

## Overview

### Useful For

Determining proliferation of tumor cells in paraffin-embedded tissue blocks from patients diagnosed with carcinoid or atypical carcinoid of the lung including metastases

### Testing Algorithm

Cases that are unable to be scanned for automated analysis will be changed to KIPM / Ki-67(MIB-1), Pulmonary, Quantitative Immunohistochemistry, Manual.

### Reflex Tests

Test Id	Reporting Name	Available Separately	Always Performed
KIPM	Ki67 Pulmonary IHC Manual	No	No

### Method Name

Immunohistochemistry, Automated Quantitation, Hot-Spot Technique

### NY State Available

Yes

## Specimen

### Specimen Type

Special

### 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.

### Specimen Required

**Supplies:** Pathology Packaging Kit (T554)

### Specimen Type:

**Preferred:** Formalin-fixed, paraffin-embedded tissue block containing carcinoid/atypical carcinoid tumor of the lung including metastases.

**Acceptable:** 2 Unstained sections containing carcinoid/atypical carcinoid tumor of the lung including metastases on charged slides cut at 4 microns <1 month ago. Tissue on the slides should have been fixed in 10% neutral buffered formalin.

**Container/Tube:** Pathology Packaging Kit

**Collection Instructions:**

1. Submit formalin-fixed, paraffin-embedded tissue block.
2. Attach the green pathology address label included in the kit to the outside of the transport container.

**Additional Information:** Paraffin block will be returned with the final report.

**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**

All specimens will be evaluated at Mayo Clinic Laboratories for test suitability.

**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**

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

**Interpretation**

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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.

Due to the limitations of the Aperio system (fixed rectangle size and the inability of the machine to distinguish stroma, benign, etc.) small/focal tumors will be converted to a manual semiquantitation by a pathologist rather than an automated measurement.

**Clinical Reference**

Boland JM, Kroneman TN, Jenkins SM, et al: Ki-67 Labeling index in pulmonary carcinoid tumors: Comparison between small biopsy and resection using tumor tracing and hot spot methods. Arch Pathol Lab Med. 2020 Jan 16;144(8):982-990

**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) quantification using the Aperio system in neuroendocrine tumors has been validated by our laboratory. Ki-67(MIB-1)-stained slides are scanned using the Aperio ScanScope instrument, which captures digital images of the patient slide. A technologist views the digitized image and selects the most intensely stained area ("hot-spot") within the tumor. Then, using a rectangle tool available in ImageScope (Aperio Technologies Inc), lays up to ten annotations in this "hot-spot," which are analyzed using an image analysis algorithm that renders the percentage of positive staining tumor nuclei. The slides, images, and test results are then reviewed by a pathologist who provides a final interpretation.(Unpublished Mayo method)

**PDF Report**

No

**Specimen Retention Time**

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

**Performing Laboratory Location**

Rochester

**Fees & Codes****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 US Food and Drug Administration.

**CPT Code Information**

88361

**LOINC® Information**

Test ID	Test Order Name	Order LOINC Value
KI67P	Ki67 Pulmonary IHC Automated	In Process

Result ID	Reporting Name	LOINC®
72132	Interpretation	29593-1
72133	Participated in the Interpretation	No LOINC Needed
72134	Report electronically signed by	19139-5
72135	Material Received	81178-6
72136	Disclaimer	62364-5
72137	Case Number	80398-1