

Incyte Swab Specimens

Infectious Disease Testing

Incyte Diagnostics offers infectious disease testing using the Incyte swab. These gynecologic tests aid in the detection, diagnosis, and treatment of viral, fungal, and bacterial infections. Nucleic acid testing using Polymerase Chain Reaction (PCR) methodology is employed to provide high levels of sensitivity and specificity in testing for the presence of these organisms. The following tests are orderable using an Incyte swab collection.



- Chlamydia
- Gonorrhea
- Trichomonas vaginalis
- Gardnerella vaginalis
- Candida albicans
- Candida glabrata
- Candida tropicalis
- Candida parapsilosis
- Mycoplasma genitalium
- Mycoplasma hominis
- Atopobium vaginae
- Ureaplasma spp.
- Mobiluncus mulieris
- Mobiluncus curtisii

For patients with suspected Vaginosis/Vaginitis:

Please use Incyte swab for specimen collection

- A thorough collection of the vaginal walls is required.

For patients with Cervicitis:

Please use Incyte swab for specimen collection

- Begin with an initial thorough collection from the cervix. A subsequent vaginal collection may be made with the same swab if vaginal organism testing is also desired.

Specimen Collection:

- Aseptically remove sterile swab from package.
- Collect specimen by vigorously swabbing site for 30 seconds.
- Aseptically remove cap from vial.
- Place swab in transport medium and break off swab against rim of the tube.
- Replace cap to vial, close tightly.
- Fill out vial label with full patient name and one other identifier.

SPECIMEN COLLECTION INSTRUCTIONS

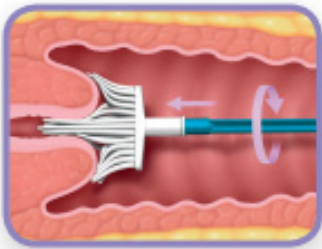
ThinPrep® Pap Specimen

Option 1

ThinPrep® sample collection with mop/broom device



1. Record the patient's name and ID number on the vial, and the patient information and medical history on the cytology requisition form.



2. Obtain an adequate sample from the transformation zone of the cervix using a cervical sampler (broom-like device). Insert the central bristles of the broom into the endocervical canal deep enough to allow the shorter bristles to fully contact the ectocervix. Push gently, and rotate the brush 360° in a clockwise direction 3-5 times.



3. Rinse the cervical sampler immediately into the vial by pushing it into the bottom of the vial 10 times, forcing the bristles apart. As a final step, swirl the brush **vigorously** to further release material. Visually inspect the cervical sampler to ensure that no material remains attached. Discard the collection device. **Do not leave the head of the cervical sampler in the vial.**



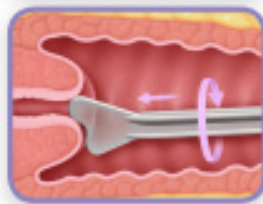
4. Tighten the cap so that the black torque line on the cap passes the black torque line on the vial. **Do not over-tighten.** Place the vial and pathology request form in a specimen bag for transportation to the laboratory.

Option 2

ThinPrep® sample collection with brush/spatula



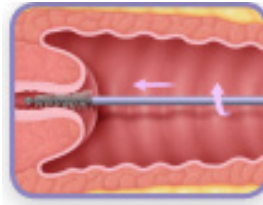
1. Record the patient's name and ID number on the vial, and the patient information and medical history on the cytology requisition form.



2. Obtain an adequate sample from the ectocervix using a plastic spatula. Select the contoured end of the plastic spatula and rotate it 360° in a clockwise direction around the entire ectocervix, while maintaining tight contact with the ectocervical surface.



3. Rinse the spatula as quickly as possible into the vial by swirling the spatula **vigorously** in the vial 10 times. Discard the plastic spatula.



4. Obtain an adequate sampling from the endocervix using an endocervical brush device. Insert the Cytobrush into the endocervical canal until only the bottom-most bristles are exposed. Slowly rotate 1/4 or 1/2 turn in one direction. **Do not over rotate the brush.**



5. Rinse the endocervical brush immediately in the same vial by rotating the device in the solution 10 times while pushing it against the vial wall. As a final step, swirl the brush **vigorously** to further release material. Discard the brush.



6. Tighten the cap so that the torque line on the cap passes the torque line on the vial. **Do not over-tighten.** Place the vial and pathology request form in a specimen bag for transport to the laboratory.

Aptima[®] Multitest Swab Specimen Collection Kit

Clinician collection procedure guide

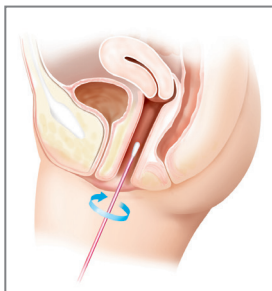
Collection for vaginal swab specimens



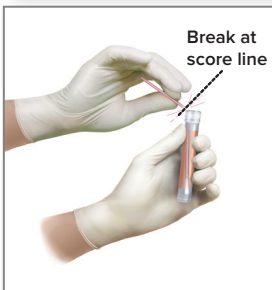
Partially open the swab package and remove the swab. Do not touch the soft tip or lay the swab down. **If the soft tip is touched, laid down, or dropped, discard and get a new Aptima Multitest Swab Specimen Collection Kit.** Hold the swab, placing thumb and forefinger in the middle of the shaft covering the black score line. Do not hold the shaft below the score line.

Swab specimen collection guide for:

- *Chlamydia trachomatis* (CT)
- *Neisseria gonorrhoeae* (NG)
- *Trichomonas vaginalis* (TV)



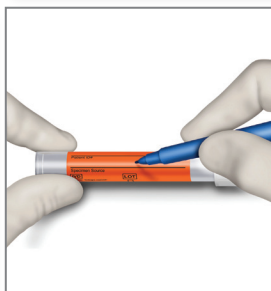
Carefully insert the swab into the vagina about 2 inches (5 cm) past the introitus and gently rotate the swab for 10 to 30 seconds. Make sure the swab touches the vaginal walls so that moisture is absorbed by the swab. Withdraw the swab without touching the skin.



Break at score line



While holding the swab in hand, unscrew the tube cap. Do not spill the tube contents. **If the tube contents are spilled, discard and replace with a new Aptima Multitest Swab Specimen Collection Kit.** Immediately place the swab into the transport tube so the black score line is at the top of the tube. Align the score line with the top edge of the tube and carefully break the shaft. The swab will drop to the bottom of the vial. Discard the top portion of the shaft.



Tightly screw the cap onto the tube. When collecting multiple specimens from the same patient, the tube label provides a specimen source field for unique identification for the specimen location.



Hologic provides this collection procedure guide as a general informational tool only; it is not an affirmative instruction or guarantee of performance. It is the sole responsibility of the clinician to read and understand the appropriate package insert and comply with applicable local, state and federal rules and regulations.

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Aptima® unisex swab kit

Female collection procedure guide

Collection for endocervical swab specimens



Use cleaning swab (white shaft swab with red printing) to remove excess mucus from cervical os and surrounding mucosa. Discard this swab.



Insert collection swab (blue shaft swab with green printing) into endocervical canal. Gently rotate swab clockwise for 10 to 30 seconds to help ensure adequate sampling. Withdraw swab carefully; avoid any contact with vaginal mucosa.



While holding swab in hand, unscrew the tube cap. Do not spill tube contents. **If the tube contents are spilled, discard and replace with a new Aptima unisex swab transport tube.** Carefully break the swab shaft at the score line against the side of the tube. Discard top portion of swab shaft.



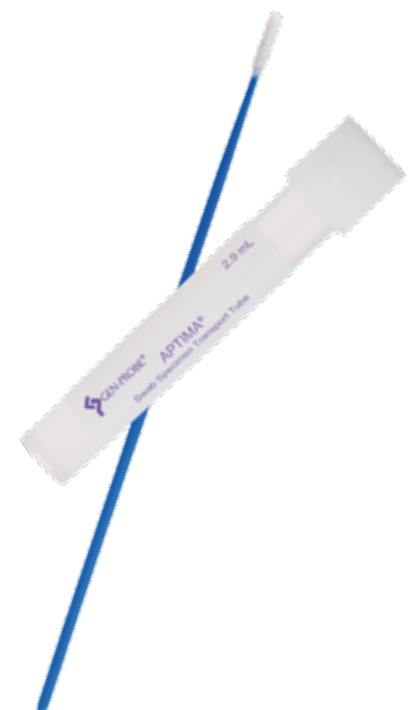
Re-cap swab specimen transport tube tightly.

Swab specimen collection guide for:

- *Chlamydia trachomatis* (CT)
- *Neisseria gonorrhoeae* (GC)
- *Trichomonas vaginalis* (TV)

Specimen Transport and Storage

- After collection, transport and store swab in unisex specimen transport tube between 2°C to 30°C until tested.
- Specimens must be assayed with the Aptima assay for CT, GC and /or TV within 60 days of collection.
- If longer storage is needed, freeze between -20°C to -70°C for up to 12 months after collection in the Aptima assay for CT and/or GC. For the Aptima assay for TV, freeze at < -20°C for up to 12 months.

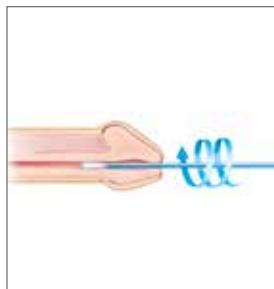


Aptima® unisex swab device

Male collection procedure guide

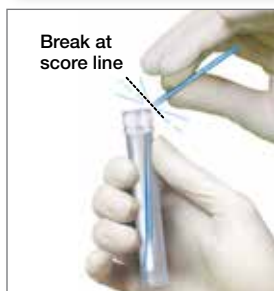
Collection for male urethral swab specimens

Patient should not have urinated for at least 1 hour prior to specimen collection.



Discard cleaning swab (white shaft with red print on label). The cleaning swab is NOT needed for male specimen collection.

Insert specimen collection swab (blue shaft swab with green printing) 2 cm to 4 cm into urethra. Gently rotate swab clockwise for 2 to 3 seconds in urethra to help ensure adequate sampling. Withdraw swab carefully.



While holding swab in hand, unscrew tube cap. Do not spill tube contents. **If tube contents are spilled, discard and replace with a new Aptima unisex swab transport tube.** Carefully break the swab shaft at the score line against the side of the tube. Discard top portion of swab shaft.



Re-cap swab specimen transport tube tightly.

Swab specimen collection guide for:

- *Chlamydia trachomatis* (CT)
- *Neisseria gonorrhoeae* (GC)

Specimen Transport and Storage

- After collection, transport and store swab in unisex specimen transport tube between 2°C to 30°C until tested.
- Specimens must be assayed with the Aptima assay for CT and/or GC within 60 days of collection.
- If longer storage is needed, freeze between -20°C to -70°C for up to 12 months after collection.

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Aptima® Urine Specimen Collection Kit

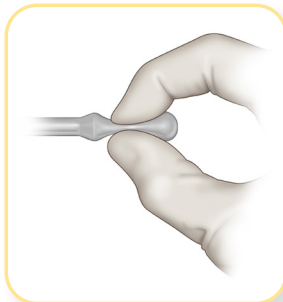
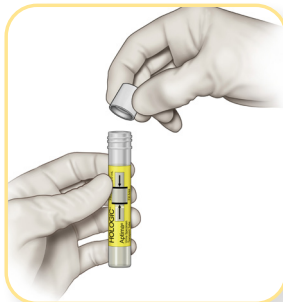
Collection procedure guide

For male and female urine specimens

Patient should not urinate for at least 1 hour prior to specimen collection.



Direct patient to provide **first-catch** urine (~20 - 30 mL of initial urine stream) into urine collection cup. Collection of larger volumes of urine may result in specimen dilution that may reduce test sensitivity. Female patients should not cleanse labial area prior to providing specimen.



Remove cap and transfer 2 mL of urine into urine specimen transport tube using the pipette provided.



The correct volume of urine has been added when the fluid level is between black fill lines on urine specimen transport tube label.



Discard pipette. Tightly screw cap onto tube. This is now known as the “processed urine specimen.”



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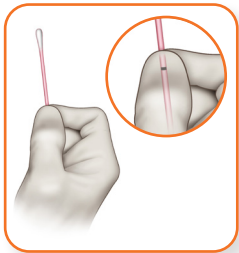
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Aptima® Multitest Swab Specimen Collection Kit

Clinician collection procedure guide

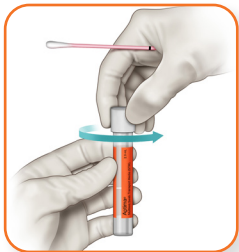
For rectal swab specimens



Partially open swab package and remove swab. Do not touch the soft tip or lay the swab down. If the soft tip is touched, laid down, or dropped, discard and get a new Aptima Multitest Swab Specimen Collection Kit. **Hold swab, placing thumb and forefinger in the middle of shaft covering black score line.** Do not hold shaft below score line.



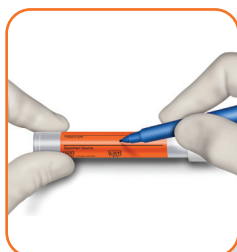
Carefully insert swab into the rectum about 1-2 inches (3-5 cm) past the anal margin (the outside of the anus) and **gently rotate swab clockwise for 5-10 seconds.** Withdraw swab without touching skin.



While holding swab in hand, unscrew tube cap. Do not spill tube contents. If tube contents are spilled, discard and replace with a new Aptima Multitest Swab Specimen Collection Kit.



Immediately place swab into transport tube so black score line is at top of tube. **Align the score line with top edge of tube and carefully break shaft.** Discard top portion of shaft.



Tightly screw cap onto tube. When collecting multiple specimens from the same patient, the tube label provides a specimen source field for unique identification for specimen location.



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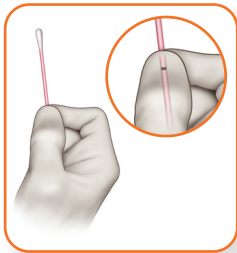
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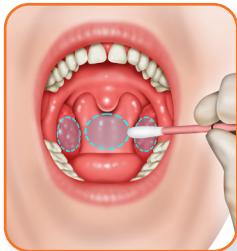
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Clinician collection procedure guide

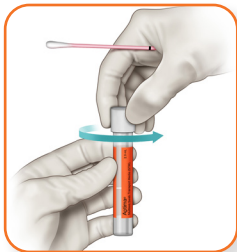
For throat swab specimens



Partially open swab package and remove swab. Do not touch the soft tip or lay the swab down. If the soft tip is touched, laid down, or dropped, discard and get a new Aptima Multitest Swab Specimen Collection Kit. **Hold swab, placing thumb and forefinger in the middle of shaft covering black score line.** Do not hold shaft below score line.



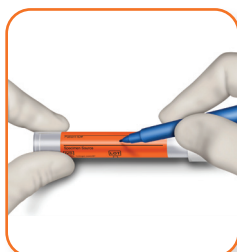
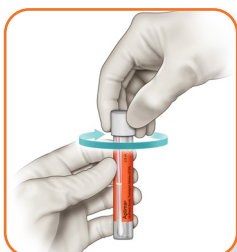
Carefully insert the swab into the throat ensuring contact with bilateral tonsils (if present) and the posterior pharyngeal wall, then withdraw the swab without touching the inside of the cheeks or tongue.



While holding swab in hand, unscrew tube cap. Do not spill tube contents. If tube contents are spilled, discard and replace with a new Aptima Multitest Swab Specimen Collection Kit.



Immediately place swab into transport tube so black score line is at top of tube. **Align the score line with top edge of tube and carefully break shaft.** Discard top portion of shaft.



Tightly screw cap onto tube. When collecting multiple specimens from the same patient, the tube label provides a specimen source field for unique identification for specimen location.



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