



Objective Precision in the Caribbean: CorePlus and the Future of AI-Driven Pathology

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Executive Summary

CorePlus is a leading private pathology laboratory in Puerto Rico, serving patients across the island under the same U.S. regulatory framework as laboratories on the mainland. Following a six-year history of fully digital workflows, CorePlus deployed the AIxURO algorithm to uncover difficult-to-detect atypical cells, significantly reducing slide reporting times by 84%.



Standardizing the Workflow

CorePlus processes approximately 3,500 urine cases (7,000 slides) per year using the SurePath preparation method. The laboratory uses 3DHISTECH P1000 scanners to digitize their slides. Uniquely, these scanners utilize water immersion technology, injecting water during the scanning process to produce exceptionally crisp, high-quality digital images

Strategic Drivers

To understand the integration of AI-assisted digital cytology at CorePlus, it is important to examine the laboratory's overarching strategic vision. CorePlus embarked on this journey driven by a foundational goal to improve patient care through the introduction of transformative and disruptive technologies.

Their pursuit of innovation in artificial intelligence-aided diagnostics was motivated by several operational and clinical objectives:

- **Operational Scalability:** The need to enable laboratory growth and effectively handle routine caseload increases.
- **Workflow Continuity:** The technological infrastructure to successfully connect remote pathologists.
- **Clinical Excellence:** A dedication to empowering the pathologists at CorePlus to act as industry leaders in their field.

Validating AI in a Real-World Setting

The laboratory conducted a comprehensive validation study involving 117 cases across a wide range of diagnostic categories (benign, AUC, HGUC). The results showed:

- **High Concordance:** A 93.7% concordance rate between manual microscopy and the AI-driven evaluation.
- **Statistical Robustness:** High sensitivity (90.4%) and specificity (94.1%), demonstrating the AI's ability to accurately identify HGUC cases while maintaining low false-positive rates.

A separate study conducted by CorePlus and presented at the 2024 Digital Pathology Association (DPA) meeting highlighted that utilizing the AIxMed algorithm reduced total reporting time by approximately 84%. Currently, CorePlus maintains a conservative, hybrid workflow: cytologists perform primary screening on physical microscopes, while the cytopathologist uses the AIxURO digital platform to analyze quantitative metrics, review the slides, and sign out the final report.



Revolutionizing Bladder Cancer Diagnosis: Insights on Urine Cytology from a Digital Pathology Laboratory

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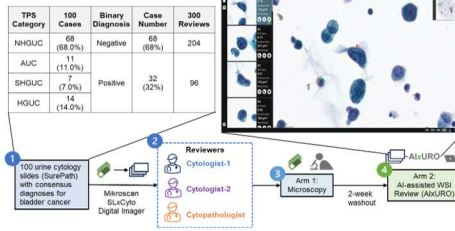
Pathology Visions 2024

Highlights

- Compare the diagnostic performance and efficiency of an AI-assisted digital urine cytology system with conventional microscopy for bladder cancer diagnosis.
- Demonstrate feasibility and potential clinical utility of AI-assisted digital cytology in a real-world reference laboratory setting.
- Underscore the significant time savings achieved with AI assistance, particularly for the high volume of negative cases.

Background

- Digital pathology has rapidly advanced, particularly in converting histology slides into whole-slide images (WSIs) for AI applications, achieving accuracy similar to conventional microscopy while improving workflow efficiency.
- However, digital cytology, especially for urine samples, has lagged behind histology in its development, prompting the need for innovative advancements in this field.
- To address this gap, an AI-assisted digital urine cytology system (AlxURO) was developed, combining a digital imager and a disease-specific AI algorithm to facilitate accurate bladder cancer diagnosis by identifying candidate cancer cells for pathologists and cytologists.
- The study compares the performance and efficiency of AlxURO with conventional microscopy in a fully digital pathology laboratory, underlining the potential of AI to enhance diagnostic accuracy and efficiency, particularly when users are trained and experienced in digital pathology.



Modality	Microscopy				AlxURO				Difference (AlxURO - Microscopy)
	Cytologist-1	Cytologist-2	Pathologist	All Three	Cytologist-1	Cytologist-2	Pathologist	All Three	
Sensitivity	90.6 (29/32)	87.5 (28/32)	81.3 (26/32)	86.5 (83/96)	90.6 (30/33)	84.4 (27/32)	90.6 (29/32)	88.5 (85/96)	2.0
Specificity	98.5 (87/88)	94.1 (84/89)	100 (88/88)	97.6 (199/204)	98.5 (87/88)	91.2 (82/90)	91.2 (82/90)	93.6 (191/204)	-4.0
PPV	96.7 (29/30)	87.5 (28/32)	100 (26/26)	94.3 (83/88)	96.7 (29/30)	81.8 (27/33)	82.9 (29/35)	86.7 (85/98)	-7.6
NPV	93.7 (87/93)	94.1 (84/89)	91.9 (84/91)	93.9 (199/212)	93.7 (87/93)	82.5 (82/67)	85.4 (82/65)	94.6 (191/202)	0.7
Accuracy	96.0 (86/100)	92.0 (90/100)	94.0 (84/100)	94.0 (282/300)	96.0 (86/100)	89.0 (89/100)	91.0 (91/100)	92.0 (276/300)	-2.0
Mean Time for All Cases (sec)	92.40	127.50	31.40	83.8	11.9	11.9	17.0	13.6	-70.2 (-83.8%)
Mean Time for (+) Cases (sec)	157.5	116.6	50.3	108.2	25.9	21.7	31.3	12.4	-95.8 (-88.5%)
Mean Time for (-) Cases (sec)	61.8	132.6	22.6	72.3	5.3	7.3	10.3	7.7	-84.6 (-89.3%)

NHGUC: Negative for High-Grade Urothelial Carcinoma; AUC: Atypical Urothelial Cells; SHGUC: Suspicious for High-Grade Urothelial Carcinoma; HGUC: High-Grade Urothelial Carcinoma
PPV: Positive Predictive Value; NPV: Negative Predictive Value

Results

- AlxURO showed comparable performance to conventional microscopy in bladder cancer diagnosis, with a 2.0% increase in sensitivity and maintained high NPV, indicating that the AI-assisted system effectively supports accurate clinical diagnoses in a digital pathology setting.
- Reviewers using AlxURO significantly reduced their reporting time, saving 83.8% overall, compared to the microscopy method.
- The consistency of reporting times across reviewers improved with AlxURO (11.9-17.0 seconds), compared to the broader (31.4-127.5 seconds) observed with microscopy.
- For negative cases, AlxURO reduced reporting time to just 10% of what was required with microscopy, a crucial improvement given that most urine cytology cases are negative, leading to substantial enhancements in laboratory efficiency.

Take-Home Messages



Link here: [Pathology Visions 2024](#)

Benefits Beyond

- Efficiency:** The 84% reduction in slide reporting time dramatically improved laboratory throughput.
- High Concordance:** First-quarter data analyzing 700 cases showed almost perfect agreement between cytologist manual screening and the pathologist's AI-assisted diagnosis.

AixURO in Real Life (695 cases)



Cytologist Diagnosis	Pathologist Diagnosis				
	UNSAT	NHGUC	AUC	SHGUC	HGUC
UNSAT	5	0	0	0	0
NHGUC	1	654	8	0	0
AUC	0	13	2	1	0
SHGUC	0	0	3	1	0
HGUC	0	0	0	2	4

 Agreement

- Benign - 654
- Abnormal - 13

 Discordance

- Minor - 27
- Major - 0

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- **Catching Outliers:** The algorithm successfully flags highly atypical cells that human screeners may miss. In a notable case, AixURO identified deeply clustered atypical cells with large nucleoli; subsequent immunohistochemistry (NKX 3.1) revealed it to be a prostatic adenocarcinoma extending into the prostatic urethra, rather than a standard urothelial carcinoma.
- **Educational Impact:** CorePlus has become a rotation site for the University of Puerto Rico's pathology residency program, exposing future pathologists to advanced AI technologies.
- **True Partnership:** The successful implementation was attributed to a close collaborative relationship with the AI development team.

Conclusion

CorePlus has demonstrated that private laboratories can lead the way in adopting advanced AI technology. By prioritizing patient care and investing in digital tools, the lab has achieved unprecedented efficiency and diagnostic precision.

Author: Based on the presentation by Juan C. Santa Rosario, M.D., Chief Medical Officer.

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