



# UNIVERSITY OF ILLINOIS

## Hospital & Health Sciences System

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**Department of Pathology**

**Laboratory Alert**

**March 1, 2016**

### **Lab Alert – REMINDER: HIGH RISK HPV TESTING OF THINPREP SPECIMENS**

On March 1, 2016, the UIC Cytology Laboratory will be switching platforms for High Risk Human Papillomavirus (HR HPV) testing of ThinPrep specimens from cervical sources. (ThinPrep specimens from vaginal, vulvar and anal sources will also be accepted, with the same disclaimer as for the current platform because HR HPV testing by any method has only been cleared by the FDA for use with ThinPrep cervical specimens.)

The new platform, the Roche COBAS® 4800 system, permits automated real-time PCR testing that has been clinically validated (Athena study) and FDA approved. It has also been internally validated in the UIC Cytology laboratory.

There is NO change in ordering procedure or specimen requirements for the HR HPV test.

The COBAS® test detects genotypes 16 and 18 individually and also detects a pool of twelve other high risk genotypes, namely 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68.

This means that the report will now indicate not only a Positive or Negative result but, if Positive, whether 16 and/or 18 genotypes were detected.

The cost per test will remain the same.

Note: Although the Roche COBAS® is approved for primary HPV screening, the peer-reviewed literature continues to demonstrate that the current ASCCP, ACOG and ACS guidelines for cervical cancer screening, including cytology and HR HPV co-testing at 5-year intervals for women 30 and older, remain the most sensitive for the detection of pre-cancerous and cancerous cervical disease.

If you have any questions about the new platform, our internal validation studies, result reporting, cervical cancer screening in general, or any other questions, please contact either Dr. Odile David, Director of Cytopathology [odavid@uic.edu](mailto:odavid@uic.edu), or Michelle Kanter, Cytology Supervisor [mbenrube@uic.edu](mailto:mbenrube@uic.edu).