

HPV (human papillomavirus) Genotypes 16, 18/45 RNA Test

HPV genotyping results and suggested comments from the pkg insert limitations that should be considered.

Result:

Genotype 16: Negative/Positive/Invalid

Genotype 18/45: Positive/Negative/Invalid

Comments:

- Detection of high-risk HPV (types 16, 18, and 45) mRNA is dependent on the number of copies present in the specimen and may be affected by specimen collection methods, patient factors, stage of infection and the presence of interfering substances.
- A negative Aptima HPV 16 18/45 genotype assay result does not exclude the possibility of cytologic abnormalities or of future or underlying CIN2, CIN3, or cancer
- Infection with HPV is not an indicator of cytologic HSIL or underlying high-grade CIN, nor does it imply that CIN2, CIN3, or cancer will develop. Most women infected with one or more high-risk HPV types do not develop CIN2, CIN3, or cancer.
- The performance of the Aptima HPV 16 18/45 genotype assay has not been evaluated for HPV vaccinated individuals.
- The Aptima HPV 16 18/45 genotype assay has not been evaluated in cases of suspected abuse
- The Aptima HPV 16 18/45 genotype assay should be interpreted in conjunction with other laboratory and clinical data available to the clinician.