

## 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
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## Specimen Stability Information

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

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. 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