

# Diagnostic for Precursor Lesions of Pancreatic Cancer

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## INVENTION NOVELTY

These highly specific biomarkers distinguish potentially malignant mucinous cysts from benign nonmucinous cysts in the pancreas to help diagnose precursor lesions of pancreatic ductal adenocarcinoma. The biomarkers can be detected through enzymatic assays with exceptional accuracy and sensitivity.

## VALUE PROPOSITION

Early stage pancreatic cancer is often asymptomatic and diagnosis is difficult and often too late for successful treatment. Only about 12%-15% of patients are diagnosed early enough for treatment. Early, accurate diagnosis would save lives and reduce costs.

Mucinous pancreatic cysts are precursors to pancreatic cancer and if accurately and timely identified can be removed by surgery. However, they are difficult to distinguish from nonmucinous benign cysts. Both types of pancreatic cysts are frequently identified during routine abdominal MRI/CT scan in as much as 20-40% of the general population but current diagnostic methods are insufficient to accurately differentiate mucinous cysts from nonmucinous lesions (with specificities around 49%-76% and sensitivity around 40%). Misclassification of these pancreatic cysts results in unnecessary pancreatectomy surgeries in 1 out of 3 cases. A huge unmet need exists for new diagnostics to reliably identify precancerous mucinous lesions to guide surgical and treatment decisions and improve clinical outcomes.

The current invention provides the following advantages:

- ▶ Novel biomarkers that specifically identify curable precursor lesions of pancreatic cancer
- ▶ Optimized fluorescent substrates that allows detection of subnanomolar marker concentrations
- ▶ Catalytic reaction that requires less than 1 microliter cyst fluid sample
- ▶ Highly accurate diagnostics validated in a large patient cohort

## TECHNOLOGY DESCRIPTION

UCSF investigators have developed a protease activity-based microplate assay with specifically designed fluorescent peptide substrates to detect the presence of key biomarker proteases in cyst fluid. This novel diagnostic method has been tested in 110 patient samples, showing 100% specificity, 93% sensitivity and 95% accuracy for distinguishing precancerous mucinous cysts from benign nonmucinous cysts. Importantly, it requires less than 1 microliter of cyst fluid to diagnose and has correctly classified all samples that were misclassified by a major commercialized technique. The investigators are continuing to further develop and

## CONTACT

Kristin A. Agopian  
[kristin.agopian@ucsf.edu](mailto:kristin.agopian@ucsf.edu)  
 tel: 415-340-2619.



## INVENTORS

- ▶ Craik, Charles S.
- ▶ Ivy, Sam
- ▶ Kirkwood, Kimberly
- ▶ O'Donoghue, Anthony J.

## OTHER INFORMATION

### KEYWORDS

Pancreatic cancer, Mucinous cysts, Diagnostic, Protease activity, Biomarker

### CATEGORIZED AS

- ▶ **Biotechnology**
  - ▶ Health
- ▶ **Medical**
  - ▶ Diagnostics
  - ▶ Disease: Cancer
  - ▶ Disease: Digestive System
  - ▶ Disease: Metabolic/Endocrinology
  - ▶ Screening

validate this diagnostic in a larger patient cohort.

## RELATED CASES

2017-037-0

## LOOKING FOR PARTNERS

To develop & commercialize the technology as a diagnostic kit to differentiate mucinous pancreatic cysts from nonmucinous lesions with high sensitivity, specificity and accuracy

## STAGE OF DEVELOPMENT

Pre-Clinical

## RELATED MATERIALS

▶ [Ivry et. al. Clin Cancer Res 2017;23:4865-4874.](#)

## PATENT STATUS

Country	Type	Number	Dated	Case
United States Of America	Issued Patent	11,726,091	08/15/2023	2017-037
European Patent Office	Published Application	3607320	02/12/2020	2017-037

Additional Patent Pending

## ADDITIONAL TECHNOLOGIES BY THESE INVENTORS

▶ [Rapid and Sensitive Diagnostic for Blood Clot Formation and Cardiovascular Disease](#)

### ADDRESS

#### UCSF

#### Innovation Ventures

600 16th St, Genentech Hall, S-272,  
San Francisco, CA 94158

### CONTACT

Tel:

[innovation@ucsf.edu](mailto:innovation@ucsf.edu)

<https://innovation.ucsf.edu>

Fax:

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