Collection Guide for Vaginosis/Vaginitis and Sexually Transmitted Infections (STI) SAMPLE COLLECTION INSTRUCTIONS

Specimens should be collected and transported following the instructions below and using the collection kits provided by Deaconess Regional Laboratory.

| TABLE 1A: | EPIC/SunQuest | Test | Codes |
|-----------|---------------|------|-------|
|-----------|---------------|------|-------|

| | EPIC code | SunQuest code |
|---------------|-----------|---------------|
| CT/GC | LAB4054 | CGPA |
| TV | LAB4055 | TVPAN |
| BV | LAB5400 | BVTMA |
| CV/TV | LAB5401 | CVTTMA |
| M. genitalium | LAB167587 | MGNTMA |

CT=C. trachomatis; GC=N. gonorrhea; TV=T. vaginalis; BV=Bacterial vaginosis; CV=Candida vaginosis

TABLE 1B: Approved APTIMA Collection Devices and Approved Body Sites STI COLLECTION MATRIX

| | | - | | | | | - | _ |
|---|---|--|-----------------------------------|-----------------------------------|-------------|----------------|--------------|-----------------------------------|
| Collection Kit | Sample Type | Combo 2 (CT/GC) Assay | Mycoplasma genitalium Assay | Trichomonas vaginalis Assay | BV Assay | CV/TV Assay | HPV Assay | HPV 16 18/45 Genotype Assay |
| | ThinPrep (PreservCYT) | ~ | | ~ | | | ~ | ~ |
| Aptima Multitest Swab Collection Kit | Clinician Collected Vaginal Swab | ~ | ~ | ~ | ~ | ~ | | |
| | Patient Collected Vaginal Swab | ~ | √ | | ~ | ~ | | |
| <u></u> | Patient Collected Penile Meatal Swab | | ✓ | | | | | |
| 1 | Clinician Collected Throat Swab | ~ | | | | | | |
| | Clinician Collected Rectal Swab | ~ | | | | | | |
| Aptima Unisex Swab Collection Kit | Clinician Collected Endocervical Swab | ~ | ~ | ~ | | | | |
| | Clinician Collected Male Urethral Swab | ~ | ✓ | * | | | | |
| Sterile Container | Female First Catch Urine (<30mLs) | ✓ | ✓ | * | | | | |
| | Male First Catch Urine (<30mLs) | ~ | ~ | * | | | | |
| | | ✓ =US-FDA Clearance or Approval for individuals ≥14 years of age | | | | | | |

✓ =US-FDA Clearance or Approval for Individuals ≥14 years of age *= Laboratory Developed Test for individuals ≥14 years of age

CT=C. trachomatis; GC=N. gonorrhea; TV=T. vaginalis; BV=Bacterial vaginosis; CV=Candida vaginosis

Instructions for Specimen Collection

VAGINAL SWAB SPECIMENS

- 1. Use Aptima Multitest Swab Specimen Collection Kit
- 2. Partially peel open the swab package. Remove the pinkshaft specimen collection swab. Do not touch the soft tip or lay the swab down. If the soft tip is touched, use a new Aptima Multitest Swab Collection Kit.
- 3. 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.
- 4. Carefully insert the pink-shaft swab into the vagina about 2 inches (5 cm) past the introitus and gently rotate the swab for 10–30 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.
- 5. While holding the swab in the same hand, unscrew the cap from the tube. Take care not to spill the contents of the tube. If you spill the contents of the tube, use a new Aptima Multitest Swab Specimen Collection tube.
- 6. Immediately place the swab into the transport tube so that the score line is at the top of the tube.
- 7. Carefully break the swab shaft at the score line against the side of the tube.
- 8. Immediately discard the top portion of the swab shaft.
- 9. Tightly screw the cap onto the tube.
- 10. Store and transport at 2°C to 30°C until tested

FIRST-CATCH URINE COLLECTION

- 1. Do not urinate for at least one hour prior to collecting specimen.
- 2. Collect approximately 20–30 mL of first-catch urine (i.e., initial urine stream) into a urine collection cup free of any preservatives. Collection of larger volumes of urine may result in rRNA target dilution, which may reduce test sensitivity. Female patients should not cleanse the labial area prior to providing the specimen.
- 3. Store and transport at 2°C to 30°C within 24 hours of collection.

4. Performed at Midtown Laboratory:

- a. Remove the cap and transfer 2 mL of urine into the urine specimen transport tube using the disposable pipette provided. The correct volume of urine has been added when the fluid level is between the black fill lines on the label of the urine specimen transport tube.
- b. Urine sample must be transferred into the Aptima Urine Specimen Collection tube within 24 hours of collection.
- c. Recap the urine specimen transport tube tightly.
- d. Store and transport at 2°C to 30°C until tested.

MALE URETHRAL SWAB SPECIMENS

- 1. Use the Aptima Unisex Swab Specimen Collection Kit
- 2. Do not urinate for at least one hour prior to collecting specimen.
- 3. Insert the specimen collection swab (blue-shaft swab in the package with the green printing) 2–4 cm into the urethra.
- 4. Gently rotate the swab clockwise for 2–3 seconds in the urethra for adequate sampling.
- 5. Withdraw the swab carefully.
- 6. Remove the cap from the Aptima Unisex Swab Specimen Collection tube and immediately place the blue specimen collection swab into the transport tube.
- 7. Carefully break the swab shaft against the side of the tube at the score line and discard the top portion of the swab shaft; use care to avoid splashing of contents.
- 8. Recap the swab specimen transport tube tightly.
- 9. Store and transport at 2°C to 30°C until tested.

MALE PENILE MEATAL SWAB SPECIMENS

- 1. Use the Aptima Multitest Swab Specimen Collection Kit
- 2. Do not urinate for at least one hour prior to collecting specimen.
- 3. For uncircumsiced men, roll the foreskin down before collecting
- 4. Roll the swab just at the tip or outside the opening to the penis. For best collection, roll completely around the opening.
- 5. Remove the cap from the Aptima Unisex Swab Specimen Collection tube and immediately place the pink specimen collection swab into the transport tube.

- 6. Carefully break the swab shaft against the side of the tube at the score line and discard the top portion of the swab shaft; use care to avoid splashing of contents.
- 7. Recap the swab specimen transport tube tightly.
- 8. Store and transport at 2°C to 30°C until tested.

FEMALE ENDOCERVICAL SPECIMENS

- 1. Use the Aptima Unisex Swab Specimen Collection Kit
- 2. Remove excess mucus from the cervical ostium and surrounding mucosa using the cleaning swab (whiteshaft swab in the package with red printing). Discard this swab.
- 3. Insert the specimen collection swab (blue-shaft swab in the package with the green printing) into the endocervical canal.
- 4. Gently rotate the blue swab clockwise for 10–30 seconds in the endocervical canal to ensure adequate sampling.
- 5. Withdraw the swab carefully; avoid any contact with the vaginal mucosa.
- 6. Remove the cap from the Aptima Unisex Swab Specimen Collection tube and immediately place the specimen collection swab into the transport tube.
- 7. Carefully break the swab shaft against the side of the tube at the score line and discard the top portion of the swab shaft; use care to avoid splashing of contents.
- 8. Recap the swab specimen transport tube tightly.
- 9. Store and transport at 2°C to 30°C until tested.

ANAL/RECTAL SWABS

- 1. Use Aptima Multitest Swab Specimen Collection Kit
- 2. Insert the pink-shaft specimen collection swab approximately 3–5 cm into the anal canal.
- 3. Rotate the swab for 5–10 seconds against the rectal wall (at least three times) to sample the mucosal surface.
- 4. If the swab is grossly contaminated with feces, discard and repeat the collection.
- 5. Withdraw the swab carefully, remove the cap from the swab specimen transport tube, and immediately place the specimen collection swab into the transport tube.
- 6. Carefully break the swab shaft against the side of the tube at the score line and discard the top portion of the swab shaft; use care to avoid splashing of contents.
- 7. Recap the swab specimen transport tube tightly.
- 8. If needed prior to insertion, the swab can be moistened with water or saline solution.

THROAT/PHARYNGEAL SWABS

- 1. Use Aptima Multitest Swab Specimen Collection Kit
- 2. Discard the large white-shaft cleaning swab.
- 3. Using the pink-shaft specimen collection swab, sample the bilateral posterior pharynx, both tonsils, and the uvula.
- 4. Withdraw the swab carefully, remove the cap from the swab specimen transport tube, and immediately place the specimen collection swab into the transport tube.
- 5. Carefully break the swab shaft against the side of the tube at the score line and discard the top portion of the swab shaft; use care to avoid splashing of contents.
- 6. Recap the swab specimen transport tube tightly.