



# 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.

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**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