PREPARING FOR SELF-COLLECTION

Clinician Communication Guide

FDA-approved HPV Self-collection Testing

Human papillomavirus (HPV) self-collection testing is FDA-approved for use in a healthcare setting when the patient and clinician determine that it is not possible for the clinician to collect a cervical specimen.[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 makes it easier for all eligible people with a cervix to get screened to prevent cervical cancer.

Self-collected (vaginal) and clinician-collected (cervical) specimens perform similarly when tested for HPV.[2,3]

For surveillance after abnormal screening tests, colposcopy or pre-cancer treatments, clinician-collected HPV-based tests are preferred but self-collected HPV tests are acceptable.

FDA-approved Lab Platforms and Collection Devices

BD	Onclarity with Copan 522C.80 swab
Roche	cobas® with Evalyn brush or Copan 522C.80 swab

- *Check with your lab to ensure they can offer this new option.*
- *You should contact the manufacturer of the device you're 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 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.
- Positive HPV results on self-collected specimen (about 1 in 10) will require a follow-up visit with a speculum exam.
- Clinician-collected cervical specimens offer the advantage of not requiring a follow-up visit with a speculum exam if additional testing is needed to complete screening (cytology or dual stain).

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Managing Self-collected HPV Test Results [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.

IT and EHR Considerations

EHR Order:
Create a new vaginal self-collect order.

CPT Codes:
Self-collect and clinician collect use the same laboratory HPV test code.

ICD-10 Visit Codes:
Use existing cervical cancer screening visit code Z12.4 for self-collect visit and also for return visit if needed for speculum exam (screening cytology or dual stain).

Screening Interval:
Adjust EHR reminders and prompts for the appropriate intervals.

For the latest resources from ACS NRTCC on self-collection, scan this QR code or visit https://cervicalroundtable.org/resource-center/.

1. 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.*
3. *Arbyn et al. 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 July 14;151(2): 308.*
4. https://dceg.cancer.gov/research/cancer-types/cervix/enduring-guidelines#publications-from-the-enduring-guidelines-effort
5. https://www.asccp.org/guidelines/enduring-guidelines/process