

CLEO Commences Analytical Validation Ahead of FDA Submission

Highlights

- **Analytical Validation (AV) has commenced following receipt of the first batch of test kits from Bio-Techne and completion of the required pre-validation activities**
- **Marks the start of formal regulatory testing of CLEO's assay, generating critical analytical performance data to support the Company's FDA 510(k) submission**
- **AV will evaluate three independently manufactured batches to demonstrate assay precision, reproducibility, manufacturing consistency and analytical robustness**
- **In parallel to AV, CLEO will progress to Clinical Validation to test its pivotal U.S. clinical trial and control samples.**

13th October 2026: Ovarian cancer diagnostics company, **Cleo Diagnostics Limited (ASX:COV) (CLEO or the Company)** is pleased to announce the commencement of Analytical Validation (AV) of its Pre-Surgical Ovarian Cancer Test, marking the first formal regulatory study of CLEO's commercial assay ahead of its planned FDA 510(k) submission in H1 CY2027.

The commencement of AV marks CLEO's transition from assay development and optimisation into formal validation testing under a prescriptive FDA framework. The program will establish the analytical performance of the test and generate the critical dataset required to support subsequent Clinical Validation (**CV**) and the Company's FDA submission.

Commencement follows receipt of the first production batch of 125 test kits manufactured by Bio-Techne (**NASDAQ:TECH**) (refer to ASX Announcement dated 3rd September 2026) and completion of CLEO's internal documentation and pre-validation activities required prior to formal testing.

Analytical Validation Program

As part of AV, CLEO will evaluate three independently manufactured production batches of its commercial test kits. Testing will assess key analytical performance characteristics across the batches to demonstrate the precision, reproducibility, manufacturing consistency and overall analytical robustness of the commercial assay, generating the analytical evidence required to support progression into CV.

AV is being conducted predominantly in-house using Bio-Techne's Ella™ automated immunoassay platform, with the resulting data forming an important component of the Company's planned FDA 510(k) submission. The second and third batch of test kits are estimated to be received in November 2026 and AV is expected to take ~3 months.

Cleo Diagnostics Ltd ASX:COV

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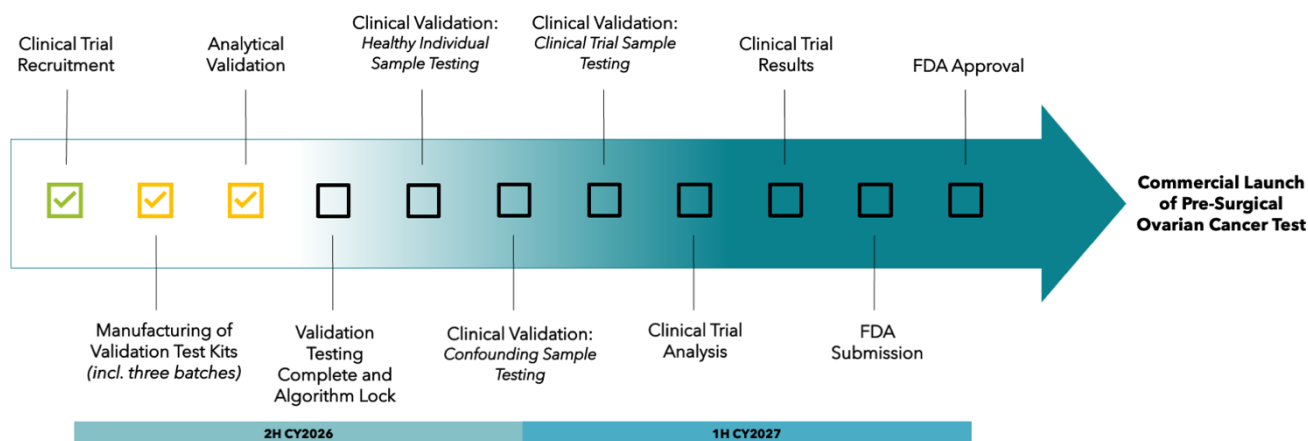
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Chief Executive Officer and Executive Director **Dr Richard Allman**
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Remaining Pathway to FDA Submission

With AV now underway, CLEO's remaining major milestones prior to FDA submission are:

- Analytical Validation (including testing of three production batches);
- Finalisation of the commercial assay algorithm;
- Clinical Validation (including testing of pivotal clinical trial and control samples);
- Clinical data analysis and trial results; and
- FDA 510(k) submission.



-ENDS-

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.

