



**Department of Health Laboratory**

**Title |** Instructions for Collection, Packaging, and Shipping of Specimens for the Cepheid Genexpert Gonorrhea and Chlamydia Assay

**Index (Document ID) |** MICRO-411

**Version |** 10.0

**Document Type |** Document

**Document Category |** Sampling Instructions

**Document Owner(s) |** Keeley Weening

**Authorized By |** Jill Warrington

**Authorized Date |** 11-Sep-2020

THE VERMONT DEPARTMENT OF HEALTH LABORATORY  
Physical: 359 South Park Drive, Colchester, VT 05446  
Mailing: PO Box 1125, Burlington, VT 05402-1125

1-800-660-9997 (VT only) or 1-802-338-4724

**INSTRUCTIONS FOR COLLECTION, PACKAGING, AND SHIPPING OF SPECIMENS FOR  
THE CEPHEID GENEXPERT GONORRHEA AND CHLAMYDIA ASSAY**

VDHL KIT # 7

**PLEASE READ INSTRUCTIONS CAREFULLY BEFORE COLLECTING SPECIMEN**

To comply with postal regulations, ensure the safety of persons involved in the specimen transport and testing, and to maintain specimen integrity, the VT Department of Health Laboratory (VDHL) will only accept specimens that are packaged per the instructions below.

**In cases of suspected child abuse, culture is the only recommended procedure for diagnosing gonorrheal or chlamydial infection. Contact VDHL for more information about culture testing.**

**The specimen may be rejected if:**

- Swab specimen is greater than 60 days old upon receipt at VDHL
- Swab is not immersed in transport medium
- Incorrect swab used or swab is missing
- 2 swabs submitted in one collection kit
- Urine submitted in sterile collection cup is unrefrigerated.
- Urine submitted in Cepheid transport media is greater than 45 days old (male)
- Urine submitted in Cepheid transport media is greater than 3 days (unrefrigerated/female)
- Urine transport tube is over filled or under filled. Refer to urine collection instructions.
- Specimen is leaking
- Transport medium has expired (see date on label)
- Patient name on kit and test request form do not match

**The **Xpert** Swab Specimen Collection kit contains:**

- Ziploc bag
- Padded envelope (Jiffy bag)
- VDHL-Clinical Test Request Form (Micro 220)
- Collection and Packaging Instructions (Micro 411)
- Xpert Swab Specimen Collection kit which includes:
  - Pink topped transport tube
  - White shaft endocervical cleaning swab
  - Thin white shaft collection swab
- Manufacturer's Instructions for Obtaining Patient-Collected Xpert Vaginal Swab Specimens

**The Urine Specimen Collection kit contains:**

- 1 Ziploc specimen transport plastic bag
- VDHL-Clinical Test Request Form (Micro 220)
- Collection and Packaging Instructions (Micro 411)
- Xpert Urine Specimen Collection Kit (includes disposable pipet)

Kits can be stored at room temperature until needed. **DO NOT USE OUTDATED TRANSPORT MEDIUM.** Expired transport tubes may be discarded or returned to the Vermont Department of Health Laboratory at the address above.

## **Instructions for Collection and Packaging of Specimens:**

1. Label transport tube with patient name and date of collection.

### **2. Self-Collected Vaginal Swab Specimens (for patient use)**

*If you have any questions about this procedure, please ask your health care provider. WASH HANDS before starting.*

- a. In the privacy of the exam room or a restroom, undress from the waist down. Comfortably position yourself to maintain balance during the procedure.
- b. Open the outer peelpack (which contains the two-package kit) and identify the larger cleaning swab. You may discard this swab.
- c. Open the package that contains the pink-capped Xpert Swab Transport Reagent Tube and the individually wrapped collection swab. Set the tube aside before beginning to collect sample.
- d. Open the collection swab wrapper by peeling open the top of the wrapper.
- e. 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.
- f. Hold the swab in your hand, placing your thumb and forefinger in the middle of the swab shaft across the scoreline.
- g. Carefully insert the swab into your vagina about two inches inside the opening of the vagina and gently rotate the swab for 10-30 seconds. Ensure the swab touches the walls of the vagina so that moisture is absorbed by the swab.
- h. Withdraw the swab carefully and continue to hold it in your hand.
- i. While holding the swab in the same hand, unscrew the pink cap from the Xpert Swab Transport Reagent tube.
- j. Do not spill the contents of the tube. If the contents are spilled, request a new collection kit.
- k. Immediately place the specimen collection swab into the transport reagent tube.
- l. 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 of the tube on skin. In the case of splashing, wash exposed skin with soap and water.
- m. Re-cap the swab transport reagent tube and tighten the cap securely to prevent leaking during transport.
- n. Return the tube as instructed by your health care provider.
- o. **HEALTH CARE PROVIDER:** Invert or gently shake the tube 3-4 times to elute the material from the swab. Avoid foaming. Ensure the tube is labeled with patient name and date of collection. Place the transport tube in the small Ziploc baggie and transport the sample and VDHL-Clinical Test Request Form (Micro 220) to the VDHL **within 60 days of collection.**

### **3. Endocervical Swabs (for Medical Provider use)**

- a. Open the Xpert **Swab** Specimen Collection kit
- b. 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.
- c. 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.
- d. Open the collection swab wrapper by peeling open the top of the wrapper.
- e. Remove the swab, taking care not to touch the tip or lay it down. If the soft tip is touched, the swab laid down, or the swab is dropped, use a new Xpert **Swab** Specimen Collection Kit.
- f. Insert the collection swab into the endocervical canal.
- g. Gently rotate the swab clockwise for 10-30 seconds in the endocervical canal to ensure adequate

- sampling.
- h. Withdraw the swab carefully.
- i. While holding the swab in the same hand, unscrew the cap from the Xpert Swab Transport Reagent tube.
- j. Do not spill the contents of the tube. If the contents are spilled, use a new collection kit.
- k. Immediately place the swab into the transport reagent tube.
- l. 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.
- m. Recap the swab transport reagent tube and tighten the top securely.
- n. Invert or shake the tube 3-4 times to elute material from the swab. Avoid foaming.
- o. Ensure that the correct patient information and date of collection are on the tube label. Place the transport tube in the small Ziploc baggie.
- p. Transport the sample and VDHL-Clinical Test Request Form (Micro 220) to the VDHL **within 60 days of collection**.

#### 4. Pharyngeal Swab Specimen Collection (for Medical Provider use)

- a. Open the Xpert Swab Specimen Collection kit
- b. Open the outer peelpack (which contains the two-package kit), and identify the larger cleaning swab and discard it.
- c. Open the collection swab wrapper by partially peeling open the top of the wrapper
- d. Remove the swab, taking care not to touch the tip or lay it down. If the soft tip is touched, the swab laid down, or the swab is dropped, use a new Xpert Swab Specimen Collection Kit.
- e. 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, posterior wall)
- f. While holding the swab in the same hand, unscrew the cap from the Xpert Swab Transport Reagent tube.
- g. Do not spill the contents of the tube. If the contents are spilled, use a new collection kit.
- h. Immediately place the swab into the transport reagent tube.
- i. 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.
- j. Recap the swab transport reagent tube and tighten the top securely.
- k. Invert or gently shake the tube 3-4 times to elute material from the swab. Avoid foaming.
- l. Ensure that the correct patient information and date of collection are on the tube label. Place the transport tube in the small Ziploc baggie.
- m. Transport the sample and VDHL-Clinical Test Request Form (Micro 220) to the VDHL **within 60 days of collection**.

#### 5. Rectal Swab Specimen Collection (for Medical Provider use)

- a. Open the Xpert Swab Specimen Collection kit
- b. Open the outer peelpack (which contains the two-package kit), and identify the larger cleaning swab and discard it.
- c. Open the collection swab wrapper by partially peeling open the top of the wrapper.
- d. Remove the swab, taking care not to touch the tip or lay it down. If the soft tip is touched, the swab laid down, or the swab is dropped, use a new Xpert Swab Specimen Collection Kit.
- e. Carefully insert the swab approximately 1 cm beyond the anal sphincter (so that the fiber tips are no longer visible) and rotate gently. Highly soiled swab specimens should not be used with Xpert CT/NG. While holding the swab in the same hand, unscrew the cap from the Xpert Swab Transport Reagent tube.
- f. Do not spill the contents of the tube. If the contents are spilled, use a new collection kit.
- g. Immediately place the swab into the transport reagent tube.
- h. 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.
- i. Recap the swab transport reagent tube and tighten the top securely.

- j. Invert or gently shake the tube 3-4 times to elute material from the swab. Avoid foaming.
- k. Ensure that the correct patient information and date of collection are on the tube label. Place the transport tube in the small Ziploc baggie.
- l. Transport the sample and VDHL-Clinical Test Request Form (Micro 220) to the VDHL **within 60 days of collection.**

## 6. Urine specimens (For Medical Provider Use)

- a. The patient should not have urinated for at least one hour prior to specimen collection. Female patients should NOT cleanse the labial area prior to collecting the specimen. Male patients should not cleanse the tip of the penis prior to collecting specimen.
- b. Direct patient to provide first-catch urine (20-50 ml) into a urine collection cup free of any preservatives.
- c. Open the package of the disposable transfer pipette provided in the kit.
- d. Remove the yellow cap from the transport tube and locate the black dashed fill line on the tube. This is the volume required for an acceptable sample.
- e. Mix the urine specimen well. Insert the transfer pipette into the urine cup so that the tip is near the bottom of the cup. Transfer approximately 7 ml of the urine into the transport tube, using the disposable pipette. The correct volume has been added when the level reaches the black dashed line on the label of the transport tube.
- f. Replace the yellow cap on the transport tube and tighten securely.
- g. Invert the transport tube 3-4 times to ensure that the specimen and reagent/preservative are well mixed.
- h. Ensure that the correct patient information and date of collection are on the tube label. Do not obscure the black dashed line on the transport tube with any labels. Place the transport tube in the small Ziploc baggie.
- i. Refrigerate until ready to transport.
- j. For female & male urine samples, transport the sample (**COLD**) and VDHL-Clinical Test Request Form (Micro 220) to the VDHL **within 45 days of collection.**

**NOTE: For female urine samples that cannot be shipped cold, the sample must be received at the VDHL within three days of collection.**

5. Fill out the VDHL-Clinical Test Request Form (Micro 220) completely. The following information is required to ensure accurate and efficient processing of the specimen and reporting of test results:

- Name and address of health care provider- including referring physician
- Patient's name, date of birth, address, and gender
- Date of specimen collection
- ICD Code
- Patient insurance (if applicable)
- Source of specimen (Endocervical, Vaginal, Urine)
- Test requested (see back of Micro 220)

6. **Swabs:** Put the Ziploc bag containing the specimen and the completed VDHL-Clinical Test Request Form (Micro 220) into the padded envelope. Do not place the completed VDHL-Clinical Test Request Form (Micro 220) inside the Ziploc bag with the specimen, and do not staple it to the Ziploc bag.

**Urines:** Put the Ziploc bag containing the specimen and the completed VDHL-Clinical Test Request Form (Micro 220) into the padded envelope. Do not place the completed VDHL-Clinical Test Request Form (Micro 220) inside the Ziploc bag with the specimen, and do not staple it to the Ziploc bag.

7. Staple or tape the padded envelope shut. Ship to the mailing address provided at the top of page 1 of these instructions.

**Specimen Acceptance Criteria:**

<b>Specimen</b>	<b>Transport and Storage Temperature</b>	<b>Must be Received at VDHL Within:</b>
Endocervical Swab, Vaginal Swab, Pharyngeal Swab, and Rectal Swab in Xpert Swab Transport Reagent	2-30° C	60 days
Female Urine	2-15° C	45 days
	15-30° C	3 days
Male Urine	2-30° C	45 days

If you have comments or questions regarding these instructions, please call 802-338-4724 or (toll free) 800-660-9997.