

HPV Testing: Human Papillomavirus (HPV), High Risk with 16 and 18 Genotype by PCR, SurePath

Indication: FDA-approved test for routine cervical cancer screening in combination with cervical cytology (Pap smear) for women 25-Lifetime screening.. Follow-up test for ASC-US cytology results in women 21-24 years. IU Health Pathology Lab performs these indications automatically for all Pap Tests received. Management of HPV status outside of ACOG/ASCCP/USPTFS guidelines requires additional instruction to the lab.

Ordering: (All contained within Cytology Pap Test)

Cervical/Endocervical: provide LMP, clinical history. (Most common scenario)

HPV Surveillance: Assumed Cervical/Endocervical source. HPV Regardless of Diagnosis or Age.

HPV HR Only; rare use when Pap Test results are available elsewhere.

Methodology: This test amplifies DNA of HPV16, HPV18 and 12 other high-risk HPV types (31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68) associated with cervical cancer and its precursor lesions. Sensitivity may be affected by specimen collection methods, stage of infection, and the presence of interfering substances. Results should be interpreted in conjunction with other available laboratory and clinical data. A negative high-risk HPV result does not exclude the presence of other high-risk HPV types, the possibility of future cytologic abnormalities, underlying CIN2-3, or cancer.

Collection: Cervical specimen with SurePath collection kit and place in SurePath media.

Reporting:

HPV High Risk type 16, PCR	Negative *
HPV High Risk type 18, PCR	Negative *
HPV other High Risk Types	Negative *

Reference: Negative for one or more other High Risk HPV types: 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68.

**** POSITIVE RESULTS ****

HPV High Risk Type 16, PCR
RESULT: **** POSITIVE ****

HPV High Risk Type 18, PCR
RESULT: **** POSITIVE ****

HPV other High Risk Types
RESULT: **** POSITIVE ****

REFERENCE VALUE: Negative

POSITIVE for one or more of the following other High Risk HPV types: 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68.

Reviewed: 4/12/21 MLR