

## **An Ai-Based Solution for Cancer Detection: First Deployment in Clinical Routine in a US Pathology Lab**

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### **Background:**

Prostate cancer is a major cause of cancer-related deaths in men, with a complex diagnosis and insufficient diagnostic reproducibility, at a period when there is a growing shortage in pathologists. Thus, deployment of AI-based solutions that can accurately detect and grade cancer, as well as multiple additional features, can help support pathologists in their diagnostic tasks. CorePlus Servicios Clínicos y Patológicos in Puerto Rico, a leading pathology and clinical laboratory, handles 53,000 accessions annually, of which ~6.4% are prostate core needle biopsies (PCNBs), with ~46% diagnosed with cancer.

### **Methods:**

An AI-based solution (Galen Prostate) has been developed to identify tissue structures and morphological features within whole-slide-images of prostate core needle biopsies, having been trained on >1M image samples from multiple institutes manually annotated by senior pathologists. The solution detects and grades prostate cancer in addition to other features, such as perineural invasion, high-grade PIN and inflammation. At CorePlus, this AI-based solution was deployed and integrated into the digital pathology workflow as a quality control system. The system raises alerts for discrepancies between the algorithmic analysis and the pathologist, prompting a second human opinion.

### **Results:**

101 retrospective prostate cases from CorePlus comprising a total of 1,279 H&E slides were analyzed by the algorithm, demonstrating high specificity and sensitivity for cancer detection (96.9% and 96.5%, respectively), and an AUC of 0.901 for differentiating low-grade (Gleason 6) from high-grade (Gleason 7+) cancer. Following 10 months clinical use, >2,200 PCNB cases (>29,000 H&E slides) were processed and the reports of 51 (2.25%) of these cases were revised as a result of alerts raised by the AI solution, that were reviewed and accepted by pathologists.

### **Conclusions:**

An AI-based QC system is extremely useful for diagnostic accuracy and safety. To the best of our knowledge, this is the first AI-based digital pathology diagnostic system deployed in a US lab and used in routine clinical practice.