EARLY OVARIAN CANCER SCREENING BREAKTHROUGH

- **New data on IIQ's ovarian cancer test presented at the *American Society of Clinical Oncology Annual Meeting 2025* in Chicago**
- **IIQ's test achieved 77% sensitivity at 99.6% specificity for detecting ovarian cancer across all stages**
- **IIQ's test accurately detected all early-stage I and II cancers with no missed diagnoses**
- **With no ovarian cancer screening test in the market, IIQ will undertake further development to advance this screening test to market**
- **New provisional patent application filed to protect IP**

INOVIQ Limited (ASX: IIQ) is pleased to announce game-changing results from its EXO-OC™ ovarian cancer test presented at the **American Society of Clinical Oncology (ASCO) Annual Meeting** on 1 June 2025 in Chicago. The Poster titled *Early detection of ovarian cancer: An accurate high-throughput extracellular vesicle test* is copied below.

The test uses proprietary technology to isolate exosomes and combines multiple exosomal biomarkers in an AI-enhanced algorithm to enable the early and accurate detection of ovarian cancer. Since reporting high level results from a biomarker study validating protein biomarkers on 3 December 2024, INOVIQ worked with one of Australia's most highly rated computational scientists, Prof Amanda Barnard, to independently analyse its miRNA biomarker data and develop AI machine-learning algorithms to enhance the detection of early-stage ovarian cancer (Stage I and II).

The test is run on a fully-automated, high-throughput instrument suitable for clinical pathology laboratories, with capacity to process over 500 samples daily.

In a 532-sample, retrospective, blinded, case-control study, the test demonstrated **77% sensitivity** at **99.6% specificity** for detection of ovarian cancer across all stages, meeting the *clinically accepted performance criteria* for effective population screening. Importantly, the test accurately detected all Stage I and II ovarian cancers, with *no missed early-stage diagnoses*.

An Australian Provisional Patent Application (APPA) was filed on 29 May 2025 to secure intellectual property rights covering various protein and RNA biomarker combinations and methods for the exosome ovarian cancer test.

Ovarian cancer is usually asymptomatic in the early stages of disease. It is often diagnosed at a late-stage after symptoms have appeared resulting in a 5-year survival rate of only 49%. Early detection of ovarian cancer may increase 5-year survival from 30% to 93%.[1] Early detection may improve treatment options, health outcomes and survival rates for women diagnosed with ovarian cancer.

The next steps in the development and commercialisation of the test are:

- **Validation studies:** to confirm the test's specificity for ovarian cancer versus other cancer types and inflammatory conditions, and to evaluate its performance in high-risk populations.
- **Clinical and regulatory:** to seek Breakthrough Device Designation and pursue FDA approval via the Premarket Approval pathway. A clinical study will be conducted to assess the test's effectiveness for screening asymptomatic, average-risk women.
- **Commercialisation**: launch the test as a Laboratory Developed Test with a US laboratory partner, enabling early access to the screening test for early ovarian cancer detection. Following

[1] SEER 18 2011-2017: https://seer.cancer.gov/statfacts/html/ovary.html

regulatory approval, EXO-OC will be marketed as an In Vitro Diagnostic to support broader clinical adoption.

Prof Carlos Salomon, Director of UQ Centre for Extracellular Vesicle Nanomedicine and Member of INOVIQ Medical and Scientific Advisory Board, said: "*This study demonstrates that the EXO-OC ovarian cancer screening test can accurately identify the disease across all stages, with outstanding sensitivity and specificity that meet internationally recognised criteria. Transferring the test to a CLIA-certified laboratory in the United States will help accelerate the translation of this innovation into clinical practice, where it has the potential to save women's lives by enabling earlier diagnosis and intervention. This achievement is a significant step forward in the fight against the world's most lethal gynaecological cancer*."

Dr Leearne Hinch, CEO, added: "*Our EXO-OC test addresses a critical unmet need for early detection of ovarian cancer. INOVIQ is now positioned as a global leader in exosome technology, offering best-in-class exosome isolation and diagnostic solutions that can transform precision oncology. We are focused on the rapid commercialisation of our test, first as a Laboratory Developed Test and then as a regulatory approved In Vitro Diagnostic for ovarian cancer screening*."

Chairman, David Williams, said: "*Ovarian cancer is the eighth most common cancer in women. Globally, there were over 314,000 new cases and 207,000 deaths in 2020. There are no recommended screening tests for ovarian cancer in average-risk, asymptomatic women so it is very exciting if our test can offer a non-invasive, accurate and reliable diagnostic test for this significant unmet need*."

Authorised by the Company Secretary, Mark Edwards.

FURTHER INFORMATION

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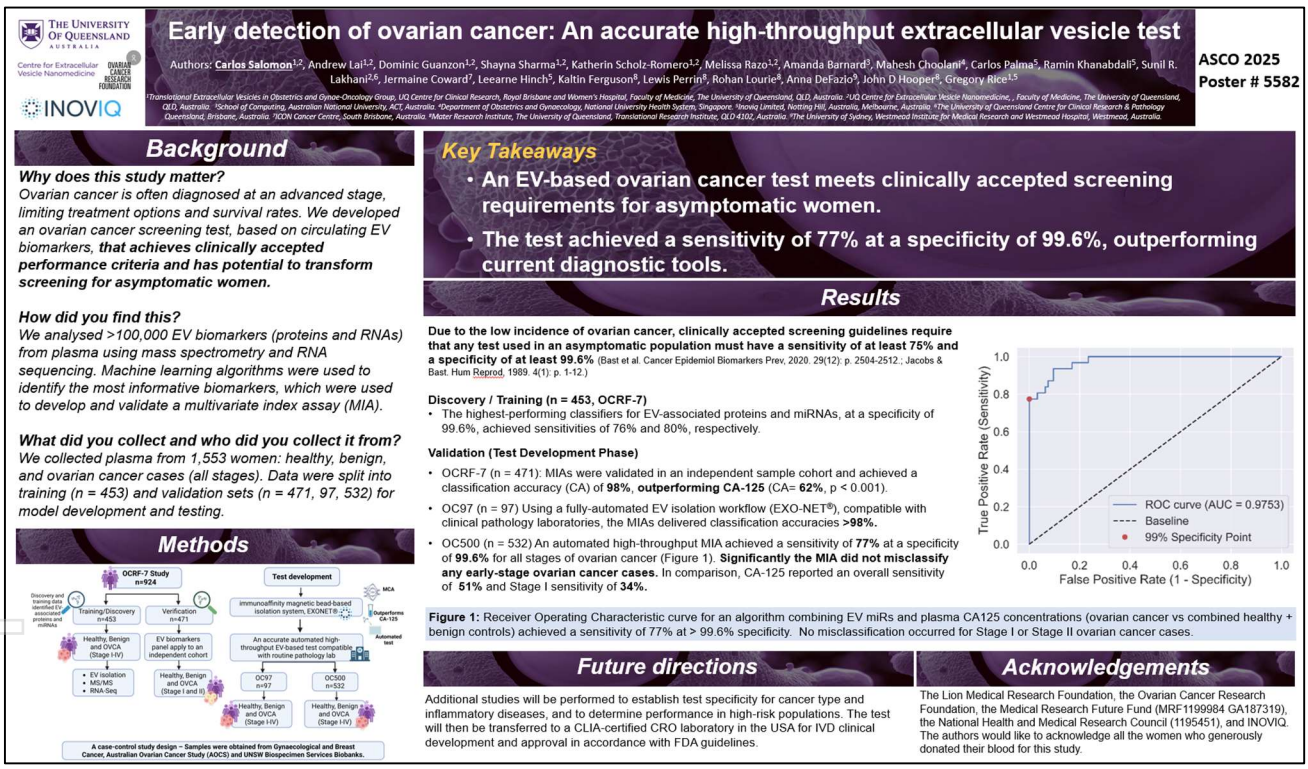
ABOUT INOVIQ LTD

INOVIQ Ltd (ASX: IIQ) is a leader in exosome technology pioneering the development of next-generation diagnostics and therapeutics to improve patient outcomes in cancer. Our product portfolio includes commercial-stage exosome isolation products, clinical-stage diagnostics for ovarian cancer screening and breast cancer monitoring, and a preclinical-stage CAR-exosome therapy for triple negative breast cancer. For more information on INOVIQ, visit www.inoviq.com.

ASCO POSTER: EARLY DETECTION OF OVARIAN CANCER

The Exosome Ovarian Cancer Test (EXO-OC™ Test) is in development for early detection of ovarian cancer in asymptomatic, average-risk women. INOVIQ's EXO-NET® technology was used to enable the biomarker discovery and translation of the exosomal test from bench-to-clinic. INOVIQ holds the option for an exclusive worldwide license to develop and commercialise the exosome-based early detection test for ovarian cancer from The University of Queensland (UQ) (ASX: 1 April 2022). UQ has received grants from the Ovarian Cancer Research Fund (OCRF), Medical Research Future Fund (MRFF) and the Lions Medical Research Foundation (LMRF) to develop the EXO-OC test because of the significant unmet need for detection of ovarian cancer.

The ASCO poster is below and the abstract is available in Appendix 1.



Early detection of ovarian cancer: An accurate high-throughput extracellular vesicle test

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ASCO 2025
Poster # 5582

Background

Why does this study matter?
Ovarian cancer is often diagnosed at an advanced stage, limiting treatment options and survival rates. We developed an ovarian cancer screening test, based on circulating EV biomarkers, ***that achieves clinically accepted performance criteria and has potential to transform screening for asymptomatic women.***

How did you find this?
We analysed >100,000 EV biomarkers (proteins and RNAs) from plasma using mass spectrometry and RNA sequencing. Machine learning algorithms were used to identify the most informative biomarkers, which were used to develop and validate a multivariate index assay (MIA).

What did you collect and who did you collect it from?
We collected plasma from 1,553 women: healthy, benign, and ovarian cancer cases (all stages). Data were split into training (n = 453) and validation sets (n = 471, 97, 532) for model development and testing.

Methods

Key Takeaways

- An EV-based ovarian cancer test meets clinically accepted screening requirements for asymptomatic women.
- The test achieved a sensitivity of 77% at a specificity of 99.6%, outperforming current diagnostic tools.

Results

Due to the low incidence of ovarian cancer, clinically accepted screening guidelines require that any test used in an asymptomatic population must have a sensitivity of at least 75% and a specificity of at least 99.6% (Bast et al. Cancer Epidemiol Biomarkers Prev. 2020. 29(12): p. 2504-2512.; Jacobs & Bast. Hum Reprod. 1989. 4(1): p. 1-12.)

Discovery / Training (n = 453, OCRF-7)
- The highest-performing classifiers for EV-associated proteins and miRNAs, at a specificity of 99.6%, achieved sensitivities of 76% and 80%, respectively.

Validation (Test Development Phase)
- OCRF-7 (n = 471): MIAs were validated in an independent sample cohort and achieved a classification accuracy (CA) of **98%**, **outperforming CA-125** (CA= **62%**, p < 0.001).
- OC97 (n = 97) Using a fully-automated EV isolation workflow (EXO-NET®), compatible with clinical pathology laboratories, the MIAs delivered classification accuracies **>98%.**
- OC500 (n = 532) An automated high-throughput MIA achieved a sensitivity of **77%** at a specificity of **99.6%** for all stages of ovarian cancer (Figure 1). **Significantly the MIA did not misclassify any early-stage ovarian cancer cases.** In comparison, CA-125 reported an overall sensitivity of **51%** and Stage I sensitivity of **34%.**

Figure 1: Receiver Operating Characteristic curve for an algorithm combining EV miRs and plasma CA125 concentrations (ovarian cancer vs combined healthy + benign controls) achieved a sensitivity of 77% at > 99.6% specificity. No misclassification occurred for Stage I or Stage II ovarian cancer cases.

Future directions

Additional studies will be performed to establish test specificity for cancer type and inflammatory diseases, and to determine performance in high-risk populations. The test will then be transferred to a CLIA-certified CRO laboratory in the USA for IVD clinical development and approval in accordance with FDA guidelines.

Acknowledgements

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APPENDIX 1: ASCO ABSTRACT

Early detection of ovarian cancer: An accurate high-throughput extracellular vesicle test

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Background:

The high mortality of Ovarian cancer (OC) has been attributed to late-stage diagnosis and the lack of an effective early detection strategy, particularly for asymptomatic women. In this study, we developed and validated a high-throughput OC detection test based on plasma extracellular vesicle (EV)-associated biomarkers.

Methods:

A case-control study was conducted to evaluate blood-borne EV-associated ovarian cancer biomarkers, including miRNAs, proteins, lncRNAs, miscRNAs, MtrRNAs, MttRNAs, rRNAs, scaRNAs, snRNAs, and tRNAs. Protein and RNA biomarkers were identified by mass spectrometry and RNA sequencing, respectively. Training (n=453) and independent test (n=471) sample sets were used to develop and validate a multivariate index assay (MIA). The MIA was further validated using a high-throughput, pathology laboratory compatible, EV isolation platform (EXO-NET) and two independent sample cohorts (n=97 and n=532). The classification accuracy, sensitivity and specificity of the MIA was compared to that of CA125 levels.

Results:

Discovery and Training phases - more than 100,000 EV-associated biomarkers were identified from 453 EV samples. The classification performance of these biomarkers was assessed using machine learning algorithms. EV-associated protein and miRNA biomarkers delivered the highest performing classifiers and, therefore, were used in subsequent MIA development and training. During the training phase, multivariate classification algorithms were validated using a 10-fold cross-validation method. The highest performing classifiers for EV-associated protein and miRNA, at specificity of 98%, achieved sensitivities of 90% and 82%, respectively. Validation phase: Locked classification algorithms (*i.e.* MIAs) were validated using two independent sample cohorts and reported classification accuracies of 92-98%, significantly outperforming CA-125 (CE = 62%, $p<0.001$). Automated high-throughput MIA – All stages OC: the best performing automated high-throughput MIA demonstrated an overall sensitivity of 92% (95% CI, 75–96%) and specificity of 93% (95% CI, 86–96%) for all stages of OC, Positive Predictive Value of 95% (CI, 93-96%) and Negative Predictive Value of 80% (CI, 76-89%) at 98% specificity (n=532). Stage I OC: Importantly, the MIA displayed a sensitivity of 90% (95% CI, 76–100%) and specificity of 96% (95% CI, 40%–99%) for stage I OC. While CA125 have an overall sensitivity for all stages of OC of 61% (95% CI, 53–69%), with a sensitivity of 44% for stage I (95% CI, 28–62%).

Conclusions:

In this study we report the development and validation of an accurate, automated high-throughput EV-based test for early detection of ovarian cancer. The test delivers significant improvements in sensitivity and specificity compared to CA-125, especially in detecting early-stage OC.