

Human Papillomavirus (HPV) Detection and High-Risk Genotyping, Self-Collect, PCR, Vaginal

Test ID: SCHPV

Useful for:

Human papillomavirus (HPV) screening for average-risk, asymptomatic individuals who are eligible for primary HPV testing, have barriers to a speculum exam for a clinician-collected cervical sample for screening and who are able to self-collect a vaginal sample *in a healthcare setting*.

This test is not intended for symptomatic patients (eg, pelvic pain, abnormal uterine bleeding).

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:

Supplies:	Evalyn Brush (T990)
Specimen Type:	Vaginal
Collection Container/Tube:	Evalyn Brush
Submission Container/Tube:	ThinPrep/PreservCyt solution vial
Specimen Volume:	3 mL of solution in ThinPrep/PreservCyt vial
Collection Instructions:	<ol style="list-style-type: none">1. Provide patient with a labeled Evalyn brush and the accompanying self-collection instruction pamphlet. Specimen must be collected by the patient <i>in a healthcare setting</i>.2. Following patient self-collection, ensure that the Evalyn brush is tightly capped and appropriately labeled.3. Place labeled Evalyn brush in a biosafety bag and send to the laboratory.4. Perform the following steps prior to shipment to Mayo Clinic Laboratories:<ol style="list-style-type: none">a. Label PreservCyt (ThinPrep) vial with appropriate patient information.

- b. Uncap PreservCyt vial. Remove pink cap from Evalyn brush.
- c. Depress the pink plunger on the Evalyn brush to expose the brush (white bristles).
- d. Vigorously plunge the brush, smashing the white brush against the bottom and interior wall of the vial 10 times to maximize sample release. Be careful not to splash.
- e. Discard Evalyn brush
- f. Tightly recap the PreservCyt vial.
- g. Submit the PreservCyt vial for testing.

Minimum Volume: 1 mL

Specimen Stability Information:

Specimen Type	Temperature
Varies	Ambient (preferred)
	Refrigerate

ThinPrep/PreservCyt Vial: Ambient (preferred) 42 days / Refrigerated 42 days

Cautions:

Patients should refrain from using feminine hygiene products for approximately 24 hours prior to self-collection of the vaginal brush. Use of carbomer-containing feminine hygiene products has been associated with invalid results by the human papillomavirus (HPV) detection/genotyping assay. Please see catalog for a list of carbomer-containing product examples.

The vaginal HPV self-collection should not be ordered if active menstrual bleeding or vaginal product use has occurred within 2 days.

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 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).

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.