

Development & Validation of an AI-based Workflow for Clinical Scoring of HER2, ER, PR & Ki-67 Immunohistochemistry in Breast Cancer Tissue.

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INTRODUCTION

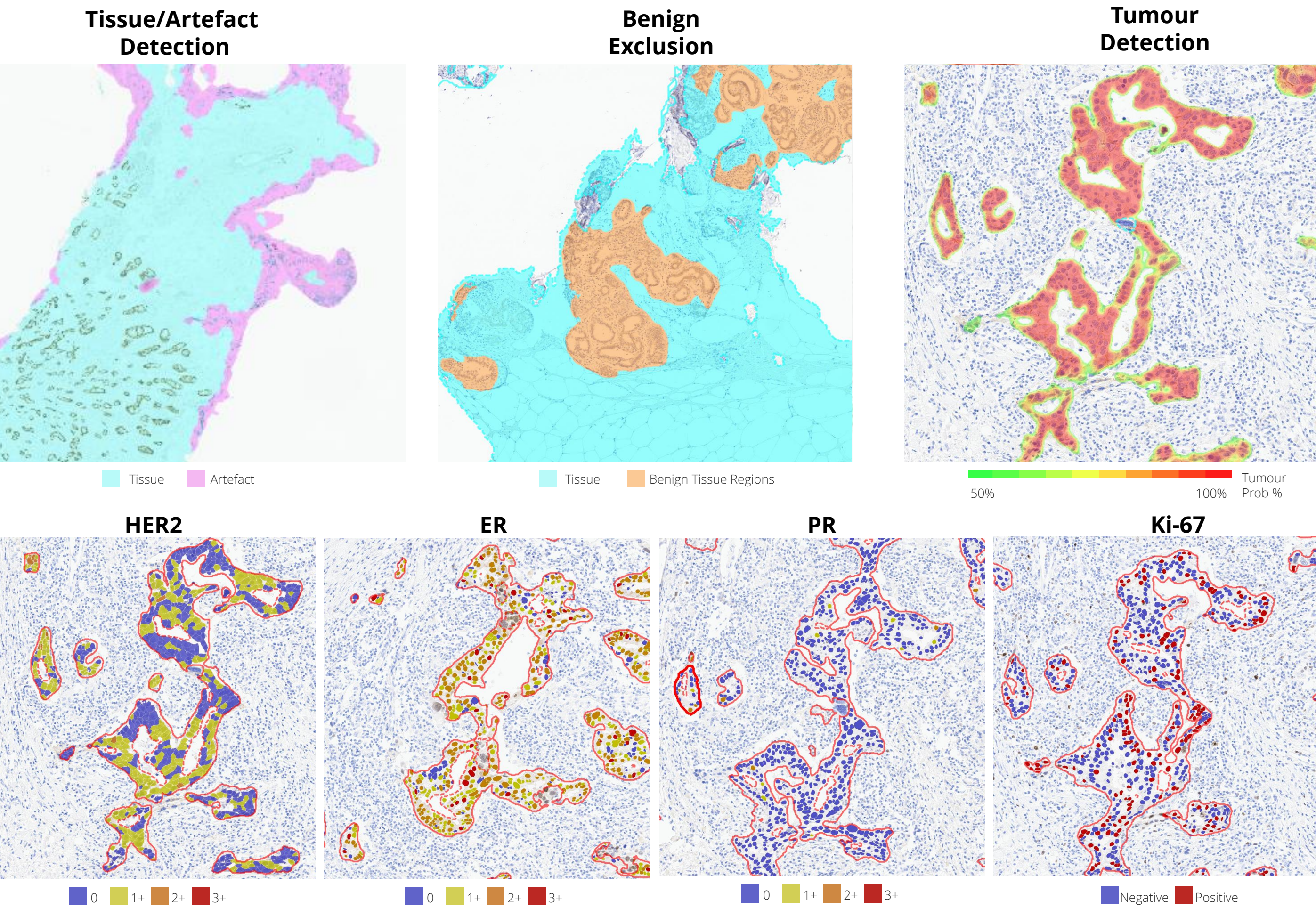
Immunohistochemical assessment of HER2 status, hormone receptors ER and PR, and proliferation marker Ki-67 forms part of the routine clinical diagnostic pathway for invasive breast carcinomas, and is the cornerstone of treatment stratification, informing both prognosis and patient management. Pathologists’ continuous scoring of immunohistochemistry (IHC) at the microscope is time-consuming and prone to significant inter- and intra-observer variability.

Here we present Breast IHC AI, a deep learning algorithm powered by Indica Labs, designed to improve efficiency and diagnostic accuracy through automating whole slide image (WSI) scoring of IHC stained breast cancer FFPE tissue sections.

WORKFLOW & DEVELOPMENT

A tumour detection, DenseNet V2 classifier (4,937 annotations), and a cancer cell classifier, Resnet 18-based network (123,901 annotations) were developed to segment tumour regions across a WSI and classify cells as ‘cancer’ or ‘other’ within these regions. Training data was sourced from three independent institutions.

Thresholds to categorise cells for **Negative (0)**, **Weak (1+)**, **Moderate (2+)** or **Strong (3+)** biomarker positivity were set *per* institute.



CONCLUSIONS

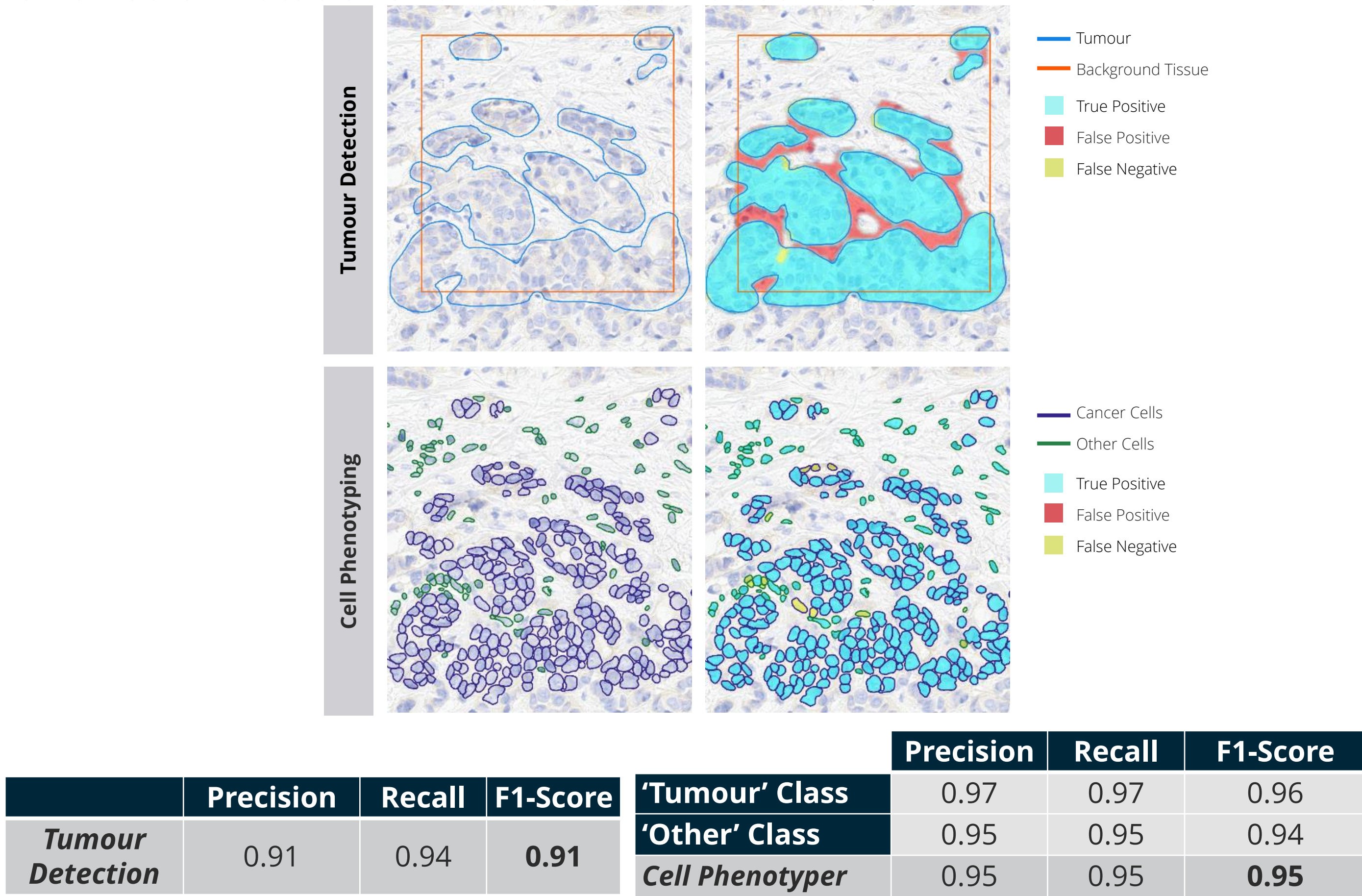
Breast IHC AI accurately detects tumour regions and tumour cells within breast cancer tissue.

Breast IHC AI demonstrates high clinical agreement when scoring routine diagnostic IHC.

Breast IHC AI can support pathologists by improving workflow efficiency and standardising results.

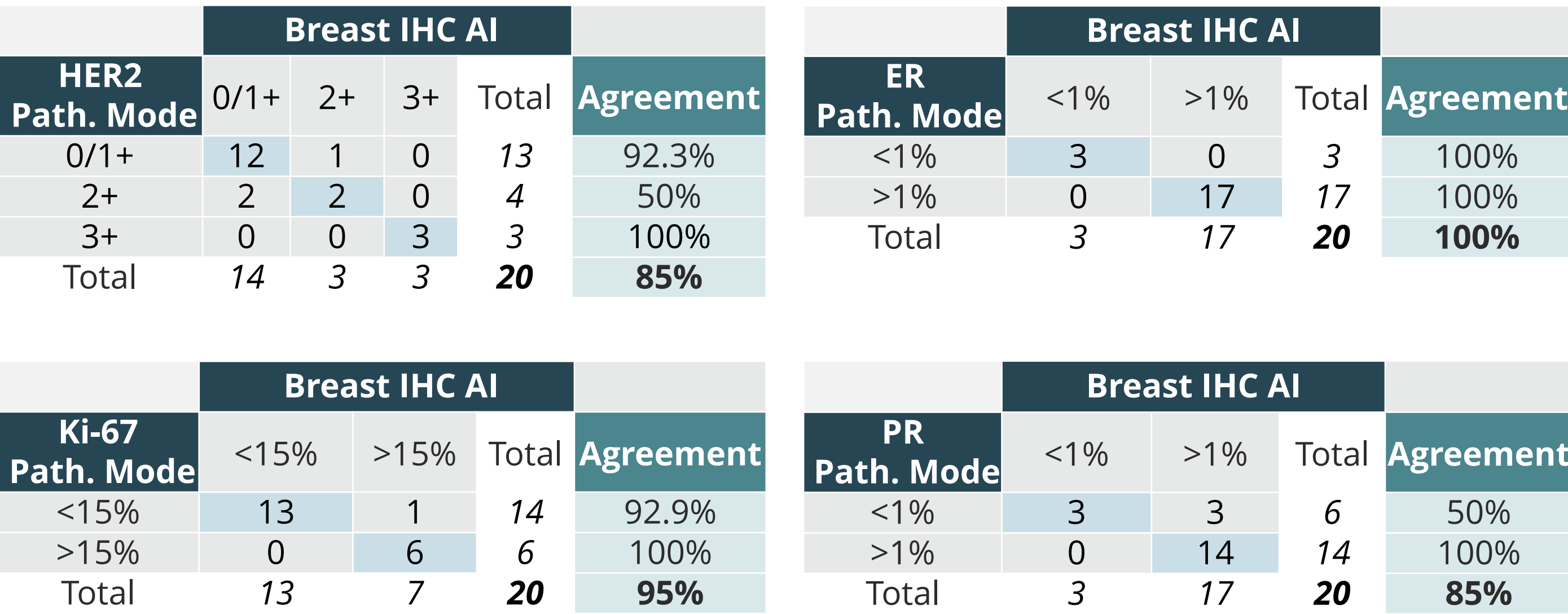
ANALYTICAL VALIDATION

Breast IHC AI was validated for trueness of object classification on 80 images unseen during algorithm development, using 1,216 pathologist-reviewed annotations for the tumour classifier and 58,796 pathologist-reviewed annotations for the cellular classifier.

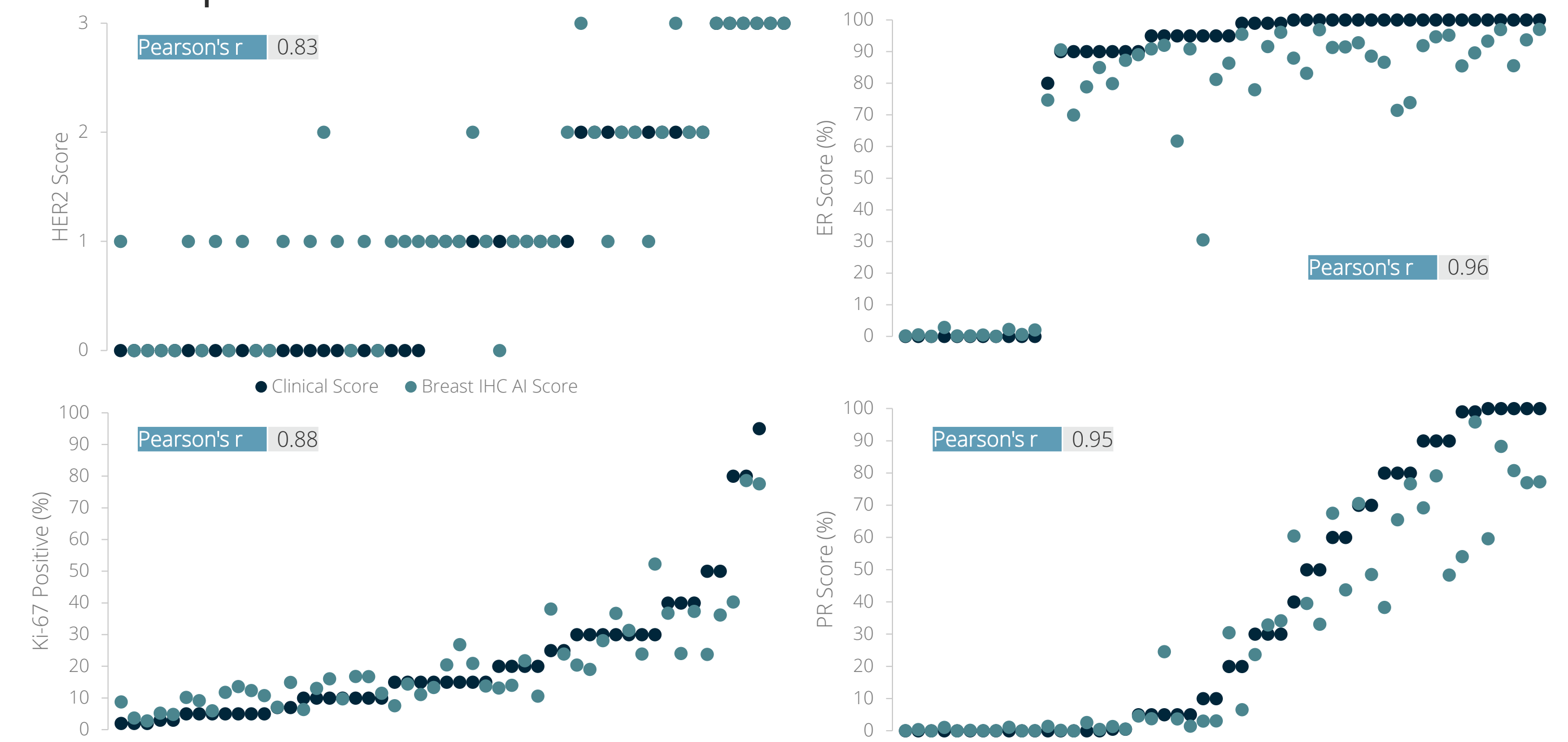


CLINICAL VALIDATION

Breast IHC AI was internally validated for clinical performance on 80 images (n=20 per marker) unseen during algorithm development. The algorithm HER2 score, and ER, PR & Ki-67 positivity were compared against the clinical scores assigned by 3 expert pathologists.



External clinical performance was assessed using n=200 WSI obtained from an independent, external institute, comparing the AI score to the clinical report.



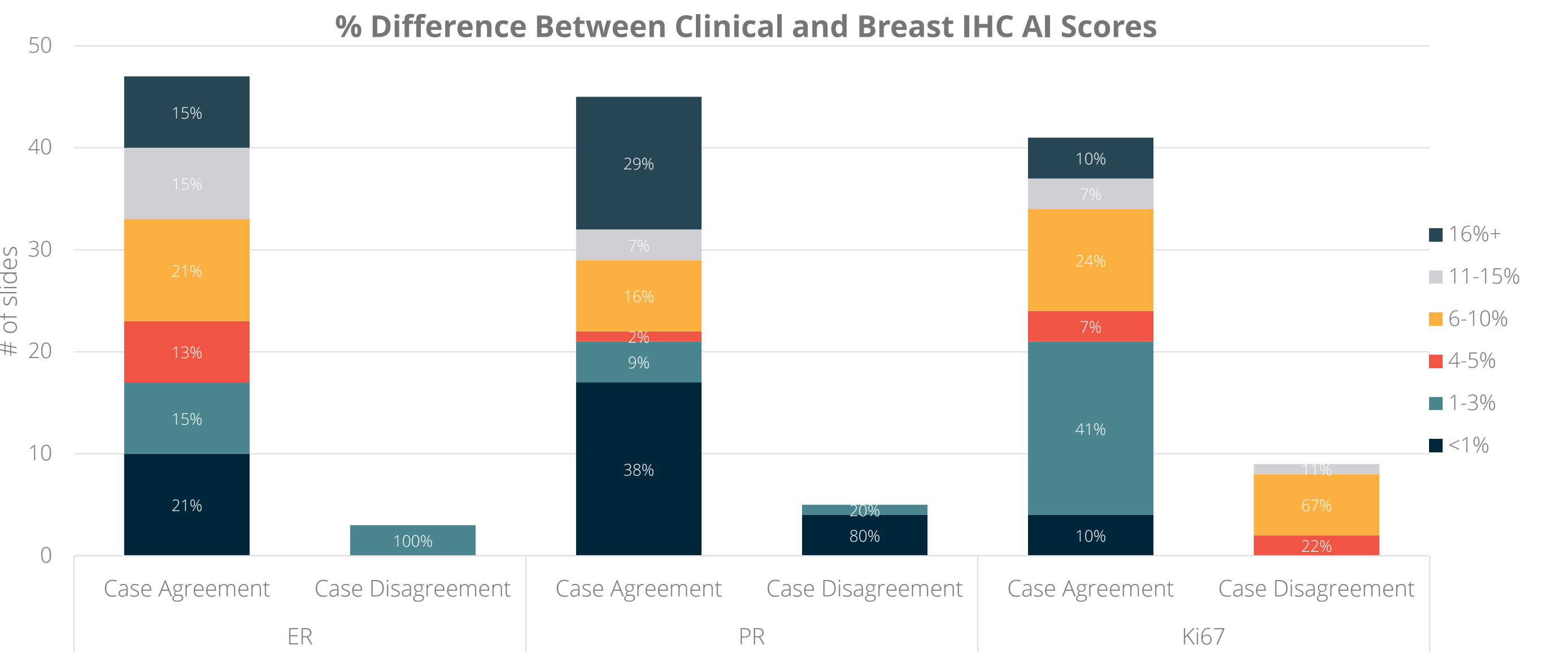
	Breast IHC AI				
HER2 Clin. Score	0/1+	2+	3+	Total	Agreement
0/1+	30	3	0	33	90.9%
2+	2	6	2	10	60%
3+	0	0	6	6	100%
Total	32	9	8	49	84%

	Breast IHC AI				
ER Clin. Score	<1%	>1%	Total	Agreement	
<1%	8	3	11	72.7%	
>1%	0	39	39	100%	
Total	8	42	50	94%	

	Breast IHC AI				
Ki-67 Clin. Score	<15%	>15%	Total	Agreement	
<15%	23	6	29	79.3%	
>15%	3	18	21	86%	
Total	26	24	50	82%	

	Breast IHC AI				
PR Clin. Score	<1%	>1%	Total	Agreement	
<1%	13	5	18	72.2%	
>1%	0	32	32	100%	
Total	13	37	50	90%	

Of the ER & PR cases that were in disagreement at the 1% clinical cut-off, the algorithm percent-positive scores were within a 1-3% range in 8 out of the 8 cases, while for Ki-67 8 out of the 9 cases in disagreement were within 10% of the clinical score.



Want to know more?
Use the QR code to check out our website for more details & contact us.
Or visit us at booth 216 @ PathVisions 2023.

Breast IHC AI is available for deployment in the HALO AP platform.
Breast IHC AI is for Research Use Only and not intended for clinical diagnostic use.
HALO AP® is CE-marked for in-vitro diagnostic use in Europe and the UK. HALO AP is For Research Use Only in the US and is not FDA cleared for clinical diagnostic use.