MAYO CLINIC LABORATORIES

Test Definition: KRASW

KRAS Somatic Mutation Analysis, Peritoneal Fluid

Overview

Useful For
Staging of the pancreatic ductal adenocarcinoma(1)

Special Instructions
- Molecular Genetics: Inherited Cancer Syndromes Patient Information

Method Name
Droplet Digital Polymerase Chain Reaction (ddPCR)

NY State Available
Yes

Specimen

Specimen Type
Peritoneal

Necessary Information
1. A pathology report (final or preliminary) is required and must accompany specimen for testing to be performed.
2. The following information must be included in the report provided.
-Patient name and second identifier
-Date of fluid collection
-Source of the fluid

Specimen Required
Container/Tube: 50-mL Falcon tube
Preferred: Fresh, peritoneal washing; no fixatives added to wash
Specimen Volume: Two 50-mL Falcon tubes
Collection Instructions: Containers must be labeled with two unique patient identifiers.

Forms
Molecular Genetics: Inherited Cancer Syndromes Patient Information (T519)

Specimen Minimum Volume
100 mL of peritoneal washing

Reject Due To

Fixative added	Reject

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Peritoneal	Refrigerated (preferred)	10 days	
	Ambient	5 days	

Clinical & Interpretive

Clinical Information

Pancreatic ductal adenocarcinoma (PDAC) is an aggressive malignancy with predilection for peritoneal dissemination. Accurate peritoneal staging is important for management of patients with PDAC. The *KRAS* oncogene is the most frequently mutated oncogene in PDAC. Detection of *KRAS* mutations within peritoneal fluid has been associated with clinically positive laparoscopic findings (gross metastases and/or positive peritoneal cytology) and elevated peritoneal fluid carbohydrate antigen 19-9 and/or carcinoembryonic antigen and may portend an increased risk of residual/recurrent pancreatic cancer metastases within the peritoneal cavity.

This test uses DNA extracted from cells shed into the peritoneum to evaluate for the presence of *KRAS* (G12A, G12C, G12D, G12R, G12S, G12V, G13D, Q61K, Q61L, Q61R, Q61H, and A146T) mutations. A positive result indicates the presence of an activating *KRAS* mutation and can be a useful marker to aid in the staging of pancreatic ductal adenocarcinoma.

Reference Values

An interpretive report will be provided.

Interpretation

The interpretation of molecular biomarker analysis includes an overview of the results and the associated diagnostic, prognostic, and therapeutic implications.

Cautions

Patients with a negative test result may still harbor a *KRAS* mutation below the level of detection.

The limit of detection of this assay is influenced by the amount of cells and DNA in the peritoneal wash. This is a biological variable that cannot be controlled.

This assay was designed to detect mutations in *KRAS* codons 12, 13, 61, and 146 (G12A, G12C, G12D, G12R, G12S, G12V, G13D, Q61K, Q61L, Q61R, Q61H, and A146T).

This test has not been clinically validated for use as a tool to monitor response to therapy or for early detection of tumors.

This test cannot differentiate between somatic and germline alterations.

Clinical Reference

1. Yonkus JA, Alva-Ruiz R, Abdelrahman AM, et al. Molecular peritoneal staging for pancreatic ductal adenocarcinoma using mutant KRAS droplet-digital polymerase chain reaction: Results of a prospective clinical trial. J Am Coll Surg. 2021;233(1):73-80.e1. doi:10.1016/j.jamcollsurg.2021.05.009
2. Kim NH, Kim HJ. Preoperative risk factors for early recurrence in patients with resectable pancreatic ductal adenocarcinoma after curative intent surgical resection. Hepatobiliary Pancreat Dis Int. 2018;17(5):450-455 doi:10.1016/j.hbpd.2018.09.003
3. Avula LR, Hagerty B, Alewine C. Molecular mediators of peritoneal metastasis in pancreatic cancer. Cancer Metastasis Rev. 2020;39(4):1223-1243. doi:10.1007/s10555-020-09924-4

Performance

Method Description

Droplet digital polymerase chain reaction is used to test for the presence of *KRAS* codon 12, 13, 61, and 146 mutations.(Yonkus JA, Alva-Ruiz R, Abdelrahman AM, et al. Molecular peritoneal staging for pancreatic ductal adenocarcinoma using mutant KRAS droplet-digital polymerase chain reaction: Results of a prospective clinical trial. J Am Coll Surg. 2021;233[1]:73-80.e1. doi:10.1016/j.jamcollsurg.2021.05.009)

PDF Report

No

Day(s) Performed

Monday through Friday

Report Available

5 to 10 days

Specimen Retention Time

Extracted DNA: 3 months

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 Definition: KRASW

KRAS Somatic Mutation Analysis, Peritoneal Fluid

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

81275-KRAS (v-Ki-ras2 Kirsten rat sarcoma viral oncogene) (eg, carcinoma) gene analysis, variants in codons 12 and 13
81276-KRAS (v-Ki-ras2 Kirsten rat sarcoma viral oncogene) (eg, carcinoma) gene analysis, additional variants

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
KRASW	KRAS Mutation Analysis, Peritoneal	21702-6

Result ID	Test Result Name	Result LOINC® Value
616453	Result Summary	50397-9
616454	Result	82939-0
616455	Interpretation	69047-9
616456	Specimen	31208-2
616457	Source	31208-2
616459	Released By	18771-6
616460	Method	85069-3
616461	Disclaimer	62364-5
616462	Additional Information	48767-8