ASX Announcement

CLEO DIAGNOSTICS

CLEO Screening Test Meets Rigorous Performance Targets in First Proof-of-Concept Study

Highlights

- **Prototype Screening Test has met and exceeded its pre-defined performance thresholds in its first proof-of-concept study of 247 individuals**
- **In a cohort enriched with 62 Stage I cancers, being the most challenging target with the greatest survival benefit, CLEO's prototype achieved (sensitivity / specificity):**
  - **High-risk screening: 92.2% / 98.7% (*against minimum 90.0% / 90.0%)***
  - **General population screening: 75.0% / 100.0% (*against minimum 75.0% / 99.6%*)**
- **Outperformed gold-standard CA125 with Area Under the Curve (AUC) of 0.99 for Stage I and 0.98 for all-stage cancers**
- **Development now progressing to bridging and expanded cohort studies, ahead of evaluation in prospectively collected intended-use populations.**

21st October 2026: Ovarian cancer diagnostics company, **Cleo Diagnostics Limited** (**ASX:COV**) (**CLEO** or **the Company**) is pleased to announce that its prototype ovarian cancer screening test (**Screening Test**) has met or exceeded all pre-defined performance targets in its first proof-of-concept study.

This successfully completes the first stage of CLEO's screening development program (*Refer to ASX Announcement dated 24th September 2026*), and represents an important development milestone in CLEO's strategy to expand its ovarian cancer detection technology beyond pre-surgical triage and into screening.

There is currently no clinically adopted screening test for ovarian cancer.

First Development Hurdle Cleared with Successful Proof-of-Concept

CLEO's first-stage retrospective study was performed in a cohort of 247 women, comprising healthy individuals (n=87), women with benign gynaecological disease (n=67), and women with ovarian cancer (n=93); and included 62 cases of early (Stage I) ovarian cancer - representing the stage at which diagnosis has the greatest survival benefit.

To successfully clear this first hurdle, CLEO set minimum performance benchmarks informed by best-practice [1,2] for the following intended-use cases:

(i) **High-risk population screening:** Minimum 90% sensitivity and 90% specificity, targeting women with hereditary or genetic factors that predispose to ovarian cancer development;

(ii) **General population screening:** Minimum 75% sensitivity and 99.6% specificity, targeting asymptomatic women within the broader population.

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CLEO's Screening Test performance for (i) early-stage cancer and (ii) all-stage cancer is summarised below:

Intended Target Population	High Risk Population (sensitivity % / specificity %)	General Population (sensitivity % / specificity %)
Minimum requirement	90% / 90%	75.0% / 99.6%
Stage I cancer detection	**92.2% / 98.7%**	**75.0% / 100.0%**
All-stage cancer detection	**90.2% / 97.4%**	**75.8% / 100.0%**

Table 1: CLEO Prototype Screening Test Performance. *Sample size n=247, including 62 Stage I cancers. Results are estimates from a retrospective proof-of-concept cohort and require confirmation in larger, independent and intended-use populations.*

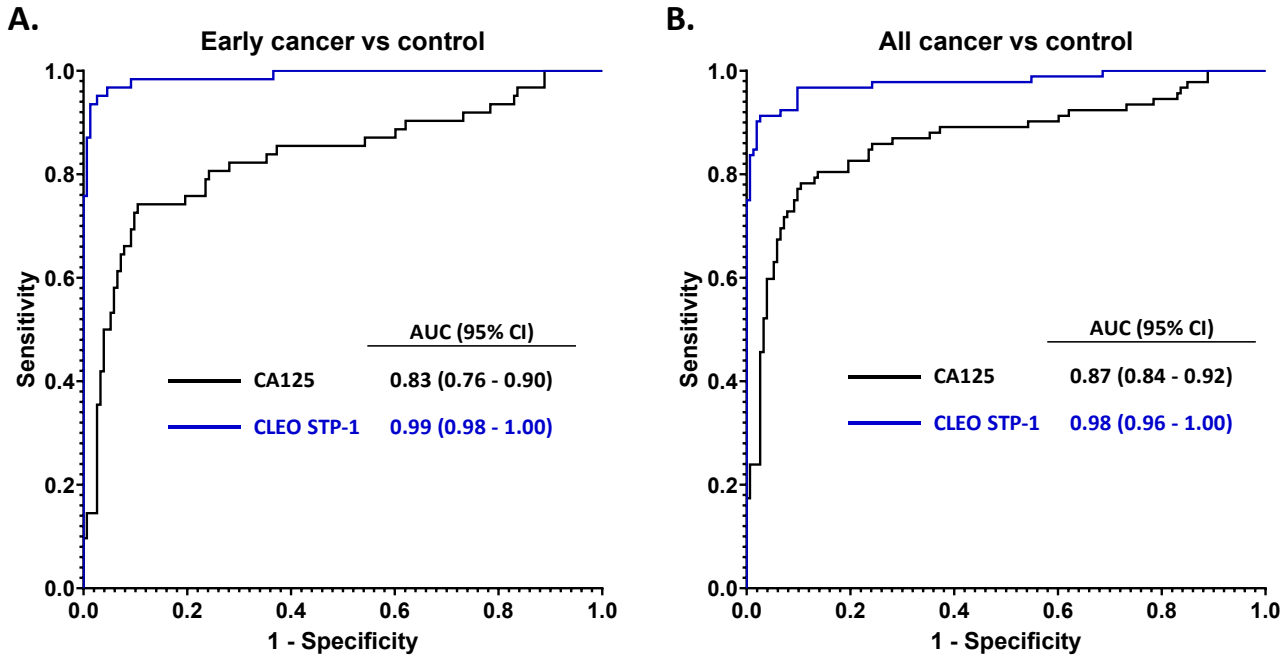

Figure 1: ROC curves for CLEO's prototype screening test (STP-1). *Performance for discrimination from controls of (A) early (Stage I) cancers, and (B) all-stage cancers. The current clinical gold-standard biomarker CA125 is shown for comparison (black line). AUC is shown with 95% confidence intervals. Sample size n=247, including 62 Stage I cancers.*

Next Steps to Advance CLEO's Screening Development Program and Strategy

These results provide the first evidence that CLEO's biomarkers may have utility in population screening, beyond its lead Pre-Surgical Ovarian Cancer Test, currently progressing towards FDA submission early next year. The Company's prototype test met the performance benchmarks for both high-risk and general population screening, including for early (Stage I) cancers - the key clinical target for a viable screening test. Screening addresses asymptomatic women, a substantially larger population than pre-surgical triage; and strategically positions CLEO across the ovarian cancer screening, triage and recurrence monitoring space.

CLEO will now advance to the next stage of its screening development pathway, to test the robustness, reproducibility and potential clinical performance of the prototype - including in the low-prevalence setting of general population screening.

Development will proceed in parallel with CLEO's near-term FDA submission for its pre-surgical Triage test. Staged analyses will continue as follows:

1. **Initial proof-of-concept studies:** *COMPLETED*
2. **Bridging and expanded cohort studies**: Next-stage testing in a larger independent cohort to confirm initial performance estimates, improve statistical power and assess reproducibility across broader patient populations, and to establish that sample collection, processing and storage conditions do not affect assay performance.

3. **Prospective intended-use population evaluation:** Evaluation using prospectively collected samples to assess performance representative of real-world screening applications. These samples have already been collected and include those from the UK Collaborative Trial of Ovarian Cancer Screening (**UKCTOCS**) and Prostate, Lung, Colorectal and Ovarian (**PLCO**) Cancer Screening Trial cohorts.

CLEO also intends to submit the results of its screening development program for publication in peer-reviewed scientific and clinical literature.

CLEO's Chief Executive Officer, Dr Richard Allman, commented:

> *"We set a demanding target before we began, informed by best-practice, precisely so that clearing it would provide meaningful progress. Meeting and exceeding those benchmarks for both high-risk and general population screening with a single assay – particularly for early, Stage I cancers, the most challenging and clinically important target – gives us confidence that the underlying biology and panel design are sound.*
>
> *Triage remains our near-term priority and our path to market. Screening is the larger long-term opportunity, and this encouraging result is the first step towards it.*
>
> *Detecting ovarian cancer at its earliest stages remains one of the greatest unmet needs in women's healthcare. The next stage is about scale and statistical power, followed by evaluation in a real-world screening population."*

References:
[1] DOI: 10.1158/1078-0432.CCR-15-2750
[2] DOI: 10.1007/978-3-540-37696-5_9

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This ASX announcement was authorised for release on behalf of the Cleo Diagnostics Ltd Board.

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About Cleo Diagnostics Ltd ASX:COV

Cleo Diagnostics (ASX:COV) is an Australian medical technology company developing a simple blood test for the early and accurate detection of ovarian cancer – the most lethal gynaecological cancer, with 51% of patients dying within five years, primarily due to late diagnosis and the lack of effective screening tools. Each year, hundreds of thousands of women are diagnosed only after the disease has advanced, highlighting a critical unmet need for earlier detection.

CLEO's technology is based on a panel of proprietary biomarkers, supported by over 15 years of scientific research and development, and is the subject of several provisional, pending and granted patents. CLEO's marker panels discriminate strongly between benign, malignant and healthy samples and are being developed for deployment across the ovarian cancer diagnostic space.

The Company is executing a staged development strategy, starting with a pre-surgical triage test, then expanding into recurrence monitoring and population screening – creating clear value inflection points along the ovarian cancer detection pathway. CLEO is currently conducting the pivotal clinical trial for its pre-surgical triage test with FDA submission and commercial launch expected in CY2027, reinforcing its goal to redefine the standard of care and enable earlier, smarter, life-changing diagnosis for women worldwide.