When Digital Pathology Thinks Like a Pathologist: An Aiforia Experience in Breast Biomarker Assessment in a High-Volume Diagnostic Laboratory

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ASDP 2026
SINGAPORE
1 – 3 NOVEMBER 2026
Shaping Tomorrow with Digital Pathology

Background

- Accurate assessment of breast cancer biomarkers including estrogen receptor (ER), progesterone receptor (PR), HER2 and Ki67 is essential for therapeutic decision-making.
- Manual interpretation is associated with inter-observer variability, particularly in equivocal and heterogeneous cases.
- AI-assisted image analysis may improve consistency and efficiency in routine practice.

Aim

To evaluate the concordance, discordance and turnaround time (TAT) for AI-assisted scoring of breast cancer biomarkers in a community pathology setting.

Methods

- A pilot cohort of **50** breast carcinoma cases, including core biopsies and resection specimens, was evaluated.
- ER, PR, HER2 and Ki67 assessed independently by 3 pathologists, with and without AI (Aiforia®).
- Concordance and discordance rates calculated.
- Turnaround time (TAT) compared.
- Proficiency Testing (PT) and External Quality Assessment Scheme (EQAS) metrics assessed.

How Aiforia® works

1. **Detects** tissue and tumour
2. **Classifies** cells (AI model)
3. **Quantifies** biomarker expression

Positive cells	47.5%
Negative cells	52.5%
Total cells	39,972

4. **Generates** visual and numeric results

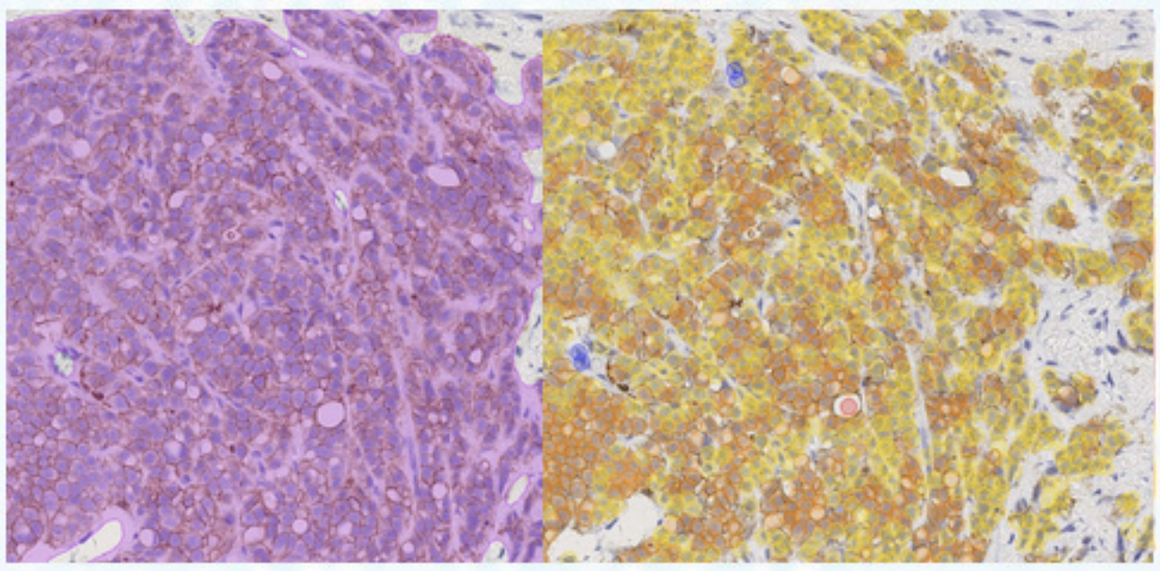


Results

ER concordance	PR concordance	HER2 discordance	Ki67 discordance	Turnaround time (reduction with AI)	PT / EQAS compliance
100%	**100%**	**4%**	**6%**	**54% ↓**	**100%**
(Allred score)	(Allred score)	(mainly 2+ equivocal cases)	(in heterogeneous tumours)		

Example Cases: Aiforia® AI Analysis

HER2 (Score 2+ – Equivocal case)

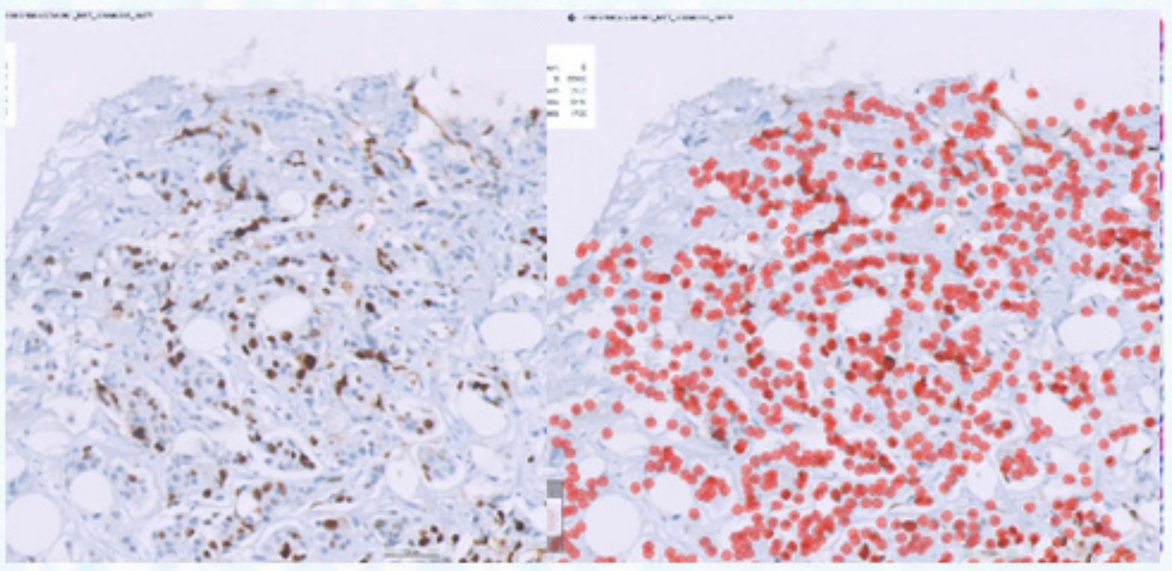


AI classification of tumour cells (membrane staining)

No staining	Faint, incomplete staining	Weak to moderate complete staining	Intense complete staining
4.6%	57.5%	37.7%	< 0.5%

HER2 score (Aiforia): 2+ (Equivocal)

Ki67 (Proliferation index 47.5%)



Aiforia cell counts and percentage (Ki67)

	Count	Percentage
Ki67– (negative)	20,984	52.50%
Ki67+ (positive)	18,988	47.50%

Ki67 proliferation index: 47.5%

Conclusions

- High concordance for ER and PR with AI-assisted scoring
- Low discordance for HER2 (4%) and Ki67 (6%), mainly in equivocal or heterogeneous cases
- Significant reduction in turnaround time (54%)
- 100% compliance with Proficiency Testing (PT) and EQAS
- AI-assisted scoring can enhance consistency and efficiency in a community pathology setting, supporting reliable breast cancer biomarker assessment

Key Takeaways

- AI provides consistent and objective biomarker quantification
- Reduces reporting time by over 50%
- Particularly valuable in HER2 equivocal cases and heterogeneous Ki67 tumours
- Supports high-quality, guideline-compliant breast cancer reporting in routine practice