FDA-Approved Human Papillomavirus (HPV) Self-Tests Now Available for Use in Clinical Settings

SELF-TESTS OFFER YOUR PATIENTS ENHANCED COMFORT, PRIVACY AND ACCESSIBILITY FOR EFFECTIVE CERVICAL CANCER PREVENTION AND DETECTION

In May 2024, the U.S. Food and Drug Administration (FDA) approved two self-administered tests for use in clinical settings for HPV[1]:

- **cobas® 4800 HPV Test** (Roche Molecular Diagnostics®)
- **BD Onclarity™ HPV Assay** (Becton Dickinson)

The tests are designed to be done in health care settings, such as primary care physician (PCP) offices, urgent care centers, pharmacies and mobile clinics, which offer clinical support and patient privacy.

The HPV self-tests are self-administered by the patient and retrieve a sample of cervical cells using either a brush or swab. The specimen is processed in a lab like the traditional, speculum-based HPV test. Research has demonstrated that self-sampling with these test kits is just as effective as speculum-based testing for HPV detection.[2,3] Both self-tests can detect 14 high-risk strains of HPV: 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68.[4] HPV 16 and HPV 18 are responsible for most HPV-related cancers.[5]

The 2019 American Society for Colposcopy and Cervical Pathology Risk-Based Management Consensus Guidelines for Abnormal Cervical Cancer Screening Tests and Cancer Precursors provide follow-up guidelines depending on the patient's risk level and can be found using the link in the references below.[6] Generally, when primary HPV testing is used for screening, cytology testing should be performed for all positive HPV test results.[7]

Benefits of self-testing

HPV self-tests deliver meaningful benefits for patients, physicians and other providers.

How patients benefit

- **Enhanced comfort and privacy:** Self-collection methods eliminate the need for a pelvic exam, which individuals may find uncomfortable or invasive. This approach can be particularly beneficial for individuals with religious or cultural beliefs that create barriers to care; a history of trauma; or disabilities or medical conditions that prevent them from getting a pelvic exam.
- **Increases screening accessibility within the clinic:** Enables completion of HPV screening during a routine visit without requiring a pelvic exam. Particularly beneficial for patients who are in clinic but not scheduled for a gynecologic exam.

(continued)

- **Promotes patient engagement and empowerment:** By allowing individuals to collect the sample themselves, patients develop self-efficacy, empowering them to take a more active role in their health care. This can lead to increased engagement and adherence to screening recommendations.

How physicians and other providers benefit

- **Operational efficiency:** Frees up exam rooms and clinician time by reducing the need to conduct pelvic exams during routine screenings, which enables efficient use of clinical space and staff, particularly in high-volume settings.
- **Supports patient-centered care:** Providing self-collection samples can increase patient comfort, autonomy and trust in the screening process. This helps foster a more collaborative patient-provider relationship.
- **Enhances screening uptake:** Offering self-collection options can help reach populations that are under-screened or have barriers to traditional screening methods, thereby improving overall screening rates.

HEDIS®[8] measure for Cervical Cancer Screening (CCS)

The HPV self-test results satisfy HEDIS screening criteria. The CCS HEDIS measure[9] reports the percentage of patients ages 21-64 who were screened for cervical cancer using any of the following criteria:

- Patient ages 21–64 who had a cervical cytology performed within the last three years.
- Patient ages 30–64 who had a cervical high-risk human papillomavirus (hrHPV) testing performed within the last five years.
- Patient ages 30–64 who had cervical cytology/high-risk HPV (hrHPV) co-testing performed within the last five years.

Coding[10]

CPT 87626: Recommended for the BD Onclarity HPV Assay and the Roche cobas HPV test.

Best practices

- **Check to see if the patient is due for any of the following** during office visits:
  - Pap or HPV test
  - Mammogram
  - Well visit
  - Chlamydia/sexually transmitted infection screening
  - Sick visit
- **Reference Cozeva®** to identify patients due for a cervical cancer screening, along with breast cancer screening, chlamydia, colorectal and flu.
- **Educate patients** that cervical cancer screening is a covered preventive service.
- **Ensure bidirectional data flow** between OB/GYN and PCP.
- **Always include** dates of service, specific test names and results in the medical record.

[1]U.S. Food & Drug Administration, FDA News Release; FDA Roundup: May 17, 2024 fda.gov/news-events/press-announcements/fda-roundup-may-17-2024.

[2]Preventive Medicine Reports, Vol. 50 February 2025, 102971 "Cervical cancer screening: Impact of collection technique on human papillomavirus detection and genotyping", A. Young, M. Olorunfemi, L. Morrison et al.; doi.org/10.1016/j.pmedr.2025.102971.

[3]Journal of Lower Genital Tract Disease, "Self-Collected Vaginal Specimens for HPV Testing: Recommendations From the Enduring Consensus Cervical Cancer Screening and Management Guidelines Committee", 29(2):p 14-152, April 2025. DOI: 10.1097/LGT.0000000000000885. journals.lww.com/jlgtd/fulltext/2025/04000/self_collected_vaginal_specimens_for_hpv_testing_.6.aspx.

[4]U.S. Centers for Disease Control and Prevention, Sexually Transmitted Infections Treatment Guidelines, 2021, HPV-Associated Cancers and Precancers. cdc.gov/std/treatment-guidelines/hpv-cancer.htm.

[5]National Cancer Institute, HPV and Cancer: What is HPV? cancer.gov/about-cancer/causes-prevention/risk/infectious-agents/hpv-and-cancer#:~:text=HPV%2Drelated%20research-,What%20is%20HPV%20(human%20papillomavirus)?,controlled%20by%20your%20immune%20system.

[6]2019 ASCCP Risk-Based Management Consensus Guidelines for Abnormal Cervical Cancer Screening Tests and Cancer Precursors. asccp.org/Default.aspx.

[7]U.S. Centers for Disease Control and Prevention, Sexually Transmitted Infections Treatment Guidelines, 2021, Follow-Up of Abnormal Cytology and Human Papillomavirus Test Results. cdc.gov/std/treatment-guidelines/hpv-cancer.htm.

[8]HEDIS: Healthcare Effectiveness Data and Information Set NCQA. HEDIS MY 2025 Technical Specifications for Health Plans, Volume 2, Washington, D.C., 2024.

[9]HEDIS – Healthcare Effectiveness Data and Information Set., Section B. Effectiveness of Care Prevention and Screening, pg. 92, Cervical Cancer Screening (CCS). ncqa.org/hedis.

[10]Billing and Coding: MolDX: Molecular Syndromic Panels for Infections Disease Pathogen Identification Testing. cms.gov/medicare-coverage-database/view/article.aspx?articleid=58761&ver=55&.

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