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## Overview

### Useful For

[Detection of](#) human papillomavirus DNA from high-risk genotypes (16, 18, 31, 33, and 51)

### Testing Algorithm

Human papillomavirus (HPV) High Risk E6/E7 RNA ISH could be performed and reported at the discretion of the Mayo pathologist if clinically indicated but will not be billed separately.

### Method Name

In Situ Hybridization (ISH)

### NY State Available

Yes

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## Specimen

### Specimen Type

Special

### Additional Testing Requirements

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

The probe set used in this human papillomavirus (HPV) DNA in situ hybridization (ISH) test cannot detect all potential HPV serotypes that are associated with oropharyngeal squamous cell carcinoma. If this test is negative, a more sensitive test, Human Papillomavirus (HPV) High Risk E6/E7 RNA In Situ Hybridization, could be performed and reported if clinically indicated but will not be billed separately.

### 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:** 5 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:

[-Immunohistochemical \(IHC\)/In Situ Hybridization \(ISH\) Stains Request \(T763\)](#)

[-Oncology Test Request \(T729\)](#)

## Reject Due To

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

## Specimen Stability Information

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

## Clinical & Interpretive

### Clinical Information

Persistent infections with high-risk human papillomavirus (HPV) genotypes (16, 18, 31, 33, and 51) 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.

### 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. Belobrov S, Cornall A, Young R, et al: The role of human papillomavirus in p16-positive oral cancers. J Oral Pathol Med. 2018;47(1):18-24
2. Ducatman B: The role of human papillomavirus in oropharyngeal squamous cell carcinoma. Arch Pathol Lab Med. 2018;142(6):715-718
3. Windon M, D'Souza G, Rettig E, et al: Increasing prevalence of human papillomavirus–positive oropharyngeal cancers among older adults. Cancer. 2018;124(14):2993-2999

**Performance****Method Description**

In situ hybridization on sections of paraffin-embedded tissue.(Unpublished Mayo method)

**PDF Report**

No

**Specimen Retention Time**

Until staining is complete.

**Performing Laboratory Location**

Rochester

**Fees & Codes****Test Classification**

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

**CPT Code Information**

88365-Primary

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88364-If additional ISH

**LOINC® Information**

Test ID	Test Order Name	Order LOINC Value
HPVHR	HPV High-Risk ONLY DNA ISH	49896-4

Result ID	Reporting Name	LOINC®
71194	Interpretation	50595-8
71195	Participated in the Interpretation	No LOINC Needed
71196	Report electronically signed by	19139-5
71198	Material Received	81178-6
71593	Disclaimer	62364-5
72111	Case Number	80398-1