

May 2021

To: Clients of the New York Hospital Laboratories (NYHL)

From: NYHL Management

Subject: **Age Restrictions for ThinPrep HPV, Genotyping, and CT/GC Testing**

Dear Valued NYHL Client,

As a reminder, ThinPrep Pap specimens collected from patients <21 years of age are not eligible for HPV, HPV Genotype, CT/GC, or Trichomonas testing.

If CT/GC and/or Trichomonas testing are needed for patients  $\geq 14$  years of age but <21 years of age, a separate specimen can be submitted. For vaginal collection, submit one Aptima® Multitest Swab. For Endocervical collection, submit one Aptima® Unisex Swab. Other sources and swabs are also acceptable for this age group. Please see the attached chart for further reference.



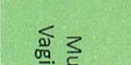



**Aptima® Multitest Swab (Vaginal)**



**Aptima® Unisex Swab (Endocervix)**

Please direct any questions regarding this process change to Lars Westblade, Director of the Clinical Microbiology Service (212)746-0833, or Selma Salter, Manager of the Clinical Microbiology Service (212) 746-2412.

As always, we appreciate your continued support of the Laboratories at NewYork-Presbyterian Hospital/Weill Cornell Medical Center.

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 Source	US FDA Approval Status/Minimum Age (Years)	Collection Device/Specimen Source	FDA Approval Status/Minimum Age (Years)	Collection Device/Specimen Source	FDA Approval Status/Minimum Age (Years)
 Aptima® Multitest Swab: <b>Vaginal Collection</b> <b>Rectal Collection</b> <b>Throat Collection</b>	US FDA-Approved ≥14	 Aptima® Multitest Swab: <b>Vaginal Collection</b>	US FDA-Approved ≥14	 Aptima® Multitest Swab: <b>Vaginal Collection</b>	Not US FDA-approved
 Aptima® Unisex Swab: <b>Endocervical Collection</b> (not FDA-approved for vaginal specimens)	US FDA-Approved ≥14	 Aptima® Unisex Swab: <b>Endocervical Collection</b> (not FDA-approved for vaginal specimens)	US FDA-Approved ≥14	 Aptima® Unisex Swab: <b>Endocervical Collection</b> (not FDA-approved for vaginal specimens)	Not US FDA-approved
 Aptima® Unisex Swab: <b>Male Urethral Collection</b> <b>Rectal Collection (LDT)*</b> <b>Throat Collection (LDT)*</b>	US FDA-Approved ≥14	 Aptima® Unisex Swab: <b>Male Urethral Collection</b>	Not US FDA-approved	 Aptima® Unisex Swab: <b>Male Urethral Collection</b>	Not US FDA-approved
 Aptima® Urine: <b>Urine Male &amp; Female</b>	US FDA-Approved ≥14, Female ≥14, Male	 Aptima® Urine: <b>Urine Male &amp; Female</b>	Not US FDA-approved	 Aptima® Urine: <b>Urine Male &amp; Female</b>	Not US FDA-approved
 ThinPrep (PreservCyt®): <b>Cervical/Endocervical or Cervical Collection</b>	US FDA-Approved ≥21, Female	 ThinPrep (PreservCyt®): <b>Cervical/Endocervical</b> (verified in-house, not offered routinely)	US FDA-Approved ≥21	 ThinPrep (PreservCyt®): <b>Cervical/Endocervical or Cervical Collection</b> <b>Vaginal (LDT)*</b>	US FDA-Approved ≥21

Collection device that are verified/validated for specimen source tested in the clinical microbiology laboratory at NewYork-Presbyterian Hospital-Wall Cornell Medical Center are colored in yellow **emboldened text**. Regarding PreservCyt® (ThinPrep) collected specimens, if specimens are labeled "cervical/endocervical" they are acceptable to test. However, specimens labeled as "endocervical only" collected in PreservCyt® should be rejected. "Cervical only" specimens can be tested. \*Vaginal specimens for HPV detection (excluding HPV genotyping) have been validated as a laboratory developed test (LDT) approved by New York State Department of Health. Abbreviations: CT, *Chlamydia trachomatis*; GC, *Neisseria gonorrhoeae*; FDA, United States Food and Drug Administration; LDT, laboratory developed test; N/A, not applicable.