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OptraSCAN receives US FDA 510(k) clearance for digital pathology system

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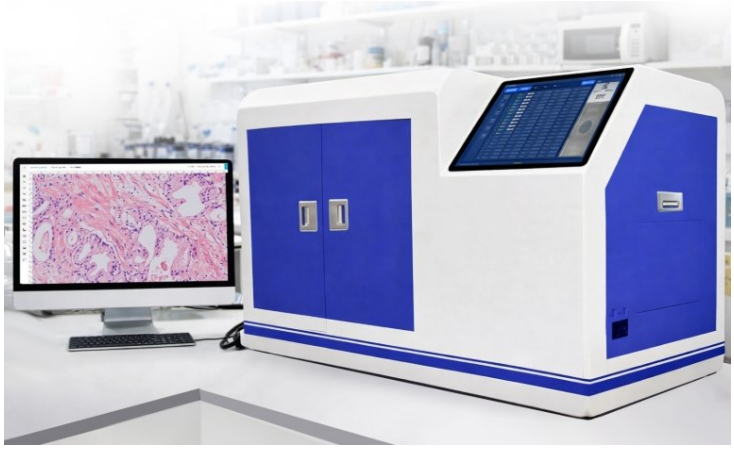
Supports pathologists in the review and assessment of HER2 expression in clinical practice



OptraSCAN, Inc., a California-headquartered digital pathology and image analysis company in which Molbio Diagnostics acquired a majority stake in 2025, has received US Food and Drug Administration (FDA) 510(k) clearance (K260755) for the OptraSCAN System.

The clearance covers the integrated OptraSCAN System comprising the OS-Ultra Whole Slide Scanner, a color display monitor, and a workstation running the company's ImagePath Image Management Software, including HER2 Image Analysis Software. Together, the system supports pathologists in the review and assessment of HER2 expression in clinical practice.

HER2 assessment plays a critical role in breast cancer characterisation and therapeutic decision-making. As pathology laboratories worldwide continue to transition towards digitised workflows, image analysis technologies are increasingly adopted to support standardisation, reproducibility, and efficiency in pathology review processes.

Commenting on the significance of the development for the global pathology community, Dr Reena Nakra, Chief Scientific Officer, Dr Lal PathLabs, said, "Digital pathology is becoming an increasingly important part of modern pathology. We have had the opportunity to work with OptraSCAN and regulatory milestones such as US FDA clearance provide additional confidence in the quality of its digital pathology platform and the clinical robustness of this technology. This milestone is an encouraging step forward for the continued adoption of digital pathology."