MAYO CLINIC LABORATORIES

NEW TEST

Notification Date: January 17, 2023
Effective Date: February 16, 2023

Human Papillomavirus (HPV) Vaginal Detection with Genotyping for High-Risk Types by PCR

Test ID: VHPV

Useful for:

- Detection of high-risk (HR) genotypes associated with the development of cervical cancer
- Aids in triaging women with abnormal Pap smear results
- Individual genotyping of human papillomavirus HPV-16 and/or HPV-18, if present
- Results of HPV-16 and HPV-18 genotyping can aid in triaging women with positive HR-HPV but negative Pap smear results

Methods:

Real-Time Polymerase Chain Reaction (PCR)

Reference Values:

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

Specimen Requirements:

Specimen Type:	Vaginal
Container/Tube:	ThinPrep/PreservCyt solution vial
Specimen Volume:	3 mL of solution in ThinPrep/PreservCyt vial
Specimen Minimum Volume:	1 mL

Specimen Stability Information:

Specimen Type	Temperature	Time
Vaginal	Ambient (preferred)	42 days
	Refrigerated	42 days

Cautions:

- This test is **not recommended for** evaluation of suspected sexual abuse.
- This test is **not intended for** use in determining the need for treatment (ie, excisional or ablative treatment of the cervix) in the absence of high-grade cervical dysplasia. Patients who are HPV16/18 positive should be monitored carefully for the development of high-grade cervical dysplasia according to current practice guidelines.
- This test is **not intended for** women who have undergone hysterectomy.
- This test is **not intended for** use with samples other than those collected by a clinician using an endocervical brush or spatula and placed in the ThinPrep Pap test PreservCyt solution.

- The cobas human papillomavirus (HPV) test is US Food and Drug Administration (FDA)-approved for cervical and endocervical samples collected in PreservCyt (ThinPrep) media. Other sample types (eg, vaginal) are not considered FDA-approved sources; however, verification studies have been completed by Mayo Clinic Laboratories and Mayo Clinic in compliance with CLIA regulations.
- 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.
- 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 squamous 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 (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.
- Cervical/vaginal specimens often show visibly detectable levels of whole blood as a pink or light brown coloration. These specimens are processed normally on the cobas 4800 System. If concentrations of whole blood exceed 1.5% (dark-red or brown coloration) in PreservCyt solution, there is a likelihood of obtaining a false-negative result.
- The cobas HPV Test performance has not been validated with PreservCyt specimens that have been treated with glacial acetic acid for removal of red blood cells. Any such processing of PreservCyt specimens prior to HPV testing would invalidate the cobas HPV Test results.
- The cobas HPV Test performance has not been validated with PreservCyt specimens that have been filled past the maximum fill line of the primary vial. ThinPrep vials that have had any additional PreservCyt fluid volume added or any dissimilar fluid volume added to the initial specimen should not be submitted for testing.
- The presence of polymerase chain reaction inhibitors may cause false-negative or invalid results.
- HPV-negative cancers of the cervix do occur in rare circumstances. Also, no cancer screening test is 100% sensitive. Use of this device for primary cervical cancer screening should be undertaken after carefully considering the performance characteristics put forth in the cobas HPV Test label, as well as recommendations of professional guidelines.
- The use of this test has not been evaluated for the management of women with prior ablative or excisional therapy, hysterectomy, who are pregnant or who have other risk factors (eg, HIV-positive, immunocompromised, history of sexually transmitted infections).
- The effects of other potential variables (eg, vaginal discharge, use of tampons, and douching), and specimen collection variables have not been evaluated.

CPT Code:

87624
G0476 (if appropriate)

Day(s) Performed:

Monday through Friday

Report Available

3 to 6 days

Questions

Contact Dunisha Messmer, Laboratory Technologist Resource Coordinator at 800-533-1710.