Cervical & Vaginal Cytology (submitted for Pap and/or HPV testing)

The Pap test (ThinPrep) is used to detect cervical cancer, its precursors, and other abnormalities of the female reproductive tract. The Cytology Laboratory processes Pap tests that are collected by the *ThinPrep* method, after which are imaged for cellular abnormalities.

The HPV High Risk DNA with 16/18 genotyping (ThinPrep) detects DNA of the following 14 high-risk types: 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68, while separately genotyping 16 and 18. This test does not detect DNA of HPV low-risk types (eg, 6, 11, 42, 43, 44) since these are not associated with cervical cancer and its precursor lesions.

Interpretation of HPV results should be made in conjunction with the patient's recent PAP smear results as stated in American Cancer Society, American Society for Colposcopy and Cervical Pathology, and American Society for Clinical Pathology Screening Guidelines for the Prevention and Early Detection of Cervical Cancer.
Link to guidelines posted on ASCP website:
http://journals.lww.com/jlgtd/PublishingImages/ASCCP%20Guidelines.pdf#zoom=80

Table 1. Summary of Recommendations as listed on the ASCP website:

Population	Recommended screening method[a]	Management of screen results	Comments
<21 Years	No Screening		HPV testing should NOT be used for screening or management of ASC-US in this age group.
21-29 Years	Cytology alone every 3 years	HPV-Positive ASC-US[b] or cytology of LSIL or more severe: Refer to ASCCP Guidelines [2] Cytology Negative or HPV-Negative ASC-US[b]: Rescreen with cytology in 3 years	HPV testing should NOT be used for screening in this age group
30-65 Years	HPV and Cytology "Co-testing" every 5 years (Preferred)	HPV-Positive ASC-US or cytology of LSIL or more severe: Refer to ASCCP Guidelines [2]	Screening by HPV testing alone is not recommended for most clinical settings.
		HPV Positive, Cytology Negative: Option 1 - 12-month follow-up with co-testing Option 2 - Test for HPV16 or HPV16/18 genotypes If HPV16 or HPV16/18 positive: refer to colposcopy If HPV16 or HPV16/18 negative: 12-month follow-up with co-testing	
		Co-test Negative or HPV-Negative ASC-US: Rescreen with co-testing in 5 years	
	Cytology alone every 3 years (Acceptable)	HPV-Positive ASC-US[b] or cytology of LSIL or more severe: Refer to ASCCP Guidelines [2]	
		Cytology Negative or HPV-Negative ASC-US[b]: Rescreen with cytology in 3 years	
>65 Years	No Screening following adequate negative prior screening		Women with a history of CIN2 or a more severe diagnosis should continue routine screening for at least 20 years.
After Hysterectomy	No Screening		Applies to women without a cervix and without a history of CIN2 or a more severe diagnosis in the past 20 years or cervical cancer ever.
HPV Vaccinated	Follow age-specific recommendations (same as unvaccinated women)		

[a] Women should not be screened annually at any age by any method.
[b] ASC-US cytology with secondary HPV testing for management decisions.

Ordering Options:

Individual Tests that can be run using a ThinPrep Vial:

Test #:	Test Name:	CPT code:	Description:
4819	Pap/Gyn Cytology	88175	Does not include any HPV testing.
1597	HPV High Risk DNA with 16/18 genotyping	87624	Does not include Pap/Gyn Cytology.
4820	Pap with HPV High Risk Reflex	88175 and when reflexed 87624	HPV High Risk will automatically reflex from the Pap only if the Pap is resulted as ASCUS.

If Pap/Gyn Cytology (Test# 4819) and HPV High Risk DNA with 16/18 genotyping (Test# 1597) are both ordered, then both tests will be performed regardless of each other's results.

Materials Needed:

- *PreservCyt* Collection Vial (supplies include collection device) used for *ThinPrep* method.
- Brush/spatula or Broom-Like Device
  - Brush/spatula is acceptable for Pap and/or HPV testing
  - Broom-Like Device is only acceptable for Pap Test, it can't be used for HPV testing
- Inpatient - Use EPIC to enter desired Gynecological cytology orders (See ordering table above)
  Outpatient - Complete and submit a "Pathology/Cytology" order either through EPIC or completed requisition form. Include billing information

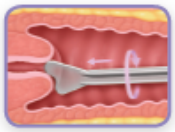
Specimen Requirements:

- All specimen's must be accompanied by a request form (paper or electronic) completely filled out including clinical history and billing information.
- Label *ThinPrep* vial with customer's name, date of birth, along with date & time collected. Label should be placed vertically on the vial for the barcode to be read.
- Minimum volume of 1 mL must be be available for extraction, and sample less than 1 mL will be canceled due to QNS.
- Lubricant should not be used as it obscures cellular detail.

Collection (*ThinPrep*) - Instruction Using:

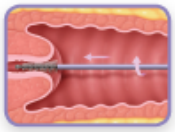
Brush/spatula:

Acceptable for Pap and/or HPV testing



Obtain an adequate sample from the ectocervix using a plastic spatula. If desired, use lukewarm water to warm and lubricate the speculum. Apply water-soluble, carbomer-free gel lubricant sparingly to the posterior blade of the speculum if necessary.[1,2] Select the contoured end of the plastic spatula and rotate it 360 degrees around the entire ectocervix, while maintaining tight contact with ectocervical surface.

Rinse the spatula as quickly as possible into the PreservCyt® Solution vial by swirling the spatula vigorously in the vial 10 times. Discard the spatula.



Obtain an adequate sampling from the endocervix using an endocervical brush device. Insert the brush into the cervix until only the bottom-most fibers are exposed. Slowly rotate 1/4 or 1/2 turn in one direction. **DO NOT OVER-ROTATE THE BRUSH.**

Rinse the brush as soon as possible in the PreservCyt Solution by rotating the device in the solution 10 times while pushing it against the PreservCyt vial wall. Swirl the brush vigorously to further release material. Discard the brush.

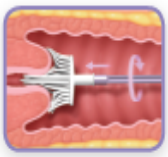
Tighten the cap so that the torque line on the cap passes the torque line on the vial.

Record the patient's name and ID number on the vial.
Record the patient information and medical history on the cytology requisition form.

Place the vial and requisition in a specimen bag for transport to the laboratory.

ThinPrep PAP TEST

Broom-Like Device:
Acceptable ONLY for Pap test



Obtain an adequate sampling from the cervix using a broom-like device. If desired, use lukewarm water to warm and lubricate the speculum. Apply water-soluble, carbomer-free gel lubricant sparingly to the posterior blade of the speculum if necessary. [1,2] Insert the central bristles of the broom into the endocervical canal deep enough to allow the shorter bristles to fully contact the ectocervix. Push gently and rotate the broom in a clockwise direction for five complete, 360 degree turns.

Rinse the broom as quickly as possible into the PreservCyt® Solution vial by pushing the broom into the bottom of the vial 10 times, forcing the bristles apart. Swirl the broom vigorously to further release material. Do not leave the head of the broom in the vial. Discard the collection device.

Tighten the cap so that the torque line on the cap passes the torque line on the vial.

Record the patient's name and ID number on the vial.
Record the patient information and medical history on the cytology requisition form.

Place the vial and requisition in a specimen bag for transport to the laboratory.

Refer to the instructions provided with the collection device for warnings, contraindications, and limitations associated with specimen collection.

Reporting: Specimen Adequacy:

Pap Test: All cervical/vaginal smears are diagnosed using the modified Bethesda Classification System. Presence or absence of endocervical cells is stated on report for all customers. The clinician may use this information with the clinical findings to determine the significance regarding the adequacy of the specimen. If there is no endocervical component and the customer is premenopausal and non-pregnant, the pap test will be reported as satisfactory but no endocervical cells present.

Unsatisfactory specimens indicate that the specimen is unreliable for the detection of cervical epithelial abnormalities. If abnormal cells are detected, the specimen is never categorized as unsatisfactory.

HPV HR Test: Indeterminate – High risk HPV status unknown due to low genomic DNA detected. This may be related to poor sample collection

CPT Code: See CPT codes in Ordering Options table above.