MAYO CLINIC LABORATORIES

TEST CHANGE

Notification Date: June 20, 2022
Effective Date: July 21, 2022

KRAS Somatic Mutation Analysis, Peritoneal Fluid

Test ID: KRASW

Explanation:

Current Specimen Required
Container/Tube: 50-mL Falcon tube with fixative **Preferred:** PreservCyt solution **Acceptable:** CytoLyt solution, methanol: glacial acidic acid (3:1) fixative, or 50% or 80% ethanol **Specimen Volume:** Two to four 50-mL Falcon tubes each containing fixed cells in equal volume to approved fixatives **Collection Instructions:** Containers must be labeled with two unique patient identifiers.

New 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. **Shipping Instructions:** Send specimens refrigerated (4 degrees C)

Current Specimen Minimum Volume
100 mL of washing in acceptable fixative

New Specimen Minimum Volume
100 mL of peritoneal washing

Current Reject Due To	
No Fixative Added	Reject

New Reject Due To	
Fixative Added	Reject

Current Report Available
8-12 days

New Report Available
4-10 days

Current Analytic Time
8 days

New Analytic Time
4 days

Current Useful For
Detecting molecular markers associated with response or resistance to specific cancer

New Useful For
Staging of the pancreatic ductal adenocarcinoma.

Current Cautions

- Not all patients whose tumors have wild-type *KRAS* respond to epidermal growth factor receptor (EGFR)-targeted therapies.
- Rare variants (ie, polymorphisms) exist that could lead to false-negative or false-positive results.
- Test results should be interpreted in context of clinical findings, tumor sampling, and other laboratory data. If results obtained do not match other clinical or laboratory findings, contact the laboratory for possible interpretation. Misinterpretation of results may occur if the information provided is inaccurate or incomplete.
- 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.

New 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.
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Questions

Contact Michelle Raths, Laboratory Technologist Resource Coordinator at 800-533-1710.