

Anal Pap Human Papillomavirus (HPV) with Genotyping, High-Risk Types, PCR, Varies

Test ID: AHPV

Note: This test, previously orderable only as a reflex from test code ATPCO (Anal ThinPrep Cytology with Human Papillomavirus (HPV) Co-Test, Varies), will now be offered as a standalone orderable.

Useful for:

Detection of high-risk (HR) genotypes associated with the development of anal cancer.

Individual genotyping of human papillomavirus (HPV)-16 and HPV-18 if present.

May aid in triaging men and women with positive HR HPV but negative anal Papanicolaou (Pap) smear test results.

This test is not intended for use in medical-legal applications.

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:

Preferred

Specimen Type: Anus or rectum

Supplies: ThinPrep Media with Spatula and Brush Kit (T434)

Collection Container/Tube: Brush

Submission Container/Tube: ThinPrep

Specimen Volume: A minimum of 20 mL or entire collection

Collection Instructions:

1. Visualize the anal opening by retracting the buttocks.
2. Insert brush past internal anal sphincter until it abuts the distal rectal wall (4-5cm).
3. Rotate the brush 360 degrees and maintain lateral pressure on brush against the walls of the anus. The brush should bow slightly due to the pressure.
4. While rotating, slowly withdraw the brush.
5. Rotate at least 10 times while withdrawing the brush. This should take 20 to 30 seconds.
6. Immediately place brush in the ThinPrep solution and swish at least 20 to 30 seconds.
7. Dispose of the brush.
8. Tighten the cap so that the torque line on the cap passes the torque line on the vial.
9. Bag ThinPrep specimens individually as they tend to leak during transport.
10. Place labels on the vial and on the biohazard bag.

Acceptable**Specimen Type:** Anus or rectum**Supplies:** PreservCyt Vial (T536)**Collection Container/Tube:** Dacron/polyester swab**Submission Container/Tube:** PreservCyt solution vial**Specimen Volume:** A minimum of 20 mL or entire collection**Collection Instructions:**

1. Visualize the anal opening by retracting the buttocks.
2. Insert Dacron or polyester swab past internal anal sphincter until it abuts the distal rectal wall (4-5cm).
3. Rotate the swab 360 degrees and maintain lateral pressure on swab against the walls of the anus. The swab should bow slightly due to the pressure.
4. While rotating, slowly withdraw the swab.
5. Rotate at least 10 times while withdrawing the swab. This should take 20 to 30 seconds.
6. Immediately place swab in the ThinPrep solution. Swish at least 20 to 30 seconds in the ThinPrep solution.
7. Dispose of the swab.
8. Tighten the cap so that the torque line on the cap passes the torque line on the vial.
9. Bag ThinPrep specimens individually as they tend to leak during transport.
10. Place labels on the vial and on the biohazard bag.

Minimum Volume: 1 mL**Specimen Stability Information:**

Specimen Type	Temperature	Time
Varies	Ambient	21 days

Cautions:

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 specimen types (eg, anal) 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 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 patients 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.

Anal specimens may show visibly detectable levels of whole blood or stool as a pink or light brown coloration. These specimens are processed normally on the cobas system. If concentrations of whole blood or stool are high, results may be impacted.

The cobas HPV test performance has been validated with PreservCyt specimens that have been treated with up to 5% glacial acetic acid for removal of red blood cells. Addition of glacial acetic acid over 5% in 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.

Human beta-globin amplification and detection is included in the cobas HPV test 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 predefined range to be identified as valid negative results.

Human papillomavirus-negative cancers of the cervix or anus do occur in rare circumstances. Also, no cancer screening test is 100% sensitive. Use of this device for primary anal 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 presence of real-time polymerase chain reaction inhibitors may cause false-negative or invalid results.

Anal specimens that are grossly contaminated with stool may yield invalid or false-negative results.

CPT Code:

87626

Day(s) Performed: Monday through Saturday

Report Available: 3 to 6 days

Questions

Contact James Conn, Laboratory Resource Coordinator at 800-533-1710.