Legacy LabAdvisor

Quarterly laboratory and pathology update from Legacy Laboratory Services in collaboration with Cascade Pathology Edition 3

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Cascade Pathology Services and Legacy Health recommend co-testing as an appropriate screening test for women 30 years and older

By Anne Rader, M.D., Director of Cytopathology, Cascade Pathology Services and Duncan Neilson, M.D., Chief of Women's Services, Legacy Health

The American College of Obstetricians and Gynecologists (ACOG) recently updated their recommendations for cervical cancer screening. For the first time, their Level A recommendations now include co-testing women 30 years and over with cytology and HPV testing.[1]

The evidence behind HPV co-testing with a Pap is significant. More than 300 published papers support co-testing with the HPV Test. Its sensitivity for CIN 2+ and CIN 3+ is 98 percent and 100 percent, respectively, among women age 30 and over.[2,3] In addition, this test combination has demonstrated a Negative Predictive Value of 99.7 percent, giving women and their providers reassurance that with a negative HPV and normal Pap, the patient is considered at minimal risk of developing cervical cancer.

Beginning January 2011, Cascade Pathology Services conducted a six-month review of appropriately screened, co-testing orders. During the six months, 4,232 negative Paps were tested for HPV in patients 30 years and older. Of those negative Paps, 8 percent (318 tests) were positive for HPV. In this review, co-testing identified 8 percent of the tested population for whom follow-up is advised.

With the sensitivity of a molecular HPV test, you can better assess a woman's risk for current, and future, cervical disease and cancer.

The methodology used by Cascade Pathology and Legacy Laboratory Services (the digene® HPV test) provides a reliable, objective measure of a patient's risk for having, or developing, this highly preventable cancer.

Cascade Pathology Services and Legacy Health partner to provide your practice with advanced technology that improves your overall cervical cancer screening strategy. For more information please contact Dr. Rader at 503-692-7631.

1. ACOG Practice Bulletin, #109. 2009:019:8

2. Cuzick, J. et al. LANCET. 2003; 362:1871-1876.

3. Lorincz A, et al. Arch Pathol Lab Med. 2003; 127:959-968

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LEGACY HEALTH

Introducing "PAP Plus" — single vial testing for cervical cancer, chlamydia and gonorrhoeae

Legacy Laboratory Services now offers chlamydia trachomatis (CT) and Neisseria gonorrhoeae (GC) testing from liquid-based cytology specimens collected during routine cervical cancer screening. Our addition of FDA-approved chlamydia and N. gonorrhoeae amplified DNA assays (BD ProbeTec™ Qx) by Strand Displacement Amplification expands your "out of vial" testing options to include: cytology (either SurePath or ThinPrep), High Risk HPV, CT and GC testing. The pairing of highly sensitive and specific nucleic acid amplification tests for CT and GC with both major liquid prep Pap tests is a welcome development, especially in women's health, as it can enhance disease detection capability from a single specimen.

New PAP Plus testing is performed via single vial for Pap, HPV and CT/GC, which is easy for clinicians and comfortable for patients. It is a convenient and trustworthy test. PAP Plus has been cleared by the FDA which requires extremely rigorous manufacturer test development. They are also the first FDA-cleared CT and GC nucleic acid amplified tests for use with both SurePath™ and ThinPrep® liquid Pap preparations, and the only assays FDA-cleared for CT and GC testing of SurePath™ Pap specimens.

In addition, PAP Plus offers improved patient management and greater accuracy than other methods. Test interpretation does not include an equivocal zone, which means less indeterminate results for patients and fewer rejected specimens due to inhibition interference.

Please note:

1. CT/GC tests from a liquid Pap must be requested on the original order; they cannot be aliquoted from a Pap that has already been processed.

2. Although there is minimal inhibition interference caused by blood, common gynecological products or spermicides, it is best to collect specimens for "out of the vial" testing during mid-cycle and with limited use of lubricants.

3. Unpreserved urine specimens must be refrigerated.

Legacy Laboratory Services' PAP Plus is performed Sunday through Friday and results are delivered in 24 hours.

CPT Codes: CT by Amplified DNA – 87491,
GC by Amplified DNA – 87591

For any questions regarding this assay, please contact Legacy Laboratory Client Services at 503-413-1234 or toll-free 1-877-270-5566.

Making lab testing affordable — Legacy LabAdvantage

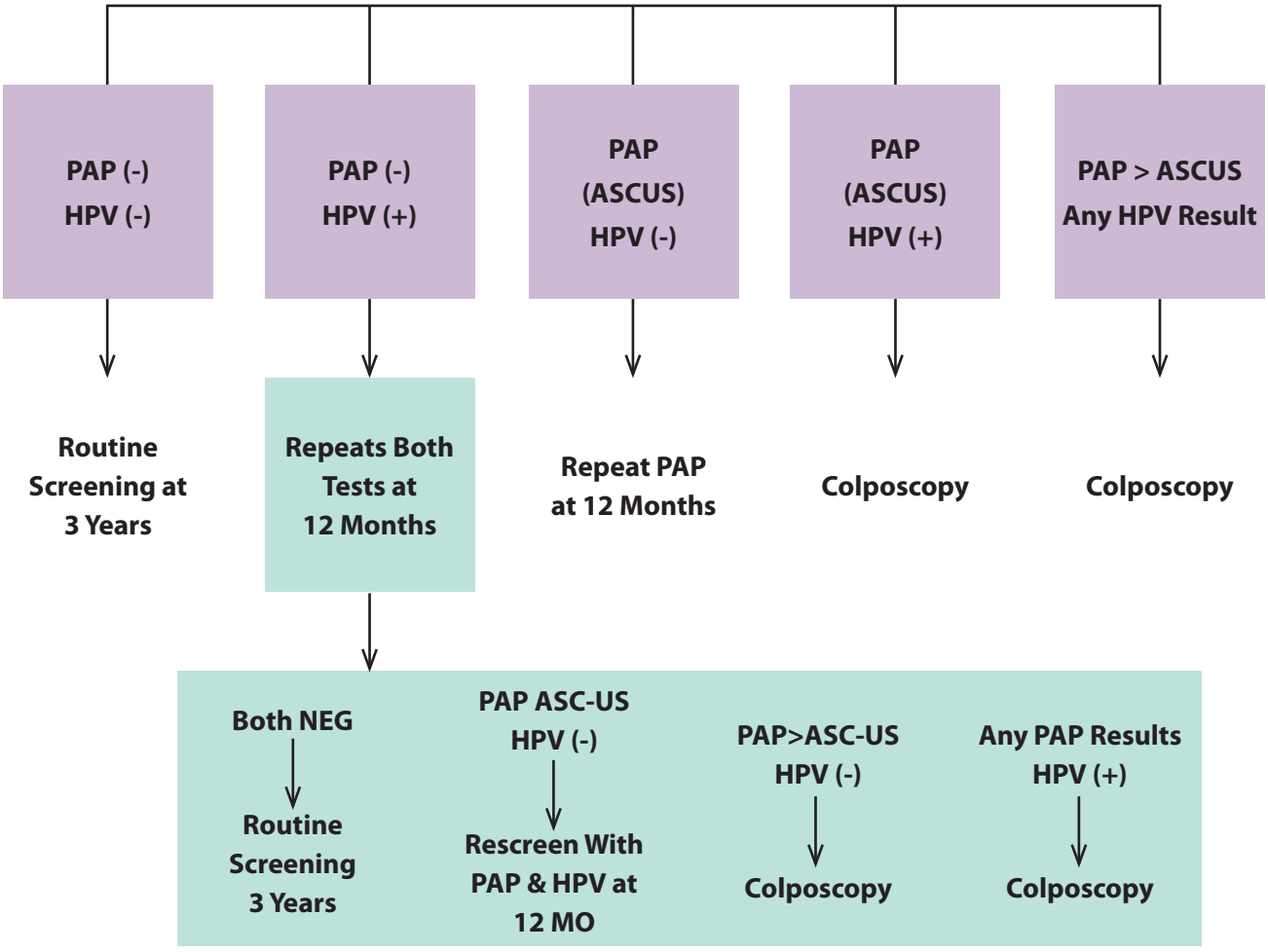
At Legacy Laboratory Services, we provide accurate, timely test results to support your patient's good health. Legacy LabAdvantage helps uninsured patients afford the lab tests they need. Uninsured patients receive a 30 percent discount on testing performed by our laboratory. The discount applies to testing received on or after Oct. 1, 2011. Cascade Pathology also offers uninsured patients a 30 percent discount on tissue biopsy, Pap and HPV tests. For additional information, please contact your Account Services Representative or Lab Client Services at 1-877-270-5566.

Annual Cervical Cancer Screening Women 30 and Older

Algorithm for Pap and HPV Test Results

CASCADE PATHOLOGY SERVICES

LEGACY HEALTH



Wright, T. et al, Obstet Gynecol, 2004;103:304-9

How to order HPV Co-testing for women 30 and older

1. Mark appropriate box:

Legacy Laboratory Services' requisition or electronic order link (EMR):

☑ HPV High Risk & Liquid Based Pap (Any Dx)

EPIC EMR- on the PAP Smear with HPV reflex screen:

☑ Liqd Based – HiRisk HPV- Any Dx

2. Add a secondary ICD-9 code, V73.81 (HPV Screening), to your routine GYN code.
(Insurance coverage for appropriate HPV Screening is universal, except for Medicare)

3. No additional specimen collection is necessary if collecting a Liquid Based Pap.

Managing HPV Test Results

• Any low-risk woman aged 30 years or older who receives "negative" test results on both cervical cytology screening and HPV DNA testing should be rescreened no sooner than 3 years subsequently. However, annual well-woman and pelvic examinations are still recommended.

• Recommendations for managing women who have a negative Pap test and positive HPV are evolving but there is agreement on this guideline:

☐ American College of Obstetrics & Gynecology (ACOG) and American Society for Colposcopy and Cervical Pathology (ASCCP) recommend repeat testing in 12 months, followed by colposcopy if HPV test is still positive.

• If any Pap test is abnormal, the patient should be managed according to published guidelines, regardless of HPV status.

Cascade Pathology Services | Legacy Health

Questions and Answers

By Anne Rader, M.D., Director of Cytopathology, Cascade Pathology Services and Duncan Neilson, M.D., Chief of Women's Services, Legacy Health

Send questions to legacylaboratoryservices@lhs.org. One of our team will respond.

HPV and Pap Co-testing for Women 30 and Older

1.) What is the scientific basis for cervical cancer screening with a combination of Human Papilloma Virus (HPV) and Pap test for women 30 and older?

Answer: Co-testing women 30 years and older with the digene® HPV DNA test and a Pap test has shown exceptional sensitivity of 98 percent for CIN2+ and 100 percent for CIN3+.[1-2] Epidemiology data have shown that the prevalence of HPV in women generally decreases over time, while the incidence of cervical cancer increases.[3] "Studies using combined HPV testing and cervical cytology have reported a negative predictive value for CIN 2 and CIN 3 of 99–100 percent."[4] A positive HPV test and a normal Pap reflect increased risk for either missed disease or for the subsequent development of CIN2/3 and cancer, requiring increased surveillance. "In a well-screened population, the risk of CIN 2+ in HPV positive, cytology negative women ranges from 2.4 to 5.1 percent."[5]

2.) What organizations recommend co-testing for women 30 and older?

Answer:

- American College of Obstetrics and Gynecology
- American Cancer Society
- American Society of Colposcopy and Cervical Pathology
- National Association of Nurse Practitioners in Women's Health
- Society for Gynecologic Oncology
- Centers for Disease Control

3.) Won't I be overloaded with counseling HPV (+) women? How many of my patients will need counseling regarding positive HPV tests?

Answer: No, our internal data combined with that of Castle et al has shown that only 4 percent–8 percent of patients that are Pap normal will be HPV positive.[6]

4.) Is co-testing really necessary for a woman who has been in a serious monogamous relationship for all her life?

Answer: Yes, even women who have had only one sexual partner could have been infected by HPV. An HPV infection can take years or even decades to appear. Any woman age 30 and older that has ever had sex should be tested.

5.) Is this test covered by insurance?

Answer: The HPV test as a co-test for women 30 and older has universal coverage, except for Medicare, with over 95 percent of claims paid on the first submission.

6.) What resources are available for counseling and educating my patients about HPV?

Answer:

- www.cancer.org
- www.asccp.org
- www.ced.gov/cancer
- www.wcn.org
- www.cancer.gov
- www.thehpvtest.com
- www.ashastd.org
- Patient education literature

References:

1.) Sankaranarayanan, R. et al. (2009) N. Engl. J. Med. 360, 1385

2.) Mayrand, M.H. et al. (2007) N. Engl. J. Med. 16, 1579

3.) Ries, L.A.G. et al. eds. SEER Cancer Statistics Review, 1975–2005

4.) ACOG 61 Practice Bulletin

5.) Kjaer S, Hogdall E, Frederiksen K, et al. Cancer Res 2006;66:10630–10636. (Level II–2)

6.) Castle, PE, et al. Obstet Gynecol 2009;113:595–600

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