HPV Test for Cervical Cancer Screening

Version 1 [Vaginal Swabs] - May 2026

Introduction

Testing for human papillomavirus (HPV) is a key way to screen for cervical cancer.

HPV is the underlying cause of over 90% of cervical cancers, as well as several other cancers.[1] While most HPV infections resolve spontaneously, persistent infection with a high-risk HPV (hrHPV) type is the primary cause of cervical precancer and cervical cancer development.[2] Because hrHPV infection precedes the development of cervical cancer, hrHPV testing is a critical component of cervical cancer screening and prevention.[2-4]

Patients can access at-home HPV testing through Color's Virtual Cancer Clinic, the first and only ASCO-certified virtual cancer clinic, supporting evidence-based screening, follow-up, and care coordination.

Guidelines recommend HPV testing to screen for cervical cancer.

The American Cancer Society (ACS), United States Preventive Services Task Force (USPSTF), and American College of Obstetricians and Gynecologists (ACOG) all recommend hrHPV testing as a preferred primary screening strategy for cervical cancer.[2-4] Current recommendations include:

- **Ages 21–29:** Cytology (Pap testing) every 3 years (ACOG/USPSTF).
- **Ages 25–65 (ACS) and 30–65 (ACOG/USPSTF)**: Primary hrHPV testing every 5 years is the preferred screening approach. Co-testing with cytology and hrHPV testing every 5 years remains an acceptable alternative, while cytology every 3 years may be used when primary hrHPV testing or co-testing is unavailable.

Recent guideline updates from ACS and ACOG, along with draft USPSTF recommendations,[5] now recognize self-collected vaginal samples as an acceptable option for hrHPV screening in certain settings. These updates reflect a broader shift toward more accessible and patient-centered screening approaches with the potential to improve participation, expand access, and support earlier detection of cervical cancer.

Utilization of cervical cancer screening is low.

Approximately 1 in 4 individuals are not up to date with recommended cervical cancer screening,[6] despite cervical cancer screening adherence being a nationally recognized quality measure by NCQA HEDIS®.[7] Screening uptake is particularly low among individuals without a high school degree, those living below the federal poverty level, those without health insurance, and those living in rural communities.[6,7] As a result, disparities in access to screening and preventive care continue to drive a disproportionate burden of cervical cancer incidence and mortality in underserved populations.[7]

Clinical Rationale for Self-Collection

Persistent gaps in cervical cancer screening adherence remain a significant contributor to preventable cervical cancer incidence. Barriers including limited access to in-person care, discomfort with pelvic examinations, scheduling challenges, geographic limitations, and prior negative healthcare experiences may reduce participation in routine screening programs.[6,7]

Self-collected vaginal sampling, including at-home collection, offers an alternative screening approach that may improve access and participation while maintaining similar accuracy with clinician-collected cervical specimens for hrHPV detection.[2,5,9,10]

Recent consensus guidelines and emerging evidence support self-collection as an important strategy to expand screening access among historically underscreened populations.[2,4,5]

Self-collection can increase access and adherence to screening.

Clinician-collected cervical samples have historically been the primary specimen type used for HPV testing in the United States. However, this approach requires an in-person visit, creating a meaningful access barrier.[2,5,8]

Self-collection offers several advantages:[2,5,8]

1. Expanded access to screening, particularly for individuals who may benefit from at-home collection options
2. Reduced delays associated with screening and attending in-person clinic visits
3. Reduced provider burden by eliminating the need to supervise specimen collection
4. A less invasive experience, which may improve screening acceptability and participation

The FDA has approved multiple molecular testing platforms that detect HPV and identify hrHPV types. While clinician-collected cervical swabs have historically been the primary sample type used for HPV testing in the United States, self-collected vaginal swab specimens are now an FDA-approved collection approach for hrHPV screening.[9]

This document describes the technical specifications of the FDA-approved BD Onclarity™ HPV Assay using self-collected vaginal swabs.[9]

Test Methodology

Step 1: Self-collection of vaginal swabs
Vaginal swab specimens are self-collected using the FDA-approved BD Onclarity™ HPV Self-Collection Kit according to the manufacturer's instructions.[9]

Step 2: Analysis with the BD Onclarity™ HPV Assay
Collected samples are analyzed using the BD Onclarity™ HPV Assay on the BD Viper™ LT System. This assay is a qualitative in vitro test that uses polymerase chain reaction (PCR) amplification and nucleic acid hybridization to detect DNA from 14 hrHPV types in a single analysis: HPV 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68.

Step 3: HPV Test results
The BD Onclarity™ HPV Assay individually identifies HPV 16, 18, 31, 45, 51, and 52. The remaining hrHPV types are reported in genotype groups: 33/58, 35/39/68, and 56/59/66. The assay includes a human beta-globin internal control to verify specimen adequacy, processing, extraction, and amplification. Samples that fail to produce a valid human beta-globin signal are reported as invalid.[9]

Result	Meaning
Positive for hrHPV (individual genotype detected)	DNA was detected from one or more of the individually-genotyped hrHPV types: 16, 18, 31, 45, 51, and/or 52
Positive for hrHPV (other hrHPV type/group)	DNA was detected from one or more of the other hrHPV types/groups: 33/58, 35/39/68, or 56/59/66
Negative for hrHPV	DNA was not detected from any of the hrHPV types included in the assay
Invalid	The sample did not produce a valid human beta-globin internal control signal. A new sample may be needed.

Table 1. Clinical result types of the Color HPV test. Samples positive for HPV 16, 18, 31, 45, 51 or 52 are reported with individual genotype results. Detection of the remaining hrHPV types will be reported as "Other HPV type," consistent with the reporting approach used in this test.

Technical Specifications of the BD Onclarity™ HPV Assay

The following technical specifications are based on the FDA-approved BD Onclarity™ HPV Assay using self-collected vaginal swab specimens, as described in FDA-authorized labeling.[9]

Analytical Sensitivity (Limit of Detection)

Target	Limit of Detection (LoD) (Cells* or Copies/mL)^	95% Confidence Interval	
		Lower	Upper
SiHa (HPV16)*	9.7	7.7	13.4
HeLa (HPV18)*	51	46	56
MS751 (HPV45)*	305	284	343
HPV31	692	650	817
HPV33	1,376	1,272	1,451
HPV35	1,552	1,317	1,780
HPV39	1,531	1,419	1,685
HPV51	1,229	1,155	1,353

Target	Limit of Detection (LoD) (Cells* or Copies/mL)^	95% Confidence Interval	
		Lower	Upper
HPV52	833	744	934
HPV56	836	737	911
HPV58	2,990	2,656	7,818
HPV59	772	722	899
HPV66	701	646	767
HPV68	2,079	1,995	2,125

^ Cell-based targets are reported in cells/reaction; plasmid targets are reported in copies/mL.

Concordance between Self-Collected Vaginal and Clinician-Collected Cervical

Multiple studies have demonstrated high concordance between self-collected vaginal samples and clinician-collected cervical samples for hrHPV detection.

Study 1: In a study of 300 women referred for colposcopy in Italy, self-collected vaginal swab specimens demonstrated strong agreement with clinician-collected cervical specimens when tested using the BD Onclarity™ HPV Assay on the BD Viper™ LT System, supporting comparable hrHPV detection performance between self-collected vaginal and clinician-collected cervical specimens.[9,10]

		Clinician-Collected Cervical Swab			
		HPV16 and/or HPV18	12 Other HR HPV	HR HPV Negative	Total
Self-Collected Vaginal	HPV16 and/or HPV18	76	12	3	91
	12 Other HR HPV	0	93	20	113
	HR HPV Negative	2	5	75	82
	Total	78	110	98	286

PPA (HR HPV) (%): 96.3 (181/188); 95% CI: (92.5, 98.2)
PPA (HPV16 and/or HPV18) (%): 97.4 (76/78); 95% CI: (91.1, 99.3)
PPA (12 Other HR HPV) (%): 84.5 (93/110); 95% CI: (76.6, 90.1)
NPA (HR HPV) (%): 76.5 (75/98); 95% CI: (67.2, 83.8)

Study 2: In a large U.S. prospective study (n=495 evaluable) evaluating self-collected vaginal swabs, agreement with clinician-collected cervical specimens was high across hrHPV detection endpoints.[9]

		Clinician-Collected Cervical Swab			
		HPV16 and/or HPV18	**12 Other HR HPV**	**HR HPV Negative**	**Total**
Self-Collected Vaginal	HPV16 and/or HPV18	57	6	13	76
	12 Other HR HPV	3	214	38	255
	HR HPV Negative	4	19	108	131
	Total	64	239	159	462
PPA (HR HPV) = 92.4% (280/303); 95%CI: (88.9, 94.9) NPA (HR HPV) = 67.9% (108/159); 95%CI: (60.3, 74.7)					

Study 3: In a U.S. general screening population (n=401 evaluable), self-collected vaginal swabs achieved high agreement with clinician-collected samples (PPA 93.1%, NPA 83.1%), with no invalid results or adverse events, supporting reliability in routine screening settings.[9]

		Clinician-Collected Cervical Swab		
		HR HPV Positive	**HR HPV Negative**	**Total**
Self-Collected Vaginal	HR HPV Positive	81	53	134
	HR HPV Negative	6	261	267
	Total	87	314	401
PPA (HR HPV) =93.1% (81/87); 95% CI: (85.8, 96.8) NPA (HR HPV) =83.1% (261/314); 95% CI: (78.6, 86.9)				

Shipping Stability

Specimen stability was evaluated under simulated shipping and storage conditions across a range of temperatures and transit durations.[9]

Specimen Configuration	Temperature	Time
Self-collected vaginal specimen (dry swab) during simulated transit	Ambient	7 days
Sample in BD Onclarity™ HPV Self-Collection Diluent Tube (after	Ambient	3 days

Specimen Configuration	Temperature	Time
specimen transfer and before pre-warming)		
Sample in BD Onclarity™ HPV Self-Collection Diluent Tube, capped after pre-warming	2-30 °C -20 °C	3 days

Summary and Clinical Relevance

Together, these data support the use of self-collected vaginal swab specimens with the BD Onclarity™ HPV Assay as a reliable approach for high-risk HPV detection. Strong agreement with clinician-collected samples and robust specimen stability support its use in accessible, patient-centered screening models, including at-home cervical cancer screening models.

Color's Virtual Cancer Clinic is designed to support cancer screening, early detection, and prevention through physician-directed testing, follow-up navigation, and care coordination for individuals requiring additional evaluation after a positive result.

References

1. Centers for Disease Control and Prevention. *Cancers Associated with Human Papillomavirus*. Published April 29, 2026. Accessed May 15, 2026. https://www.cdc.gov/united-states-cancer-statistics/publications/hpv-associated-cancers.html
2. Perkins RB, Wolf AMD, Church TR, et al. Self-collected vaginal specimens for human papillomavirus testing and guidance on screening exit: An update to the American Cancer Society cervical cancer screening guideline. *CA Cancer J Clin*. 2026;76(1):e70041. doi:10.3322/caac.70041
3. US Preventive Services Task Force, Curry SJ, Krist AH, et al. Screening for Cervical Cancer: US Preventive Services Task Force Recommendation Statement. *JAMA*. 2018;320(7):674-686.
4. American College of Obstetricians and Gynecologists. *Screening for Cervical Cancer*. Committee Statement. Published online April 15, 2026. Accessed May 15, 2026. https://www.acog.org/clinical/clinical-guidance/committee-statement/articles/2026/07/screening-for-cervical-cancer
5. Screening for Cervical Cancer With High-Risk Human Papillomavirus Testing: A Draft Evidence Update for the U.S. Preventive Services Task Force. Evidence Synthesis No. 244. Rockville, MD: Agency for Healthcare Research and Quality; 2024. AHRQ Publication No. 24-05318-EF-1.
6. Suk R, Hong YR, Rajan SS, Xie Z, Zhu Y, Spencer JC. Assessment of US Preventive Services Task Force Guideline-Concordant Cervical Cancer Screening Rates and Reasons for Underscreening by Age, Race and Ethnicity, Sexual Orientation, Rurality, and Insurance, 2005 to 2019. *JAMA Netw Open*. 2022;5(1):e2143582.
7. National Committee for Quality Assurance. Cervical Cancer Screening (CCS). In: HEDIS® MY 2026 Volume 2: Technical Specifications for Health Plans. NCQA; 2026. Accessed May 21, 2026. https://www.ncqa.org/hedis/measures/
8. Neibart S, Zhou N, Chino J, et al. Health equity, disparities, and barriers to cervical cancer care in the U.S.: A consensus statement by SGO, ACOG, ASCCP, ASTRO, and ABS addressing the WHO cervical Cancer elimination campaign goals related to treatment. *Gynecol Oncol*. 2025;200:186-192. doi:10.1016/j.ygyno.2025.07.029
9. BD Onclarity™ HPV Assay Package Insert. Becton, Dickinson and Company. 8089894(10); revised April 2026. Accessed May 15, 2026. Available from: https://eifu.bd.com/hcp/ids/US/general?keycode=441990
10. Martinelli M, Latsuzbaia A, Bonde J, et al. Performance of BD Onclarity HPV assay on FLOQSwabs vaginal self-samples. *Microbiol Spectr*. 2024;12(3):e0287223. doi:10.1128/spectrum.02872-23