PancraGEN®
PANCREATIC CANCER RISK CLASSIFIER

Rule in cancer when cytology is inconclusive

PancraGEN® significantly improves detection of cholangiocarcinoma and pancreatic cancer when cytology results are not definitive.

How PancraGEN® Works

- Testing of normally discarded free-DNA obtained from standard ERCP duct brushing or EUS-FNA specimens[1-6]
- PancraGEN testing does not require actual cellular material, but instead uses cell free DNA. Diagnostic cells can be reserved for cytologic evaluation.
- Mutation analysis of free-DNA enables classification into Benign or HGD/Malignant results

Why

- PancraGEN detects 20-30% more pancreaticobiliary malignancies than use of cytology alone[1,2,7]
- The presence of any one mutation in the PancraGEN panel is 97% specific for malignancy[1,2,7]
- PancraGEN improves the diagnostic yield of each individual ERCP and EUS procedure to more than 96%[1,2]

Oncogenes	Genomic Loci
KRAS	12p
GNAS	20q

Tumor Suppressor Genes	Genomic Loci
VHL, OGG1	3p
PTEN, MXI1	10q
TP53	17p
SMAD4, DCC	18q
CDKN2A	9p
RNF43, NME1	17q
PSEN2, TFF1	21q
CMM1, LMYC	1p
MCC, APC	5q
NF2	22q

Limitations and Disclaimers

Although PancraGEN is very specific (>97%) for malignancy of solid pancreaticobiliary lesions (SPLs), some malignant SPLs may not be detected.[1,2,7] There may also be individuals who are falsely identified as having a malignant SPL. Diagnosis and appropriate patient management are the responsibility of the referring physician or health care provider.

References

1. Kushnir VM, et al. The diagnostic yield of malignancy comparing cytology, FISH and molecular analysis of cell free cytology brush supernatant in patients with biliary strictures undergoing endoscopic retrograde cholangiography (ERC): a prospective study. *J Clin Gastroenterol*. Manuscript In press (2018).
2. Gonda TA, Viterbo D, Gausman V, Kipp C, Sethi A, et al. Mutation profile and fluorescence in situ hybridization analyses increase detection of malignancies in biliary strictures. *Clin Gastroenterol Hepatol*. 2017;15(6):913-919.e1.
3. Finkelstein SD, Bibbo M, Kowalski TE, Loren DE, Siddiqui AA, et al. Mutational analysis of cytocentrifugation supernatant fluid from pancreatic solid mass lesions. *Diagn Cytopathol*. 2014;42(8):719-25.
4. Finkelstein, SD, Bibbo M, Loren DE, Siddiqui AA, Solomides C, et al. Molecular analysis of centrifugation supernatant fluid from pancreaticobiliary duct samples can improve cancer detection. *Acta Cytol*. 2012;56(4):439-47.
5. Malhotra, N, Jackson SA, Freed LL, Styn MA, Sidawy MK, et al. The added value of using mutational profiling in addition to cytology in diagnosing aggressive pancreaticobiliary disease: review of clinical cases at a single center. *BMC Gastroenterol*. 2014;14:135.
6. Deftereos, G, Finkelstein SD, Jackson SA, Ellsworth EM, Krishnamurti U, et al. The value of mutational profiling of the cytocentrifugation supernatant fluid from fine-needle aspiration of pancreatic solid mass lesions. *Mod Pathol*. 2014;27(4):594-601.
7. Khosravi F, Sachdev M, Alshati A, Abdulameer A, Jackson SA, et al. Mutation profiling impacts clinical decision making and outcomes of patients with solid pancreatic lesions indeterminate by cytology. *JOP*. 2018;19:6-11.

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