

HPV Testing and Updated Cytology Requisitions

Offering our providers state-of-the-art testing is part of Clinical Labs of Hawaii (CLH) and Pan Pacific Pathologists (PPP) commitment to excellence.

Effective September 19, 2022, CLH/PPP, will offer the Roche cobas® Human papillomavirus (HPV).

Cervical cancer is one of the most common cancers in women with more than 14,000 new cases estimated in the United States in 2021.¹ The link between cervical cancer and HPV has become clear over the past few decades. It is well known that a persistent HPV infection with high-risk genotypes account for nearly all cases of cervical cancer.² While most HPV infections resolve on their own, some HPV infections can progress to high-grade cervical intra-epithelial neoplasia, CIN2 or CIN3. If left untreated, CIN2 or CIN3 can progress to cervical cancer years or decades after initial infection.³

The cobas® HPV test is FDA approved for cervical cancer screening for ASC-US reflex, co-testing, and HPV primary screening. The test offers:

- An internal cellular control used to monitor the presence of human cells and confirms reaction completion to prevent false-negative results;
- Three results (HPV 16, HPV 18, and 12 pooled high-risk HPV genotypes (31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68) in one test run eliminating the need to reflex;
- No cross-reactivity with low-risk HPV genotypes, helping to ensure that a positive result is a true positive; and
- HPV DNA-based amplification which detects risk at an early stage.

The cobas® HPV test is clinically validated in two of the largest cervical cancer screening trials, the ATHENA Study⁴ and IMPACT Trial⁵.

Cervical specimens collected in a ThinPrep® vial (vaginal specimens are validated but not FDA approved) can be submitted with the GYN cytology requisitions with newly updated test options (Pap test only, Pap Test with Reflex to HPV if ASC-US, Pap and HPV test (co-test), HPV primary screening, or HPV test only). Please note that these new requisitions also have a section for the ordering provider to date, print, and sign his/her name.

References:

¹ National Cancer Institute Cancer Stat Facts: Cervical Cancer. Accessed August 16, 2021. Available at: <https://seer.cancer.gov/statfacts/html/cervix.html>

² Key Statistics for Cervical Cancer. American Cancer Society. Accessed August 13, 2021. <https://www.cancer.org/cancer/cervical-cancer/about/key-statistics.html>

³ American Cancer Society. What is cervical cancer? Accessed August 14, 2021. <https://www.cancer.org/cancer/cervical-cancer/about/what-is-cervical-cancer.html>

⁴ cobas® HPV test. Package insert v17, U.S. Roche Diagnostics; 2018.

⁵ 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.