

1. PATIENT INFORMATION

Patient Name _____
Date of Birth _____ MRN/Other Patient ID _____ Sex at Birth _____

2. ORDERING PROVIDER

Name _____
Institution/Account Name _____

3. SPECIMEN INFORMATION

Collection Date _____
Specimen Received Date _____
Specimen ID _____
Specimen Type _____
Report Date _____

RESULTS



DETECTED

An ABNORMAL Epigenomic Signal was DETECTED.

- This signal in circulating cell free DNA has been associated with the presence of malignancy in the pancreas.
- It could also represent other abnormal conditions of the pancreas including Intraductal Papillary Mucinous Neoplasm (IPMN) and pancreatitis. There is a small possibility it could represent the detection of a malignancy outside the pancreas.
- Consultation with a physician or licensed genetic professional is recommended.
- Additional clinical and radiologic evaluation is required to establish a diagnosis.

ABOUT THE TEST

- The test is intended to evaluate the presence or absence of a signal in circulating cell-free DNA (cfDNA) associated with *pancreatic cancer* by assessing epigenomic and genomic signals derived by next generation sequencing (NGS) of 5-hydroxymethylation (5hmC) enriched cfDNA and total cfDNA².
- Based on a case-control validation study of pancreatic cancer (n=102) and non-cancer subjects (n=2048), the sensitivity for detection of pancreatic cancer for this test is 66.7% (95% CI: 56.6% - 75.7%) and the specificity of this test is 96.9% (95% CI: 96.0% - 97.6%). Further test performance information is available upon request.
- In **newly diagnosed** (within 36 months) **patients with type 2 diabetes** over the age of 50 years, the risk of pancreatic cancer is up to **eight-fold** greater compared to the general population³. Nearly 25% of all new diagnoses of pancreatic cancer in the United States are identified in newly diagnosed type 2 diabetes patients¹.

LIMITATIONS AND REGULATORY

Not all patients with pancreatic cancer will be classified as "signal detected," and some patients without pancreatic cancer will have a "signal detected" result. The Avantect Pancreatic Cancer Test is intended for clinical use and should not be regarded as investigational or for research. The test has been developed, and the performance characteristics determined, by the ClearNote Health Clinical Laboratory, which is certified under the Clinical Laboratory Improvement Act of 1988 (CLIA) as qualified to perform high complexity clinical testing. The Avantect Pancreatic Cancer Test has not been cleared or approved by the U.S. Food and Drug Administration.

References: **1.**Chari ST, Leibson CL, Rabe KG, et al. Probability of pancreatic cancer following diabetes: a population-based study. *Gastroenterology* 2005;129:504-511. **2.**Guler GD, Ning Y, Ku CJ, Phillips T, McCarthy E, Ellison CK et al. Detection of early-stage pancreatic cancer using 5-hydroxymethylcytosine signature in circulating cell free DNA. *Nat Commun.* 2020 Oct 19;11(1):5270. doi: 10.1038/s41467-020-18965-w. PMID: 33077732; PMCID: PMC7572413. **3.**Huxley R, Ansary-Moghaddam A, Berrington De-González A, et al. Type-II diabetes and pancreatic cancer: a meta-analysis of 36 studies. *Br J Cancer* 2005;92:2076-2083.



Shimul Chowdhury, PhD, FACMG
Clinical Laboratory Director

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RESULTS



NOT DETECTED

An ABNORMAL Epigenomic signal was NOT DETECTED. This does not exclude the presence of pancreatic cancer. If signs or symptoms appear and are suggestive of cancer, please consult your physician.

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