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
**Additional Information:** Broken or cracked unstained slides will be rejected. Stained slides that were broken and repaired (ie, double mounted) at the client site will not be rejected, as, in most cases, they can still be reviewed under the microscope. However, due to the double mounting, digital scanning cannot be performed.

### 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 | Reject |
| Cytology smears | Reject |
| Non-formalin fixed tissue | Reject |
| Nonparaffin embedded tissue | Reject |
| Noncharged, ProbeOn or Snowcoat slides | Reject |
| Broken or cracked unstained slides | Reject |
| Broken or cracked stained slides that cannot be repaired | 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.

Broken or cracked unstained slides are not compatible with the instrumentation used in our performing laboratories and will be rejected. Additional material may be requested.

Attempts will be made to repair broken or cracked stained slides; however, if they are unable to be repaired (ie, shattered in transit), they will be rejected and discarded due to safety concerns.

### 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

### 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 |