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Physicians Laboratory strives to maintain the highest quality of patient care possible. Part of that goal involves continually evaluating new technologies and screening strategies with regard to our cytology services.

As many of you are already aware, an HPV test marketed by Roche (the cobas HPV test) was recently approved by the FDA for primary cervical cancer screening in women aged ≥ 25 years. The purpose of this letter is to inform you of why Physicians Laboratory is in favor of cytology remaining the front-line screening test for cervical cancer and why we stand behind HPV testing in conjunction with the Pap test either as a reflex to ASC-US cytology, or in screening with Pap+HPV for women aged 30-65 (referred to as co-testing).

Recent studies have argued that HPV-only screening may be more effective than Pap-only screening for cervical precancer and cancer at screening intervals ≥ three years; however those trials failed to compare HPV-only with the guideline-recommended co-testing. Also, 20% of the women aged 25-29 used to support FDA-approval for the HPV alone indication were positive for HPV.[1] Using the HPV test in this way would not only require significant patient education and physician counseling but would increase the number of colposcopies and the subsequent associated harms, while having virtually no impact on reducing cervical cancer rates in that age group.

A large study of Pap and HPV testing of over 200,00 women in multiple practices by Blatt, et[2] al found that 26.6% of women who were diagnosed with adenocarcinoma were HPV negative. Other studies have also found high rates of negative HPV results in cervical adenocarcinoma specimens. These findings suggest significant limitations regarding the detection of HPV in glandular neoplasms.

It is for these reasons that Physicians Laboratory will stand behind the best options for patient care:

- Screening with Pap in women under 30 years of age, with HPV testing used as a reflex for ASC-US patients (current 2012 consensus guidelines)
- Screening with the ThinPrep® Pap Test and the Aptima®HPV assay in women aged 30-65

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[1] ATHENA FDA Summary

[2] Blatt et al. *Cancer Cytopathology*. Published online April 2015.