SPECIMEN SAMPLE GUIDE

ThinPrep® Liquid-based Pap

- Gyn Cytology [1]
- HPV HR reflex to Genotyping [1]
- Chlamydia/Gonorrhea [1]
- Trichomonas [1]
- Candida species with reflex speciation*
  - *-albicans*
  - *-glabrata*
  - *-tropicalis*
  - *-parapsilosis*
- BV (Gardnerella overgrowth)*
- HSV 1&2 -anogenital spatula scraping of skin lesion*

10% Neutral Buffered Formalin

- Tissue biopsy specimens

RPMI

- Flow Cytometry (lymph node sample)

Michel's Solution

- Direct Immunoflourescence (DIF)

Aptima Unisex Swab

Endocervical or male urethral

- Chlamydia/Gonorrhea†: female [1] or male [1]
- Trichomonas†: female [1] or male*
- CV (Candida) species with reflex speciation*
  - *-albicans*
  - *-glabrata*
  - *-tropicalis*
  - *-parapsilosis*
- BV (Gardnerella vaginalis overgrowth)*
- Expanded BV Panel for treatment resistant or recurrent BV*:
  - Gardnerella Vaginalis *
  - Atopobium Vaginae *
  - L. Iners *
  - BVAB2 *
  - Megasphera *
  - Lactobacillus Sp.*

Aptima Urine Collection Kit

- Chlamydia/Gonorrhea†: female [1] or male [1]
- Trichomonas: female* or male*

-Urine Collection is NOT recommended due to low sensitivity

CytoLyt® Solution (Cytology)

- Nipple discharge
- Fine-Needle aspiration
- Urine

Aptima Multitest Swab

Vaginal or Anogenital

- Chlamydia/Gonorrhea†: vaginal [1]
- Trichomonas†: vaginal [1]
- CV (Candida) with reflex speciation*
  - *-albicans*
  - *-glabrata*
  - *-tropicalis*
  - *-parapsilosis*
- BV (Gardnerella vaginalis overgrowth)*
- Expanded BV Panel for treatment resistant or recurrent BV*:
  - Gardnerella Vaginalis *
  - Atopobium Vaginae *
  - L. Iners *
  - BVAB2 *
  - Megasphera *
  - Lactobacillus Sp.*
- HSV 1&2 -anogenital swab of skin lesion: female [1] or male [1]

†CPA can only accept these specimens if the client is NOT currently using Hendrick Regional Lab for these tests
* = Sent to our reference lab
[1] = FDA Approved

CLINICAL PATHOLOGY ASSOCIATES

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Aptima® HPV Assay

The Aptima HPV assay is an in vitro nucleic acid amplification test for the qualitative detection of E6/E7 viral messenger RNA (mRNA) from 14 high-risk types of human papillomavirus (HPV) in cervical specimens. The high-risk HPV types detected by the assay include: 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68. The Aptima HPV assay does not discriminate between the 14 high-risk types. Cervical specimens in ThinPrep Pap Test vials containing PreservCyt Solution and collected with broom-type or cytobrush/spatula collection devices* may be tested with the Aptima HPV assay. The assay is used with the Tigris DTS System or the Panther System.

The use of the test is indicated:

1. To screen women 21 years and older with atypical squamous cells of undetermined significance (ASC-US) cervical cytology results to determine the need for referral to colposcopy. The results of this test are not intended to prevent women from proceeding to colposcopy
2. In women 30 years and older, the Aptima HPV assay can be used with cervical cytology to adjunctively screen to assess the presence or absence of high-risk HPV types. This information, together with the physician's assessment of cytology history, other risk factors, and professional guidelines, may be used to guide patient management.

* Broom-type device (e.g., Wallach Pipette) or endocervical brush/spatula

WARNING:

- *This assay is not intended for use as a screening device for women under age 30 with normal cervical cytology.*
- *The Aptima HPV assay is not intended to substitute for regular cervical cytology screening.*
- *Detection of HPV using the Aptima HPV assay does not differentiate HPV types and cannot evaluate persistence of any one type.*
- *The use of this assay has not been evaluated for the management of HPV vaccinated women, women with prior ablative or excisional therapy, hysterectomy, who are pregnant, or who have other risk factors (e.g., HIV+, immunocompromised, history of sexually transmitted infection).*
- *The Aptima HPV assay is designed to enhance existing methods for the detection of cervical disease and should be used in conjunction with clinical information derived from other diagnostic and screening tests, physical examinations, and full medical history in accordance with appropriate patient management procedures.*

Aptima® Combo 2 Assay for Chlamydia and Gonorrhea

The Aptima Combo 2® Assay is a target amplification nucleic acid probe test that utilizes target capture for the in vitro qualitative detection and differentiation of ribosomal RNA (rRNA) from Chlamydia trachomatis (CT) and/or Neisseria gonorrhoeae (GC) to aid in the diagnosis of chlamydial and/or gonococcal urogenital disease using the Panther® System as specified.

On the Panther System, the assay may be used to test the following specimens from symptomatic and asymptomatic individuals: clinician-collected endocervical, vaginal and male urethral swab specimens, clinician-collected gynecological specimens collected in the PreservCyt® Solution, patient-collected vaginal swab specimens,1 and female and male urine specimens.

1 Patient-collected vaginal swab specimens are an option for screening women when a pelvic exam is not otherwise indicated. The vaginal and multitest swab specimen collection kits are not for home use.

Aptima® Trichomonas vaginalis Assay

The Aptima Trichomonas vaginalis Assay is an in vitro qualitative nucleic acid amplification test (NAAT) for the detection of ribosomal RNA (rRNA) from Trichomonas vaginalis to aid in the diagnosis of trichomoniasis using the Panther System.

The assay may be used to test the following specimens from symptomatic or asymptomatic women: clinician-collected endocervical swabs, clinician-collected vaginal swabs, and specimens collected in PreservCyt Solution.

Aptima Herpes Simplex Viruses 1 & 2 Assay

The Aptima® Herpes Simplex Viruses 1 & 2 assay (Aptima HSV 1 & 2 assay) is an in vitro diagnostic nucleic acid amplification test (NAAT), using real time transcription-mediated amplification (TMA), for the qualitative detection and differentiation of herpes simplex virus type 1 (HSV-1) and type 2 (HSV-2) messenger RNA (mRNA) in clinician-collected swab specimens from anogenital skin lesions. The assay is intended for use with swab specimens placed in Aptima specimen transport medium (STM) or in viral transport media (VTM) that is immediately diluted into STM.

The Aptima HSV 1 & 2 assay is intended for use as an aid in the diagnosis of HSV-1 and/or HSV-2 infections in symptomatic male and female patients. The Aptima HSV 1 & 2 assay is indicated for use on the Panther® system.

WARNING:

The Aptima HSV 1 & 2 assay is not FDA-cleared for use with cerebrospinal fluid (CSF) or for prenatal screening.

-Use of these assays outside of the intended uses or approved specimens should be considered investigational or for research and the clinician must determine the relevance.