MAYO CLINIC LABORATORIES

Test Definition: KIBM

Ki-67(MIB-1), Breast, Semi-Quantitative Immunohistochemistry, Manual

Overview

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

Special Instructions
- Pathology/Cytology Information

Method Name
This is not an orderable test. Order PATHC / Pathology Consultation. The consultant will determine the need for special stains.

Immunohistochemistry, Manual Semi-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.

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
This is not an orderable test. Order PATHC / Pathology Consultation. The consultant will determine the need for special stains.

Supplies: Pathology Packaging Kit (T554)

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 <1 month ago. Tissue on the slides should have been fixed in 10% neutral buffered formalin.
Submission Container/Tube: Pathology Packaging Kit (T554)
Collection Instructions: Submit paraffin-embedded invasive or metastatic breast carcinoma tissue.
Additional Information: Paraffin block will be returned with the final report.

Forms
1. Pathology/Cytology Information (T707) in Special Instructions

Reject Due To
No specimen should be rejected.

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 information in various tumor types.

Reference Values
This is not an orderable test. Order PATHC / Pathology Consultation. The consultant will determine the need for special stains.

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.

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.

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 Jr, 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

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.(Unpublished Mayo method)

PDF Report

No

Day(s) Performed

Monday through Friday

Report Available

4 to 6 days

Specimen Retention Time

Until 1 week after results are reported

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.

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CPT Code Information

88360

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
KIBM	Ki67 Breast IHC Manual	85330-9

Result ID	Test Result Name	Result LOINC® Value
71669	Interpretation	85330-9
71670	Participated in the Interpretation	No LOINC Needed
71671	Report electronically signed by	19139-5
71672	Material Received	81178-6
MA035	Tumor type	44638-5
MA036	Tumor classification	21918-8
71673	Disclaimer	62364-5
71844	Case Number	80398-1