



**PRODUCT DESCRIPTION**

OvAware™ is a blood test that measures the levels of several lipids in the blood as a risk factor for ovarian cancer. The output is a quantitative value to determine whether a woman has increased or decreased risk of ovarian cancer.

**CLINICAL UTILITY**

The purpose of OvAware is to reduce ovarian cancer associated mortality by identifying a subset of women from the general population who have increased risk, and who should consider further screening options or possibly opportunistic salpingectomy (surgical removal of the fallopian tubes). Screening based on CA-125 and transvaginal ultrasound alone has failed to yield survival benefits, with up to 70% of cases still diagnosed at a late stage. Since it is now believed that many ovarian cancers originate in the fallopian tube, attention has recently shifted to the use of salpingectomy as a prophylactic means of reducing risk among women. Performing the procedure, however, on all women is likely not feasible. OvAware, therefore, represents a necessary tool with respect to this approach by identifying high-risk subjects who should consider prophylactic options, while eliminating the need for low-risk women to undergo the procedure.

**CLINICAL STUDIES**

OvAware has been evaluated in numerous clinical studies including:

- Discovery sample population where several ultra long chain polyunsaturated fatty acids and ethanolamine phospholipids showed altered profiles in ovarian cancer patients (n=20) versus controls (n=50).
- Reductions in lipid panels discovered above were validated in samples from Japan (122 ovarian, 96 control), and the dataset used to refine the number of analytes based on logistic regression and linear discriminant analysis. The resulting receiver-operator area under the curve (ROC-AUC) was 0.99 in differentiating ovarian from control.
- Canadian validation 1: This was a large study of ovarian cancers (n=234), endometrial cancers (62) and other benign/borderline cases (202) combined with over 600 control female samples from two independent geographic regions. Results were consistent with an ROC-AUC > 0.95 for control versus ovarian cancer.
- Canadian validation 2: In this study, which is currently in progress, 917 samples are being analyzed in a blinded manner. The samples represent over 200 individual cases with longitudinal collections during treatment, as well as a subset of women who are BRCA1/2 carriers.

**BIOLOGICAL MECHANISM**

OvAware measures the ratios among eight lipids in the blood. Two of the lipids are 28-carbon long-chain unsaturated fatty acids involved in controlling inflammation within the body, while the other six lipids are glycerophospholipids containing ethanolamine and combinations of 18:1, 18:2, 18:3, 20:4 and 22:6 unsaturated fatty acids. The ratios between the lipids suggest an overall increased fatty acid desaturase activity, or increased *de novo* fatty acid synthesis in ovarian cancer patients, both of which are well known to contribute to a cancer phenotype.

**TEST METHOD**

The OvAware 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 OvAware 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**

OvAware is pending approval by Health Canada and other regulatory bodies. It is currently run as a research-use only lab developed test (LDT) at Phenomenome Laboratory Services, Inc.

**INTELLECTUAL PROPERTY**

- Methods for the Diagnosis of Colorectal Cancer and Ovarian Cancer By the Measurement of Vitamin E-related Metabolites. 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.
- Methods for the Diagnosis of Ovarian Cancer Health States and Risk of Ovarian Cancer Health States. Issued in Japan (5221566) and Australia (2008210207), and pending in other countries.