

Implementing an AI-assisted digital system in real-world practice: the IMP Diagnostics experience.

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Background

Digital Pathology systems offer a transformative opportunity to improve diagnostic accuracy and streamline workflows. Despite these benefits, integrating such systems into clinical practice is complex, involving changes in processes, infrastructure, and training. We present a roadmap for the successful implementation of the **Genius™ Digital Diagnostics System** (Hologic), an advanced AI platform for **cervical cancer screening**, detailing strategic planning, execution, and adaptive measures taken to overcome real-life challenges in a high-volume Pathology laboratory.

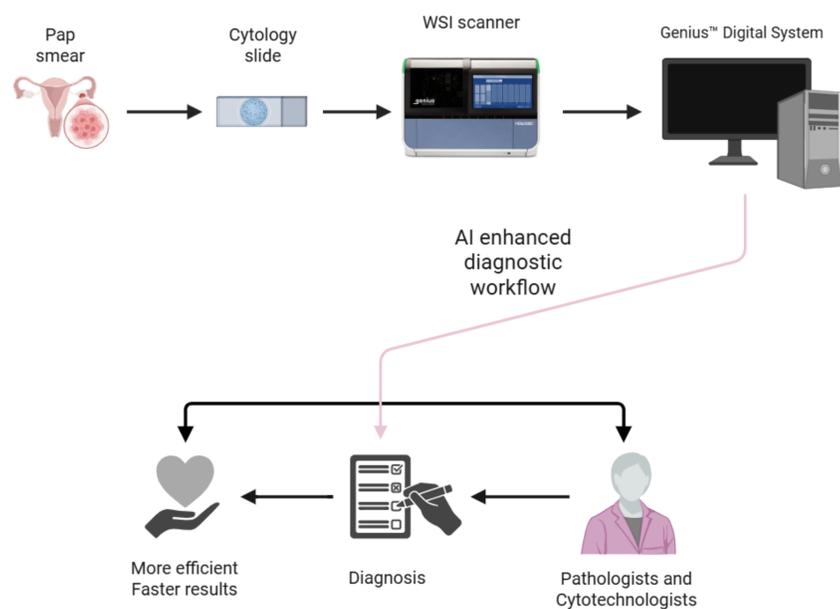


Figure 1. Schematic representation of the AI-supported cytopathology workflow.

Methods

IMP Diagnostics implementation began in August 2023, following a preparatory phase to negotiate and assess logistical needs, with the installation of the digital equipment. A workflow redesign was initiated to shift from the analogic cytology process to the digital workflow. The training was conducted in two phases: an initial training session by Hologic (November 2023), involving hands-on experience, case reviews, and competency evaluation; followed by an internal training program in early 2024 to reinforce the new diagnostic protocols and ensure staff proficiency (n=1300 cases, 8 participants). Previous diagnoses were revised and compared with the AI-assisted diagnoses in this dataset. A satisfaction enquiry was also performed (1-5 rating scale). Routine roll-out started in May 2024 and continuous monitoring and iterative adjustments were made throughout the early adoption phase to address emerging challenges. Workload capacity was evaluated following the system's implementation.

Descriptive statistical analysis was performed using Microsoft® Excel® 2019.

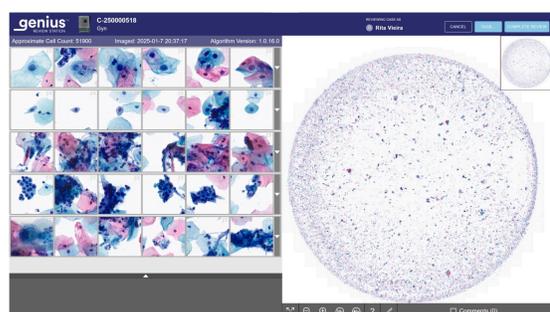


Figure 2. Genius™ system interface. The system assists in cervical screening of ThinPrep™ Pap test slides, for the presence of atypical cells, cervical neoplasia, including precursor lesions and SCC, as well as all other categories (such as adenocarcinoma).

Diagnostically relevant cells are grouped into five rows of the gallery (30 images). E.g., cells with enlarged nuclei or koilocytes are placed in the first row, while microorganisms are grouped in the final row.

Results

IMP Diagnostics processes \approx 90,000 gynaecologic cytology exams annually, scanning 90% (liquid-based cytology). Regarding workflow adaptations, the most significant changes were: batch case registration in the morning (instead of continuous daily registration); staining protocol modification; and the use of the system's dedicated workstations.

In the internal dataset, the Genius™ system identified 22 additional cases with \geq LSIL diagnosis, compared to the analogic screening.

Regarding challenges faced, there were initial delays in service distribution (due to unforeseen increase in overall exam volume; initial learning curve; limitation to three workstations and technical errors, which affected the targeted digitization timeframe). To mitigate these issues, new staff schedules were developed, and an extra workstation and second scanner were acquired. Staff satisfaction surveys (table 2) showed high ratings for ease of navigation (4.8), diagnostic quality (3.9), and overall system evaluation (4.1), demonstrating confidence in the system. The system enables the resident cytotechnicians to screen two to three times more cases per day.

Diagnoses	Genius						AGC (endoc.)	AGC (endom.)
	NILM	Parak	ASC-US	LSIL	ASC-H	HSIL	SCC	
NILM	845	23	57	15	3			1
Parakeratosis	40	16	13	2				1
Manual ASC-US	8	1	124	24	3	1		
Manual LSIL			4	116	4	1		
Manual ASC-H					25			
Manual HSIL					2	12	1	
Manual SCC							4	

Table 1. Internal evaluation (n= 1300 cases).

Survey	Mean
Ease to navigate the image gallery	4.8
Ease to interpret the data	4.0
Confidence in making the diagnosis	3.6
Quality and accuracy of diagnosis	3.9
Fine focus	4.0
Learning curve	4.2
Overall evaluation comparing to conventional microscopy	4.1
Overall mean	4.1

Table 2. Satisfaction survey results.

Conclusions

The successful implementation of the Genius™ system in a Pathology Laboratory setting requires meticulous planning, comprehensive training, and dynamic problem-solving to adapt to unforeseen challenges. We present a practical framework for other laboratories aiming to adopt similar DP systems, highlighting the critical role of continuous staff engagement and flexible resource management. Our findings demonstrate that this system can significantly enhance diagnostic accuracy and operational efficiency, providing a replicable model for digital transformation in Cytopathology.

Acknowledgments

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References:

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