit can be stored at 2 °C – 30 °C for up to 36 months (see expiration date).

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**Important** Do not use after the expiration date which is clearly printed on the outer box label.

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### 9.1 Specimen Stability

Refer to the Instructions for Use for the Xpert CT/NG test or the Xpert TV test (as appropriate).

## 10 Limitations

Use this collection kit only with the Xpert CT/NG test or the Xpert TV test.

## 11 Specimen Collection and Handling

### 11.1 Patient-collected Vaginal Swab Specimen Collection

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**Caution** Do NOT expose swab to Xpert Swab Transport Reagent prior to collection.

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**Caution** Wash your hands before starting.

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**Note** If you have any questions about this procedure, please ask your doctor, nurse, or care-provider.

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1. In the privacy of the examination room or restroom, undress from the waist down. Comfortably position yourself to maintain balance during the collection procedure.
2. Open the outer peelpack (which contains the two-package kit), and identify the larger cleaning swab and discard it.
3. Open the package that contains the pink-capped Xpert Swab Transport Reagent tube and individually wrapped collection swab. Set the tube aside before beginning to collect sample.
4. Open the collection swab wrapper by peeling open the top of the wrapper.
5. Remove the swab, taking care not to touch the tip or lay it down. If the soft tip is touched, the swab is laid down, or the swab is dropped, request a new collection kit.
6. Hold the swab in your hand, placing your thumb and forefinger in the middle of the swab shaft across the scoreline.
7. Carefully insert the swab into your vagina about 5 cm (two inches) inside the opening of the vagina and gently rotate the swab for 10 to 30 seconds. Ensure the swab touches the walls of the vagina so that moisture is absorbed by the swab.
8. Withdraw the swab carefully and continue to hold it in your hand.
9. While holding the swab in the same hand, unscrew the pink cap from the Xpert Swab Transport Reagent tube.
10. Do not spill the contents of the tube. If the contents of the tube are spilled, request a new collection kit.

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**Warning** If the contents of the tube are spilled on your skin, wash the affected area with soap and water. If the contents of the tube are splashed in your eyes, immediately flush your eyes with water. Notify your doctor, nurse or care-provider if irritation develops. If the contents of the tube are spilled, your test result may be invalidated. Do not take internally.

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11. Immediately place the specimen collection swab into the transport reagent tube.
12. Identify the scoreline on the collection swab shaft. Carefully break the swab shaft against the side of the tube at the scoreline and discard the top portion of the swab shaft. If needed, gently rotate the swab shaft to complete the breakage. Use care to avoid splashing contents on the skin. Wash with soap and water if exposed.
13. Re-cap the swab transport reagent tube and tighten the cap securely.
14. Return the tube as instructed by your doctor, nurse, or care-provider to complete the following steps.

## 11.2 Steps for Caregiver to Perform

1. Invert or gently shake the tube 3-4 times to elute material from the swab. Avoid foaming.
2. Label the transport tube with the sample identification information, including date of collection, as required.
3. Transport and store the swab samples in the Xpert Swab Transport Reagent tube according to the conditions as indicated in Table 1 for the Xpert CT/NG test or for the Xpert TV test (as appropriate).

## 11.3 Clinician-collected Endocervical Swab Specimen Collection

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**Caution** Do NOT expose swab to Xpert Swab Transport Reagent prior to collection.

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1. Open the Xpert Vaginal/Endocervical Specimen collection kit.
  2. Before collecting the endocervical specimen with the Xpert Vaginal/Endocervical Specimen Collection Kit, remove excess mucus from the cervical os and surrounding mucosa using the large individually wrapped cleaning swab. Partially peel open the cleaning swab wrapper and remove the swab. Clean the cervical os and surrounding mucosa and then discard the swab.
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**Note** If collecting multiple specimens, excess mucus need only be removed once.

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3. Open the package that contains the pink-capped Xpert Swab Transport Reagent tube and the individually wrapped collection swab. Set the tube aside before proceeding.
  4. Open the collection swab wrapper by peeling open the top of the wrapper.
  5. Remove the swab, taking care not to touch the tip or lay it down. If the soft tip is touched, the swab is laid down, or the swab is dropped, use a new Xpert Vaginal/Endocervical Specimen Collection Kit.
  6. Insert the collection swab into the endocervical canal.
  7. Gently rotate the swab clockwise for 10 to 30 seconds in the endocervical canal to ensure adequate sampling.
  8. Withdraw the swab carefully.
  9. While holding the swab in the same hand, unscrew the cap from the Xpert Swab Transport Reagent tube.
  10. Do not spill the content of the tube. If the contents of the tube are spilled, use a new collection kit.
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**Warning** If the contents of the tube are spilled on your skin, wash the affected area with soap and water. If the contents of the tube are splashed in your eyes, immediately flush your eyes with water.

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11. Immediately place the swab into the transport reagent tube.
12. Identify the scoreline on the collection swab shaft. Carefully break the swab shaft against the side of the tube at the scoreline and discard the top portion of the swab shaft; use care to avoid splashing the contents. Wash with soap and water if exposed.
13. Re-cap the swab transport reagent tube and tighten the cap securely.
14. Invert or gently shake the tube 3-4 times to elute material from the swab. Avoid foaming.
15. Label the transport tube with the sample identification information, including date of collection, as required. Transport and store the swab samples in the Xpert Swab Transport Reagent tube according to the conditions indicated in Section 9.

## 12 References

1. Centers for Disease Control and Prevention. Biosafety in microbiological and biomedical laboratories (refer to latest edition). [www.cdc.gov/biosafety/publications](http://www.cdc.gov/biosafety/publications).
2. Clinical and Laboratory Standards Institute. Protection of laboratory workers from occupationally acquired infections; Approved Guideline. Document M29 (refer to latest edition).

## 13 Technical Assistance

### Before Contacting Us

Collect the following information before contacting Cepheid Technical Support:

- Product name
- Lot number

### United States

















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Contact information for all Cepheid Technical Support offices is available on our website: [www.cepheid.com/en/support/contact-us](http://www.cepheid.com/en/support/contact-us)

## 14 Table of Symbols

Symbol	Meaning
	Catalog number
	CE marking – European Conformity
	<i>In vitro</i> diagnostic medical device
	Contains sufficient for <i>n</i> tests
	Sterilized using ethylene oxide
	Authorized Representative in the European Community
	Do not reuse
	Manufacturer
	Temperature limitation
	Batch code
	Caution
	Consult instructions for use
	Expiration date
	Biological risks
	For prescription use only.
	Handle with care



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## 15 Revision History

**Description of Changes:** 302-6826 Rev A.

**Purpose:** To align with the requirements of Regulation (EU) 2017/746 and other applicable updates.

Section	Description of Change
3	Added Intended Purpose, Intended User/Environment per IVDR requirements. Also made minor content updates to this section.
Legal Page	Added Trademark, Patents and Copyright Statement page.
Throughout	Instances of "assay" used as a brand name changed to "test".
9	Updated specimen stability.
11.3	Removed table.
13	Added Technical Assistance section.
14	Added importer details for EU and Switzerland.
15	Added Revision History section.