

Effective December 1, 2014

NEW: Human Papilloma Virus (HPV) Assay

To: Clients of UR Medicine Labs

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On Monday, December 1st, 2014, our current Human Papilloma Virus (HPV) High Risk assay will change to a real-time PCR methodology. The Cobas HPV Test from Roche Diagnostics will replace the Digene Hybrid Capture Assay, HC2. The new assay is performed on the fully automated Cobas 4800 instrument and we expect that its use will substantially improve laboratory efficiency and turnaround time.

Unlike the HC2 assay, the Cobas HPV assay individually identifies the two highest-risk HPV genotypes, 16 and 18, that are responsible for more than 50% of cervical cancer cases, as well as simultaneously detecting a pool of 12 other high risk HPV genotypes (HPV types 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68).

The performance of the Cobas HPV test was clinically validated in the landmark Athena study that demonstrated equivalent performance to HC2 in an Atypical Squamous Cells of Undetermined Significance (ASC-US) population. Verification of this assay has been completed in our laboratory.

In addition to being a superior alternative to HC2 in conjunction with Pap cervical cytology testing, the Roche assay is the only assay approved by the FDA (April 2014) for primary screening.

See page 2 for specimen requirements and reporting details...



Specimen Collection

- PreservCyt ThinPrep is the **only** acceptable specimen.
- FDA cleared for HPV testing directly from the PreservCyt ThinPrep vial

Storage/Transport

- Transport at ambient temperature.
- Can be stored at room temperature for up to 3 months. Do not freeze.

Reports

- Reports will include positive and negative status for:
 - HPV 16, HPV 18, and pooled HR types
- Example:
 - HPV 16: Positive
 - HPV 18: Negative
 - Other HR HPV: Negative

For further information contact Kim Handley, Virology Lab at 275-7801.

References

Stoler MH, Wright TC, Sharma A, et al. High-risk human papillomavirus testing in women with ASC-US cytology: results from the ATHENA HPV study. *Am J Clin Pathol.* 2011;135(3):468-475.

Cui M, Chan N, Liu M, Thai K, Malaczynska J, Singh I, Zhang D, Ye F. 2014. Clinical performance of Roche cobas 4800 HPV test. *J. Clin. Microbiol.* 52:2210–2211. doi:10.1128/JCM.00883-14