Excellence in Pathology and Laboratory Services

TECHNICAL UPDATE

Associated Pathologists/PathGroup Labs is now offering the ***Cervical DNA Dtex*** test as part of its panel of cervical cancer screening tests. It is performed on ThinPrep™ PapTest specimens, and is intended as a supplemental test for patients with high-risk HPV infection. This Fluorescence In Situ Hybridization (FISH) assay utilizes a novel biomarker to identify gains in chromosomal region 3q26 and/or 5p15, specific chromosomal abnormalities in HPV-infected cervical cells that have been linked to cervical cancer.[1] ***Cervical DNA Dtex™*** can help identify patients with HPV+ ASCUS or LSIL cytology who are at higher risk of an underlying high grade lesion or future disease progression.

The National Cancer Institute sponsored ASCUS-LSIL Triage Study (ALTS) found that 26.7% of women with HPV+ ASCUS and 27.6% of women with LSIL had biopsy-confirmed high grade lesions (CIN2 or more severe) in the 2 years following the initial abnormal Pap test. [2,3] Although colposcopy and directed biopsy is the standard for disease definition and the basis for treatment decisions, it can miss significant disease. ALTS data showed that among the HPV+ ASCUS and LSIL patients with biopsy-confirmed high grade lesions, 56% were identified during the initial colpsocopy.[2,3] The remainder were identified during two years of follow-up.

Cervical DNA Dtex (Dtex) can be used in conjunction with the Pap test, high-risk HPV test, and colposcopic examination to create more individualized risk assessments and patient management strategies. Patients with a positive Dtex assay merit close follow-up, including consideration of shorter intervals between colposcopic examinations. Although follow-up and treatment strategies are evolving, current recommendations are based on The American College of Obstetricians and Gynecologists (ACOG) consensus guidelines.[4] Timely colposcopic examination should not be deferred on the basis of a negative Dtex result. Dtex results should not alter established treatment protocols for biopsy-confirmed lesions. Excisional treatments should not be performed for a positive Dtex assay in the absence of a biopsy-confirmed high grade lesion (CIN2 or more severe).

Clinical Utility

- Cervical DNA Dtex is a molecular cytology test designed to complement standard cervical screening procedures. It is intended to identify patients whose HPV infections have a higher risk for aggressive biologic behavior (higher risk of progression).

Methodology: Cervical DNA Dtex (Fluorescence In Situ Hybridization)

CPT Codes: 88367 x 3

Specimen Collection: ThinPrep™ collected cytology specimens

Shipping and Handling: Room temperature storage and transport.

Reference Ranges: Negative test result: < 1.0% abnormal cells
Positive test result: ≥ 1.0% abnormal cells

References

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   Fitzpatrick et al., 2006 Gynecologic Oncology, 103: 458–462
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   Rao et al., 2005 BMC Cancer, 4:5–14

2. The ALTS Group. 2003 Am J Obstet Gynecol, 188:1393
3. Castle,et al. 2005 J Natl Cancer Inst, 97:1066-1071
4. Abnormal Cervical Cytology and Histology. 2008. ACOG Practice Bulletin 99. American College of Obstetricians and Gynecologists