CLINICAL LABS OF HAWAII

Client Communication

July 2023

HPV Testing - Updated Cytology Test Options

Effective July 1, 2023, CLH/PPP will be updating our Cytology GYN test options and will include HPV (Patient-Self-Collected) specimens as an acceptable source.

The Human Papilomavirus (HPV) assay is indicated for use for both routine cervical cancer screening and for the management of prior abnormal cytology/histology results as per professional medical guidelines. This includes triage of ASC-US cytology, co-testing with cytology, HPV primary screening, and as part of follow-up management strategies for various cytologic and histologic abnormalities with the goal of cervical cancer prevention through risk assessment, monitoring and treatment of precursor lesions.

Clinical Labs of Hawaii (CLH) and Pan Pacific Pathologists (PPP) are proud to continue to offer our providers state-of-the-art testing as part of our ongoing commitment to the advancement of diagnostic care for women. Our HPV assay is performed on the Roche cobas® which utilizes qualitative real-time PCR. It is an FDA approved test for the detection of high-risk HPV types 16 and 18, as well as the other 12 high-risk types (31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68) associated with cervical cancer and its precursor lesions. Although the assay is not FDA approved for vaginal source specimens, CLH/PPP has validated the assay. By adding patient-self-collected specimens to our menu, healthcare providers may be able to reach patients living in populations with low screening rates.

Note: It should be emphasized that HPV self-collection is not intended to replace provider-obtained specimens at the time of office visits to OB-Gyn or primary care providers. While cervical cancer screening programs have had dramatic effects on the incidence of invasive cervical cancer, we continue to see cases of invasive cancer including advanced disease. National data, as well as our own tumor registry data, clearly show these cases occur in patients with either no cervical screening or markedly inadequate screening histories. One attempt to address this situation is to offer HPV self-collection in the hope that it may increase the screening population, particularly in certain communities where high rates of invasive cervical cancer are seen. Currently, this approach is not designed to be implemented at home, but rather in a clinic setting where a connection with any appropriate follow-up services can be established. We hope to work closely with our providers and community leaders in an attempt to impact those populations.

Test information

HPV Test Options (updated on 7/1/23)	
Test Option	Order GYN in your EMR or select one of the following options on your CLH cytology requisition. *For cervical specimens:* • Pap and HPV test (co-test) • Pap Test with Reflex to HPV if ASCUS • HPV Primary Screening Protocol (reflex to Pap if HPV+) • HPV Test only *For vaginal specimens (provider collected or patient-self-collected):* • HPV Test only ***Indicate the specimen source on the requisition or EMR lab order.***
Specimen Collection	**Cervical:** Obtain adequate sampling via a cervical broom/spatula/brush and rinse vigorously in the ThinPrep® vial 10 times. **DISCARD** the collection device after rinsing. Tighten the cap and label the vial with the patient's name as it appears on the lab order, date of birth, and date/time of collection. **Vaginal (Patient-self-collect in a clinical setting ie at the provider's clinic):** Requires a custom HPV vaginal FLOQSwab® (contact CLH to obtain a kit) which must be inoculated into a ThinPrep® vial by office staff.

	• Direct the patient to the bathroom and provide written and verbal instructions on collection. Refer to CLH's HPV Patient Self-Collection Instructions with graphics. ***Do not send patients to CLH for collection.*** Patient Instructions: • Wash hands with soap and water, rinse and dry. • Remove the swab from the tube by swirling the cap avoiding contact with the tip of the swab. The tip must not touch any surfaces. • Hold the swab by placing fingers on the red mark on the shaft. • Insert the swab into the vaginal opening until fingers are in contact with the opening of the vagina. • Collect the sample by rotating the swab tip for 10-30 seconds in either direction. • Re-insert the swab into the FLOQSwab® tube and press the swab cap tightly until you hear a "click". • Write your name (last,first), date of birth, and date/time of collection on the tube. • Return the specimen to the clinic staff. Clinic Staff Instructions once the patient submits the HPV FLOQSwab® specimen: • Process the sample into a ThinPrep® vial within 1 hour of collection • Uncap the ThinPrep® vial and place on a stable, flat surface. • Slowly pull the FLOQSwab® cap off to remove the swab from the tube minimizing touching the inner walls of the tube as you remove it. • With one hand, hold the ThinPrep® vial while swirling the FLOQSwab® along the inner vial wall for 20 seconds while ensuring the swab remains immersed in the vial medium (be careful not to splash). • Carefully hold the tip against the inner vial wall to drain fluid off of the swab. • Place the FLOQSwab® into the tube and DISCARD. • Recap the ThinPrep® vial and tighten. Store upright. • Label the ThinPrep® vial with the patient's name as it appears on the lab order, date of birth, and date/time of collection. **NOTE: To avoid specimen rejection, clinic staff must inoculate the FLOQSwab® into the ThinPrep® vial.**
Stability after collection	30 days at room temperature or refrigerated once in the ThinPrep® vial. The FLOQSwab® for vaginal collection should be inoculated into the ThinPrep® vial at the clinic's office within 1 hour of collection.
Turn-around Time	Reports in 1-2 days (performed Monday to Friday)
Results	Qualitative
Reference Range	Negative
Methodology	Real-Time PCR
CPT Codes	87624

Please contact your CLH representative to request the HPV Patient-Self-Collection Kit (FLOQSwab®).

References:

1. cobas® HPV for cobas® 6800/8800. Package Insert v1. U.S. Roche Diagnostics; 2020.

If you have any questions, please contact our Client Services Department at 808-677-7998 (Oahu) or 1-866-281-6816 (toll-free).

Thank you for choosing Clinical Labs of Hawaii.