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Reveille™ E6/E7 Cell Transformation Alert Assay

May 9, 2011

Dear Colleague:

Pathology, Inc. is pleased to announce the availability, **effective May 16, 2011**, of a new assay in our women's health molecular test menu: **Reveille™ E6/E7 Cell Transformation Alert Assay**. This new flow cytometry-based test helps increase the specificity and positive predictive value in identifying patients who are at risk of progressing to **cervical cancer**.

The assay **identifies over-expression of the HPV E6/E7 oncogenes** in individual cervical cells. Over-expression of these oncogenes has been demonstrated to be a trigger for the beginning of the cellular transformation cycle, and plays a significant role in cervical carcinogenesis.

Liquid-based Pap specimens (**ThinPrep® or SurePath™**) are analyzed by flow cytometry with rapid reporting (24-48 hour turnaround time) of over-expression of E6/E7 HPV mRNA. By identifying over-expression, clinicians can identify which patients are progressing and need to be more closely followed.

We thank you for choosing Pathology, Inc. for your testing services and look forward to your continued support. For additional information, please visit our website at www.pathologyinc.com or contact client services at 877.922.7284.

Sincerely,

A handwritten signature in black ink, appearing to read 'Alfred Lui', written in a cursive style.

Alfred Lui, M.D.
Chief Medical Officer

New Tests (Pathology, Inc.) – Effective May 16, 2011

642 Reveille™ E6/E7 Cell Transformation Alert Assay

Component	Method	Result
E6/E7 mRNA	Flow Cytometry	Positive/Negative for E6/E7 mRNA overexpression

Specimen	ThinPrep® or SurePath™ liquid-based Pap specimens (from patients with previous history of or currently positive for high-risk HPV)
Setup Schedule	Tuesday-Saturday
Report	24-48 hours
Methodology	Flow Cytometry
Clinical Utility	<p>The assay identifies over-expression of the HPV E6/E7 oncogenes in individual cervical cells. Over-expression of these oncogenes has been demonstrated to be a trigger for the beginning of the cellular transformation cycle, and plays a significant role in cervical carcinogenesis. Patients for whom the transformation process has begun should be monitored closely and treated as clinically indicated.</p> <p>Reference: Coquillard G., Palao B., Patterson B.K. Quantification of intracellular HPV E6/E7 mRNA expression increases the specificity and positive predictive value of cervical cancer screening compared to HPV DNA. <i>Gyn Oncol</i> 2011; 120:89-93.</p> <p>This test was developed and its performance characteristics determined by Pathology, Inc. It has not been cleared by the U.S. Food and Drug Administration. The FDA has determined that such clearance and approval is not necessary. This test is used for clinical purposes. It should not be regarded as investigational or for research. This laboratory is certified under the Clinical Laboratory Improvement Amendments (CLIA) as qualified to perform high-complexity clinical laboratory testing.</p>