An Integrated Multi-omic Assay Combining Lipids, Metabolites, and Proteins: **OMIRA™ OC Enables Accurate Detection of Early-Stage Ovarian Cancer in Symptomatic Women**

Check out our recent publication in *Diagnostics!*

Check out our recent publication in AACR's *Cancer Research Communications!*

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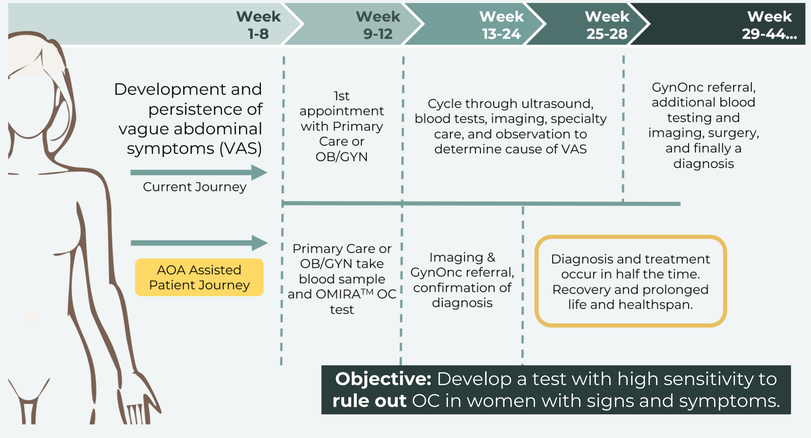
BACKGROUND

Ovarian cancer (OC) remains highly lethal primarily due to late-stage diagnosis[1]. Existing diagnostic tools lack sensitivity and specificity to detect early-stage disease[2].

5-year survival rates for stage I are >90%, but OC is often detected **at late stages (III/IV)** when **survival is <30%**[1].

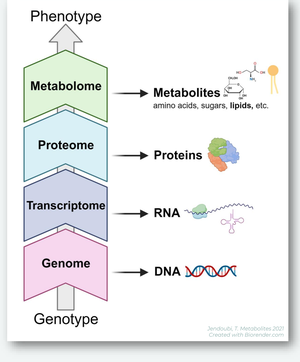
~85% of patients present with symptoms[3], but they are often vague and misattributed, leading to a 9-month diagnostic delay[4].

There is a clear **unmet need for improved diagnostic tools** to accurately triage symptomatic women and enable earlier detection.



[1] Siegel RL, Kratzer TB, et al. Cancer Statistics, CA Cancer J Clin. 2025. [2] Matteson KA, Gunderson C, Richardson DL. Obstet. Gynecol. 2017. [3] Coffi BA, Matthews B, et al. Cancer 2011. [4] Hueppchen SP, Sun CS, et al. Cancer 2021.

Tumors undergo metabolic reprogramming, supporting every cancer hallmark

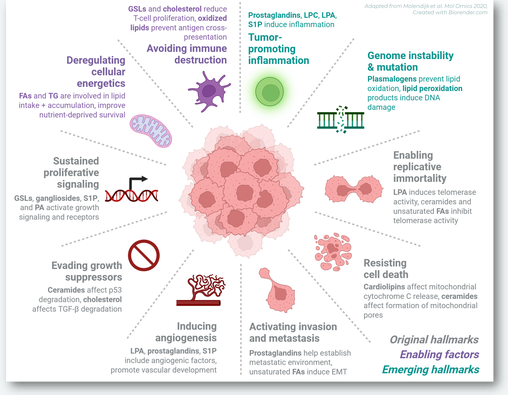


Metabolic reprogramming is a cancer driver, not just a downstream byproduct:

Metabolites and lipids support every cancer hallmark.

Small molecules reprogram in the earliest stages of tumor development, capturing biology that protein and genomic markers miss.

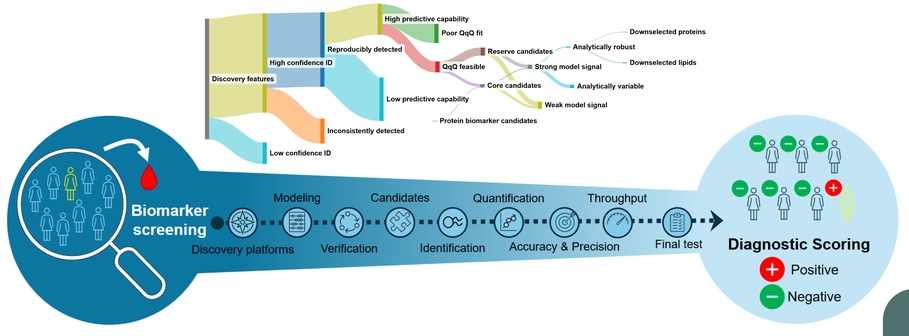
Metabolomics and lipidomics are novel "omics" in oncology, offering a view of the phenotype of the tumor microenvironment.



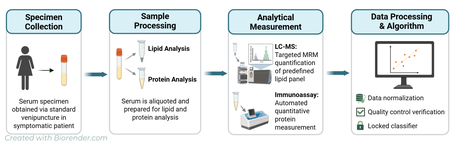
We have built an end-to-end biomarker development pipeline.

Discovery lipidomics of patient cohorts generates candidate lipid features, which advance through sequential stages:
1. Modeling and verification narrow the pool to high-confidence candidates
2. Structural identification confirms lipid identity
3. Quantification establishes accuracy and precision
4. High-throughput format enables clinical deployment

Result: a biomarker panel with confirmed IDs suitable for diagnostics.



METHODS

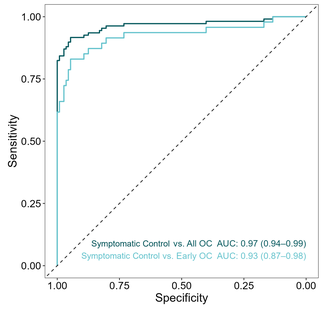


	Training Cohort	Independent Holdout Cohort
All OC	108	99
Early-stage OC	*47*	*61*
Late-stage OC	*61*	*38*
Symptomatic Control	112	73
Total	**220**	**172**

Serum was collected from symptomatic patients in an independent, prospective, multi-site U.S. study, supplemented with commercial samples. Cohorts comprised OC patients with early- (I/II) or late-stage (III/IV) disease. Symptomatic controls were individuals first seeking care with confirmed absence of malignancy.
Lipids were quantified by targeted MRM (LC-MS), metabolites by semi-targeted LC-MS, and proteins by immunoassay. Data were normalized and verified by quality control prior to modeling. First, an ensemble machine learning model was built on the training cohort, using <10 features across lipid, metabolite, and protein classes, selected from a panel identified in prior discovery cohorts. Next, we further downselected features and then evaluated the model by training and testing in an independent holdout.

RESULTS

Building on our discovery work (Culp-Hill et al. *Diagnostics* 2026) we developed a multi-omic assay that enables detection of early-stage OC in symptomatic women, demonstrating the utility of lipids and metabolites in a multi-omic context.



<10 features spanning lipid, metabolite, and protein classes

96.3% Sensitivity, all OC

91.5% Sensitivity, early OC

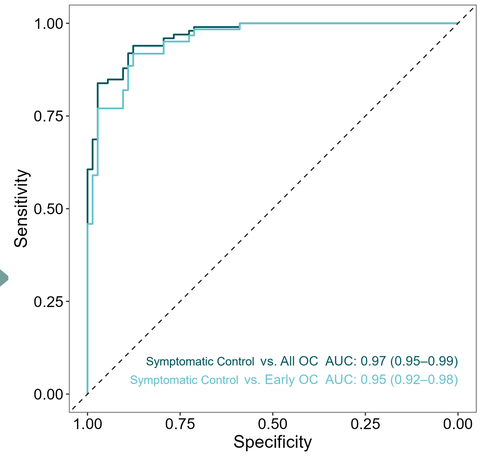
80.4% specificity

Feature Downselection

KEY TAKEAWAYS

- A multi-omic model of <10 lipid, metabolite, and protein features showed strong performance in a single cohort. The model was then downselected further and a locked threshold was selected and validated in an independent holdout
- **Holdout performance**: OMIRA OC shows 90.2% early-stage sensitivity and 92.9% all-stage sensitivity at 87.7% specificity
- **High-grade serous OC**: 100% early-stage (13/13), 96.8% late-stage (30/31) sensitivity
- **OMIRA OC vs. CA125** alone: early-stage sensitivity 54.1% → 90.2%, no significant difference in specificity (p = 0.289)
- High early-stage sensitivity in an independent holdout supports use of **OMIRA OC** to rule out OC in women presenting with symptoms.

OMIRA OC achieves 90.2% sensitivity for early-stage OC in an independent holdout set



Early-stage OC vs. Symptomatic	All OC vs. Symptomatic
90.2% sensitivity *AUC: 0.95 (0.92–0.98)*	**92.9%** sensitivity *AUC: 0.97 (0.95–0.99)*

87.7% specificity

Sensitivity in High-Grade Serous OC

100% Early-stage HGS	96.8% Late-stage HGS
13 TP / 0 FN, n = 13	30 TP / 1 FN, n = 31

Performance of OMIRA OC vs. CA125

Metric	CA125 at 35 U/mL	OMIRA OC	McNemar exact p
All-stage OC Sensitivity	66.7% (66/99)	92.9% (92/99)	2.98×10^{-8}
Early-stage OC Sensitivity	54.1% (33/61)	90.2% (55/61)	4.77×10^{-7}
Symp. Control Specificity	93.2% (68/73)	87.7% (64/73)	0.289

In a head-to-head comparison, OMIRA OC significantly improves sensitivity for all-stage and early-stage OC when compared to CA125 alone.