High Risk HPV with 16/18 Genotype

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Legacy Laboratory Services and Cascade Pathology Services are pleased to announce that the High Risk (HR) HPV assay using the FDA-approved Roche cobas-4800 PCR method has been validated for both ThinPrep® and Surepath™ samples. The Roche cobas-4800 PCR method detects HPV genotypes 16 and 18 plus other HR types in a single analysis.

The Roche cobas® HPV Test was clinically validated in 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 found it 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 and/or HPV 18 positive women who had ASC-US or normal cytology.

Legacy Laboratory Services Validated cobas® HPV Test:

- Legacy Laboratory Services previously reported the verification study of the cobas® HPV test using the FDA-approved format for ThinPrep® collected samples.
- Legacy Laboratory Services has completed the in-house laboratory validation using SurePath™ collected samples, including: precision, analytical sensitivity, analytical specificity, carryover, interference, patient correlations, and discrepant result resolution using linear array.
- In-house studies showed no significant difference between the ThinPrep® and SurePath™ samples except for specimen stability, as cited below.

ACOG guidelines support co-testing and genotyping for HPV types 16 and 18:

- 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 five 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.

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### Specimen Collection:
- Collect cervical specimen with endocervical brush/spatula or broom device, as per the ThinPrep® Pap Test™ or BD SurePath™ Pap test method.
- May be collected and ordered simultaneously with Pap test
- Unacceptable specimens: Endocervical swabs

### Ordering:
1. **Select HPV option:**
   - HPV reflex from ASC-US
   - HPV any diagnosis (Co-testing on women over 30)
   - HPV only

### Stability:
- **ThinPrep®**
  - 4 weeks post collection
- **SurePath™**
  - 3 days at ambient temperature or 14 days refrigerated

### Test Performed:
- 5 times weekly

### Turnaround Time:
- 2-7 working days from collection date

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

### References: