NewYork-Presbyterian
The University Hospital of Columbia and Cornell

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 ≥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® *Trichomonas vaginalis*		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: **Vaginal Collection Rectal Collection Throat Collection**	US FDA-Approved ≥14	Aptima® Multitest Swab: **Vaginal Collection**	US FDA-Approved ≥14	Aptima® Multitest Swab: Vaginal Collection	Not US FDA-approved
 Aptima® Unisex Swab: **Endocervical Collection** (not FDA-approved for vaginal specimens)	US FDA-Approved ≥14	Aptima® Unisex Swab: **Endocervical Collection** (not FDA-approved for vaginal specimens)	US FDA-Approved ≥14	Aptima® Unisex Swab: Endocervical Collection (not FDA-approved for vaginal specimens)	Not US FDA-approved
 Aptima® Unisex Swab: **Male Urethral Collection Rectal Collection (LDT)* Throat Collection (LDT)***	US FDA-Approved ≥14	Aptima® Unisex Swab: Male Urethral Collection	Not US FDA-approved	Aptima® Unisex Swab: Male Urethral Collection	Not US FDA-approved
 Aptima® Urine: **Urine Male & Female**	US FDA-Approved ≥14, Female ≥14, Male	Aptima® Urine: Urine Male & Female	Not US FDA-approved	Aptima® Urine: Urine Male & Female	Not US FDA-approved
 ThinPrep (PreservCyt®): **Cervical/Endocervical or Cervical Collection**	US FDA-Approved ≥21, Female	ThinPrep (PreservCyt®): Cervical/Endocervical (verified in-house, not offered routinely)	US FDA-Approved ≥21	ThinPrep (PreservCyt®): **Cervical/Endocervical or Cervical Collection Vaginal (LDT)***	US FDA-Approved ≥21

Collection devices that are verified/validated for specimen sources tested in the clinical microbiology laboratory at NewYork-Presbyterian Hospital-Weill Cornell Medical Center are colored in **yellow 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.
***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