A first-of-its-kind multi-omic assay using lipids and proteins accurately identifies early-stage ovarian cancer in symptomatic individuals

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2026 ASCO ANNUAL MEETING

Check out our poster from AACR 2026 to see how we got here!

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Check out our publication in *Cancer Research Communications!*

Background and Rationale

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].

30%
While stage I disease shows survival rates above 90%, most OC is detected **at late stages (III/IV)**, when **5-year 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].

HGSOC **doubles in volume every 2–4 months**, leaving a narrow detection window before metastasis; earlier diagnosis is associated with significantly improved survival[5,6,7].

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

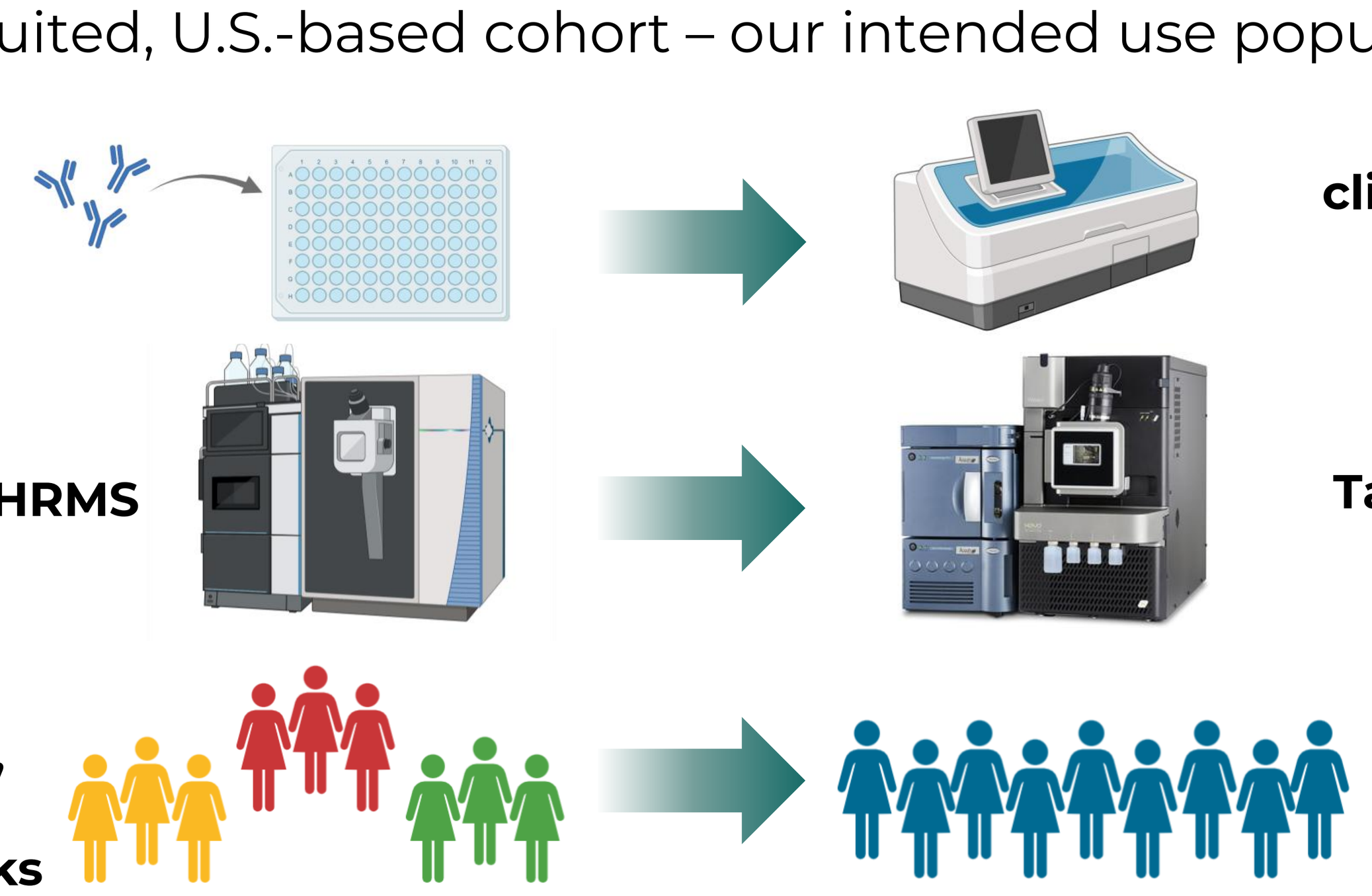
Patient Journey to OC Diagnosis

	Week 1-8	Week 9-12	Week 13-24	Week 25-28	Week 29-44...
Current Journey	Development and persistence of VAS	1st appointment with Primary Care or OB/GYN	Cycle through blood tests, imaging, specialty care, and observation to determine cause of VAS		GynOnc referral, additional blood testing and imaging, surgery, and finally a diagnosis
AOA Assisted Patient Journey		Primary Care or OB/GYN take blood sample and use AKRIVIS GD™ test	Imaging & GynOnc referral, confirmation of diagnosis	Diagnosis and treatment occur in half the time. Recovery and prolonged, healthy life.	

Objective:
Develop a test with high sensitivity to **rule out** OC in women with signs and symptoms.

Targeted Assay Development

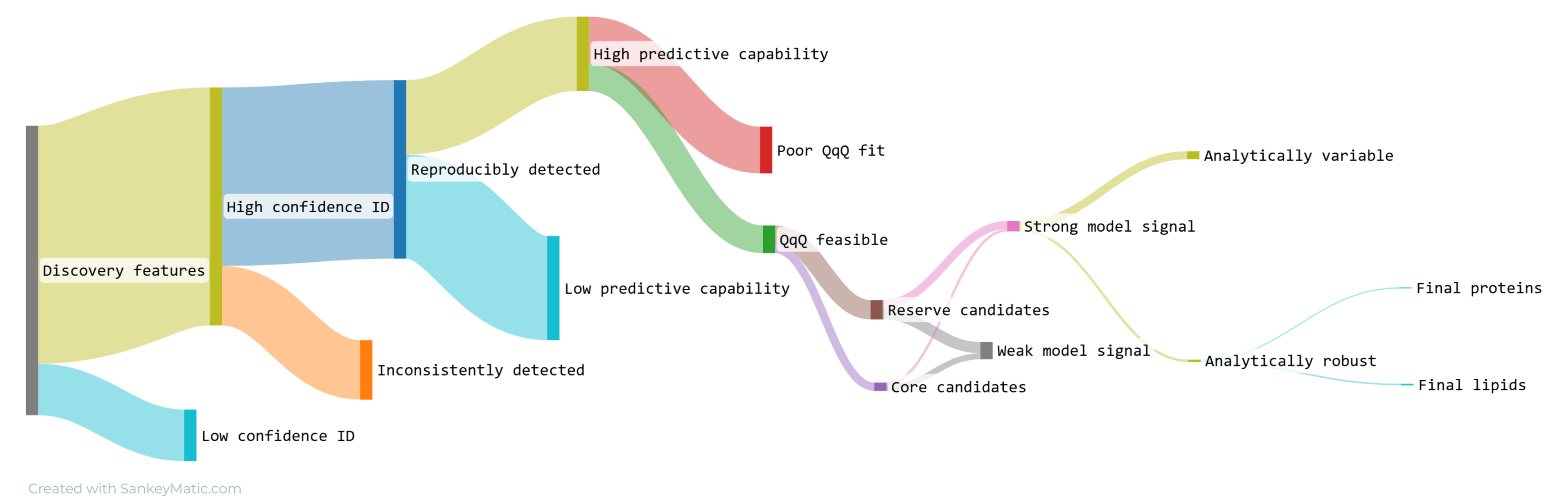
Candidate lipid + protein biomarkers identified in discovery were transferred to **targeted assays,** enabling **precise quantification** in a prospectively recruited, U.S.-based cohort – our intended use population.



Discovery	→	Targeted
Manual Immunoassay	→	**Automated, clinically validated immunoassay (cobas®)**
Discovery LC-HRMS	→	**Targeted LC-QqQ**
Retrospective, multi-source global biobanks	→	**Prospective, U.S. cohort (intended use)**

Biomarker Down-selection

Biomarker down-selection began with <1,000 features identified in discovery analyses (see AACR 2026 poster.) Features were iteratively filtered based on reproducibility, cross-cohort/model support, predictive performance, analytical robustness, and assay compatibility. This multi-stage process resulted in a final panel of 8 biomarkers (3 proteins, 8 lipids) optimized for clinical assay development.



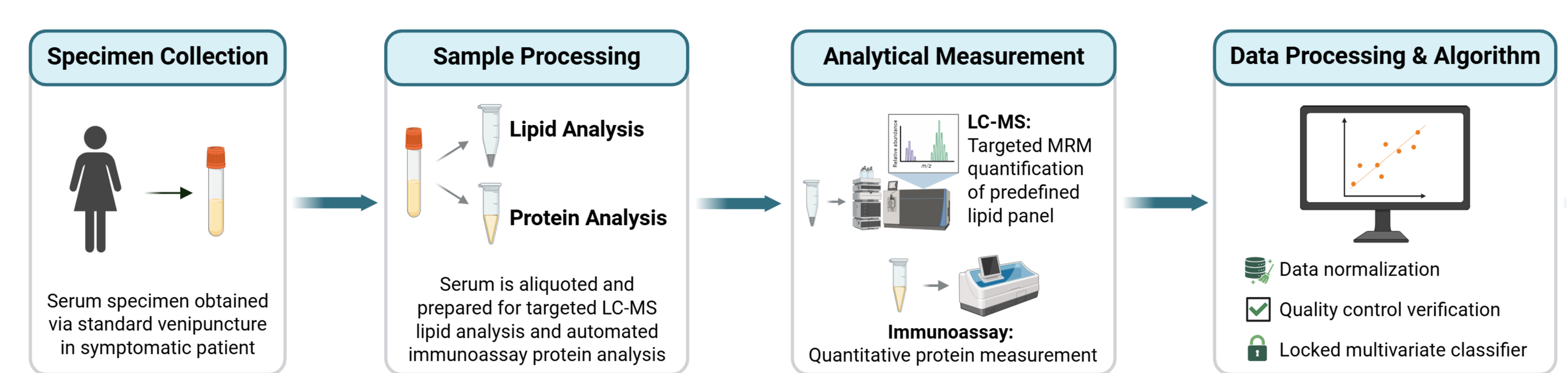
Discovery features → **High confidence ID**: Features with confident molecular identification.
High confidence ID → **Reproducibly detected**: Features consistently detected across samples.
Reproducibly detected → **High predictive capability**: Features supported across models and cohorts.
High predictive capability → **QqQ feasible**: Filtered for compatibility with targeted MS detection.
QqQ feasible → **Core / Reserve candidates**: Stratified features by priority and supporting evidence.
Core / Reserve → **Strong model signal**: Features with stable signal in repeated subsampled training (n=200).
Strong model signal → **Analytically robust**: Filtered based on precision and stability.
Analytically robust → **Final panel**: Final biomarkers based on combined performance.

A minimal multi-omic panel of just **8 lipids + 3 proteins** delivers powerful OC detection, especially at early stages.

Study Design + Methods

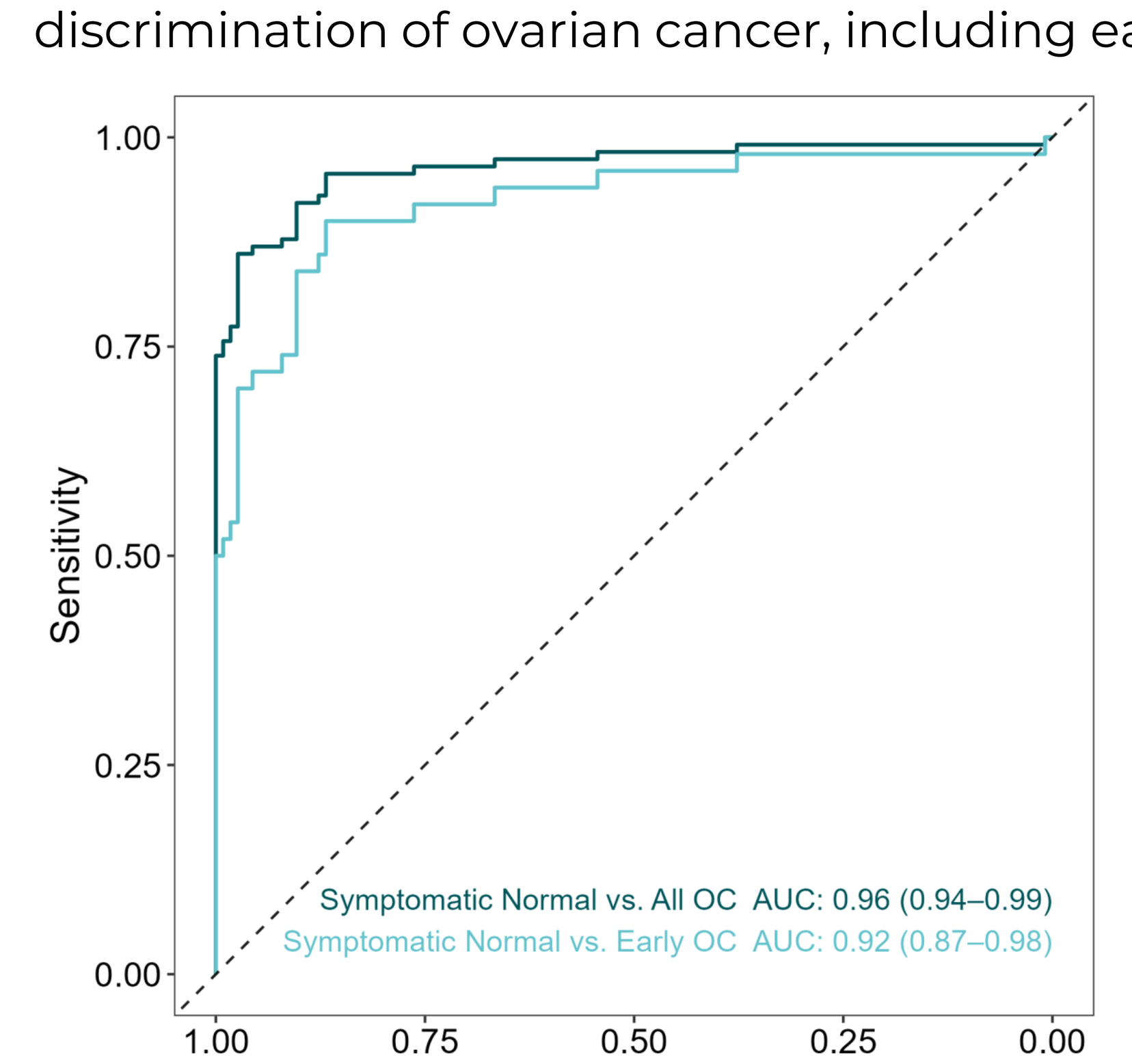
Group Description	Total
All OC	116
Early-Stage OC (I/II)	50
Late-Stage OC (III/IV)	66
All Controls	230
Benign gyn. conditions + masses	116
Symptomatic	114
Grand Total	**346**

- Targeted lipid + protein biomarkers evaluated from prior discovery[8]
- Prospective, multi-site U.S. cohort of symptomatic women
- Includes OC + controls (benign + longitudinally confirmed non-malignant)
- Treatment-naïve, blinded samples
- Supplemental samples from commercial source
- Integrated lipid + protein dataset analyzed using multivariable modeling



Clinical Performance in Intended-Use Population

A targeted multi-omic model (**8 lipids + 3 proteins**) demonstrates strong and consistent discrimination of ovarian cancer, including early-stage, in a symptomatic population.

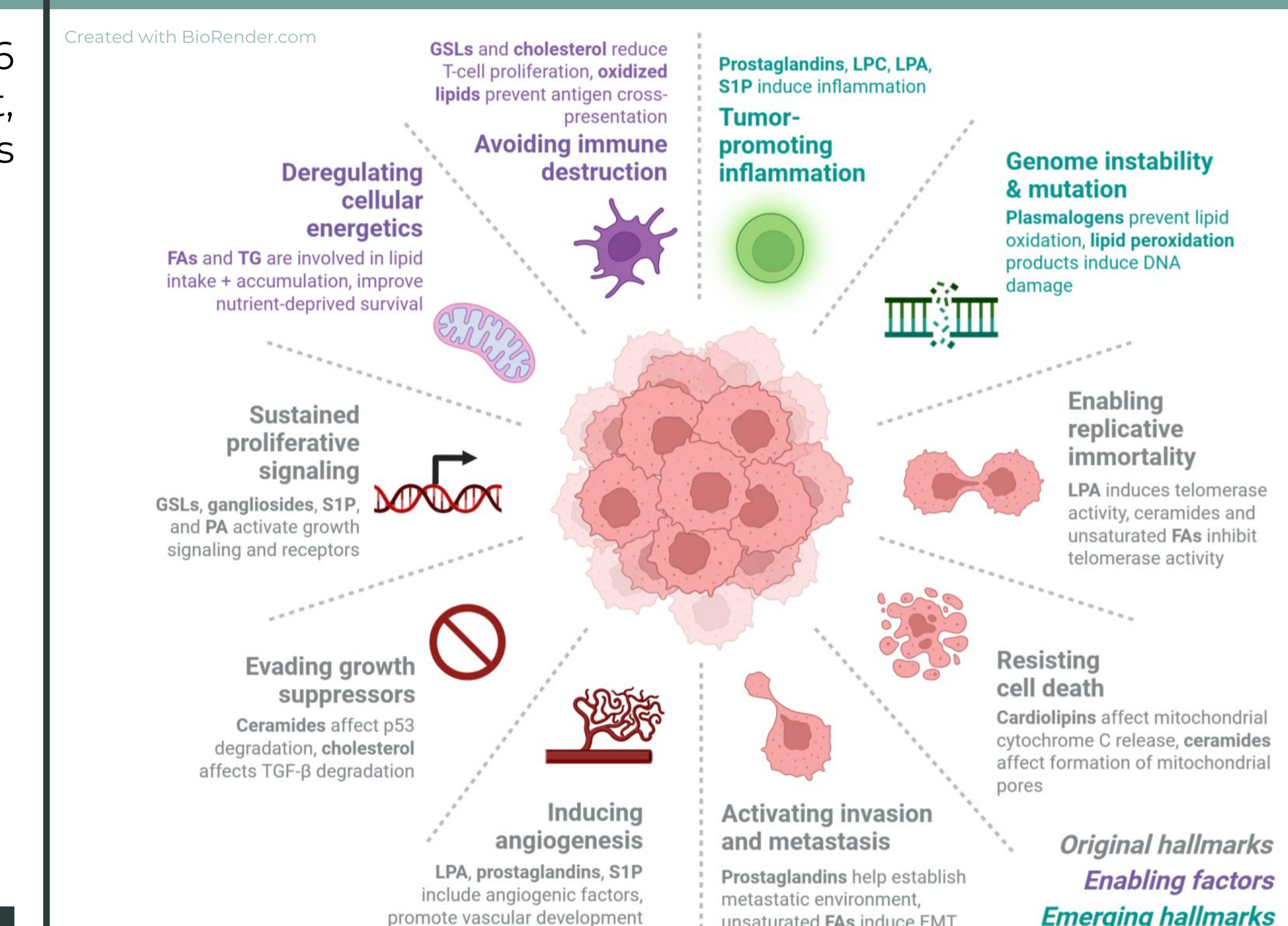


OC vs. Symptomatic
Sensitivity: 96.5%
Specificity: 80.6%

Early-stage OC vs. Symptomatic
Sensitivity: 92%
Specificity: 80.6%

Performance is maintained when translated to a targeted, clinical-grade assay, further supporting the performance from previous discovery cohorts (Giles & Culp-Hill et al. 2025)

Why Lipids? Biologically Relevant



- Tumors undergo metabolic reprogramming
- Reprogramming supports proliferation, invasion, and more
- Lipids...
  - are involved in multiple cancer hallmarks[9]
  - Reflect tumor metabolism and signaling
  - Capture biology not represented by protein biomarkers alone

Lipid metabolism is a core driver of tumor biology, not just downstream.

Why MS? Proven + Scalable

Mass spectrometry is already widely deployed in clinical labs[10,11]:

Endocrinology	Newborn Screening	Vitamins	Clinical Toxicology
Comprehensive hormone panels (congenital adrenal hyperplasia) **Cortisol** (Cushing's syndrome) **Sex steroid panels** (hypogonadism, PCOS)	**Newborn screening panels** (>30–60 inborn metabolic errors) **Acylcarnitine profiling** (fatty acid oxidation disorders) **Amino acid analysis** (phenylketonuria)	**Vitamin D** (deficiency diagnosis) **Vitamin B6** (nutritional, metabolic assessment) **Vitamin A + E** (malabsorption, deficiency disorders)	**Opioid + drug panels** (pain management) **Therapeutic drug monitoring** (anti-epileptics) **Toxicology** (overdose evaluation)

Compatible with standard clinical workflows and automation, providing robust and reproducible measurements.

Analytical Robustness

Analyte	Within-Day %CV	Between-Day %CV
Lipid #1	1.84%	0.59%
Lipid #2	0.79%	1.29%
Lipid #3	1.22%	2.43%
Lipid #4	1.59%	3.70%
Lipid #5	1.50%	2.64%
Lipid #6	1.37%	1.10%
Lipid #7	3.05%	3.42%
Lipid #8	4.80%	0.00%

The targeted lipid panel demonstrates high analytical precision (CV <5%) across runs, supporting reproducible measurement in a clinical workflow.

Panel features were selected in part for consistent, reliable quantification using targeted LC-MS.

Conclusions

- **High sensitivity detection of early-stage OC** in symptomatic individuals
- **Final panel defined: 8 lipids + 3 proteins**, translated into a targeted clinical-grade assay
- **Performance holds** in a prospective, real-world intended-use population
- **Establishes a clinically aligned, deployable multi-omic diagnostic**

References
[1] Siegel R.L., Kratzer, T.B.; et al. "Cancer Statistics" CA. cancer J. Clin. 2025, 75(1), 10 [2] Matteson K.A., Gunderson C., Richardson D.L. Committee Opinion No. 716 Summary: The Role of the Ob–Gyn in Early Detection of Epithelial OC in Women at Average Risk. Obstet. Gynecol. 2017;130:664–665. [3] Goff, B.A.; Matthews, B.; et al. "How are symptoms of OC managed?" Cancer 2011, 117(19), 4414 [4] Huepenbecker, S.P.; Sun, C.S. et al. "Factors impacting time to OC diagnosis based on classic symptom presentation in the US" Cancer 2021, 127(22), 4151 [5] Narayanan B, Buddenkotte T, Smith H, et al. Growth kinetics of high-grade serous ovarian cancer using longitudinal clinical data - implications for early detection. medRxiv. 2024. [6] Brown PO, Palmer C. The preclinical natural history of serous ovarian cancer: defining the target for early detection. PLoS Med. 2009;6(7):e1000114 [7] Soppe SE, Kuo TM, Bae-Jump VL, et al. Diagnostic timing and ovarian cancer survival. JAMA Network Open. 2026;9(3):e262434. [8] Giles BM; Culp-Hill R.; et al. Utilizing Serum-Derived Lipidomics with Protein Biomarkers and Machine Learning for Early Detection of OC in the Symptomatic Population. Cancer Research Communications 1 September 2025; 5 (9): 1516–1529. [9] Molendijk J, Robinson H, Djuric Z, Hill MM. Lipid mechanisms in hallmarks of cancer. Mol Omics. 2020 Feb 17;16(1):6-18. [10] Hristova J & Svinarov D (2022) Enhancing precision medicine through clinical MS platform, Biotechnology & Biotechnological Equipment, 36:1, 107-117 [11] Vogeser M, Habler K. Applications of mass spectrometry in the routine diagnostic medical laboratory – a status report 2025. Journal of Chromatography B, Volume 1273, 2026, 124958.