PHM INITIATIVE

For Providers: Primary HPV Testing and HPV Self-collected Testing

An Implementation Guide for Clinics – Provider Guide

**See Written Resource: "Primary HPV Testing and HPV Self-Collection: A Guide to Implementing HPV Self-Collection in Clinics" for more details and references.

How to Use This Resource

- This deck is meant to be a supplement to the written resource: "Primary HPV Testing and HPV Self-Collection: A Guide to Implementing HPV Self-Collection in Clinics"
- It can be used for provider updates on the topic.
- Feel free to take the slides that are most relevant to your intended audience.
- Information is up to date as of May 30, 2025. This is a rapidly changing area of cancer screening, and this will require regular updates and awareness of changing recommendations.

Why is Primary HPV Screening Accepted?

ATHENA: 3 Year CIR of CIN2+ or CIN3+
Stratified by screening test result at baseline

Test result	CIN2+	CIN3+
Cytology (-)	**1.7** (1.2-2.2)	**0.8** (0.5-1.1)
HPV (-)	**0.9** (0.5-1.5)	**0.3** (0.1-0.7)
Cytology & HPV (-)	**0.9** (0.4-1.4)	**0.3** (0.1-0.6)
Cytology (+)	**14.0** (12.5-15.5)	**9.2** (7.9-10.5)
HPV (+)	**15.5** (14.3-16.8)	**7.5** (6.7-8.3)

Wright *et al.* 2015 Gynecol Oncol

Takeaways:

- Pap alone is the worst for detecting CIN 3.
- Neg Pap plus Neg HPV is no better than Neg HPV alone.
- No statistical difference between + HPV and + Pap.
- Results support use of HPV primary screening with triage of HPV+ using genotyping for HPV 16/18 and reflex cytology.
- Co-testing results in more colposcopies.

HPV Vaginal Self-Collection?

Because of Athena and other studies, we can accept primary HPV testing from cervical collection as cervical cancer screening model.

What about vaginal HPV self-collection? Is it as good as clinician-collected cervical HPV collection?

- Self-collection meta- analysis shows similar sensitivity and specificity to clinician collected cervical samples.[4-6] (Oncogenic HPV is not confined to the cervix hence the concordance)

HPV self-collection tests (2) were FDA approved in 5/2024. – Approved ONLY for self collection in a clinical setting (Clinic or lab)

Teal Health home collection kit was approved by the FDA 5/2025. Not available yet for clinics to order directly. Currently, patients would have to use Teal Health online services.

Two HPV Self-Collection Tests were FDA Approved in 5/2024

BD Onclarity™HPV Assay - reports HPV 16, 18, 45,31,51,52 individually and HPV 33,58 together, HPV 35,39,68 together, and HPV 56,59,66 together.

Sample is shelf stable for 7 days

Roche cobas HPV test– reports High risk 16, 18 individually and 12 other high risk HPV types as a pool.

Not approved as shelf stable and needs to be put in ThinPrep media. Samples need to get to the lab the same day and processed w/in 24 hours

Applying for FDA approval for shelf stable

When ordering, make sure these specific tests are ordered. Check with the lab on order numbers.

How often to do the self-collect HPV test?

ASCCP currently (4/2025) recommends a 3 year follow up for self-collected normal results.

Differs from 2024 Draft USPSTF which has 5 yr follow up for normal screening, same as primary HPV from cervical collection.

ASCCP was more conservative since no longitudinal data for US specifically and concern that patients who opt for self-collection may be a higher risk cohort.

Who should NOT use HPV Self-Collection?

- People less than 30 years old
- People living with HIV
- People with a history of In utero DES exposure
- Surveillance after colposcopy for AGUS with no CIN 2 found
- Surveillance after diagnosis of adenocarcinoma in situ and excision with negative margins

ASCCP Follow-up of HPV Self-Collection Tests

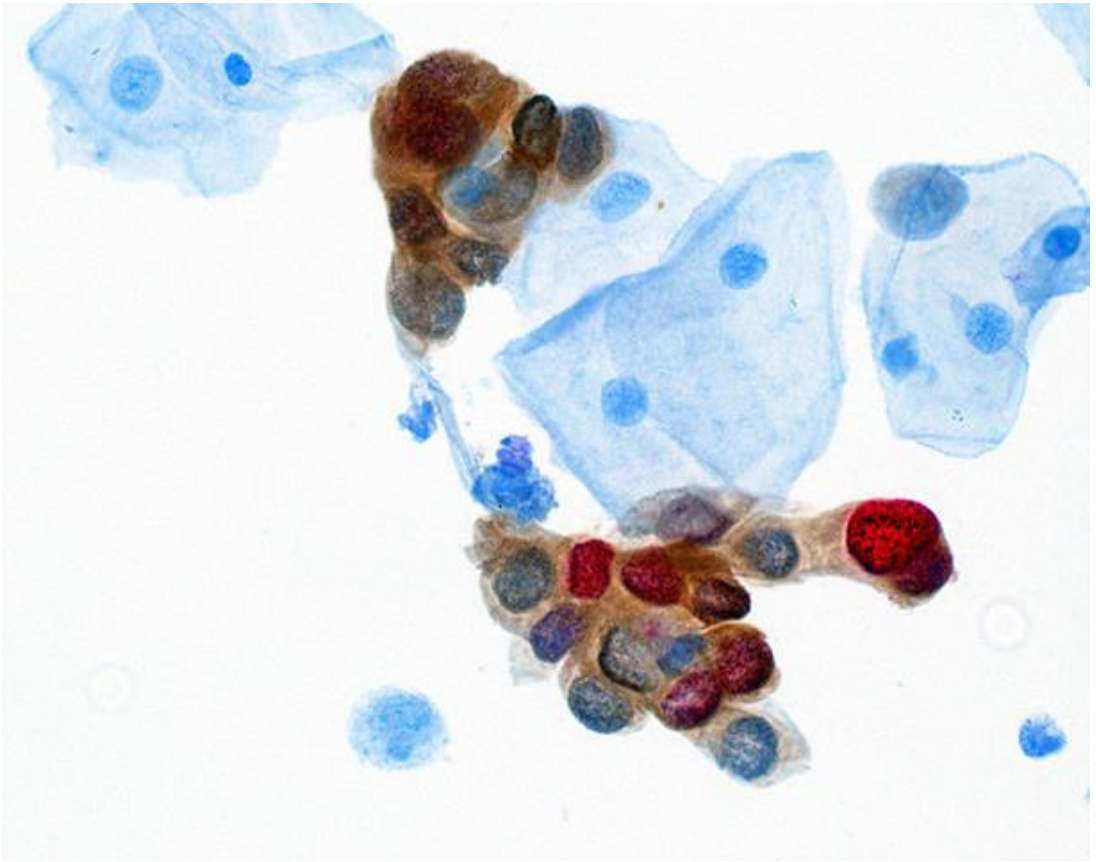
Clinical management for self-collected vaginal specimens by test results

RESULT	CLINICAL MANAGEMENT
HPV-negative	Repeat HPV testing in three years
HPV 16 or 18	Colposcopy with collection of cytology and biopsies
HPV 45, 33/58, 31, 52, 35/39/68, 51 or other pooled HPV types Negative for HPV 16/18	Clinician-collected sample for cytology or dual-stain triage testing
HPV 56/59/66 Negative for all other carcinogenic types	Repeat HPV testing in one year

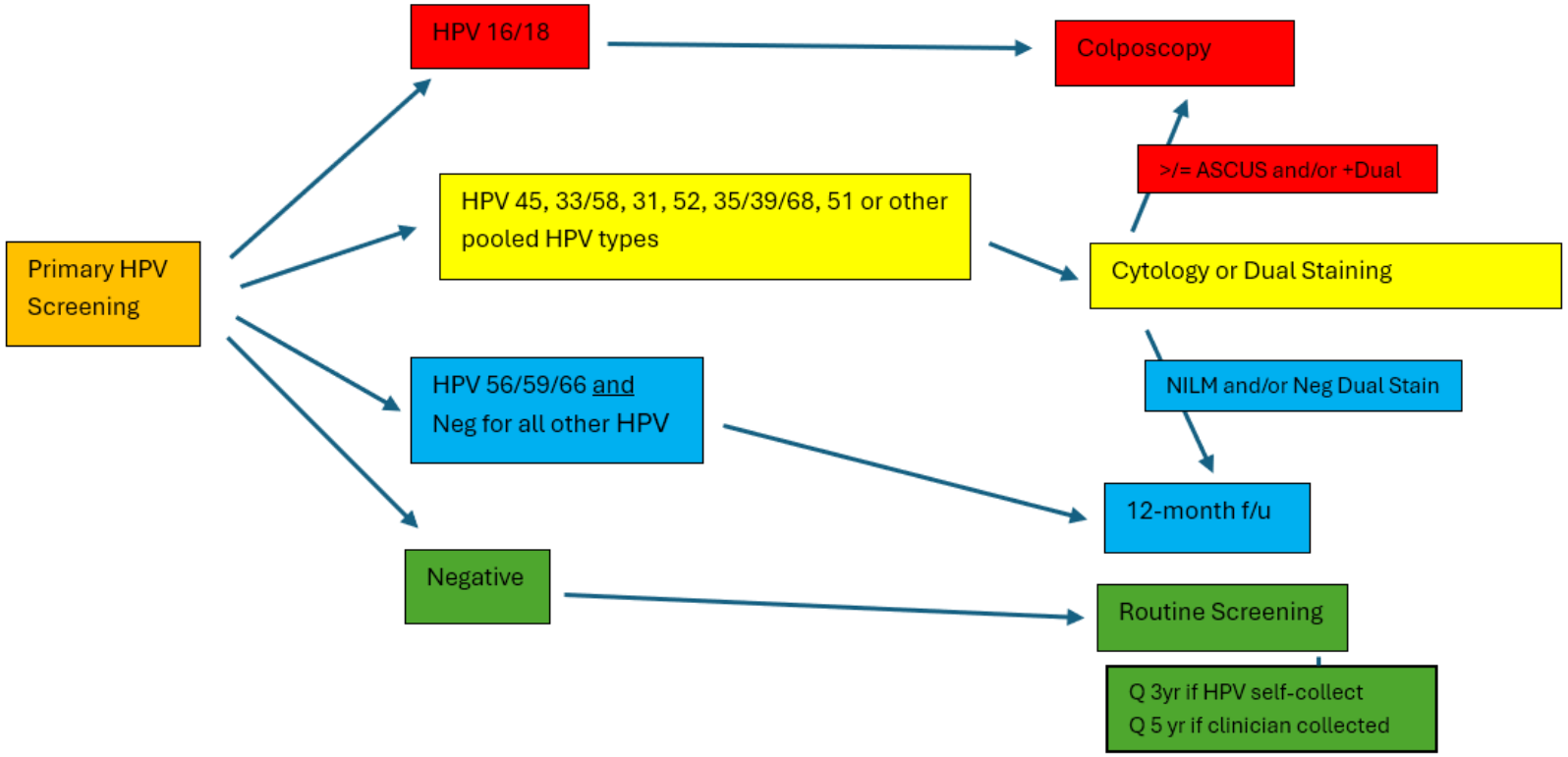
Guidelines for the recommended management of self-collected vaginal specimens by test results.
Credit: NCI DCEG

Dual Staining (FYI)

- DS detects a marker of HPV-related oncogene activity (p16) and a marker of cell proliferation (Ki-67) which, when detected in the same cell, are associated with precancerous cellular changes (CIN3+).
- If the test is DS +, then patient should be seen for colposcopy.
- If results are DS negative, then treat same as negative pap with follow up in 12 months.
- DS results in less false positives compared to cytology (pap) and thus less colposcopies.
- Dual staining must be done in ThinPrep for now.



Follow-Up Algorithm:



Note: If HPV is clinician collected, Cytology or Dual Staining can be done as a reflex test for + HPV 45, 33/58, 31, 52, 35/39/68, 51 or other pooled HPV types if available from lab on same specimen. If the results are from a patient's self-collected specimen, then patients need to be recalled for a cytology based test (pap or DS).

Considerations for Implementation

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Collection must be done in the clinic or lab (excluding Teal home collection test which is not available to CHCs currently).	• Consider this in your outreach workflows. Where will they do the test? When will it be done in clinic and when in lab? Do workflows need to include front office?
Patients should be given a choice for clinician-collected vs self-collection.	• Clinician collected is currently preferred when possible.
Benefits of clinician collection over self-collection:	• reflex cytology or DS can be obtained at the same visit which prevents a recall visit if HPV + • The interval to rescreening for clinician collected is 5 years if results are normal, whereas it is 3 years for patient self- collection per ASCCP.
Patients should be aware that if Self-collected HPV is +, they will need an in-person follow up.	• Consider your patient education materials and messaging. Make sure this distinction is clear. • Do you know how to reach patients that do self-collection? Consider special populations (i.e., unhoused). • Consider training for providers and staff – can they have a shared decision-making discussion with patients? Do they understand the details?

Considerations for Implementation

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Self- collection is ideal for patients who may have a visit in the clinic and are due for routine screening, but the provider or patient is not equipped to do the clinician collection.

- Consider the workflows in both scenarios.

Self-collection is also ideal for patients who would not otherwise come in for any clinician collection visit. They can come to the lab.

- Consider how you order self-collection in the lab vs the clinic.
- Consider the messaging when reaching out to these patients. When a patient declines an appointment for a clinic visit for screening, can you offer self collection instead? Are there specific groups who may not come for a speculum exam due to prior trauma, physical challenges, mental health challenges, cultural or religious beliefs, embarrassment, transgender men, poor access in clinic? Can this be part of your trauma informed care discussions?
- Consider what coordination is needed with the lab. Will they give the patient the collection instructions? Do they have a bathroom for patient collection?

Considerations for Implementation

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Self-collection is better than NO collection at all.	• Hence, this is the best method for someone who would otherwise not be screened at all.
Recommendations only apply to tests (collection kits and HPV assays) with an FDA approval for primary HPV screening using self-collected vaginal specimens (BD Onclarity and Roche cobas).	• Ensure you have the correct order numbers to align with these specific HPV tests. Can you hardwire this to prevent errors? (i.e. order sets, smart sets)
In the surveillance setting (i.e. NOT routine screening with previous normal history), clinician-collected cervical specimens are preferred.	• If a clinician-collected cervical specimen cannot be obtained, a self-collected vaginal specimen is acceptable following shared decision-making. • If a self-collected vaginal specimen is obtained, management per 2018 guidelines is recommended.

Considerations for Implementation

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If Self-collected HPV is NEGATIVE repeat screening is recommended again in 3 years. This differs from the 5-year screening interval of clinician collected HPV screening. This 3-year screening interval will likely be an interim recommendation as 5-year interval screening will likely be approved for HPV self-collection in near future.

EMRs and Pop Health Platforms will need to be able to distinguish the difference to prompt when patients are due for screening again.

Do you have a way to address this in your EMR and pre-visit planning and outreach?

Can you create a standing order for this?

Who will review the results, and do they know the plan?

What is your workflow for outreach/ in-reach, collection, resulting and follow up?

Talking with Patients About Self- Collection

NO pelvic exam or speculum is needed.

The patient does NOT need to completely undress.

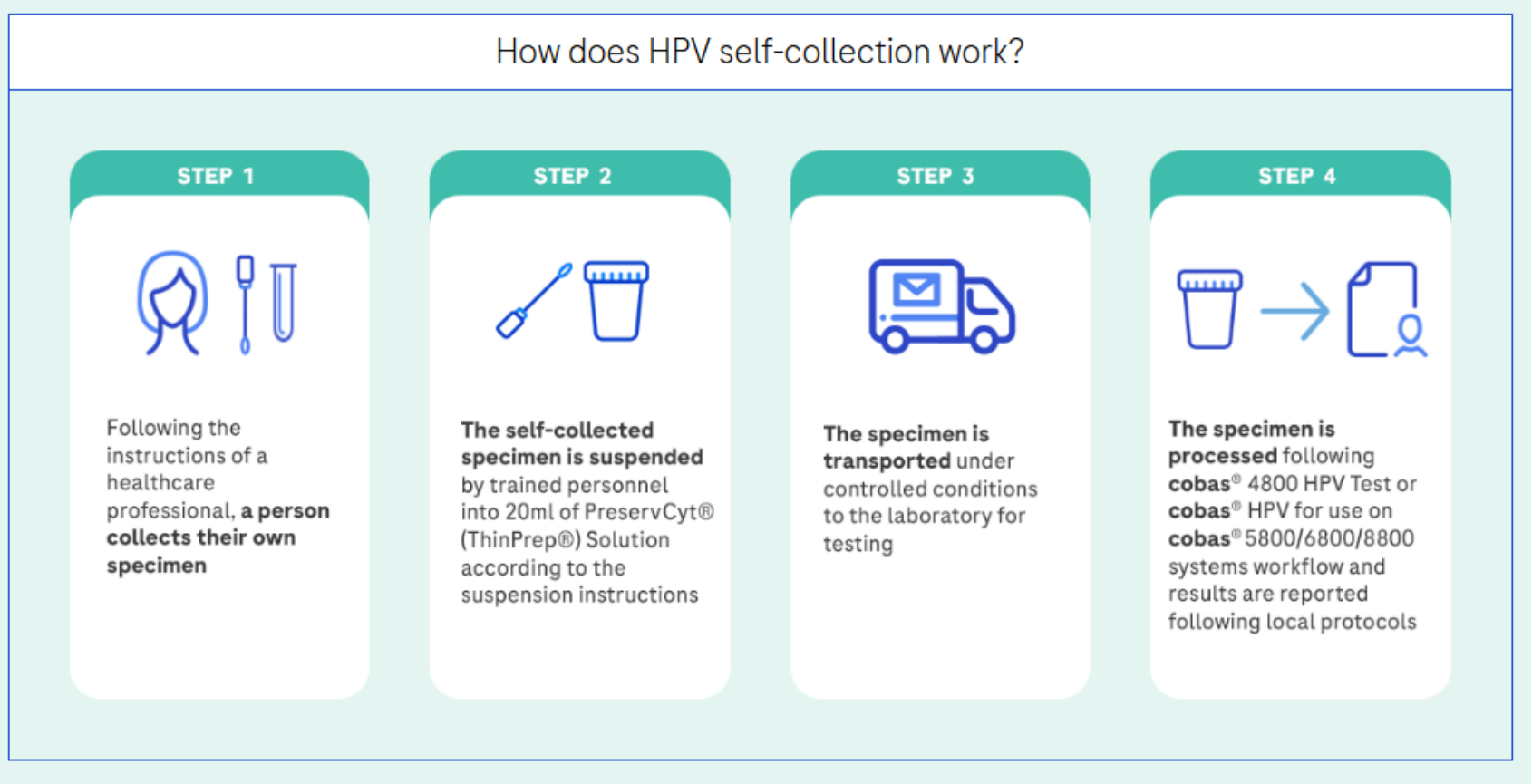
The patient can complete the collection themselves in the office or lab in private without special preparation or hygiene.

When the results are normal, repeat testing is due in 3 years for now.

Abnormal results indicate a higher risk for cervical cancer and follow up testing will be needed, which will require a speculum exam.

Note: Self-collection should not be done if patient is actively bleeding or if they have used any vaginal products within the last 2 days.

Clinic/Lab Process



Source: Roche HPV Self-Collection Solution

Note: Roche swab is not shelf stable and must be put in ThinPrep after collection. Specimens need to be sent to lab and processed per lab instructions, generally the same day.

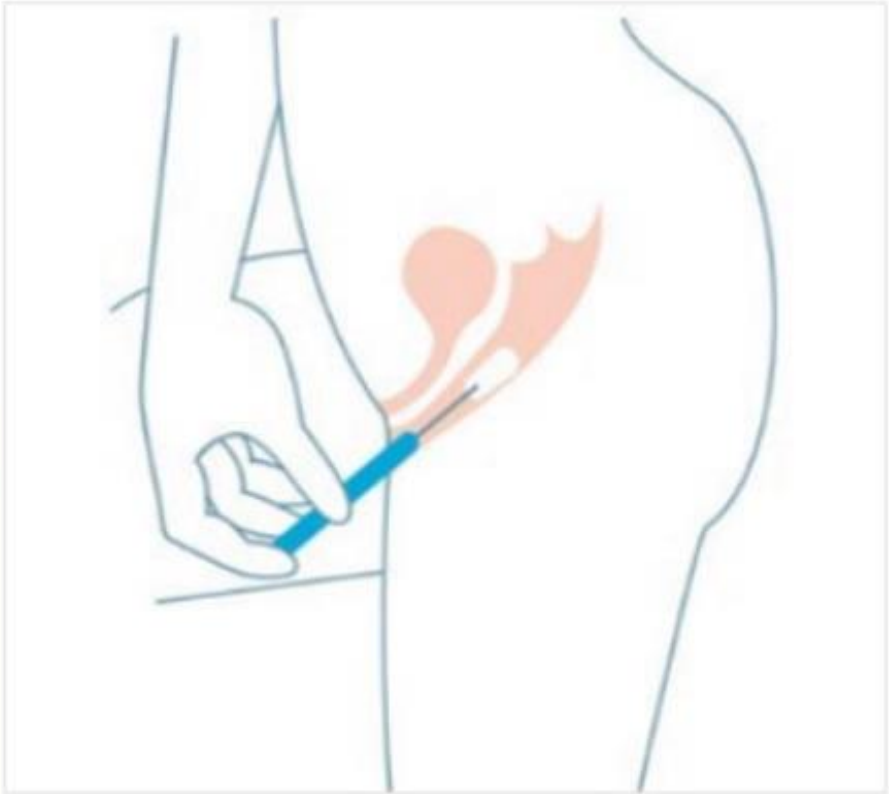
Do NOT Use If….

- If patient is pregnant or in the three months after giving birth.
- If recently undergone gynecological surgery.
- If there is unusual bleeding or pelvic pain that has not been evaluated.
- If during the menses.
- If in the 3 days prior to self-collection of a vaginal sample, there has been use of vaginal ovules, creams or washes, vaginal contraceptives or condoms.
- If in the 2 days prior to self-collection of a vaginal sample there has been sexual intercourse, vaginal ultrasound scans or gynecological exams.

How to complete the Self Swab

HPV Test Steps

- Wash your hands.
- Place the swab at least 2 inches into the vagina.
- Gently twist the swab for 10 to 30 seconds. Make sure the swab touches the sides of the vagina.
- Put the swab in the tube. Close the tube tightly.
- Give the tube to the clinical staff.
- Clinical staff will process collection swab in Thin Prep fluid, label and package for Lab (see lab instructions)



Credit: Partnership HealthPlan Presentation 4/2025

Lab Specifics

How to Get Supplies

Contact Your Lab Rep for Availability and Ordering

Quest

- HPV DNA (16,18, Other High Risk), PCR, self-collected
  - Vaginal specimen collected using a Roche FLOQSwabs® 552C.RM
  - CPT code **87626** Test Code **14263**
  - The high-risk HPV types include: HPV 16, 18, (31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68)

The kit includes:

- Copan FLOQSwab® #552C.RM
- ThinPrep PreservCyt® Solution
- Patient Collection Instruction Sheet
- Healthcare Professional Suspension Instruction Sheet

LabCorp

- HPV DNA (16,18, Other High Risk), PCR, self-collected
  - Vaginal specimen collected using a Roche FLOQSwabs® 552C.RM
  - CPT code **87626** Test Code **507401**
  - The high-risk HPV types include: HPV 16, 18, (31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68)

The kit includes:

- Copan FLOQSwab® #552C.RM
- ThinPrep PreservCyt® Solution
- Patient Collection Instruction Sheet
- Healthcare Professional Suspension Instruction Sheet

Credit: Partnership HealthPlan Presentation April 2025

Payor Coverage Issues:

Under the Affordable Care Act (ACA), women's preventive health care, including screenings for cervical cancer, is covered with no cost sharing.

Insurers are required to cover cervical cancer screening for anyone w/ a cervix age 21-65

Medicare Part B covers HPV testing as part of cervical cancer screening once every 5 years for people 30-65, as long as the test is FDA approved and done in a healthcare setting.

Private insurance plans are required to cover cervical cancer screenings, including HPV tests, for individuals 21-65 without a co-pay, as mandated by the Affordable Car Act. Patients should consult their insurance providers for specific coverage details, as policies may differ between plans.

Most state Medicaid plans follow the 2018 U.S. Preventive Services Task Force recommendations, which include coverage for primary HPV screening. **However, coverage for newer screening methods like HPV self-collection kits may still be limited, and patients should check with their state's Medicaid office for specific coverage details.** ***

Per Covered CA /Pre Preventive Care- Human papillomavirus (HPV) DNA test every three years for women with normal cytology results who are 30 or older.

Note: January 10, 2025, the Supreme Court agreed to hear a challenge to whether screening services, including cervical cancer screening tests, recommended by the USPSTF must be fully covered at no charge to patients under the ACA. The court will likely hear arguments this spring and rule on the case in late June or July.

Coding:

CPT coding:

- CPT code 87626 (New 2025 allows for separate reporting of high-risk HPV types)
- Infectious agent detection by nucleic acid (DNA or RNA); Human Papillomavirus (HPV), separately reported high-risk types (eg, 16, 18, 31, 45, 51, 52) and high-risk pooled result(s)
- Medicare Fee schedule: $70.2 effective 1/1/2025
- 3/31/25 Noted in HEDIS 2025 Value Set – so it should be counted for HEDIS
- Do not report with other HPV CPT codes

Understanding the Differences: 87626 vs. 87624 vs. 87625

CPT Code	Description	Fee Schedule	What It Detects
87624	High-risk HPV test (pooled result)	$35.09	Detects a **group** of high-risk HPV types but does **not** identify specific genotypes.
87625	High-risk HPV test (types 16 & 18 only)	$40.55	Detects only **HPV 16 and 18**, including **type 45 if performed**.
87626	New high-risk HPV test (separate & pooled results)	$70.2	Identifies **specific high-risk HPV types (e.g., 16, 18, 31, 45, 51, 52)** while also providing a **pooled result**.

Why This Matters:

The ability to **separately report high-risk genotypes** is essential for **risk stratification** in cervical cancer screening. For example, if **HPV 31** is detected, it indicates a **higher risk of cervical precancer** than HPV 18, helping **guide clinical decisions**.

Credit: Lab Revenue Navigator January 2025, Understanding the New HPV Test Code: What Labs Need to Know for 2025

Reporting Issues for Quality Measures: HEDIS vs UDS

- HEDIS, which is based on the value set from NCQA, does have the CPT code 87626 included in the 2025 value set. So, it should get picked up.

- UDS (HRSA) measures use the eCQM value set which comes from the National Library of Medicine (NLM) Value Set Authority Center (VSAC) and it does **not** currently include this CPT 87626 code. There are lab codes (LOINC) that labs put in which are included in the eCQM value set and these codes are often mapped to the CPT codes, so through the mapping the CPT could be captured even though it is not specifically in the value set directly for eCQM. However, the current LOINC codes are all specific to cervical collection HPV tests, so this will not get captured for a vaginal self-collected test result. So ultimately, as of now the test will not be captured by UDS and thus will not contribute to the HRSA goals. **This may change midyear if a newer version of the value set from eCQM is released with this update.**

- **Bottom line is that it will get captured for HEDIS but NOT UDS as of today. It may change midyear.**