HUMAN PAPILLOMAVIRUS (HPV) MOLECULAR DETECTION WITH GENOTYPING

NEW TEST OFFERS HIGH-RISK HPV DETECTION (14 HIGH-RISK TYPES)
WITH SPECIFIC GENOTYPING FOR HPV-16 AND HPV-18
THE DIFFERENCE BETWEEN GOOD AND GREAT IS ATTENTION TO DETAIL

To better accommodate important updates in the screening guidelines for HPV, an infection present in 20 million people in the United States and resulting in 6.2 million new infections per year, Mayo Medical Laboratories now offers testing for the detection of high-risk HPV (hr-HPV), with genotyping for HPV-16 and HPV-18.

IMPORTANTANCE OF TRIAGING WOMEN WITH HIGH-RISK HPV

A recent study published in the American Journal of Clinical Pathology evaluated the role of HPV-16 and -18 genotyping in women with a positive high-risk HPV Nucleic Acid Amplification Test (NAAT) result, but negative cytology. The data from this study suggested:

- Women with HPV-16 or HPV-18 had an absolute risk of 11.4% for the development of grade 2 cervical intraepithelial neoplasia (CIN-2) or greater lesions
- Women with ‘other’ high-risk HPV that was determined not to be genotypes 16 or 18 had an absolute risk of 6.1%
- Women that were negative for high-risk HPV altogether had an absolute risk of only 0.8%

The conclusion that genotyping is important in triaging women with hrHPV has been supported in several studies, including one that concluded “Incorporating screening with HPV and triage of HPV-positive women by a combination of genotyping for HPV-16/18 and cytology provided a good balance between maximizing sensitivity and specificity by limiting the number of colposcopies.”

HIGH-GRADE DISEASE OCCURS MOSTLY IN HPV-16/18+

A seminal study of 20,810 women with normal cytology in the Kaiser Permanente healthcare system found that women with normal cytology who were HPV-16+ and HPV-18+ had highest risk of developing grade 3 or higher CIN

*The pooled hr-HPV genotypes were as follows: HPV 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, and 68.
Both graphs adapted from “cobas® HPV Test: Know the Risk” educational booklet. Used with permission from Roche Molecular Systems, Branchburg, NJ.
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SCREENING GUIDELINES

Currently, the American Cancer Society, the American Society for Colposcopy and Cervical Pathology, and the American Society for Clinical Pathology recommend that:

- Routine screening for HPV not start until a woman reaches the age of 21
- Between the ages of 21 and 29, women be screened at 3 year intervals using cytology alone
- At age 30, patients can continue to be screened by cytology alone every 3 years, or alternatively, by co-testing using cytology and an HPV NAAT test every 5 years
- Recent interim clinical guidance supports primary high-risk HPV screening as an alternative to cytology alone or cytology and HPV co-testing
- For additional information on HPV screening guidelines visit: MayoMedicalLaboratories.com/HPV

ADVANTAGES OF THIS NEW TEST

- 3-in-1 testing for every sample: High-risk HPV detection (14 high-risk types) with specific genotyping for HPV-16 and HPV-18
- Enables women with positive results for HPV-16 and/or HPV-18 to be referred to colposcopy right away
- Performed on cervical/endocervical and vaginal samples collected in ThinPrep or SurePath media
- **Now available:** Primary screening by high-risk HPV with genotyping. Samples that are positive for high-risk HPV types other than 16 and 18 will reflex to cytology

FEATURED TESTS

- Human Papillomavirus (HPV) DNA Detection with Genotyping, High-Risk Types by PCR (Test ID: HPV)
- Human Papillomavirus (HPV) DNA Detection with Genotyping, High-Risk Types by PCR, SurePath (Test ID: SHPV)
- Human Papillomavirus (HPV) DNA Detection with Genotyping, High-Risk Types by PCR with Papanicolaou Smear Reflex, ThinPrep (Test ID: HPVP)

HPV-16 & HPV-18 ARE THE MOST PREVALENT hr-HPV GENOTYPES CAUSING CERVICAL CANCER

PREVALENCE OF hr-HPV GENOTYPES

- **68%** HPV-16/18+
- **83%** HPV-16/18+

PREVALENCE (%)


