

## 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

### Reflex Tests

Test Id	Reporting Name	Available Separately	Always Performed
KINM	Ki67 GI/Pancreas NET 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, Hot-Spot Technique

### NY State Available

Yes

## Specimen

### Specimen Type

Special

### Ordering Guidance

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

**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 1 of the following forms with the specimen:

[-Oncology Test Request \(T729\)](#)

[-Immunohistochemical \(IHC\)/In Situ Hybridization \(ISH\) Stains Request \(T763\)](#)

**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**

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**

Due to the limitations of the Aperio system (fixed rectangle size and the inability of the machine to distinguish stroma, benign, etc) small or focal tumors will be reflexed (by a pathologist) to a manual semiquantitation method rather than

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an automated measurement.

**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.

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 on a computer monitor and using a rectangle tool available in ImageScope (Aperio Technologies Inc), identifies up to ten "hot" regions of the most intensely staining areas within the tumor. The selected areas are then analyzed using an image analysis algorithm that renders the percentage of positive-staining tumor nuclei. The slides and test results are then reviewed by a pathologist who provides a 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.

# Test Definition: KINET

Ki-67(MIB-1), Gastrointestinal/Pancreatic  
Neuroendocrine Tumors, Quantitative  
Immunohistochemistry, Automated

## Performing Laboratory Location

Rochester

## 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. 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
KINET	Ki67 GI/Pancreas NET IHC Automated	29593-1

Result ID	Test Result Name	Result LOINC® Value
71385	Interpretation	29593-1
71402	Participated in the Interpretation	No LOINC Needed
71403	Report electronically signed by	19139-5
71404	Material Received	81178-6
71628	Disclaimer	62364-5
71842	Case Number	80398-1