MAYO CLINIC LABORATORIES

Test Definition: KINET

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

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 "Attention Pathology" address label (T498) to the outside of the transport container before putting into the courier mailer.

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
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

Broken or cracked unstained slides	Reject

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.

The scoring method using Aiforia artificial intelligence for image analysis was developed and validated in the Biomarker and Image Analysis Laboratory, Department of Laboratory Medicine and Pathology, Mayo Clinic (see Method Description).

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.

Broken or cracked unstained slides are not compatible with the instrumentation used in our performing laboratories and will be rejected. Additional material may be requested.

Clinical Reference

1. La Rosa S. Diagnostic, Prognostic, and Predictive Role of Ki67 Proliferative Index in Neuroendocrine and Endocrine Neoplasms: Past, Present, and Future. Endocr Pathol. 2023;34(1):79-97. doi:10.1007/s12022-023-09755-3
2. Nagtegaal ID, Odze RD, Klimstra D, et al. The 2019 WHO classification of tumours of the digestive system. Histopathology. 2020;76(2):182-188. doi:10.1111/his.13975

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)-stained slides are scanned using the Leica Aperio GT450 digital scanner. The captured digital image is analyzed using a validated AI (Artificial Intelligence) algorithm by Aiforia that calculates the percentage of positive staining tumor nuclei. The Aiforia data and corresponding slide are reviewed by a pathologist for final interpretation.(Unpublished Mayo method)

PDF Report

No

Day(s) Performed

Monday through Friday

Report Available

4 to 6 days

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Specimen Retention Time

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

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.

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