Lab Dept: Anatomic Pathology

Test Name: HPV HIGH RISK, DNA DETECTION WITH GENOTYPING, THINPREP

General Information

Lab Order Codes: HPVHRG

Synonyms: HPV PCR with Genotyping; Human Papillomavirus PCR and Genotyping; HPV-16 HPV-18; HPV with Genotyping ThinPrep Cervical

CPT Codes: 87626 – Infectious agent detection by nucleic acid

G0476 (if appropriate)

Test Includes: Positive or negative PCR detection of HPV High Risk Types 16 and 18, with positive or negative results for twelve *other* High Risk types (31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68).

Logistics

Test indications: Useful for:

Detecting high-risk (HR) genotypes associated with the development of cervical cancer.

Aiding in triaging patients with abnormal Pap smear test 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 patients with positive HR-HPV but negative Pap smear results

This testing is intended for use in clinical use. It is **not intended for** use in medical-legal applications.

This test is **not intended for** use in determining the need for treatment (i.e., 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** 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.

Lab Testing Sections: Molecular Diagnostics - Sendouts

Referred to:	Mayo Clinic Laboratories (Mayo Test: HPV)
Phone Numbers:	MIN Lab: 612-813-6280
	STP Lab: 651-220-6550
Test Availability:	Daily, 24 hours
Turnaround Time:	3 - 6 days
Special Instructions:	N/A

Specimen

Specimen Type:	Cervical/Endocervical
Container:	ThinPrep PreservCyt Media solution with Spatula and Brush Kit (Mayo Supply T434)
Collection Volume:	Follow kit instructions, do not overfill.
Processed Volume:	Same as collection volume

Collection:	**One ThinPrep collection kit should be used for Pap ThinPrep (PAPSC) and HPV High Risk (HPVHRG) testing. (e.g., the same container for both orders is sufficient.)** 1. Obtain an adequate sampling from the ectocervix using a plastic spatula. If desired, use lukewarm to warm water and lubricate the speculum. Select contoured end of plastic spatula and rotate it 360 degrees around the entire exocervix while maintaining tight contact with exocervical surface. 2. Rinse spatulas 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 one 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. 8. Bag ThinPrep specimens individually as they have a tendency to leak during transport.
Special Processing:	Lab Staff: Ensure cap on vial is secure. Send only one patient's specimen per bag as vials have a tendency to leak. Forward promptly. Ship at ambient temperature. Specimen stable ambient (preferred) or refrigerated for 42 days. Specimens are retained at reference lab for 14 days after report is issued.
Patient Preparation:	For optimal interpretation, Pap smears should be collected near the middle of the menstrual cycle. Avoid douching, lubricant use, and sexual intercourse for 24 hours prior to specimen collection.
Sample Rejection:	Specimens not collected in ThinPrep media; specimen type other than indicated; unlabeled or mislabeled specimens; samples collected in expired media vials.

Interpretive

Reference Range:	Negative for human papillomavirus (HPV) genotypes 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68
Critical Values:	N/A

Limitations:

The cobas human papillomavirus (HPV) test is US Food and Drug Administration (FDA)-approved for cervical and endocervical samples collected in PreservCyt (ThinPrep) media.

The cobas HPV test detects DNA from high-risk genotypes 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 specimens often show visibly detectable levels of whole blood as a pink or light brown coloration. These specimens are processed normally on the cobas Systems. If concentrations of whole blood exceed 10% (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 over 5%. Addition of glacial acetic acid over 5% in PreservCyt specimens prior to HPV testing would invalidate the cobas HPV Test results.

Human beta-globin amplification and detection is included in cobas HPV to differentiate HPV negative specimens from those that do not exhibit HPV signal due to insufficient cell mass in the specimen. All HPV negative specimens must have a valid beta-globin signal within a pre-defined range to be identified as valid negatives.

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 (e.g., HIV positive, immunocompromised, history of sexually transmitted infections). The effects of other potential variables (e.g., vaginal discharge, use of tampons, douching) and specimen collection variables have not been evaluated.
Methodology:	Real-Time Polymerase Chain Reaction (PCR)
References:	Mayo Clinic Laboratories January 2025
Updates:	1/21/2025: Initial entry. Replaces obsolete test previously sent to ANW.