

Xpert[®] Swab Specimen Collection Kit

REF SWAB/G-50

Instructions for Use

IVD CE

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See Section 17, Revision History for a description of changes.

Xpert[®] Swab Specimen Collection Kit

In Vitro Diagnostic Medical Device



1 Proprietary Name

Xpert[®] Swab Specimen Collection Kit

2 Common Name

Xpert Swab Specimen Collection Kit

3 Intended Purpose

3.1 Intended Use

The Xpert[®] Swab Specimen Collection Kit is designed to collect, preserve, and transport endocervical, vaginal, pharyngeal, and rectal swab specimens. This transport system is used for testing with Xpert tests.

3.2 Intended User Environment

The Xpert Swab Specimen Collection Kit is intended to be used by trained users.

4 Summary and Explanation of the Procedure

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

5 Reagent

5.1 Materials Provided

Xpert Swab Specimen Collection Kits: (quantity: 50) Each kit contains a sealed package containing:

Individually wrapped sterile large cleaning swab	1 per kit
Package containing:	
• Tube containing Xpert Swab Transport Reagent (pink cap)	1 per kit
• Individually wrapped sterile flocked collection swab	1 per kit
• Instructions for collection of patient-collected vaginal swabs	50

- Instructions for collection of endocervical swabs and clinician-collected vaginal swabs 1 per kit
- Instructions for clinician-collected pharyngeal swabs and rectal swabs 1 per kit

5.2 Materials Required but Not Provided

- Disposable gloves
- Adhesive labels or permanent markers for recording specimen information

6 Swab Specimens Appropriate for Use

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

Table 1. Swab Specimen Types

Xpert Test	Target	Endocervical Swab	Vaginal Swab	Pharyngeal Swab	Rectal Swab
Xpert CT/NG	<i>Chlamydia trachomatis</i> and <i>Neisseria gonorrhoeae</i>	Yes	Yes	Yes	Yes
Xpert TV	<i>Trichomonas vaginalis</i>	Yes	Yes	No	No

7 Warnings and Precautions

- For prescription use only.
- Treat all biological specimens, including used cartridges, as if capable of transmitting infectious agents. All biological specimens should be considered as infectious and treated with standard precautions. Guidelines for specimen handling are available from the U.S. Centers for Disease Control and Prevention and the Clinical and Laboratory Standards Institute.^{1,2}
- Avoid cross contamination during sample handling steps. Sample one patient specimen at a time.
- 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 appropriate Xpert tests.
- Follow your institution’s safety procedures for working with chemicals and handling biological samples.
- Refer to the appropriate Xpert test Instructions for Use for additional information regarding substance(s) with the potential to cause assay interference.

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

8 Kit Storage and Transport Requirements

Store the Xpert Swab Specimen Collection Kit at 2° C – 30° C. The Xpert Swab Specimen Collection Kit can be stored at 2° C – 30° C for up to 36 months (see expiration date).

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

9 Product Deterioration

The Xpert Swab Specimen Collection Kit should not be used if (1) evidence of damage or contamination to the product, (2) evidence of leakage, (3) expiration date has passed on any of the components, or (4) swab pouch is open.

10 Limitations

- Handle specimens aseptically.
- The Xpert Swab Specimen Collection Kit is intended to be used with the transport reagent tube and swab provided. The use of transport reagent tubes or swabs from any other source could affect the performance of the product.
- Use this collection kit only with the appropriate Xpert tests. See the appropriate Xpert test Instructions for Use.

11 Specimen Collection Procedure

11.1 Patient-collected Vaginal Swab Specimen Collection

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

Caution Wash your hands before starting.

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

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.

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.

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 For Patient-Collected Vaginal Swabs

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.

11.3 Clinician-collected Vaginal Swab Specimen Collection

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

Caution Wash your hands before starting.

1. Open the outer peelpack (which contains the two-package kit), and identify the larger cleaning swab and discard it.
 2. 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.
 3. Open the collection swab wrapper by peeling open the top of the wrapper.
 4. 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.
 5. Hold the swab in your hand, placing your thumb and forefinger in the middle of the swab shaft across the scoreline.
 6. Carefully insert the swab into the patient's 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.
 7. Withdraw the swab carefully and continue to hold it in your hand.
 8. While holding the swab in the same hand, unscrew the pink cap from the Xpert Swab Transport Reagent tube.
 9. 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.

10. Immediately place the specimen collection swab into the transport reagent tube.
 11. 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 contents. Wash with soap and water if exposed.
 12. Re-cap the swab transport reagent tube and tighten the cap securely.
 13. Invert or gently shake the tube 3-4 times to elute material from the swab. Avoid foaming.
 14. Label the transport tube with the sample identification information, including date of collection, as required.
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11.4 Clinician-collected Endocervical Swab Specimen Collection

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

1. Open the Xpert Swab Specimen Collection Kit.
 2. Before collecting the endocervical specimen with the Xpert Swab 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.

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 Swab 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 contents 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.

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.
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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.

11.5 Clinician-collected Pharyngeal Swab Specimen Collection

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

1. Open the Xpert Swab Specimen Collection Kit.
2. Open the outer peelpack (which contains the two-package kit), and identify the larger cleaning swab and discard it.
3. Open the collection swab wrapper by partially peeling open the top of the wrapper.
4. 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 Swab Specimen Collection Kit.
5. Instruct the patient to open mouth widely. Position the tongue toward the bottom of the mouth. Swab areas of the pharynx (tonsil, posterior wall, uvula).
6. While holding the swab in the same hand, unscrew the cap from the Xpert Swab Transport Reagent tube.
7. Do not spill the contents of the tube. If the contents of the tube are spilled, use a new collection kit.

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.

8. Immediately place the swab into the transport reagent tube.
9. 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.
10. Re-cap the swab transport reagent tube and tighten the cap securely.
11. Invert or gently shake the tube 3–4 times to elute material from the swab. Avoid foaming.
12. Label the transport tube with the sample identification information, including date of collection, as required.

11.6 Clinician-collected Rectal Swab Specimen Collection

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

1. Open the Xpert Swab Specimen Collection Kit.
2. Open the outer peelpack (which contains the two-package kit), and identify the larger cleaning swab and discard it.
3. Open the collection swab wrapper by partially peeling open the top of the wrapper.
4. 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 Swab Specimen Collection Kit.

Warning Do not wet or use lubricant on swab.

5. Carefully insert the swab approximately 1 cm beyond the anal sphincter (so that the fiber tips are no longer visible), and rotate gently for 10 seconds. See Figure 1 for examples of acceptable swab specimens to be used with the appropriate Xpert test. See Figure 2 for examples of highly soiled swab specimens that should not be used with the Xpert test.

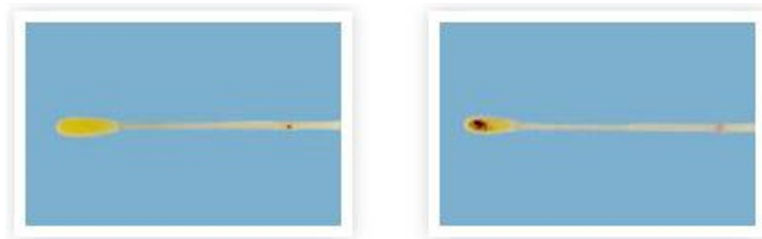


Figure 1. Examples of Acceptable Rectal Swabs

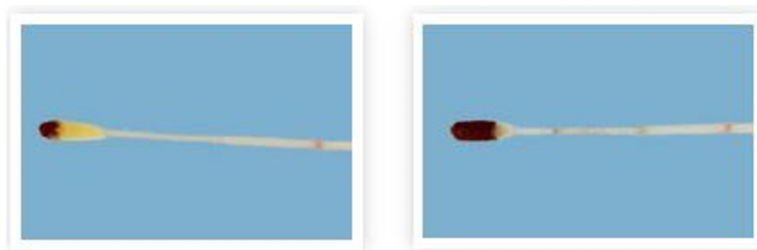


Figure 2. Examples of Unacceptable Rectal Swabs

6. While holding the swab in the same hand, unscrew the cap from the Xpert Swab Transport Reagent tube.
7. Do not spill the contents of the tube. If the contents of the tube are spilled, use a new collection kit.

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.

8. Immediately place the swab into the transport reagent tube.
9. 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.
10. Re-cap the swab transport reagent tube and tighten the cap securely.
11. Invert or gently shake the tube 3–4 times to elute material from the swab. Avoid foaming.
12. Label the transport tube with the sample identification information, including date of collection, as required.
13. Transport and store the swab samples in the Xpert Swab Transport Reagent tube according to the conditions indicated in Section 12.

12 Specimen Transport and Storage

Transport and store the swab samples in the Xpert Swab Transport Reagent tube according to the conditions indicated in the appropriate Xpert test Instructions for Use.

13 References

1. Centers for Disease Control and Prevention. Biosafety in Microbiological and Biomedical Laboratories (refer to latest edition). 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).

14 Cepheid Headquarters Locations

Corporate Headquarters

Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089
USA

Telephone: + 1 408 541 4191
Fax: + 1 408 541 4192
www.cepheid.com

European Headquarters

Cepheid Europe SAS
 Vira Solelh
 81470 Maurens-Scopont
 France

Telephone: + 33 563 825 300
 Fax: + 33 563 825 301
 www.cepheidinternational.com

15 Technical Assistance**Before Contacting Us**

Collect the following information before contacting Cepheid Technical Support:

- Product name
- Lot number

United States











Telephone: + 1 888 838 3222
 Email: techsupport@cepheid.com









France

Telephone: + 33 563 825 319
 Email: support@cepheideurope.com

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

16 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
	Sterilized using irradiation
	Authorized Representative in the European Community
	Do not reuse
	Manufacturer
	Temperature limitation

Symbol	Meaning
	Batch code
	Caution
	For prescription use only
	Consult instructions for use
	Control
	Expiration date
	Do not use if package is damaged
	Country of manufacture



Cepheid
 904 Caribbean Drive
 Sunnyvale, CA 94089
 USA

Phone: + 1 408 541 4191

Fax: + 1 408 541 4192



Cepheid Europe SAS
 Vira Solelh
 81470 Maurens-Scopont
 France

Phone: + 33 563 825 300

Fax: + 33 563 825 301

Importers for EU and Switzerland

Cepheid Netherlands BV
 1e Tochtweg 11
 2913LN
 Nieuwerkerk aan den IJssel
 Netherlands

Cepheid Switzerland GmbH
 Zurcherstrasse 66
 Postfach 124, Thalwil
 CH-8800
 Switzerland

17 Revision History

Description of Changes: Revised from 302-0175 Rev C to 302-6827 Rev A

Purpose: To align with requirements of Regulation (EU) 2017/746

Section	Description of Change
Throughout	Revised formatting to be consistent with other instructions for use.
Legal Page	Added Trademark, Patents and Copyright Statement page.
1, 2, 3	Added Proprietary Name, Common Name, and Intended User/Environment.
5	Updated.
6	Added title to table of swab specimen types.
11.6	Removed table of Specimen Transport and Storage.
16	Updated temperature limitation symbol. Added Netherlands and Switzerland addresses.
17	Added Revision History.