MAYO CLINIC LABORATORIES

NEW TEST

Notification Date: July 1, 2025
Effective Date: July 1, 2025

ThinPrep with Human Papillomavirus (HPV) Co-Test-Screen with p16/Ki67 Dual Stain Reflex, Varies

Test ID: CTPCO

Useful for:

Screening for cervical carcinoma or intraepithelial lesions and the presence or absence of high-risk human papillomavirus (HR-HPV) when screening women aged 30 to 65 years for possible cervical neoplasia

Aiding in triaging women with abnormal Papanicolaou (Pap) smear results

Aiding in triaging women with positive HR-HPV but negative Pap smear results

Aiding in triaging women aged 30 to 65 years with NILM (negative for intraepithelial lesion or malignancy) and 12 other HR-HPV positive test results using the cobas 4800 HPV Test in adjunctive cervical cytology and HR-HPV screening, to determine the need for referral to colposcopy

Additional Tests:

Test ID	Reporting Name	Available Separately	Always Performed
HPV	HPV with Genotyping, PCR, ThinPrep	Yes	Yes

Reflex Tests:

Test ID	Reporting Name	Available Separately	Always Performed
TPSPC	Physician Interp Screen	No (Bill Only)	No
CINPC	CINtec IHC Multiplex	No (Bill Only)	No

Methods:

Light Microscopy/Real-Time Polymerase Chain Reaction (PCR)/Immunocytochemistry as needed

Reference Values:

ThinPrep PAPANICOLAOU
Satisfactory for evaluation. Negative for intraepithelial lesion or malignancy.

HUMAN PAPILLOMAVIRUS (HPV)

Negative for HPV genotypes 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68

CINtec PLUS Cytology, Immunocytochemical dual stain for p16/Ki-67 has been performed.
Result: Negative

Specimen Requirements: Submit only 1 of the following specimens

Specimen Type:	Cervical
Supplies:	ThinPrep Media with Broom Kit (T056)
Container/Tube:	ThinPrep/PreservCyt vial
Specimen Volume:	16 mL
Collection Instructions:	1. Obtain adequate sampling from cervix using a broom-like collection device. If desired, use lukewarm water to warm and lubricate the speculum. 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 5 times. 2. Rinse the broom as quickly as possible into the PreservCyt solution vial by pushing broom into bottom of vial 10 times, forcing the bristles apart. 3. As a final step, swirl broom vigorously to further release material. Discard the broom collection device. 4. Tighten cap on vial so that the torque line on the cap passes the torque line on the vial. 5. **Specimen vial must be labeled with a minimum of 2 unique identifiers** (patient's name and medical record number or date of birth). 6. Bag ThinPrep specimens individually as they tend to leak during transport. 7. Place labels on the vial and on the bag

Specimen Type:	Ectocervix and endocervix
Supplies:	Thin Prep Media with Spatula and Brush Kit (T434)
Container/Tube:	ThinPrep/PreservCyt vial
Specimen Volume:	16 mL
Collection Instructions:	1. Obtain an adequate sampling from the ectocervix using a plastic spatula. If desired, use lukewarm water to warm and lubricate the speculum. Select contoured end of plastic spatula and rotate it 360 degrees around the entire ectocervix while maintaining tight contact with ectocervical surface. 2. Rinse spatula as quickly as possible into the PreservCyt solution vial by swirling spatula vigorously in vial 10 times. Discard the spatula. 3. Next, obtain an adequate specimen from endocervix using an endocervical brush device. Insert the brush into the cervix until only the bottommost fibers are

exposed. Slowly rotate one-quarter or one-half turn in 1 direction. **Do not over-rotate.**

4. Rinse the brush as quickly as possible in the PreservCyt solution by rotating the device in the solution 10 times while pushing against the PreservCyt vial wall.

5. Swirl brush vigorously as final step to further release material. Discard the brush.

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

7. **Specimen vial must be labeled with a minimum of 2 unique identifiers** (patient's name and medical record number or date of birth).

8. Bag ThinPrep specimens individually as they tend to leak during transport.

9. Place labels on the vial and bag.

Specimen Stability Information:

Specimen Type	Temperature	Time	Special Container
Varies	Ambient (preferred)	42 days	ThinPrep
	Refrigerated	42 days	ThinPrep

Cautions:

For women aged 30 to 65 years old with NILM (negative for intraepithelial lesion or malignancy) and HPV16/18 positive test results using the cobas 4800 HPV Test in adjunctive cervical cytology and HR HPV screening, the CINtec PLUS Cytology test results should be used in conjunction with the healthcare professional's assessment of patient screening history, other risk factors, and professional guidelines to guide patient management.

The Papanicolaou (Pap) test is a screening test for cervical cancer with inherent false-negative results. A negative human papillomavirus (HPV) test or Pap smear result does not preclude the presence of carcinoma or intraepithelial lesion. The false-negative rates of the Pap test range from 15% to 30%.

The cobas HPV test detects DNA of the high-risk types 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68. 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.

The cobas HPV test is not recommended for evaluation of suspected sexual abuse.

Prevalence of HPV infection in a population may affect performance. Positive predictive values decrease when testing populations with low prevalence or individuals with no risk of infection.

Infection with HPV is not an indicator of cytologic high-grade intraepithelial lesion (HSIL) or underlying high-grade cervical intraepithelial neoplasia (CIN), nor does it imply that CIN2-3 or cancer will develop. Most women infected with 1 or more high-risk HPV (HR-HPV) types do not develop CIN2-3 or cancer.

A negative HR-HPV result does not exclude the possibility of future cytologic HSIL or underlying CIN2-3 or cancer.

Performance of the CINtec *PLUS* Cytology test was not established for women older than 65 years.

CPT Code:
88142
G0123 (Government payers)
G0124 (Government payers, if appropriate)
88141 -TPSPC (if appropriate)
88344 -CINTC/CINPC (if appropriate)

Day(s) Performed: Monday-Friday

Report Available: 5 to 15 days

Questions
Contact Gina L Kahnke, Laboratory Resource Coordinator at 800-533-1710.