

Overview**Useful For**

Distinguishing carcinoma from mesothelioma and sarcoma

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 \(no pathologist interpretation is performed\). If diagnostic consultation by a pathologist is required order PATHC / Pathology Consultation.](#)

Shipping Instructions

Attach the green pathology address label and the pink Immunostain Technical Only label included in the kit to the outside of the transport container.

Specimen Required

Supplies: Immunostain Technical Only Envelope (T693)

Specimen Type: Tissue

Container/Tube: Immunostain Technical Only Envelope

Preferred: 2 Unstained positively charged glass slide (25- x 75- x 1-mm) per test ordered; sections 4-microns thick

Acceptable: Formalin-fixed, paraffin-embedded (FFPE) tissue block

Digital Image Access

1. Information on accessing digital images of immunohistochemical (IHC) stains and the manual requisition form can be accessed through this website: www.mayocliniclabs.com/test-info/ihc/index.html
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: www.mayocliniclabs.com/test-info/ihc/faq.html

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 Cytology smears Nonformalin fixed tissue Nonparaffin embedded tissue Noncharged slides ProbeOn slides	Reject
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Specimen Stability Information

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

Clinical and Interpretive

Clinical Information

Claudin-4 is a component of tight junction strands and is expressed on the membrane of cells of epithelial origin.

Claudin-4 has been shown to distinguish carcinoma from mesothelioma and carcinoma from sarcoma.

Interpretation

This test does not include pathologist interpretation; only technical performance of the stain. If an 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 and documentation is retained at Mayo Clinic Rochester. If a control tissue is not included on the slide, a scanned image of the relevant quality control tissue is available upon request, call 855-516-8404.

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.

Clinical Reference

1. Jo VY, Cibas ES, Pinkus GS: Claudin-4 immunohistochemistry is highly effective in distinguishing adenocarcinoma from malignant mesothelioma in effusion cytology. *Cancer Cytopathol.* 2014 Apr;122(4):299-306
2. Ohta Y, Sasaki Y, Saito M, et al: Claudin-4 as a marker for distinguishing malignant mesothelioma from lung carcinoma and serous adenocarcinoma. *Int J Surg Pathol.* 2013 Oct;21(5):493-501
3. Ordonez NG: Value of claudin-4 immunostaining in the diagnosis of mesothelioma. *Am J Clin Pathol.* 2013 May;139(5):611-619
4. Schaefer IM, Agaimy A, Fletcher CD, Hornick JL: Claudin-4 expression distinguishes SWI/SNF complex-deficient undifferentiated carcinomas from sarcomas. *Mod Pathol.* 2017 Apr;30(4):539-548

Performance

Method Description

Immunohistochemistry on sections of paraffin-embedded tissue.(Cartun RW, Taylor CR, Dabbs DJ: Techniques of immunohistochemistry: Principles, pitfalls, and standardization. In: Dabbs DJ, ed. *Diagnostic Immunohistochemistry.* 5th ed. Elsevier; 2019:1-46)

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

Rochester

Fees and 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 Regional Manager. For assistance, contact [Customer Service](#).

Test Classification

This test has been cleared, approved, or is exempt by the US Food and Drug Administration and is used per manufacturer's instructions. Performance characteristics were verified by Mayo Clinic in a manner consistent with CLIA requirements.

CPT Code Information

88342-TC, primary

88341-TC, if additional IHC

LOINC® Information

Test ID	Test Order Name	Order LOINC Value
CLDN4	Claudin-4 IHC, Tech Only	Order only;no result

Result ID	Test Result Name	Result LOINC Value
607335	Claudin-4 IHC, Tech Only	Bill only; no result