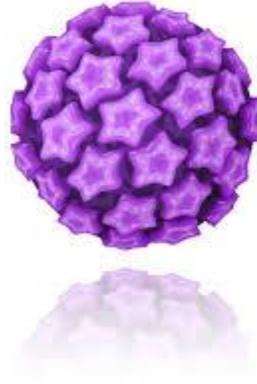


## Aptima® HPV assay

Human  
papillomavirus  
(HPV)



### Clinical use

- Diagnose high-risk HPV types 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68 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.<sup>(1,2,3)</sup> HPV is a common sexually transmitted DNA virus comprised of more than 100 genotypes.<sup>(1)</sup> The HPV viral genome is a double-stranded circular DNA approximately 7900 base pairs in length. The genome has eight overlapping open reading frames. There are six early (E) genes, two late (L) genes, and one untranslated long control region. The L1 and L2 genes encode the major and minor capsid proteins. Early genes regulate HPV viral replication. The E6 and E7 genes of high-risk HPV genotypes are known oncogenes. Proteins expressed from E6/E7 polycistronic mRNA alter cellular p53 and retinoblastoma protein functions, leading to disruption of cell-cycle check points and cell genome instability.<sup>(1,4)</sup> Fourteen HPV genotypes are considered pathogenic or high-risk for cervical disease.<sup>(5)</sup> Multiple studies have linked genotypes 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68 to disease progression.<sup>(2,6,7)</sup> Women with a persistent infection with one of these types have an increased risk for developing severe dysplasia or cervical carcinoma.<sup>(5,8)</sup> HPV infections are very common and most women will clear HPV infections within 6 to 12 months.<sup>(2,9)</sup> The presence of HPV nucleic acid does not mean that cervical dysplasia or cervical cancer is present. However, an effective approach for detection of cervical disease is to target those oncogenic elements of HPV that foster persistent viral infection and cellular transformation.<sup>(10)</sup>

### Indications for testing:

- To screen women 21 years and older with atypical squamous cells of undetermined significance (ASC-US) cervical cytology results to determine the need for referral to colposcopy. 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 to adjunctively screen to assess the presence or absence of high-risk HPV types. This information, together with the physician's assessment of cytology history, other risk factors, and professional guidelines, may be used to guide patient management.

### 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 any one or more of the high-risk types

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.

### mRNA and Cervical Disease

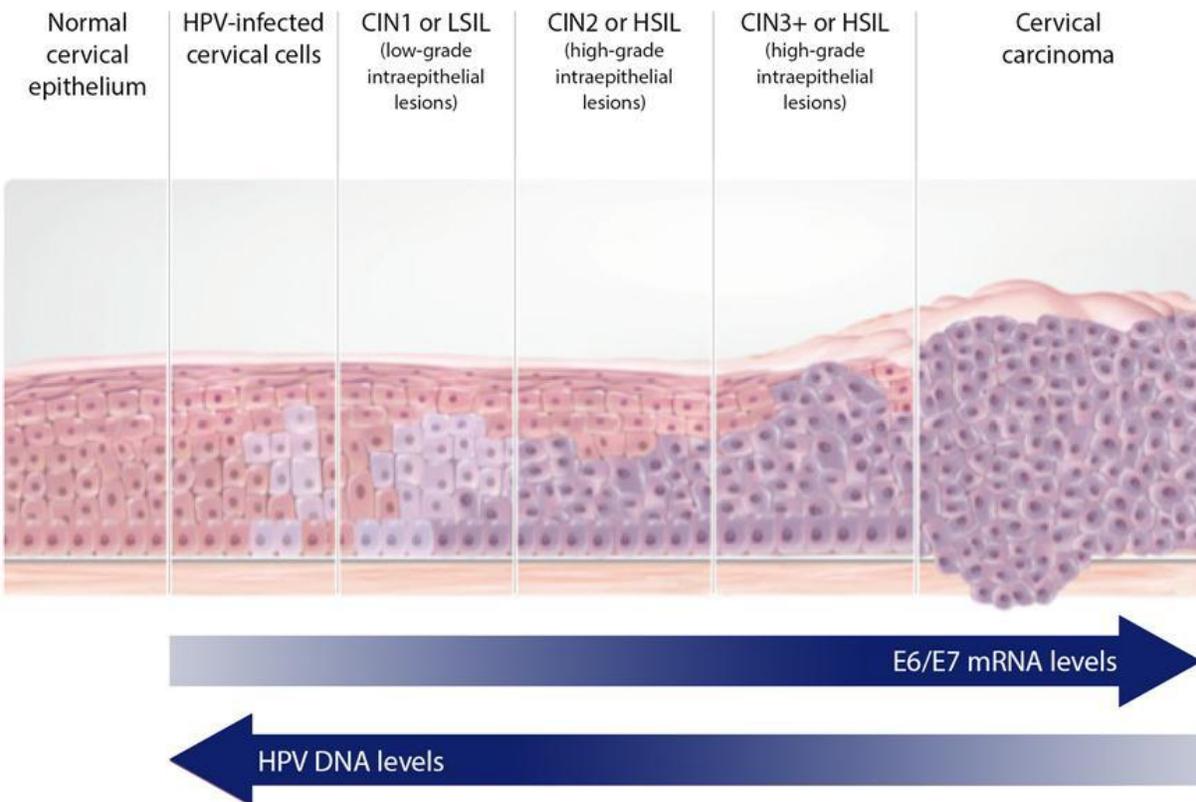


Image provided courtesy of HOLOGIC, Inc. and affiliates.

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