MAYO CLINIC LABORATORIES

Test Definition: HPVE6

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

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

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.

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.

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

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