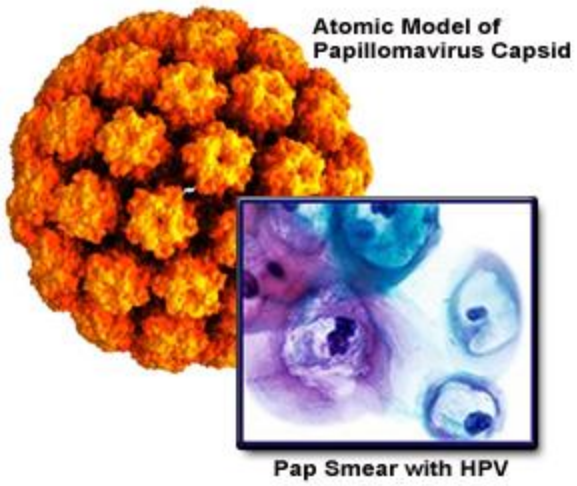
APTIMA® HPV 16 18/45 Genotype Assay



Clinical use

- Diagnose high-risk HPV types 16, 18/45 infection

Clinical Background

Cervical cancer is one of the most common female cancers in the world. HPV is the etiological agent responsible for more than 99% of all cervical cancers.[1,2,3] HPV is a common sexually transmitted DNA virus comprised of more than 100 genotypes.[4]

Studies have shown that different types of high-risk HPV confer different levels of risk for developing severe dysplasia or cervical carcinoma. World-wide, HPV types 16, 18, and 45 are associated with 80% of all invasive cervical cancers. These three types are found in 75% of all squamous carcinomas, with type 16 alone found in over 60% of all squamous carcinomas. In adenocarcinoma, HPV types 16, 18, and 45 are found in 80-94% of cases, with types 18 and 45 comprising almost half of these infections.[2,5] The presence of HPV type 18 in early stage cervical cancer has been reported to be associated with a poor prognosis.[6] HPV types 18 and 45 are under-reported in precancerous lesions, which may be caused by the presence of occult lesions of the cervical canal inaccessible to colposcopic examination.[7] In women infected with HPV types 16 and/or 18, the cumulative risk of developing cervical disease is 10-fold higher compared to the risk for disease development due to other high risk types.[8,9,10]

Indications for testing:

Testing should be performed on HPV positive samples only.

- To screen women 21 years and older with atypical squamous cells of undetermined significance (ASC-US) cervical cytology results, in conjunction with HPV positive results to assess the presence or absence of HPV types 16, 18/45. . This information, together with the physician's assessment of cytology history, other risk factors, and professional guidelines, may be used to guide patient management. Note: The results of this test are not intended to prevent women from proceeding to colposcopy.
- In women 30 years and older, the APTIMA HPV Assay can be used with cervical cytology in conjunction with HPV positive results to assess the presence or absence of

HPV types 16, 18/45. This information, together with the physician's assessment of cytology history, other risk factors, and professional guidelines, may be used to guide patient management. Note: The results of this test are not intended to prevent women from proceeding to colposcopy.

Specimen type

- Room Temperature or refrigerated Clinician-collected PreservCyt Solution liquid Pap specimen (Thin Prep vial)

Method

- Qualitative nucleic acid amplification test (NAAT) for the detection of messenger RNA (mRNA)

Interpretation

Positive – Positive results indicate the presence of HPV E6/E7 mRNA of indicated type

Negative – Negative results indicate HPV E6/E7 mRNA was not detected, or
Negative results may occur with HPV E6/E7 mRNA concentrations that are below the pre-set threshold **(Reference Range)**

Note: *Results of this test should only be interpreted in conjunction with information available from clinical evaluation of the patient and patient history. Negative results are not intended to prevent women from proceeding to colposcopy.*

References

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