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
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

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.

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;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

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