ASX Announcement

CLEO Establishes U.S. Lab Infrastructure Ahead of Clinical Validation

Highlights

- **CLEO has commenced preparations for Clinical Validation (CV), the final major clinical testing program supporting its FDA 510(k) submission**
- **Clinical testing infrastructure established at CLIA-certified laboratory, Asuragen, with inter-laboratory reproducibility studies underway**
- **CV program will involve testing ~1,470 samples across three study populations to evaluate clinical performance of CLEO's Pre-Surgical Ovarian Cancer Test**
- **Testing anticipated to commence within the next month, supporting CLEO's planned FDA 510(k) submission in H1 CY2027.**

12th November 2026: Ovarian cancer diagnostics company, **Cleo Diagnostics Limited** (**ASX:COV**) (**CLEO** or **the Company**) is pleased to announce that the U.S. laboratory infrastructure required for Clinical Validation (**CV**) of its Pre-Surgical Ovarian Cancer Test has been established. CV testing is anticipated to commence within the next month following receipt of test kits at the laboratory. Testing will be carried out with Asuragen, the CLIA-certified U.S. laboratory of Bio-Techne (**NASDAQ: TECH**) (*refer to ASX Announcement dated 10 September 2026*).

CV represents the final major clinical testing program in CLEO's regulatory pathway and will establish the clinical performance of the Company's commercial assay in its intended-use population.

Establishing U.S. Clinical Testing Readiness

Three of Bio-Techne's Ella™ automated immunoassay instruments have recently been installed and commissioned at Asuragen, establishing the laboratory infrastructure required to undertake clinical testing of CLEO's assay.

Inter-laboratory reproducibility studies are now underway to demonstrate consistent assay performance between CLEO's Melbourne facility and Asuragen in the U.S, allowing direct comparison of results generated across both laboratories using the same manufacturing batch. Demonstrating reproducibility across laboratory environments is an important step in establishing readiness for clinical testing and supporting the reliability of the clinical data that will underpin CLEO's regulatory submission.

Clinical Validation Program

CLEO's CV program will comprise the following three studies involving approximately 1,470 samples:

- **Pivotal Clinical Performance Study (~600 samples):** Utilising prospectively collected blood samples from CLEO's pivotal U.S. clinical trial conducted across 19 sites, this study will evaluate the test's ability to distinguish between benign and malignant ovarian disease in women presenting with a suspicious ovarian mass.
- **Clinical Specificity Study (~570 samples):** Evaluating samples from patients with non-ovarian benign and malignant conditions to assess potential confounding factors that may influence test results and inform appropriate product labelling.
- **Healthy Individuals Study (~300 samples):** Evaluating samples from healthy women to establish the expected distribution of test scores in a population without known disease.

Together, these studies will generate clinical performance data, including sensitivity and specificity, within its intended clinical application. The resulting clinical dataset, together with results from CLEO's ongoing AV program will form the core evidence package supporting the Company's planned FDA 510(k) submission.

Remaining Pathway to FDA Submission

With AV now underway and CV set to commence shortly, CLEO's remaining major milestones prior to FDA submission are:

- Completion of Analytical Validation, including testing across three independently manufactured production batches;
- Finalisation of commercial assay algorithm;
- Completion of Clinical Validation, including pivotal clinical trial and control sample testing;
- Clinical data analysis and trial results; and
- FDA 510(k) submission.

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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 – a disease with the highest five-year mortality rate of all cancers affecting women, 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 patented technology is based on the CXCL10 biomarker, supported by over 15 years of scientific research and development. CXCL10 is produced early and at high levels in ovarian cancer but is largely absent in benign disease, making it a powerful discriminator between malignant and non-malignant growths.

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