Preparing for Self-collection
Clinician Communication Guide

American Cancer Society

NATIONAL ROUNDTABLE ON CERVICAL CANCER

FDA-approved Self-collection HPV Testing

Human papillomavirus (HPV) self-collection testing is FDA-approved for use in a health care setting when the patient and clinician agree that a clinician-collected cervical specimen is not the preferred option.[1] FDA-approved lab platforms and collection devices must be used.

Cervical cancer screening by vaginal specimen self-collection for HPV testing can increase health equity by expanding access and focusing efforts on those never screened or overdue for screening.

This approach can reduce barriers for all eligible people with a cervix to get screened to help prevent cervical cancer. Self-collected (vaginal) and clinician-collected (cervical) specimens perform similarly when tested for HPV.[2,3]

According to the American Society for Colposcopy and Cervical Pathology (ASCCP) and Enduring Consensus Cervical Cancer Screening and Management Guidelines (Enduring Guidelines), clinician-based HPV tests are preferred for surveillance after abnormal screening tests, colposcopy, or precancer treatments.[4]

FDA-approved Lab Platforms and Collection Devices

BD	Onclarity with Copan 522C.80 swab	*Check with your lab to ensure that this new option is available.*
Roche	cobas® with Evalyn brush or Copan 522C.80 swab	*Contact the manufacturer of the device you are using to get both written (print) and video-based instructions on how to use the device properly and safely.*

Patient Eligibility for Self-collection

- Asymptomatic and eligible for primary HPV testing
- No symptoms of abnormal bleeding
- Not HIV positive
- No active menstrual bleeding or use of vaginal product within two days
- No history of cervical cancer
- No DES exposure

Talking Points for Patients Eligible for Cervical Cancer Screening With Self-collection

- Vaginal self-collection for HPV testing is a new screening option.
- While positive HPV results from self-collected specimens (about 1 in 10) require a follow-up speculum exam, clinician-collected cervical specimens can be used for reflex testing (such as cytology or dual stain), eliminating the need for an additional visit.

Managing Self-collected HPV Test Results

The American Cancer Society defers to the ASCCP and Enduring Guidelines for cervical cancer screening management and surveillance as shown below.[4,5]

- **If HPV negative:**
  Repeat screening in three years
- **If HPV 16 or HPV 18 detected:**
  Refer or return visit for colposcopy
- **If other HPV detected (i.e., without extended genotyping):**
  Return visit for clinician-collected cervical specimen for cytology or dual stain
- **If HPV types 56/59/66 detected with extended genotyping:**
  Re-testing in one year at clinician's discretion
- **If other HPV detected with extended genotyping:**
  Return visit for clinician-collected cervical specimen for cytology or dual stain

Considerations

- **Electronic Health Record (EHR):**
  Work with the information technology department to create a new vaginal self-collection order with adjusted reminders and prompts for the appropriate intervals.
- **CPT Codes:**
  Self-collection and clinician collection use the same laboratory HPV test code.
- **ICD-10 Visit Codes:**
  Use existing cervical cancer screening visit code Z12.4 for self-collection visit and also for return visit if needed for speculum exam (screening cytology or dual stain).

For the latest resources from the American Cancer Society National Roundtable on Cervical Cancer, scan the QR code or visit cervicalroundtable.org/resource-center

1. FDA. FDA Roundup: May 17, 2024. Accessed April 7, 2025. https://www.fda.gov/news-events/press-announcements/fda-roundup-may-17-2024.
2. Arbyn M, Smith SB, Temin S, Sultana F, Castle P; Collaboration on Self-Sampling and HPV Testing. Detecting cervical precancer and reaching underscreened women by using HPV testing on self samples: updated meta-analyses. *BMJ*. 2018;363:k4823. doi:10.1136/bmj.k4823.
3. Arbyn M, Castle PE, Schiffman M, Wentzensen N, Heckman-Stoddard B, Sahasrabuddhe VV. Meta-analysis of agreement/concordance statistics in studies comparing self- vs clinician-collected samples for HPV testing in cervical cancer screening. *Int J Cancer*. 2022;151(2):308-312. doi:10.1002/ijc.33967.
4. NCI. Enduring Consensus Cervical Cancer Screening and Management Guidelines. Accessed April 7, 2025. https://dceg.cancer.gov/research/cancer-types/cervix/enduring-guidelines#publications-from-the-enduring-guidelines-effort.
5. ASCCP. Enduring Guidelines Process. Accessed April 7, 2025. https://www.asccp.org/guidelines/enduring-guidelines/process.