Test Definition: P16

p16 (INK4a/CDKN2A) Immunostain, Technical Component Only

Overview

Useful For
Aids in the identification of human papilloma virus infection

Reflex Tests

Test Id	Reporting Name	Available Separately	Always Performed
IHTOI	IHC Initial, Tech Only	No	No
IHTOA	IHC Additional, Tech Only	No	No

Testing Algorithm
For the initial technical component only immunohistochemical (IHC) stain performed, the appropriate bill-only test ID will be reflexed and charged (IHTOI). For each additional technical component only IHC stain performed, an additional bill-only test ID will be reflexed and charged (IHTOA).

Method Name
Immunohistochemistry (IHC)

NY State Available
Yes

Specimen

Specimen Type
TECHONLY

Ordering Guidance
This test includes only technical performance of the stain; **no pathologist interpretation is provided**.

Technical component only stains **should not** be ordered with PATHC / Pathology Consultation. If ordered with PATHC, the technical component stains **will be canceled**. Any immunohistochemistry (IHC)/in situ hybridization (ISH) stain performed as a part of the PATHC will be performed at the reviewing pathologist's discretion at an additional charge.

Shipping Instructions
Attach the green "Attention Pathology" address label (T498) and the pink Immunostain Technical Only label included in the kit to the outside of the transport container.

Specimen Required
Specimen Type: Tissue

Supplies: Immunostain Technical Only Envelope (T693)
Container/Tube: Immunostain Technical Only Envelope
Submit:
-Formalin-fixed, paraffin-embedded tissue block
OR
-2 Unstained, positively charged glass slides (25- x 75- x 1-mm) per test ordered; sections 4-microns thick
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.

Digital Image Access

1. Information on accessing digital images of immunohistochemical (IHC) stains and the manual requisition form can be accessed through this website: https://news.mayocliniclabs.com/pathology/digital-imaging/
2. Clients ordering stains using a manual requisition form will not have access to digital images.
3. Clients wishing to access digital images must place the order for IHC stains electronically. Information regarding digital imaging can be accessed through this website: https://news.mayocliniclabs.com/pathology/digital-imaging/#section3

Forms

If not ordering electronically, complete, print, and send a Immunohistochemical (IHC)/In Situ Hybridization (ISH) Stains Request (T763) with the specimen.

Reject Due To

Wet/frozen tissue	Reject
Cytology smears	Reject
Nonformalin fixed tissue	Reject
Nonparaffin embedded tissue	Reject
Noncharged slides	Reject
ProbeOn slides	Reject
Snowcoat slides	Reject
Broken or cracked unstained slides	Reject
Broken or cracked stained slides	Reject

that cannot be repaired	

Specimen Stability Information

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

Clinical & Interpretive

Clinical Information

p16 (INK4a/CDKN2A) is a cell cycle regulatory protein that is overexpressed in cervical dysplasia related to human papilloma virus (HPV) infection. Nuclear and cytoplasmic staining is seen in dysplastic squamous cervical epithelial cells infected with HPV but not in normal cells. A subset of pancreatic islet cells and dendritic cells show expression of p16 and can serve as positive control.

Interpretation

This test does not include pathologist interpretation, only technical performance of the stain. If interpretation is required, order PATHC / Pathology Consultation for a full diagnostic evaluation or second opinion of the case.

The positive and negative controls are verified as showing appropriate immunoreactivity.

Interpretation of this test should be performed in the context of the patient's clinical history and other diagnostic tests by a qualified pathologist.

Cautions

Age of a cut paraffin section can affect immunoreactivity. Stability thresholds vary widely among published literature and are antigen dependent. Best practice is for paraffin sections to be cut within 6 weeks.

The charge of glass slides can be affected by environmental factors and subsequently may alter slide staining. Sending unsuitable glass slides can result in inconsistent staining due to poor slide surface chemistry.

Best practices for storage of positively charged slides:
-Minimize time slides are stored after being unpackaged
-Limit exposure to high humidity and heat
-Minimize exposure to plastics

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. Castle PE. A LASTing impression: incorporating p16 immunohistochemistry into routine diagnosis of cervical neoplasia. Pathol Case Rev. 2013;18:154-157
2. Doxtader EE, Katzenstein AL. The relationship between p16 expression and high-risk human papillomavirus infection in squamous cell carcinomas from sites other than uterine cervix: a study of 137 cases. Hum Pathol. 2012;43(3):327-332
3. El-Naggar AK, Westra WH. p16 expression as a surrogate marker for HPV-related oropharyngeal carcinoma: a guide for interpretative relevance and consistency. Head Neck. 2012;34(4):459-461
4. Klaes R, Benner A, Friedrich T, et al. p16INK4a immunohistochemistry improves interobserver agreement in the diagnosis of cervical intraepithelial neoplasia. Am J Surg Pathol. 2002;26(11):1389-1399
5. Singhi AD, Westra WH. Comparison of human papillomavirus in situ hybridization and p16 immunohistochemistry in the detection of human papillomavirus-associated head and neck cancer based on a prospective clinical experience. Cancer. 2010;116(9):2166-2173
6. Abdelhakam DA, Huenerberg KA, Nassar A. Utility of p16 and HPV testing in oropharyngeal squamous cell carcinoma: An institutional review. Diagn Cytopathol. 2021;49(1):54-59
7. 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

Immunohistochemistry on sections of paraffin-embedded tissue.(Unpublished Mayo method)

PDF Report

No

Day(s) Performed

Monday through Friday

Report Available

1 to 3 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 has been modified from the manufacturer's instructions. Its performance characteristics were 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

88342-TC, Primary
88341-TC, If additional IHC

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
P16	p16 (INK4a/CDKN2A) IHC, Tech Only	Order only;no result

Result ID	Test Result Name	Result LOINC® Value
70836	p16 (INK4a/CDKN2A) IHC, Tech Only	Bill only; no result