MAYO CLINIC LABORATORIES

Test Definition: KI67B

Ki-67(MIB-1), Breast, Quantitative Immunohistochemistry, Automated

Overview

Useful For
Determining proliferation of tumor cells in paraffin-embedded tissue blocks from patients diagnosed with breast carcinoma

Reflex Tests

Test Id	Reporting Name	Available Separately	Always Performed
KIBM	Ki67 Breast IHC Manual	No	No

Testing Algorithm
Cases that are not able to be scanned for automated analysis will be changed to the manual process for analysis.

Method Name
Immunohistochemistry, Automated Quantitation

NY State Available
Yes

Specimen

Specimen Type
Special

Ordering Guidance
Ki-67 immunohistochemistry testing on intracystic papillary carcinoma and solid papillary carcinoma, without clearly stating invasive carcinoma, is not appropriate and will be canceled without processing.

If ordering for diagnostic purposes, order PATHC / Pathology Consultation and request the stain.

Shipping Instructions
Attach the green pathology address label included in the kit to the outside of the transport container.

Necessary Information
1. Pathologist's name, address, and phone number are required.
2. Include accompanying pathology report stating the final diagnosis. If not available, a preliminary diagnosis is acceptable **only if** it refers to invasive or metastatic breast carcinoma.

Specimen Required
Supplies: Pathology Packaging Kit (T554)

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Specimen Type: Preferred: Formalin-fixed, paraffin-embedded tissue block containing invasive or metastatic breast carcinoma
Acceptable: 2 Unstained sections, containing invasive or metastatic breast carcinoma, on charged slides cut at 4 microns less than 1 month ago. Tissue on the slides should have been fixed in 10% neutral buffered formalin. Also send one hematoxylin and eosin-stained slide if possible.
Submission Container/Tube: Pathology Packaging Kit
Collection Instructions: Submit paraffin-embedded invasive or metastatic breast carcinoma tissue.
Additional Information: Paraffin block will be returned with the final report.

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

Broken or cracked unstained slides	Reject

Specimen Stability Information

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

Clinical & Interpretive

Clinical Information

Ki-67 (MIB-1 clone) is a monoclonal antibody that reacts with cells undergoing DNA synthesis by binding to the Ki-67 antigen, a marker known to be expressed only in proliferating cells. By measuring the amount of tumor cells expressing Ki-67, an estimate of DNA synthesis can be determined. Studies suggest that Ki-67 (MIB-1) analysis of paraffin-embedded tissue specimens may provide useful prognostic and predictive information in various tumor types.

Reference Values

Varies by tumor type; values reported from 0% to 100%

Interpretation

Results will be reported as a percentage of tumor cells staining positive for Ki-67 (MIB-1). Quantitative Ki-67 (MIB-1) results should be interpreted within the clinical context for which the test was ordered.

The scoring method using Aiforia artificial intelligence for image analysis was developed and validated in the Biomarker and Image Analysis Laboratory, Department of Laboratory Medicine and Pathology, Mayo Clinic (see Method Description).

Cautions

The paraffin block analyzed must be representative of the patient's tumor.

Test results should be interpreted in the context of clinical findings and other laboratory data.

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.

Clinical Reference

1. Urruticoechea A, Smith IE, Dowsett M: Proliferation marker Ki-67 in early breast cancer. J Clin Oncol 2005 Oct 1;23(28):7212-7220
2. de Azambuja E, Cardoso F, de Castro G, et al: Ki-67 as prognostic marker in early breast cancer: a meta-analysis of published studies involving 12,155 patients. Br J Cancer 2007 May 21;96(10):1504-1513
3. Nielsen TO, Leung SCY, Rimm DL, et al: Assessment of Ki67 in breast cancer: updated recommendations from the International Ki67 in Breast Cancer Working Group. J Natl Cancer Inst. 2021 Jul 1;113(7):808-819. doi: 10.1093/jnci/djaa201
4. Zhang A, Wang X, Fan C, et al: The role of Ki67 in evaluating neoadjuvant endocrine therapy of hormone receptor-positive breast cancer. Front. Endocrinol. 2021 Nov 3;12:687244
5. Polewski MD, Nielsen GB, Gu Y, et al: A standardized investigational Ki-67 immunohistochemistry assay used to assess high-risk early breast cancer patients in the monarchE Phase3 Clinical Study identifies a population with greater risk of disease recurrence when treated with endocrine therapy alone. Appl Immunohistochem Mol Morphol. 2022 Apr 1;30(4):237-245. doi: 10.1097/PAI.0000000000001009

Performance

Method Description

A 4 micron-thick section is cut from the paraffin block. The section is stained with an immunoperoxidase method using the monoclonal antibody Ki-67 (MIB-1 clone). This is the paraffin nuclear epitope to the Ki-67 antigen. Any nucleus that has an antigen-antibody complex will cause the bright-field, brown chromogen, diaminobenzidine (DAB), to precipitate onto it. All nuclei, both DAB positive and negative, are counterstained with diluted hematoxylin.

Ki-67 (MIB-1)-stained slides are scanned using the Leica Aperio GT450 digital scanner. The captured digital image is analyzed in Aiforia by an artificial intelligence algorithm. The Aiforia software renders a percentage of positive-staining tumor nuclei. A technologist reviews the analyzed digital image and ensures at least 80% of the total invasive or metastatic cancer is analyzed appropriately. The Aiforia data and corresponding slide are reviewed by a pathologist for final interpretation.(Unpublished Mayo method)

PDF Report

No

Day(s) Performed

Monday through Friday

Report Available

4 to 6 days

Specimen Retention Time

1 week after results are reported. Material made at Mayo Clinic may be retained at Mayo Clinic indefinitely.

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

88361

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
KI67B	Ki67 Breast IHC Automated	85330-9

Result ID	Test Result Name	Result LOINC® Value
MA023	Tumor type	44638-5
MA024	Tumor classification	21918-8
70995	Interpretation	85330-9
70996	Participated in the Interpretation	No LOINC Needed
70997	Report electronically signed by	19139-5
70999	Material Received	81178-6
71627	Disclaimer	62364-5
71841	Case Number	80398-1