CLINICAL LABS OF HAWAII

Human Papillomavirus (HPV)

New Methodology and Algorithm - Test Update

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

Effective November 11, 2019, CLH/PPPL will be performing Human Papillomavirus (HPV) testing locally on Oahu using the Aptima® nucleic acid amplification assay.

- HPV assays run locally
- Faster turn around time
- Discrete results for quality measures
- Similar sensitivity but improved specificity
- Reduced false positives of high-risk types

The Aptima assay is an FDA approved test that targets the E6/E7 viral messenger RNA (mRNA) from 14 high-risk HPV types in cervical specimens submitted in ThinPrep® vials. The high-risk types detected include 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68, which are associated with precancerous lesions and cervical cancer. This assay demonstrates improved specificity while offering the same excellent sensitivity as compared to DNA based tests. By targeting mRNA, the false positive rate is reduced by 24%, which consequently reduces the number of unnecessary biopsies.[1]

In addition to an improved methodology, we are also updating our algorithm for HPV testing to align with the American Society for Colposcopy and Cervical Pathology (ASCCP) and American College of Obstetricians and Gynecologists (ACOG) professional society guidelines. HPV 16 and 18/45 genotyping is typically recommended as part of co-testing when the pap result is NEGATIVE and the HPV screen is POSITIVE. Cytology-negative and HPV-positive co-test results occur in approximately 3.7% of women 30 and older.[2] Other clinical decisions may also be facilitated by HPV genotyping. Because additional charges may be applied if abnormal or reflex testing is triggered, requisitions have been revised to indicate the reflex option (see right).

Check this box in addition to the co-test box if reflex to genotype is needed

GYN CYTOLOGY - PAP TEST PROTOCOL OPTION

- ☐ **Pap Test Only***
- ☐ **Pap Test with Reflex to HPV if ASCUS***
- ☐ **Pap* and HPV test (Co-test), (30 - 65 years)**
- ☐ **Reflex to HPV 16, 18/45 genotype if PAP is Negative and HPV Screen is Positive***

If HPV Genotype 16, 18/45 is needed, please call the Cytology Department
*Additional charges may be applied if abnormal or reflex testing is triggered

- ☐ **HPV Primary Screening Protocol** **reflex to Pap if HPV+, 16/18 -, [25 years & older]
  Interim Clinical Guidelines: *Obstet Gynecol.* 2015 Feb;125(2):330-7.
- ☐ **HPV Test only,** other than Primary Screening Protocol or for repeat due to previous indeterminate result (please submit in ThinPrep vial only)

Testing will be performed daily from Monday through Saturday. HPV results will also be reported in discrete fields, making it easier to track quality measures, as well as in the standard pathology report.

If you have any questions, please contact our Client Services Department.

— Thank you for choosing Clinical Labs of Hawaii.

1. Aptima® HPV Assay (Package Insert). AW-12820. Rev.003. San Diego, CA; Hologic, Inc. 2017.
2. ACOG. Practice Bulletin No. 168: Cervical Cancer Screening and Prevention. October 2016. 128(4)e121.