MAYO CLINIC LABORATORIES

Test Definition: HPVHL

Human Papillomavirus (HPV) High/Low Risk, In Situ Hybridization

Overview

Useful For
Detecting human papillomavirus for both low-risk (6, 11) and high-risk (16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 53, 56, 58, 59, 66, 68, 73, and 82.) genotypes

Method Name
In Situ Hybridization (ISH)

NY State Available
Yes

Specimen

Specimen Type
Special

Additional Testing Requirements
If additional interpretation or analysis is needed, request PATHC / Pathology Consultation along with this test.

Shipping Instructions
Attach the green pathology address label included in the kit to the outside of the transport container.

Necessary Information
A pathology/diagnostic report and a brief history are required.

Specimen Required
Supplies: Pathology Packaging Kit (T554)
Specimen Type: Formalin-fixed, paraffin-embedded tissue block
Specimen Volume: Entire block

Specimen Type: Slides
Slides: 6 Unstained glass, positively charged slides with 5 (+ or - 1)-microns formalin-fixed, paraffin-embedded tissue

Forms
If not ordering electronically, complete, print, and send 1 of the following forms with the specimen:
-Oncology Test Request (T729)
-Immunohistochemical (IHC)/In Situ Hybridization (ISH) Stains Request (T763)

Reject Due To

Wet/frozen tissue Cytology smears Nonformalin fixed tissue Nonparaffin embedded tissue Noncharged slides ProbeOn slides	Reject

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Special	Ambient (preferred)		
	Refrigerated		

Clinical & Interpretive

Clinical Information

Human papillomavirus (HPV) infections with low-risk genotypes (6, 11) can cause benign hyperplasia such as condylomas and papillomas. Persistent infections with high-risk genotypes (16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 53, 56, 58, 59, 66, 68, 73, and 82) are associated with cervical, vaginal, vulvar, and head and neck malignancies. Patients with HPV-related oropharyngeal squamous cell carcinoma (OPSCC) have shown better disease-specific survival and overall survival when compared to HPV-negative cases of OPSCC.

Reference Values

Results are reported as positive or negative for types 6 and 11 (low risk), and 16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 53, 56, 58, 59, 66, 68, 73, and 82(high risk).

Interpretation

This test, when not accompanied by a pathology consultation request, will be answered as either positive or negative. If additional interpretation or analysis is needed, request PATHC / Pathology Consultation along with this test.

Cautions

Age of a cut paraffin section can affect staining quality. Stability thresholds vary widely among published literature. Best practice is for paraffin sections to be cut within 6 weeks.

Clinical Reference

1. Lindemann ML, Dominguez MJ, de Antonio JC, et al: Analytical comparison of the cobas HPV test with hybrid capture 2 for the detection of high-risk HPV genotypes. J Mol Diagn. 2012 Jan;14(1):65-70

2. Bishop JA, Ma XJ, Wang H, et al: Detection of transcriptionally active high-risk HPV in patients with head and neck squamous cell carcinoma as visualized by a novel E6/E7 mRNA in situ hybridization method. Am J Surg Pathol. 2012 Dec;36(12):1874-1882
3. Mirghani H, Casiraghi O, Guerlain J, et al: Diagnosis of HPV driven oropharyngeal cancers: Comparing p16 based algorithms with the RNAscope HPV-test. Oral oncology. 2016;62:101-108

Performance

Method Description
In situ hybridization on sections of paraffin-embedded tissue.(Unpublished Mayo method)

PDF Report
No

Day(s) Performed
Monday through Friday

Report Available
5 to 7 days

Specimen Retention Time
Until staining is complete.

Performing Laboratory Location
Mayo Clinic Laboratories - Rochester Main Campus

Fees & Codes

Fees
- Authorized users can sign in to Test Prices for detailed fee information.
- Clients without access to Test Prices can contact Customer Service 24 hours a day, seven days a week.
- Prospective clients should contact their account representative. For assistance, contact Customer Service.

Test Classification
This test was developed and its performance characteristics determined by Mayo Clinic in a manner consistent with CLIA requirements. It has not been cleared or approved by the US Food and Drug Administration.

CPT Code Information
88365-Primary
88364-If additional ISH

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LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
HPVHL	HPV High/Low Risk ISH	In Process

Result ID	Test Result Name	Result LOINC® Value
71199	Interpretation	50595-8
71200	Participated in the Interpretation	No LOINC Needed
71203	Material Received	81178-6
71594	Disclaimer	62364-5
72112	Case Number	80398-1
71201	Report electronically signed by	19139-5