PanaSee™
Know your risk.

# Program Highlights Page

## PRODUCT DESCRIPTION

PanaSee is a blood test that measures levels of a metabolite called PC-594 as a risk factor for pancreatic cancer. The output is a quantitative value that determines whether a subject has normal or deficient levels. A deficient level represents a positive PanaSee result, which means increased risk of pancreatic cancer. PanaSee detects approximately 86% of existing pancreatic cancers, independent of stage.

## CLINICAL UTILITY

There are currently NO screening tests for pancreatic cancer. Most patients present with symptoms when the tumor is already advanced to stage III or IV. Like other cancers, the earlier that pancreatic cancer can be detected and treated, the better the overall prognosis. Therefore, there is an immediate clinical need for products such as PanaSee that can identify early-stage, or high-risk subjects.

Subjects with a positive PanaSee test have a risk of pancreatic cancer that exceeds that associated with having three first degree relatives with the disease. PanaSee-positive subjects should consider follow-up medical imaging to detect cysts or early-stage cancer by magnetic resonance cholangiopancreatography (MRCP), multi-detector low-dose computed tomography (CT), or high definition transabdominal ultrasound.

## CLINICAL STUDIES

PanaSee has been evaluated in numerous clinical studies including:

- Initial discovery study, which included blood samples from 40 pre-treatment Japanese pancreatic cancer patients and 50 controls. A 36 carbon long-chain fatty acid, called PC-594, was identified as the top discriminating pancreatic cancer metabolite marker.
- First validation in Japanese patients, where we used the first-generation PanaSee test to confirm a PC-594 reduction in 122 Japanese pancreatic cancer patients compared to 138 healthy controls.
- Second validation in 64 Japanese patients and 140 controls to investigate the effect of surgery on PC-594 levels. PC-594 levels were again confirmed to be significantly reduced in pancreatic cancer patients, but not restored following surgery. This suggested that their reduction was not caused by the tumor.
- First validation in North America, where we confirmed a PC-594 reduction in 20 North American patients compared to 1040 controls aged 30 to 80. We used the results to determine a cut-off and show an inverse association between PC-594 and age.
- Second validation in North America, where we further validated a PC-594 reduction in 84 pancreatic cancer patients compared to 99 cancer-free controls, and showed superior results to CA19-9.

## PC-594 MECHANISM

Although the precise mechanism of PC-594 is not known, it is part of a large family of long-chain polyunsaturated fatty acids that possess anti-inflammatory and anti-proliferative activity; activities that are consistent with protection against cancer. Our current hypothesis is that as PC-594 levels decline with age, the ability to counteract the accumulation of chronic pancreatic inflammation becomes compromised, ultimately leading to cellular damage and cancer.

## TEST METHOD

The current PanaSee test is performed on 15µL of serum, collected using conventional phlebotomy. The assay is based on tandem mass spectrometry, and has been optimized to run on PDI's custom platform that can process up to 1000 samples per day. A proof-of-concept blood-spot version of PanaSee has recently been developed to eliminate the need for conventional phlebotomy and improve distribution. The prototype product is based on a helical serum-separator technology that requires approximately two drops of blood from a finger-prick.

## REGULATORY STATUS

PanaSee is approved for use in Canada by Health Canada. The test is currently performed at Phenomenome Laboratory Services Inc (PLSI), a licensed medical laboratory in Saskatoon that is CLIA-compliant and certified by the College of American Pathologists (CAP) and the College of Physicians and Surgeons of Saskatchewan (SPSS).

## INTELLECTUAL PROPERTY

Methods for the Diagnosis of Colorectal Cancer and Ovarian Cancer By the Measurement of Vitamin E-related Metabolites (LEG-117) US Prov 60/716,310 and US Prov 60/804,764. Issued in Canada (2619732), Australia (2006291988), Japan (5038311) and Singapore (165370); other countries pending.

## PUBLICATIONS


- Pancreatic cancer serum biomarker PC-594: Diagnostic performance and comparison to CA19-9. *World J Gastroenterol*. Jun 7, 2015; 21(21): 6604-6612
- Metabolic system alterations in pancreatic cancer patient serum: potential for early detection. *BMC Cancer*. 2013 Sep 12;13:416.


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