

Overview

Useful For

A marker of proliferation in neoplasms

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

NY State Available

Yes

Specimen

Specimen Type

TECHONLY

Advisory Information

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

Preferred: 2 Unstained positively charged glass slides (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

Ki-67 (antibody clone MIB-1), is a nuclear protein playing a pivotal role in maintaining cell proliferation. Ki-67 is present in all non-G0 phases of the cell cycle. Beginning in the mid-G1, the level increases through S and G2 to reach a peak in M phase. In the end of M phase, it is rapidly catabolized. Ki-67 has been employed as a marker of proliferation and, hence, prognosis in neoplasms of many types, such as malignant lymphomas, prostatic and breast adenocarcinomas, astrocytic neoplasms, and soft tissue neoplasms.

Interpretation

This test includes only technical performance of the stain (no pathologist interpretation is performed). Mayo Clinic cannot provide an interpretation of tech only stains outside the context of a pathology consultation. If an interpretation is needed, refer to PATHC / Pathology Consultation for a full diagnostic evaluation or second opinion of the case. All material associated with the case is required. Additional specific stains may be requested as part of the pathology consultation, and will be performed as necessary at the discretion of the Mayo pathologist.

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. Contact 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 fresh.

Clinical Reference

1. [Yerushalmi R, Woods R, Ravdin PM et al: Ki67 in breast cancer: prognostic and predictive potential. Lancet 2010;11:174-183](#)

2. Leonardo E, Volante M, Barbareschi M, et al: Cell membrane reactivity of MIB-1 antibody to Ki67 in human tumors: fact or artifact? Appl Immunohistochem Mol Morphol 2007;15(2):220-223

3. Potemski P, Pluciennik E, Bednarek AK, et al: Ki-67 expression in operable breast cancer: a comparative study of immunostaining and a real-time RT-PCR assay. Pathol Res Pract 2006;202:491-495

4. Li R, Heydon K, Hammond ME, et al: Ki-67 staining index predicts distant metastasis and survival in locally advanced prostate cancer treated with radiotherapy: an analysis of patients in Radiation Therapy Oncology Group Protocol 86-10. Clin Cancer Res 2004;10:4118-4124

5. Trihia H, Murray S, Price K, et al: Ki-67 expression in breast carcinoma-its association with grading systems, Clinical parameters, and other prognostic factors-a surrogate marker? Cancer 2003;97(5):1321-1331

Performance

Method Description

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

PDF Report

No

Day(s) and Time(s) Test Performed

Monday through Friday

Analytic Time

1 day

Maximum Laboratory Time

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 was developed and its performance characteristics determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the U.S. 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
KI67	Ki-67 (MIB-1) IHC, Tech Only	Order only;no result

Result ID	Test Result Name	Result LOINC Value
70793	Ki-67 (MIB-1) IHC, Tech Only	Bill only; no result