

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

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). 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

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

88360

LOINC® Information

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

Result ID	Reporting Name	LOINC®
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