# Legacy Laboratory Services

## Roche cobas® HPV Test High-Risk HPV with 16/18 Genotype

**October 2013**

## New HR-HPV assay detects types 16 and 18 plus other High Risk Types

Legacy Laboratory Services is pleased to announce a new HR (high risk) HPV assay using the FDA-approved Roche cobas-4800 PCR method which detects HPV genotypes 16 and 18 plus other high risk types in a single analysis[1]. **This HPV test is currently available only on specimens collected in ThinPrep® Pap Test vials, for which it is FDA cleared.** The fee, the CPT code, and the turnaround time are the same as for Qiagen's Digene HC2 High-Risk HPV DNA Test, which we continue to offer.

The Roche cobas® HPV Test was clinically validated in the ATHENA HPV trial, the first screening trial that evaluated simultaneous real-time genotyping of 12 pooled HR-HPV genotypes plus HPV 16 and HPV 18 individually. The ATHENA trial evaluated the performance of the cobas® HPV Test in multiple clinical situations, including ASC-US triage and co-testing and was comparable to the current standard of pooled HR-HPV testing. In addition, the trial quantified risk of pre-cancer and cervical cancer in HPV 16 positive and/or HPV 18 positive women who had ASC-US or who had normal cytology[2-4].

**Legacy Laboratory Verified cobas® HPV Test:**

Legacy Laboratory has performed a verification study of the cobas® HPV test and since Dec 2012 has analyzed 1232 samples. Of those samples, 179 (14.5%) have had positive results with the following breakdown:

| Type | Percentage | Number |
|---|---|---|
| HPV 16 | 25.1% | 45/179 |
| HPV 18 | 6.7% | 12/179 |
| Other High Risk types | 74.9% | 134/179 |

This validation was done with the FDA-approved format for ThinPrep® collected samples; we are currently undergoing in-house validation using SurePath™ collected samples.

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LEGACY HEALTH

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**ACOG guidelines support co-testing and genotyping for HPV types 16 and 18[5]:**

- Co-testing using the combination of Pap cytology plus HPV DNA testing is the preferred cervical cancer screening method for women 30-65 years old. For any low-risk woman between 30-65 years old who receives negative test results on both Pap cytology screening and HPV DNA testing, rescreening in 5 years is recommended.
- Immediate HPV genotype-specific testing for HPV 16 alone or HPV 16/18 can be used as an adjunct in women whose Pap test results are negative, but who have tested positive for HR-HPV by an assay testing for 13 or 14 high-risk types.
    - Women who test positive for HPV 16 or HPV 16/18 should be referred directly for colposcopy
    - Women with negative results for HPV 16 or HPV 16/18 should be co-tested in 12 months

**Specimen Collection:**

- Collect cervical specimen with endocervical brush/spatula or broom device, as per the ThinPrep® Pap Test™ method, using laboratory provided vials (PreservCyt® solution), making sure to rinse and discard collection devices
- May be collected and ordered simultaneously with Pap test
- Unacceptable specimens: SurePath™ Pap samples, Endocervical swabs

**Ordering:**

- Select HPV option, either HPV reflex from AS-CUS, HPV any diagnosis, or HPV only
- **Specify "HPV with Genotype"**

**Stability:**

- 4 weeks post collection

**Test Performed**:

- 3 times weekly

**Turnaround Time:**

- 5 working days

**Reports:**

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

**References:**


1. cobas® 4800 HPV Test US package insert. April 2011.
2. 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.
3. Wright TC Jr, Stoler MH, Sharma A, Zhang G, Behrens CM, Wright TL. Evaluation of HPV-16 and HPV-18 genotyping for the triage of women with high-risk HPV+ cytology-negative results. Am J Clin Pathol. 2011;136:578-586.
4. Castle PE, Stoler MH, Wright TC Jr., Sharma A, Wright TL, Behrens CM. Performance of carcinogenic human papillomavirus (HPV) testing and HPV16 or HPV18 genotyping for cervical cancer screening of women aged 25 years and older: a subanalysis of the ATHENA study. Lancet Oncol. 2011;12(9):880–890
5. The American Congress of Obstetricians and Gynecologists. ACOG Practice Bulletin. Clinical Management Guidelines for Obstetrician-Gynecologists: Screening for Cervical Cancer. November, 2012.