ASCCP Practice Advisory: Self Collection for Cervical Cancer Screening
Updated October 2025

The majority of cervical cancers in the United States occur among individuals who are unscreened or under screened.

Primary HPV screening is one of the available options for cervical cancer screening in the United States, is the preferred method endorsed by the draft 2024 USPSTF and ACS (2020) for women ages 30-65. Other options include cytology with HPV cotesting every 5 years (acceptable), or if HPV testing is not available, cytology alone every 3 years (acceptable). [2,3]

Use of self-collected vaginal specimens for primary HPV screening is an opportunity to expand access to cervical cancer screening for unscreened and underscreened individuals.

Barriers that may be overcome by self-collection include those related to health system (e.g., lack of available clinicians, difficulty accessing gynecologic care), clinician (e.g., clinician does not perform pelvic exams, lack of time in visit), and patient (e.g., limited mobility, vaginismus, history of sexual trauma, gender dysphoria, not comfortable with clinician, prefers self-collection).[4,5]

Clinician collected samples are preferred, and self-collected samples are acceptable to improve access and ease of screening.[6]

Clinician collected samples are taken from the cervix using a broom or spatula and cytobrush. This allows the ability for additional reflex testing (cervical cytology or dual stain testing) to be performed from the same specimen. Because the patient self-collected specimen is vaginal and the cervix is not sampled directly, the patient will need a speculum exam by a clinician if the self-collected specimen is HPV positive. Similarly, if the clinician collects a vaginal sample, it should be processed like a self-collected specimen.

It is important that individuals undergoing HPV self-collection be asymptomatic and in a routine screening situation (i.e., not for surveillance testing or follow-up after treatment of precancer). Patients should not be on menses at the time of collection, nor have used any vaginal products for 48 hours prior to testing.

Candidates who are **not** eligible for self-collection HPV are those whose screening recommendations are based on cytology (HIV+, DES exposed, or ages 21-24). Additionally, individuals who are symptomatic (e.g. abnormal bleeding) would not be candidates. Finally, individuals who are in surveillance following abnormal screening test results, colposcopy or treatment are not candidates. There is limited data to guide recommendations in these cases and clinician-collected cervical specimens are preferred.

Overall performance of patient self-collected specimens is similar to that of clinician collected samples, when using target amplification-based (PCR) assays. Studies show that testing from

self-collected specimens using mRNA or signal amplification tests is less sensitive compared with clinician collected specimens.[7-10]

There are currently three FDA approved tests for primary HPV screening[11]. It is important to note that each test must use its approved self-collection device and lab platform. ASCCP does not endorse any one device or platform, and **the goal of this advisory is to educate patients and providers about currently available options as of September 2025 (Table 1)**.

The BD Onclarity™ HPV assay by Becton Dickson and company documents presence or absence of 14 high-risk HPV subtypes. The test has extended genotyping with high-risk HPV types in the following channel configurations: HPV16, HPV18, HPV45, HPV33/58, HPV31, HPV52, HPV35/39/68, HPV51, HPV56/59/66. This test requires use of the Copan 522C.80 dry swab FLOQ swab ® for HPV self-collection.[12]

The cobas® by Roche test reports pooled detection for 12 high-risk subtypes with individual results for HPV 16 and 18. This self-collected test can use either the Copan 522C.80 FlowQ swab (Copan Diagnostics) or Evalyn brush (Rovers medical devices) collection device. [12-13]

The Abbott Alinity m HR HPV assay reports if high-risk HPV was detected and if so, what type. The extended genotyping has the following grouped types: HPV 16, HPV 18, HPV 45, Other HR HPV A (HPV 31/33/52/58) and Other HR HPV B (HPV 35/39/51/56/59/66/68). The Abbott Alinity m HR HPV assay is FDA approved for primary HPV screening in clinician-collected cervical specimens and self-collected vaginal specimens.[14,15] Specimens collected using an endocervical brush/spatula and placed in ThinPrep PreservCyt Solution or using a cervical broom-like collection device and placed in SurePath Preservative Fluid can be used with the Alinity m HR HPV assay. Self-sampling can be performed using the simpli-COLLECT™ HPV collection kit or the Evalyn brush (Rovers medical devices) collection device.

The Teal Wand® is approved for at-home self-collection for average risk individuals aged 25-65. The patient completes a form on the company's website, they are connected virtually with a provider, who then orders the kit and will review the results. The kit is mailed to the home of the patient, who collects the sample using the Teal Wand® dry swab and sends it to the lab for processing.[16]

Abbott Alinity, BD Onclarity, and Roche Cobas tests are approved for self-collection in "a healthcare setting."[11] A healthcare setting is not strictly defined, however should be in a location where specimens can be processed by trained personnel and transported to a testing laboratory under controlled conditions. A healthcare setting may include, but is not limited to a hospital, emergency department, urgent care center, ambulatory clinic, physician office, mobile clinic, pharmacy, lab collection site, or a medical director-staffed school or community health clinic.

ASCCP Practice Advisory: Self Collection for Cervical Cancer Screening
Updated October 2025

Effective management of HPV-positive self-collected test results is critical to the successful implementation of this innovative screening approach, especially in settings aiming to improve access and reduce disparities in cervical cancer prevention. This process hinges first on collecting reliable patient contact information at the time of self-collection to ensure timely and accurate follow-up communication. Clear and standardized tracking systems must be in place to monitor test results and ensure that patients receive appropriate follow-up instructions tailored to their individual risk profiles. Equally important, clinics must establish coordinated mechanisms—including patient navigation services, appointment scheduling assistance, and culturally sensitive communication strategies—to support patients in completing the next steps in evaluation, such as dual stain testing, cytology, or colposcopy. Without comprehensive systems to manage positive results and guide patients through necessary follow-up, the effectiveness of self-collection programs may be significantly compromised, potentially delaying diagnosis and treatment. Therefore, building robust infrastructure for result communication and follow-up care is essential to realizing the full clinical and public health benefits of self-collected HPV testing.

References

1. Benard VB, Jackson JE, Greek A, et al. A population study of screening history and diagnostic outcomes of women with invasive cervical cancer. *Cancer Med*. 2021;10(12):4127-4137. doi:10.1002/cam4.3951.

2. Draft Recommendation: Cervical Cancer: Screening | United States Preventive Services Taskforce. Accessed June 23, 2025. https://www.uspreventiveservicestaskforce.org/uspstf/draft-recommendation/cervical-cancer-screening-adults-adolescents#fullrecommendationstart.

3. Fontham ETH, Wolf AMD, Church TR, et al. Cervical cancer screening for individuals at average risk: 2020 guideline update from the American Cancer Society. *CA Cancer J Clin*. 2020;70(5):321-346. doi:10.3322/caac.21628.

4. Fuzzell LN, Perkins RB, Christy SM, Lake PW, Vadaparampil ST. Cervical cancer screening in the United States: Challenges and potential solutions for underscreened groups. *Prev Med*. 2021; 144:106400. doi: 10.1016/j.ypmed.2020.106400

5. Fontenot HB, Fuzzell L, Brownstein NC, et al. Health Care Provider Willingness to Recommend Self-collected Tests for Human Papillomavirus: A Mixed Methods Examination of Associated Factors. *Womens Health Issues Off Publ Jacobs Inst Womens Health*. 2024;34(5):506-517. doi: 10.1016/j.whi.2024.05.005.

6. Wentzensen N, Massad LS, Clarke MA, et al. Self-Collected Vaginal Specimens for HPV Testing: Recommendations from the Enduring Consensus Cervical Cancer Screening and Management Guidelines Committee. *J Low Genit Tract Dis*. 2025;29(2):144-152. doi:10.1097/LGT.0000000000000885.

7. 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.

8. 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.

9. Arbyn M, Latsuzbaia A, Castle PE, Sahasrabuddhe VV, Broeck DV. HPV testing of self-samples: Influence of collection and sample handling procedures on clinical accuracy to detect cervical precancer. *Lancet Reg Health Eur*. 2022; 14:100332. doi: 10.1016/j.lanepe.2022.100332.

10. Inturrisi F, Aitken CA, Melchers WJG, et al. Clinical performance of high-risk HPV testing on self-samples versus clinician samples in routine primary HPV screening in the Netherlands: An observational study. *Lancet Reg Health Eur*. 2021; 11:100235. doi: 10.1016/j.lanepe.2021.100235

11. FDA Roundup: May 17, 2024. FDA. August 9, 2024. Accessed June 23, 2025. https://www.fda.gov/news-events/press-announcements/fda-roundup-may-17-2024

12. FLOQSwabs® Flocked Swabs. COPAN. Accessed June 23, 2025. https://www.copanusa.com/products/flocked-swabs-traditional-swabs/floqswabs-flocked-swabs/

13. Devices Archive. Rovers Medical Devices. Accessed June 23, 2025. https://www.roversmedicaldevices.com/cell-sampling-devices/

14. https://www.fda.gov/medical-devices/recently-approved-devices/alinity-m-hr-hpv-use-alinity-m-system-p230003

15. https://www.linkedin.com/feed/update/urn:li:activity:7371966870024986625/

16. Primary HPV Test. Accessed June 23, 2025. https://www.getteal.com/primary-hpv-test

ASCCP Practice Advisory: Self Collection for Cervical Cancer Screening
Updated October 2025

Assay	Hybrid Capture 2 (HC2) (Digene)	Aptima® (Hologic)	Cobas® (Roche)	Onclarity™ (BD)	Alinity m (Abbott)
Detection of…	HPV DNA hybrids	HPV E6/E7 mRNA	HPV DNA PCR	HPV DNA E6, E7 PCR	HPV DNA PCR
# of high-risk HPV types	13	14	14	14	14
Approved for primary screening	No	No	**Yes**	**Yes**	**Yes**
Approved for Self-collection	No	No	**Yes**	**Yes**	**Yes**
Specimen adequacy control	No	No	**Yes**	**Yes**	**Yes**
HPV genotyping available	No	**Yes** [16] [18/45]	**Yes** [16] [18] [12 other]	**Yes** [16] [18] [45]	**Yes** [16] [18] [45]

				[31] [51] [52] [33,58] [56,59,66] [35,39,68]	[31,33,52,58] [35,39,51,56,59,66,68]

Table 1. Commercial high-risk HPV tests with FDA approval.