Pancreatic Cancer: Sequencing Panel

Test Code: MM402  
Turnaround time: 4 weeks

CPT Codes: 81211 x1, 81292 x1, 81295 x1, 81298 x1, 81317 x1, 81404 x1, 81405 x1, 81406 x1

**Condition Description**

The American Cancer Society estimates 46,420 people (23,530 men and 22,890 women) will be diagnosed with pancreatic cancer in 2014. The lifetime risk of developing pancreatic cancer is about 1 in 78 (1.47%). Pancreatic tumors arise from either the exocrine cells or endocrine cells of the pancreas. Exocrine tumors are the most common type of pancreatic cancer. An adenocarcinoma is a cancer that starts in gland cells. About 95% of cancers of the exocrine pancreas are adenocarcinomas. These cancers usually begin in the ducts of the pancreas, but they sometimes develop from the cells that make the pancreatic enzymes (acinar cell carcinomas). Less common types of cancers of the exocrine pancreas include adenosquamous carcinomas, squamous cell carcinomas, signet ring cell carcinomas, undifferentiated carcinomas, undifferentiated carcinomas with giant cells, and solid pseudopapillary neoplasms of the pancreas.

Tumors of the endocrine pancreas are uncommon. As a group, they are known as pancreatic neuroendocrine tumors (NETs), or sometimes as islet cell tumors. There are several subtypes of islet cell tumors.

Reference:

**Genes**

APC, ATM, BRCA1, BRCA2, CDKN2A, MLH1, MSH2, MSH6, PALB2, PMS2, PRSS1, STK11, TP53, VHL

**Indications**

The test is indicated for:
- Individuals with a clinical or suspected diagnosis of pancreatic cancer.

**Methodology**

**Next Generation Sequencing:** In-solution hybridization of all coding exons is performed on the patient's genomic DNA. Although some deep intronic regions may also be analyzed, this assay is not meant to interrogate most promoter regions, deep intronic regions, or other regulatory elements, and does not detect single or multi-exon deletions or duplications. Direct sequencing of the captured regions is performed using next generation sequencing. The patient's gene sequences are then compared to a standard reference sequence. Potentially causative variants and areas of low coverage are Sanger-sequenced. Sequence variations are classified as pathogenic, likely pathogenic, benign, likely benign, or variants of unknown significance. Variants of unknown significance may require further studies of the patient and/or family members.

**Detection**

**Next Generation Sequencing:** Clinical Sensitivity: Unknown. Mutations in the promoter region, some mutations in the introns and other regulatory element mutations cannot be detected by this analysis. Large deletions/duplications will not be detected by this analysis. Results of molecular analysis should be interpreted in the context of the patient's clinical/biochemical phenotype.

Analytical Sensitivity: ~99%.

**Specimen Requirements**

Submit only 1 of the following specimen types

**Type: Whole Blood**

Specimen Requirements:
- In EDTA (purple top) tube:
  - Infants (2 years): 3-5 ml
  - Older Children & Adults: 5-10 ml

Specimen Collection and Shipping: Ship sample at room temperature with overnight delivery.

**Type: Isolated DNA**

Specimen Requirements:
- In microtainer: 60 ug

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Isolation using the Qiagen™ Puregene kit for DNA extraction is recommended.

Specimen Collection and Shipping: Refrigerate until time of shipment in 100 ng/ul of TE buffer. Ship sample at room temperature with overnight delivery.

**Special Instructions**

This test is for germline mutation analysis. DNA isolated from FFPE tumor samples is not suitable for this test.

**Related Tests**

- Hereditary Cancer Syndrome: Sequencing Panel.
- Pancreatic Cancer: Deletion/Duplication Panel.