

## Overview

### Useful For

Determining proliferation of tumor cells in paraffin-embedded tissue blocks from patients diagnosed with neuroendocrine tumors of the pancreas or gastrointestinal tract including metastases

### Testing Algorithm

Includes pathology consultation charged separately.

### Method Name

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

Immunohistochemistry, Semi- Quantitation, Hot-Spot Technique

### NY State Available

Yes

## Specimen

### Specimen Type

Special

### Ordering Guidance

This is not an orderable test. 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.

### 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 neuroendocrine tumor of the pancreas or gastrointestinal (GI) tract including metastases.

**Acceptable:** 2 unstained sections, containing neuroendocrine tumor of the pancreas or GI tract 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.

**Submission Container/Tube:** Pathology Packaging Kit (T554)

**Collection Instructions:** Submit formalin-fixed, paraffin-embedded tissue block

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

## Forms

If not ordering electronically, complete, print, and send an [Oncology Test Request](#) (T729) form with the specimen.

## Reject Due To

No specimen should be rejected.

## Specimen Stability Information

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

## Clinical and 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). Semi-quantitative Ki-67(MIB-1) results should be interpreted within the clinical context for which the test was ordered.

### Cautions

No significant cautionary statements.

### Clinical Reference

1. Bosman F, Carneiro F, Hruban R, et al: WHO classification of tumours of the digestive system. Lyon: International Agency for Research on Cancer, 2010
2. Hochwald SN, Zee S, Conlon KC, et al: Prognostic factors in pancreatic endocrine neoplasms: an analysis of 136 cases with a proposal for low-grade and intermediate-grade groups. J Clin Oncol 2002;20:2633-2642

3. Klimstra DS, Modlin IR, Coppola D, et al: The pathologic classification of neuroendocrine tumors: a review of nomenclature, grading, and staging systems. *Pancreas* 2009;39:707-712

4. Klimstra DS, Modlin IR, Adsay NV, et al: Pathology reporting of neuroendocrine tumors: application of the Delphic consensus process to the development of a minimum pathology data set. *Am J Surg Pathol* 2010;34:300-313

5. *Pathology and Genetics Tumours of Endocrine Organs*. Edited by RA DeLellis, RV Lloyd, PU Heitz, C Eng. IARC Press, 2004

## 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

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

### Performing Laboratory Location

Rochester

## Fees and 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 Regional Manager. 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. This test has not been cleared or approved by the US Food and Drug Administration.

### CPT Code Information

88360

### LOINC® Information



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Test ID	Test Order Name	Order LOINC Value
KINM	Ki67 GI/Pancreas NET IHC Manual	29593-1

Result ID	Test Result Name	Result LOINC Value
71674	Interpretation	29593-1
71675	Participated in the Interpretation	No LOINC Needed
71676	Report electronically signed by	19139-5
71677	Material Received	81178-6
71678	Disclaimer	62364-5
71845	Case Number	80398-1