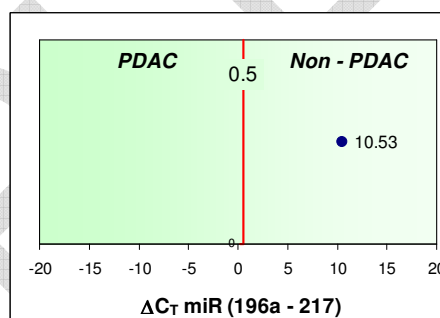


Patient and Order Information

Patient Name:	DOB:	Sex: <M F>
Order ID:	Lab ID:	Type of Sample: FFPE
MRN:	Sample ID:	
Attending Provider:	Date Collected:	Date Received:

Pancreatic Ductal Adenocarcinoma miRNA 196a:217 Assay

	Reference Range ΔC_T	Patient Result ΔC_T
Other (Non-PDAC)	>0.50	10.53
Pancreatic Ductal Adenocarcinoma (PDAC)	≤ 0.50	N/A


Comments

Test Result Negative: The ΔC_T value in the range of 0.50 (non-inclusive) to 20.00 (inclusive) ($0.50 < \Delta C_T \leq 20.00$) is not consistent with Pancreatic Ductal Adenocarcinoma. This specimen tested as negative for Pancreatic Ductal Adenocarcinoma. Other pancreatic malignancies cannot be excluded.

For further interpretation of this result, please contact the Medical Director at (phone number provided).

Assay Description and Methodology:

Expression difference is based on a qRT-PCR expression analysis of 2 gene loci using a TaqMan[®] approach. The loci consist of a balanced set of one locus expected to be up-regulated (miR-196a) and one expected to be down-regulated (miR-217) in pancreatic ductal adenocarcinoma, as compared to normal pancreas and chronic pancreatitis specimens. Expression difference based on a balanced set does not require a normalizer locus to control for differential mass load into the RT or PCR reactions. The "raw" (not normalized) cycle number difference between miR-196a and miR-217 provides an expression difference range from which tissue phenotype is inferred: other (non-PDAC) vs pancreatic ductal adenocarcinoma (PDAC). A blinded validation study on a set of 60 pancreatic FFPE specimens (39 benign, 21 pancreatic ductal adenocarcinoma) using the threshold value of 0.5 ΔC_T resulted in an assay sensitivity of 95.24% (95%CI: 77.33- 99.15) and a specificity of 94.87% (95%CI: 83.11- 98.58).

Intended Use:

This laboratory developed test is intended to aid in the clinical diagnosis and disease management of pancreatic ductal adenocarcinoma on FFPE tissue specimens that contain equal or more than 60% abnormal area. The test has not been validated on other pancreatic sample types or other pancreatic malignancies.

Disclaimer:

This laboratory developed test was developed and its performance determined by Asuragen's CLIA Laboratory. This test has not been cleared or approved by the US Food and Drug Administration. Although, such approval is not required for clinical implementation, Asuragen may choose to seek such approval. The Asuragen laboratory is CLIA registered to perform high complexity testing.