

Aptima Combo 2® (CT/GC)		Aptima® <i>Trichomonas vaginalis</i>		Aptima® HPV (including Aptima® HPV 16 18/45 Genotype Assay [only performed as a reflex test in the setting of a positive HPV detection test])	
Collection Device/Specimen	US FDA Approval Status/Minimum Age	Collection Device/Specimen	US FDA Approval Status/Minimum Age	Collection Device/Specimen	US FDA Approval Status/Minimum Age
Aptima® Multitest Swab: Vaginal Collection ¹ , Rectal Collection, Throat Collection, Eye Collection (LDT) [ARUP MISC]	US FDA cleared ≥14 years	Aptima® Multitest Swab: Vaginal Collection ¹	US FDA cleared ≥14 years	Aptima® Multitest Swab: Vaginal Collection	Not US FDA cleared
Aptima® Unisex Swab: Endocervical Collection	US FDA cleared ≥14 years	Aptima® Unisex Swab: Endocervical Collection	US FDA cleared ≥14 years	Aptima® Unisex Swab: Endocervical Collection	Not US FDA cleared
Aptima® Unisex Swab: Male Urethral Collection, Rectal Collection (LDT), Throat Collection (LDT), Eye Collection (LDT) [ARUP MISC]	US FDA cleared ≥14 years	Aptima® Unisex Swab: Male Urethral Collection	Not US FDA cleared	Aptima® Unisex Swab: Male Urethral Collection	Not US FDA cleared
Aptima® Urine: Urine Male & Female	US FDA cleared ≥14 years, Female ≥14 years, Male	Aptima® Urine: Urine Male & Female [ARUP]	US FDA cleared ≥14 years, Female ≥14 years, Male	Aptima® Urine: Urine Male & Female	Not US FDA cleared
ThinPrep (PreservCyt): Cervical Collection, Cervical/Endocervical Collection	US FDA cleared ≥21 years, Female	ThinPrep (PreservCyt): Cervical Collection, Cervical/Endocervical Collection	US FDA cleared ≥21 years, Female	ThinPrep (PreservCyt): Cervical Collection, Cervical/Endocervical Collection, Vaginal Collection (LDT), Anal Collection (LDT) [Quest]	US FDA cleared ≥21 years, Female

Collection and transport devices that are verified or validated for specimen sources tested in the Clinical Microbiology Laboratory at NewYork-Presbyterian Hospital/Weill Cornell Medical Center are highlighted in yellow-colored emboldened text. Regarding PreservCyt® (ThinPrep) collected specimens, if specimens are labelled "cervical/endocervical" they are acceptable to test. However, specimens labelled as "endocervical only" collected in PreservCyt® should be rejected. "Cervical only" specimens can be tested and are the preferred source. Vaginal specimens collected and transported in PreservCyt (ThinPrep) for HPV detection – **but not HPV genotyping** – have been validated as an LDT approved by New York State Department of Health (NYS DOH). Rectal and throat specimens collected in Aptima Unisex Swabs for GC/CT testing have been validated as LDTs approved by NYS DOH. Collection and transport devices that are verified or validated for specimen sources available as send-out testing to reference laboratories that are NYS DOH approved are highlighted in purple-colored emboldened text.

Abbreviations: CT, *Chlamydia trachomatis*; GC, *Neisseria gonorrhoeae*; FDA, United States Food and Drug Administration; LDT, laboratory developed test; N/A, not applicable; MISC, Miscellaneous send-out test.

¹Note that only **clinician-collected** vaginal specimens are validated for in-house testing. **Patient self-collected** vaginal specimens are available as send-out testing at special request.

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