PHM INITIATIVE

For Back Office Staff: Primary HPV Testing and HPV Self-collected Testing

An Implementation Guide for Clinics

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

What is Primary HPV Testing?

Primary HPV Testing is a method of cervical cancer screening by screening for Human Papilloma Virus which causes cervical dysplasia and cancer.

If HPV is detected (a positive test result) further testing is done depending on the strain of HPV detected.

How to do Primary HPV testing?

Clinician Collected: Speculum examination where a provider collects a sample from the cervix.

- Best option if patient is available and able to do a speculum exam. Preferred method.
- Allows collection of pap in case HPV is detected without another visit – pap is done as a reflex test automatically if HPV+
- If negative with previously normal history, repeat testing in **5** years

OR

Patient Self-Collected: Patient uses a swab to get a sample from the vagina

- HPV detection comparable to provider collection
- FDA approved 5/2024 for collection in clinical setting only (Clinic or Lab)
- Good for patients who don't want a speculum exam or who cannot make it to a women's health visit
- Expands screening opportunities
- Does not require a speculum, can be done in private
- Does require a follow up appointment for a speculum exam if HPV is detected.
- If negative with previously normal history, repeat testing in **3** years

How often to do the self-collect HPV test?

ASCCP currently (4/2025) recommends a

3 year follow up for

self-collected normal results

vs.

5 year follow up for clinician collected

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

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.

Talking with Patients About Self- Collection

NO pelvic exam or speculum is needed.

The patient does NOT need to completely undress.

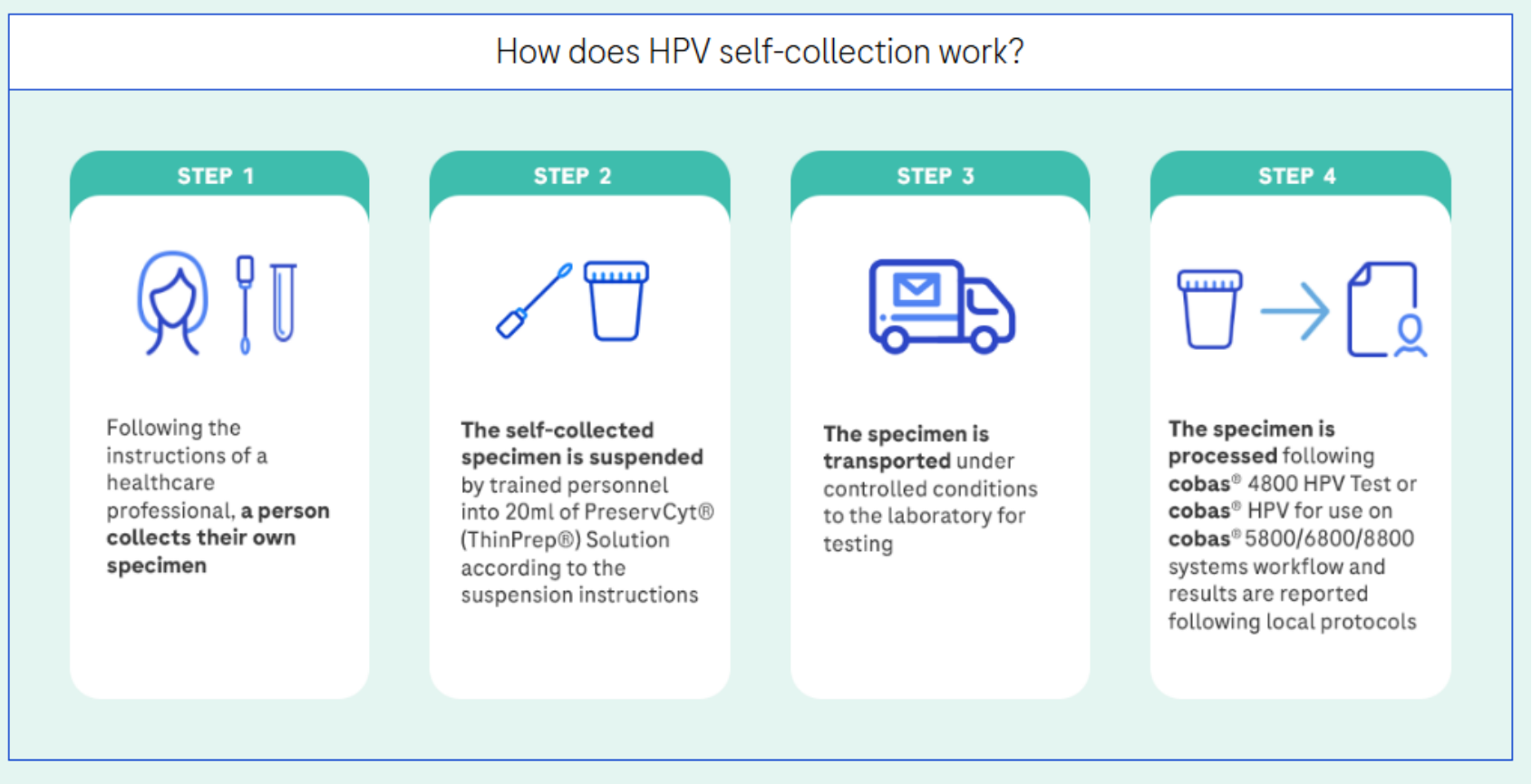
The patient can complete the collection themselves in the office or lab in private without special preparation or hygiene.

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



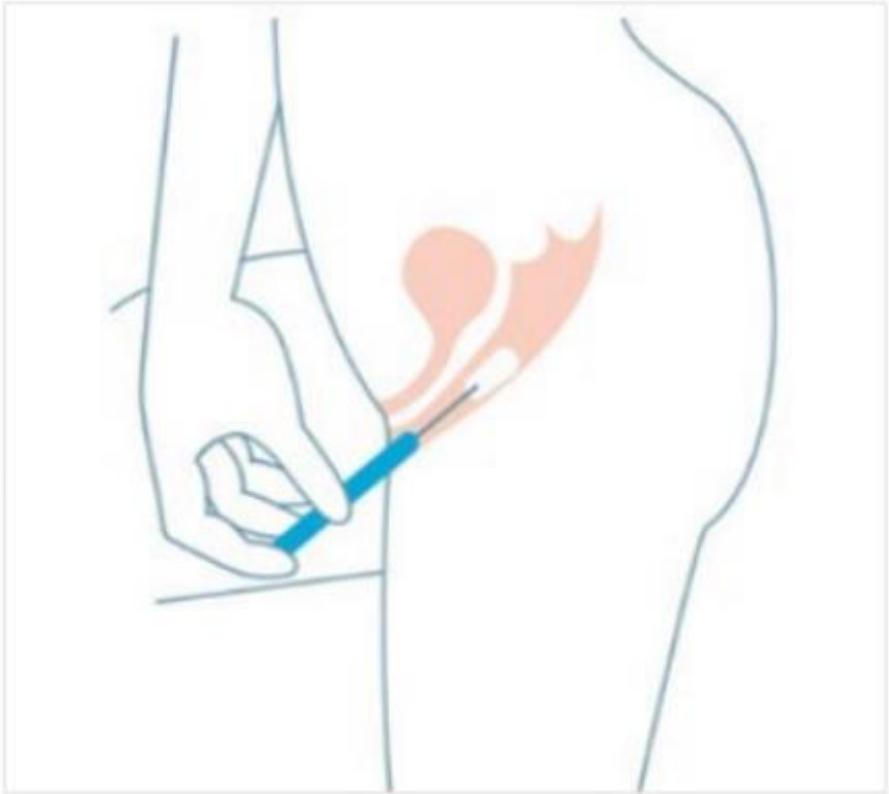
Source: Roche HPV Self-Collection Solution

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.

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

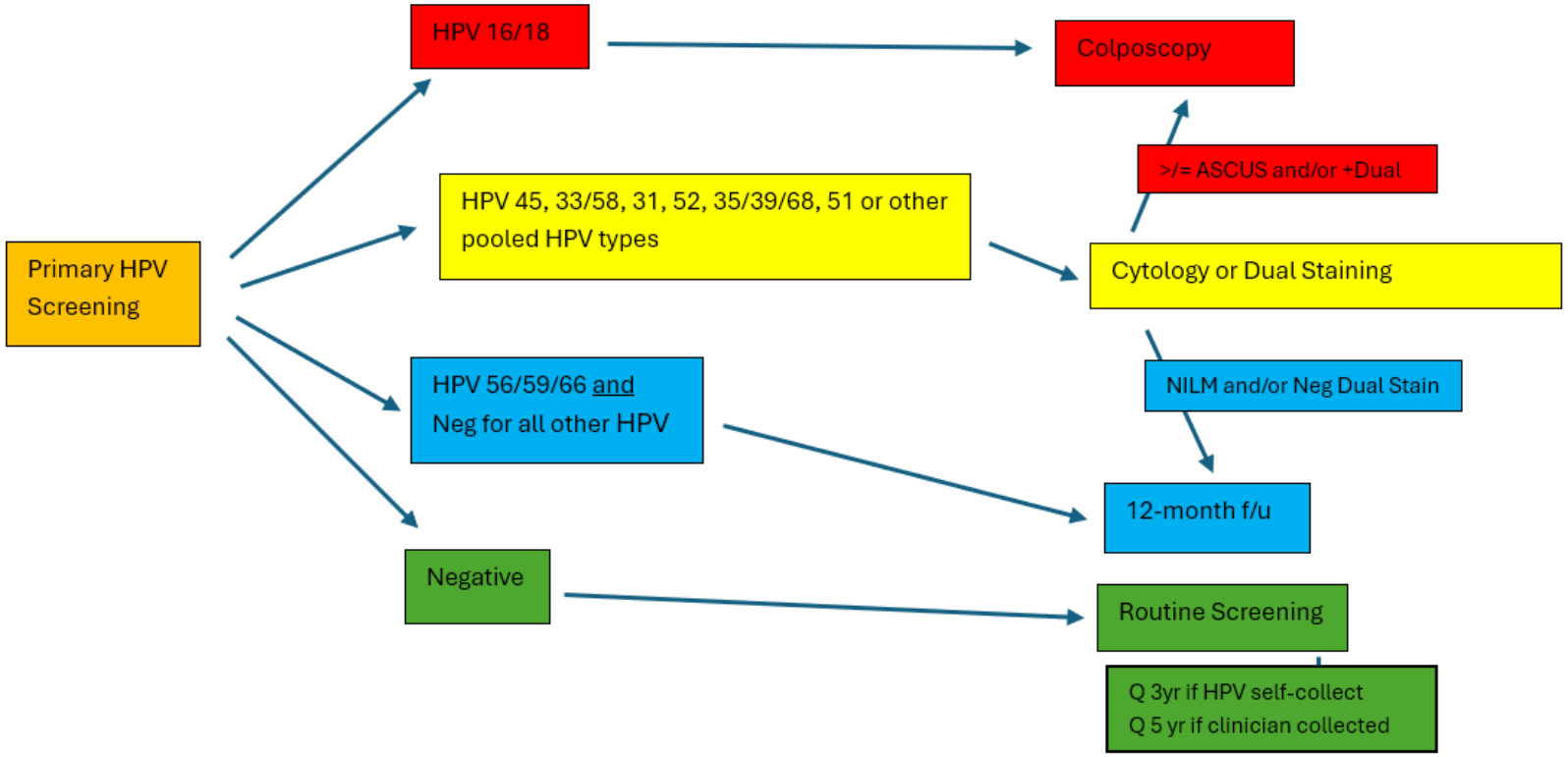
- HPV DNA (16,18, Other High Risk), PCR, self-collected
  - Vaginal specimen collected using a Roche FLOQSwabs® 552C.RM
  - CPT code **87626** Test Code **507401**
  - The high-risk HPV types include: HPV 16, 18, (31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68)

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

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.