MAYO CLINIC LABORATORIES

Test Definition: KI67

Ki-67 (MIB-1) Immunostain, Technical Component Only

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 (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).

For immunostain detection of Ki-67 for primary invasive or metastatic breast specimens with interpretation by digital analysis, order KI67B / Ki-67(MIB-1), Breast, Quantitative Immunohistochemistry, Automated.

For immunostain detection of Ki-67 for primary or metastatic gastrointestinal/pancreatic neuroendocrine tumors with interpretation by digital analysis, order KINET / Ki-67(MIB-1), Gastrointestinal/Pancreatic Neuroendocrine Tumors, Quantitative Immunohistochemistry, Automated.

For immunostain detection of Ki-67 for primary or metastatic pulmonary carcinoid tumors with interpretation by digital analysis, order KI67P / Ki-67(MIB-1), Pulmonary, Quantitative Immunohistochemistry, Automated.

For interpretation and diagnosis of submitted pathology specimens with appropriate additional stains and other ancillary testing, order PATHC / Pathology Consultation.

Additional material may be needed if alternative testing is requested. See the specific specimen requirements for any alternative requested testing.

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

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 Cytology smears Nonformalin fixed tissue Nonparaffin embedded tissue Noncharged slides ProbeOn slides Snowcoat	Reject

slides	

Specimen Stability Information

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

Clinical & 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 phase, the level increases through the S and G2 phases 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 does not include pathologist interpretation, only technical performance of the stain.

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

Clinical Reference

1. Yerushalmi R, Woods R, Ravdin PM et al. Ki67 in breast cancer: prognostic and predictive potential. Lancet. 2010;11(2):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(7):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(12 Pt 1):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
6. 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 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

Test Definition: KI67

Ki-67 (MIB-1) Immunostain, Technical Component Only

88342-Primary
88341-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