

## English

For *in vitro* diagnostic use only.



### 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. The Xpert Swab Specimen Collection Kit has not been evaluated for home use.

### Summary and Explanation of the Procedure

Endocervical (ES), vaginal (VS), pharyngeal (PS), or rectal (RS) swab 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 delivered for testing on the GeneXpert systems.

### Materials Provided

Xpert Swab Specimen Collection Kits: (quantity: 50 per box)

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 per box)
- Instructions for collection of endocervical swabs and clinician-collected vaginal swabs (quantity: 1 per box)
- Instructions for clinician-collected pharyngeal swabs and rectal swabs (quantity: 1 per box)

### Materials Required but Not Provided

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

### Swab Specimens Appropriate for Use

The swab specimen types are provided in the appropriate Xpert test Instructions for Use.

### 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.<sup>1,2</sup>
- 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.

### Kit Storage Requirements

Store collection kit at 2°C to 30°C.

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

### Product Deterioration

The Xpert Swab 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.

### Limitations

- Handle specimens aseptically.
- The Xpert Swab 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.
- Use of the Xpert Swab Specimen Collection Kit for patient-collected vaginal swab specimens is not designed to replace cervical exams and endocervical samples for diagnosis of female urogenital infections.
- Women who have symptoms suggesting pelvic inflammatory disease (PID) should not use the Xpert Swab Specimen Collection Kit to obtain patient-collected vaginal swab specimens as a replacement for a pelvic exam.
- Use of the Xpert Swab Specimen Collection kit for patient-collected vaginal swab specimens is limited to health care facilities where support/counseling is available to explain the procedures and precautions.

### Specimen Collection Procedure 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.

### 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.

### 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 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, 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.

10. Immediately place the 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 the 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.

### 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.

**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.



**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.
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.

## 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.

## 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.

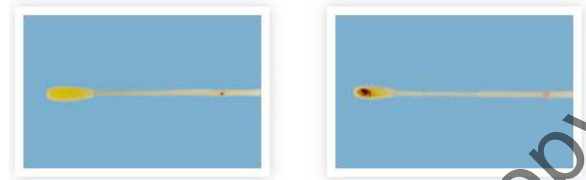


Figure 1. Examples of Acceptable Rectal Swabs



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.
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.



**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.
















## 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

## 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).

## Table of Symbols

Symbol	Meaning
	Catalog number
	<i>In vitro</i> diagnostic medical device
	Contains sufficient for <n> tests
	Sterilized using ethylene oxide
	Sterilized using irradiation
	Do not reuse
	Manufacturer
	Temperature limitation
	Batch code
	Caution
	For prescription use only
	Consult instructions for use
	Expiration date
	Do not use if package is damaged
	Country of manufacture

## Technical Support Contact

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