

How to collect a specimen for *Trichomonas* Amplified Probe

Specimen collection for *Trichomonas vaginalis*
8940/AB8940

Aptima <i>Trichomonas</i> assay performance		
Specimen Type	Sensitivity (%)	Specificity (%)
Vaginal swab	100	99.0
Endocervical swab	100	99.4
Female urine	95.2	98.9

SPECIMENS AND CONTAINERS:

Vaginal: Aptima Multitest Swab Specimen Collection Kit (pink-shafted swab)

Endocervical: Aptima Unisex Swab Specimen Collection Kit (blue-shafted swab)

Female Urine: Aptima Urine Specimen Collection Kit

**Hysterectomy
Patients:** Collect vaginal or urine specimen

Unacceptable:

- No swab, white swab or two swabs in Aptima swab transport tube
- Swab not from Aptima Unisex swab collection kit
- Pink-shafted swab for endocervical source
- Blue-shafted swab for vaginal source
- Urine transport tube not filled to "Fill Area" (above or below-rejected)
- **Urine not in Aptima transport tube**
 - Client may transfer urine to Transport tube within 24 hours of collection. *Due to nucleic acid cross-contamination issues, this must be done at the client site and will not be done at Allina Health Laboratory.* If the urine has not been opened in the lab, it may be returned to the client to be transferred to the transport tube; otherwise, recollection is required.
- M4 or M5 media
- Frozen
- Catheterized urine
- Male urethral
- Male urine

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SPECIMEN COLLECTION

The following instructions are provided on the kit packages.

Female endocervical swab specimens:

Use Aptima **Unisex** Swab Specimen Collection Kit. *Specimen will be rejected if collected with Aptima Vaginal Swab Specimen Collection Kit.*

1. Remove excess mucus from cervical os and surrounding mucosa using cleaning swab (white-shafted swab in package with red printing). **Discard the white swab.**
2. Insert specimen collection swab (**blue-shafted** swab in package with green printing) into endocervical canal.
3. Gently rotate swab clockwise for 10 to 30 seconds in endocervical canal to ensure adequate sampling.
4. Withdraw swab carefully; avoid any contact with vaginal mucosa.
5. Remove cap from swab specimen transport tube and immediately place specimen collection swab into specimen transport tube.
6. Carefully break swab shaft at score line and discard the top portion of the swab shaft; use care to avoid splashing contents.
7. Re-cap swab specimen transport tube tightly.

Female vaginal specimens (clinician-collected only):

Use Aptima **Multitest** Swab Specimen Collection Kit. *Specimen will be rejected if collected with Aptima Unisex Swab Specimen Collection Kit.*

1. Partially peel open the swab package. Remove the swab. Do not touch the soft tip or lay the swab down. If the soft tip is touched, the swab is laid down, or the swab is dropped, use a new Aptima Multitest Swab Specimen Collection Kit.
2. Hold the swab, placing your thumb and forefinger in the middle of the swab shaft covering the score line. Do not hold the swab shaft below the score line.
3. Carefully insert the swab into the vagina about 2 inches past the introitus and gently rotate the swab for 10 to 30 seconds. Make sure the swab touches the walls of the vagina so that moisture is absorbed by the swab and then withdraw the swab without touching the skin.
4. While holding the swab in the same hand, unscrew the cap from the tube. Do not spill the contents of the tube. If the contents of the tube are spilled, use a new Aptima Multitest swab Specimen Collection Kit.
5. Immediately place the swab into the transport tube so that the score line is at the top of the tube.
6. Carefully break the swab shaft at the score line against the side of the tube.
7. Immediately discard the top portion of the swab shaft.
8. Tightly screw the cap onto the tube.

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Female urine specimens:

Patient should not have urinated for at least 1 hour prior to specimen collection, and should not cleanse the labial area prior to providing the specimen.

1. Direct patient to provide first-catch urine (approximately 20 to 30 mL of initial urine stream) into urine collection cup free of any preservatives. Collection of larger volumes of urine may result in specimen dilution that may reduce test sensitivity.
2. Remove cap from urine specimen transport tube and transfer 2 mL of urine into urine specimen transport tube using disposable pipette provided. The correct volume of urine has been added when fluid level is between black fill lines on urine specimen transport tube label.
3. If refrigerated, urine may be transferred to the transport tube at the collection site within 24 hours.
4. Re-cap urine specimen transport tube tightly.

SPECIMEN TRANSPORT

- Ambient or refrigerated temperatures
- Transport swab specimens within 60 days or urine in transport tube within 30 days
- Place each transport tube in an individual zip lock bag.
 - Do **not** group multiple tubes together in one bag due to the risk of DNA cross-contamination and rejection of all specimens if there is leakage.

METHOD LIMITATIONS

- To ensure proper endocervical sampling, excess mucus should be removed.
- Urine and vaginal swab specimen sampling is not designed to replace cervical exams and endocervical specimen for diagnosis of female urogenital infections. Patients may have cervicitis, urethritis, urinary tract infections, or vaginal infections due to other causes or concurrent infections with other agents.
- Performance with other specimen types has not been evaluated.
- Therapeutic failure or success cannot be determined with APTIMA *Trichomonas vaginalis* Assay since nucleic acid may persist following appropriate antimicrobial therapy.
- Results from the APTIMA *Trichomonas vaginalis* Assay should be interpreted in conjunction with other clinical data available to the clinician.
- Performance of the vaginal swab specimen has not been evaluated in pregnant women or women less than 14 years of age.
- A negative result does not preclude a possible infection because the presence of *Trichomonas tenax* or *Pentatrichomonas hominis* in a specimen may affect the ability to detect *T. vaginalis* rRNA. *T. tenax* is a commensal of the oral cavity, and *P. hominis* is a commensal of the large intestine.