LOUISIANA CANCER PREVENTION & CONTROL PROGRAMS

HPV Self-Sampling at the Clinic

Guidance for Health Care Providers

Background

The U.S. Preventative Service Task Force (USPSTF) notes the country has seen a significant decrease in cervical cancer deaths due to the widespread implementation of human papillomavirus (HPV) screening. New case rates of cervical cancer are often among women who are rarely screened, and subsequently, not properly diagnosed and treated. By increasing preventative strategies, such as implementing **HPV self-collection**, we can decrease incidence and mortality rates of cervical cancer in Louisiana.

USPSTF Cervical Screening Recommendations:

- Women ages 21 to 29 years
  every 3 years with cervical cytology alone
- Women ages 30 to 65
  every 5 years with clinician- or patient-collected high-risk HPV primary screening.

Benefits

- **Studies confirm that self-sampling for HPV testing is as effective as clinician-sampling testing.**
- It may increase screening coverage among specific populations, including individuals who are un- or under-screened, women who decline or are unable to undergo pelvic examinations for personal, cultural, or medical reasons, and patients living in areas with shortages of gynecologists.

How It Works

Self-collected HPV tests—such as the FDA-approved BD Onclarity HPV Assay (Becton, Dickinson and Company) and the cobas HPV Test (Roche Molecular Systems, Inc.)—work by detecting high-risk strains of HPV that may be present in cervical or vaginal cells. Traditionally, these samples are collected during a pelvic exam conducted by a healthcare provider. However, the FDA has recently approved several self-collection devices for HPV testing, expanding access and convenience.

HPV Self-Collection Kits and Devices:

HPV self-collection kits typically contain a flocked Dacron swab, such as a FloqSwab, preserving fluid, labeling, and packaging for returning the sample. Both LabCorp and Quest Diagnostics have kits available.

Each is inserted into the vagina and gently rotated to collect a sample, which is then sent to a laboratory for analysis using an FDA-approved HPV test.

Sample Clinic Instructions

Identify Eligible Patients

Patient Eligibility:

- ✓ Age: 30 to 64 years
- ✓ Has a cervix
- ✓ Due for cervical cancer screening
- ✗ History of cervical cancer or high-grade cervical lesions
- ✗ High-risk status: including living with HIV, in utero diethystilbestrol exposure
- ✗ Currently on menstrual cycle or sexual activity within the past 24 hours
- ✗ Currently pregnant or in the three months after giving birth
- ✗ Experiencing symptoms such as abnormal bleeding, discharge or pelvic pain

Not eligible

Inform Patient

Confirm patient understands the process and agrees to collect self sample.

Provide Self-Collection Kit and Instructions

- **Explain self-collection procedure.** If needed, provide a brief demonstration on how to use the self-collection device (refer to provided video instructions as needed).
- **Give patient the HPV self-collection kit**, which includes a sterile swab and labeled specimen tube. Ensure patient has access to step-by-step instructions sheet in the screening area.
- **Facilitate sample collection:** Allow patients to collect their samples independently in a designated private area (on-site restroom or exam room). Instruct the patient to return the sample to staff when done.
- **Verify labeling:** Ensure accurate patient identification by properly labeling the sample collection container. Mark as HPV-only testing (no reflex to cytology).

Store and Transport Sample per Protocol

Follow established procedures for storing and transporting samples to the laboratory (same as Pap test samples).

Communicate Results and Follow-up

- **Result notification:** Clearly communicate test results to patients, including the meaning of positive and negative findings. **For positive results**, provide appropriate counseling and discuss next steps such as scheduling a follow-up appointment for further testing.
- **Patient support:** Address any questions or concerns patients may have regarding their results and next steps.

Clinical management for self-collected vaginal specimens by test results

RESULT	CLINICAL MANAGEMENT
HPV-negative	Repeat HPV testing in three years
HPV 16 or 18	Colposcopy with collection of cytology and biopsies
HPV 45, 33/58, 31, 52, 35/39/68, 51 or other pooled HPV types Negative for HPV 16/18	Clinician-collected sample for cytology or dual-stain triage testing
HPV 56/59/66 Negative for all other carcinogenic types	Repeat HPV testing in one year

To view the full enduring guidelines for HPV self-collected vaginal specimens visit:
https://www.asccp.org/guidelines/enduring-guidelines/process

Additional Information

USPSTF cervical cancer screening guidelines:
https://www.uspreventiveservicestaskforce.org/uspstf/draft-recommendation/cervical-cancer-screening-adults-adolescents#bootstrap-panel--3--content

American Cancer Society cervical cancer screening guidelines:
https://www.cancer.org/cancer/types/cervical-cancer/detection-diagnosis-staging/cervical-cancer-screening-guidelines.html

HPV self-collect FDA approval links:
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160037
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P100020
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P190028