ASX Announcement

CLEO Selects CLIA Certified Laboratory for Pivotal U.S. Clinical Validation

Highlights

- **CLEO has engaged CLIA-certified U.S. laboratory, Asuragen, to assist in executing its pivotal Clinical Validation program for its Pre-Surgical Ovarian Cancer Test**
- **The program will generate clinical performance data from over 1,300 samples to establish the sensitivity, specificity, PPV and NPV of CLEO's test**
- **Extends CLEO's strategic relationship with Bio-Techne across commercial test kit manufacture, the Ella™ diagnostic platform and pivotal U.S. clinical testing.**

10th September 2026: Ovarian cancer diagnostics company, **Cleo Diagnostics Limited** (**ASX:COV**) (**CLEO** or **the Company**) is pleased to announce it has executed a Statement of Work (**SOW**) with Asuragen, the Clinical Laboratory Improvement Amendments (**CLIA**) certified U.S. clinical laboratory of Bio-Techne Corporation (**NASDAQ: TECH**), to conduct Clinical Validation (**CV**) for CLEO's Pre-Surgical Ovarian Cancer Test.

The engagement further strengthens CLEO's strategic relationship with Bio-Techne, integrating commercial test kit manufacture, the Ella™ diagnostic platform, and execution of the Company's pivotal U.S. clinical testing program through Asuragen.

The appointment of Asuragen follows the recent receipt of the first production batch of test kits from Bio-Techne (*refer to ASX announcement dated 3rd September 2026*), which are progressing through internal verification ahead of formal commencement of Analytical Validation (**AV**).

Asuragen will conduct the clinical testing required to evaluate CLEO's commercial test performance in the intended patient population and relevant control groups. The program will generate key clinical performance data, including sensitivity, specificity, positive predictive value (**PPV**) and negative predictive value (**NPV**).

Clinical validation is a critical step in demonstrating that CLEO's commercial assay performs reliably in its intended clinical setting. Together with the analytical performance data generated through AV, the results of the CV program will form the core evidence base supporting the Company's planned FDA 510(k) submission targeted for 1H CY2027.

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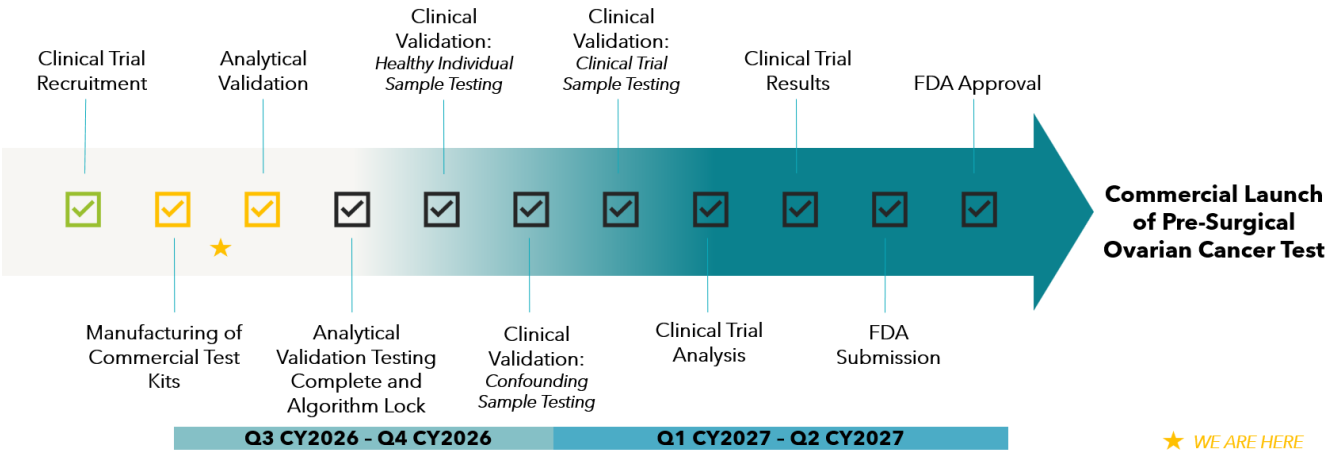
Pivotal Clinical Validation Program

The program comprises three principal studies:

- **Pivotal Clinical Performance Study:** ~600 samples, collected through CLEO's U.S. pivotal clinical trial across 19 sites, assessing the test's ability to distinguish benign from malignant ovarian disease.
- **Clinical Specificity Study:** ~570 samples from patients with non-ovarian benign or malignant conditions, to demonstrate the specificity of CLEO's test.
- **Healthy Individuals Study:** ~300 samples from healthy individuals to establish expected value ranges in a non-disease population.

Remaining Pathway to FDA 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.