

Human Papillomavirus (HPV) High-Risk E6/E7, RNA In Situ Hybridization

## Overview

#### **Useful For**

Stratification of oropharyngeal squamous cell carcinoma

## **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 "Attention Pathology" address label (T498) to the outside of the transport container before putting into the courier mailer.

# **Necessary Information**

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

# Specimen Required

Supplies: Pathology Packaging Kit (T554)

Specimen Type: Tissue

Container/Tube: Immunostain Technical Only Envelope

Collection Instructions: Formalin-fixed, paraffin-embedded tissue block; or 5 unstained glass, "positively charged" slides

with 4-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	Reject



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tissue
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**

This assay is intended to identify the presence of human papillomavirus (HPV) E6/E7 transcripts from high-risk genotypes. 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. An indication for this test is p16 expression by immunohistochemistry.

## **Reference Values**

<u>Results are reported as positive or negative for types 16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 53, 56, 58, 59, 66, 68, 73, and 82.</u>

# 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;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.



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2012;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
- 4. Magaki S, Hojat SA, Wei B, So A, Yong WH. An introduction to the performance of immunohistochemistry. Methods Mol Biol. 2019;1897:289-298. doi:10.1007/978-1-4939-8935-5\_25

#### **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 <u>Test Prices</u> for detailed fee information.
- Clients without access to Test Prices can contact <u>Customer Service</u> 24 hours a day, seven days a week.
- Prospective clients should contact their account representative. For assistance, contact <u>Customer Service</u>.

## **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
HPVE6	HPV E6/E7 ISH	Obsolete

Result ID	Test Result Name	Result LOINC® Value
71212	Interpretation	50595-8
71213	Participated in the Interpretation	No LOINC Needed
71449	Report electronically signed by	19139-5
71451	Material Received	81178-6
71597	Disclaimer	62364-5
72114	Case Number	80398-1