



INTERPRETATION GUIDELINES

HUMAN PAPILOMAVIRUS (HPV) SUBTYPING
High Risk / Low Risk of Cervical Cancer by PCR

Methodology:

This methodology utilizes a consensus multiplex PCR technique to detect high-risk (HPV 16/18), low risk (HPV 6/11), and over 40 other types of human papillomavirus (HPV), separately but simultaneously, by mixing three pairs of consensus primers in the same PCR mixture, for gene amplification.

Result Interpretation:

Primers	HPV Subtypes Detected
1 st Set	6, 11, 16, 18, 30, 31, 33, 35, 39, 40, 42, 43, 45, 51, 52, 53, 54, 55, 56, 57, 58, 59, and at least 20 other unidentified subtypes.
2 nd Set	6, 11 (Low Risk)
3 rd Set	16, 18 (High Risk)

ND: Not Detected. HPV DNA was not detected in the specimen submitted.

Positive: Presence of HPV DNA detected.

General HPV: Presence of an HPV subtype other than low or high-risk types.

Low Risk: Presence of either HPV-6 or HPV-11. These subtypes deemed low risk because they are related to benign proliferative lesions such as condyloma acuminata that infrequently progress to malignancy.

High Risk: Presence of either HPV-16 or HPV-18. These subtypes are deemed high risk because of a close association with cervical cancer.

Clinical Significance:

Human Papillomavirus (HPV) is one of the most common sexually transmitted infections in the United States. Laboratory diagnosis can be difficult due to the inability of a feasible way to propagate the virus in cell culture and a lack of reliable serological methods. The advent of molecular diagnostic techniques, such as the Polymerase Chain Reaction (PCR) method, provides the clinician with a valuable tool for highly sensitive and specific detection of HPV infection. It may be utilized as a primary screening either alone or in combination with cytologic methods such as the Papanicolaou test (Pap smear) and liquid based cytology such as the ThinPrep®; stratification of patients with atypical squamous cells of undetermined significance (ASCUS) and low-grade cervical smears; and surveillance of high grade cervical intra-epithelial neoplasia and localized (micro) invasive disease after treatment.