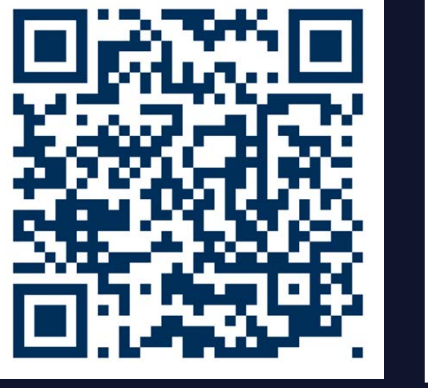


# Successful Deployment of an Artificial Intelligence Solution for Primary Diagnosis of Breast Biopsies in Clinical Practice

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## BACKGROUND

- Breast cancer is the most common malignant disease in women worldwide and the leading cause of cancer death in over 100 countries<sup>1</sup>
- Artificial-intelligence (AI)-based diagnostic solutions can support pathologists and improve diagnostic accuracy and efficiency<sup>2</sup>

## OBJECTIVE

To assess an AI-based solution (Galen™ Breast, Ibex Medical Analytics) for breast biopsies primary diagnosis, which was previously validated<sup>2</sup>, and its implementation within a digital pathology workflow in a hospital pathology laboratory setting

## METHODOLOGY

- 6 pathologists underwent training and used the Galen Breast solution for prospective primary diagnosis
- 355 consecutive breast biopsies (437 H&E slides) were reported
- 180 (51%) cancer
- 175 (49%) benign
- All the slides were digitized and blindly processed by the AI solution
- Pathologists were presented with the AI pre-classifications on invasive, in-situ and other features, reviewed and reported the cases
- AI results were compared with the final pathologist reports

## RESULTS

### Workflow with the AI solution



- Galen Breast pre-classifies slides/cases into 3 categories of cancer likelihood: high, medium and low
- Automation of the diagnostic workflow by AI:
- Display diagnostic insights, heatmaps and AI results for multiple features: invasive carcinoma, IDC vs. ILC, DCIS/ADH, DCIS grading, LVI, TILs and more
- Includes slide and case report

### High Accuracy for Breast Cancer Detection

| Tissue             | AUC [95% CI]         | NPV | PPV |
|--------------------|----------------------|-----|-----|
| Cancer*            | 0.99<br>[0.988; 1.0] | 99% | 84% |
| Invasive Carcinoma | 0.99<br>[0.988; 1.0] | 99% | 91% |

\* Comprising all invasive, papillary lesions, and in-situ breast cancers cases, including 16 DCIS cases

### Performance of the AI solution

**NPV = 99%**  
(Negative Predictive Value)

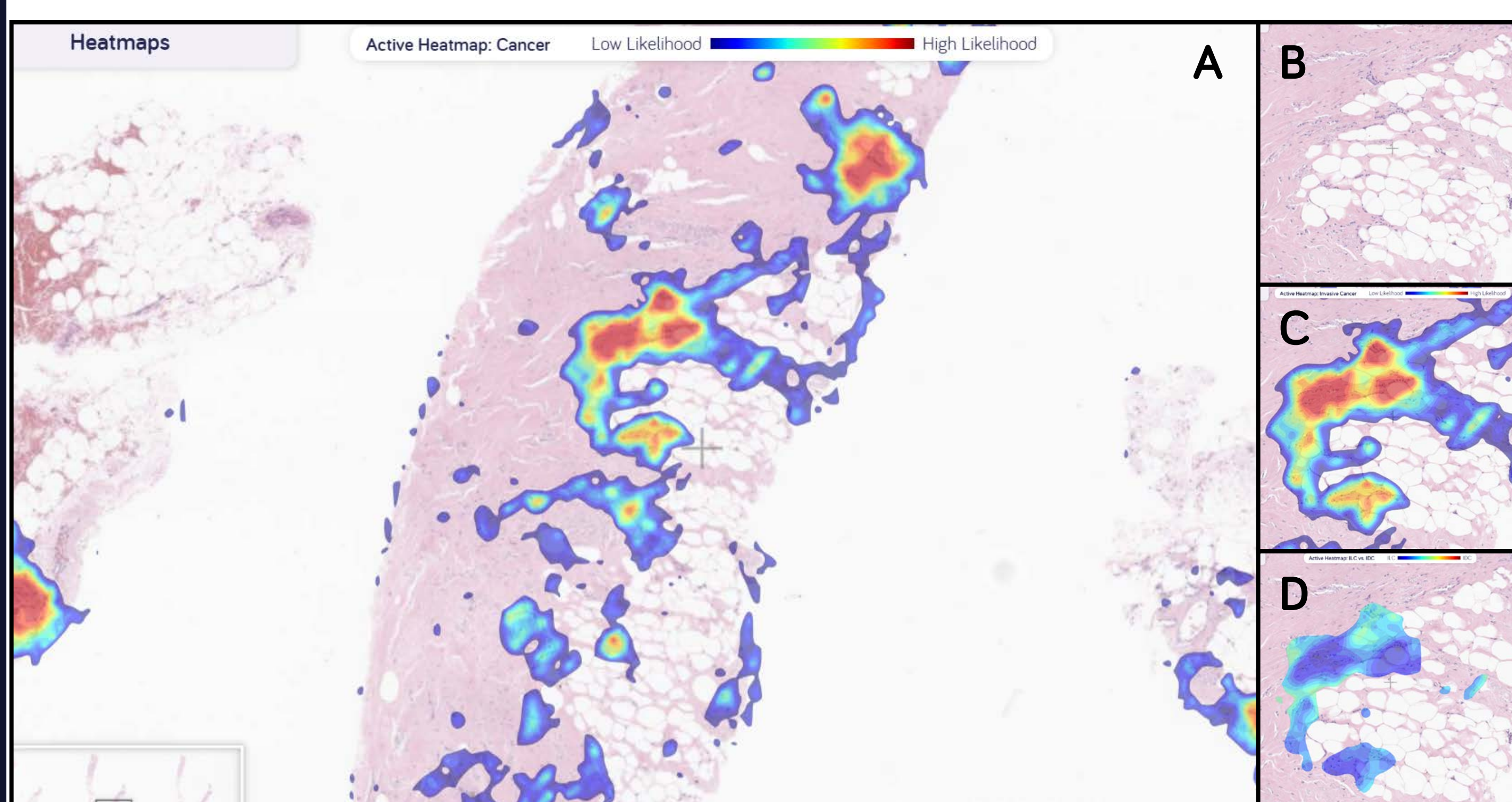
**PPV = 91%**  
(Positive Predictive Value)

| Ibex AI Result*   | Pathologists Results | Count (%)   |
|-------------------|----------------------|-------------|
| Low Likelihood    | Invasive             | 2 (0.6%)    |
|                   | Non-Invasive**       | 180 (50.7%) |
| High Likelihood   | Invasive             | 109 (30.7%) |
|                   | Non-Invasive**       | 2 (0.6%)    |
| Medium Likelihood | Invasive             | 48 (13.5%)  |
|                   | Non-Invasive**       | 14 (3.9%)   |

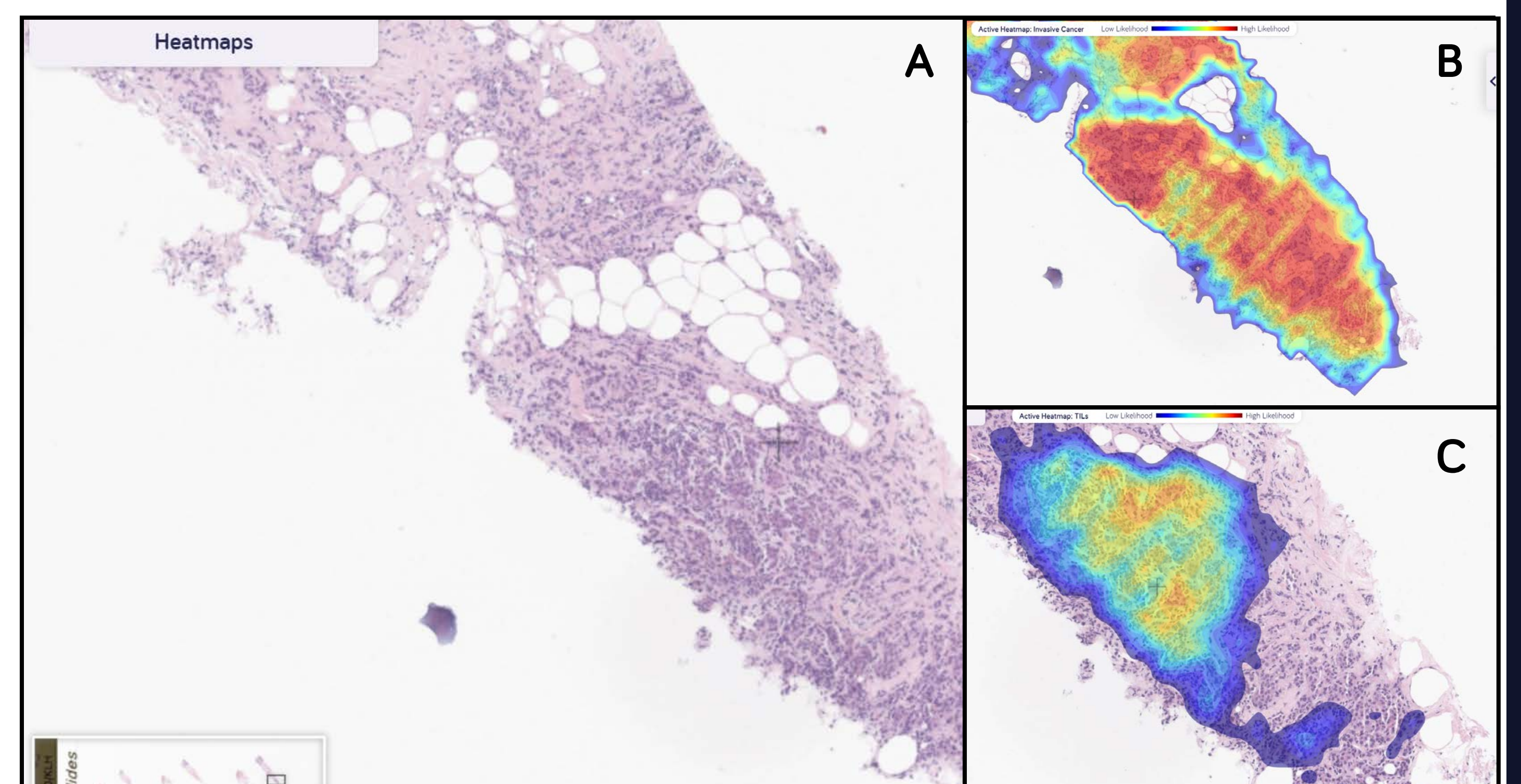
\* Analysis on 355 consecutive breast biopsies

\*\* Including all benign cases and in-situ breast cancer cases (including DCIS)

### Examples of Diagnoses with the Galen Breast



**Figure 1.** Small invasive lobular carcinoma as detected by the AI in a low (2x magnification) (A) and high (9x magnification) resolution (B); (C) displays the invasive cancer heatmap overlay; (D) shows the ILC vs. IDC heatmap overlay



**Figure 2.** Invasive ductal carcinoma as detected by the AI (A); (B) displays the invasive cancer heatmap overlay; (C) shows the TILs heatmap overlay

## CONCLUSIONS

We reported here the successful implementation in clinical practice of a multi-feature AI solution

This study reported high levels of accuracy of an AI-solution and demonstrated the AI ability to accurately pre-classify cancer and contribute to workflow efficiency

References: 1. Bray et al, CA: A Cancer Journal for Clinicians, 2018; 2. Sandbank et al, npj Breast Cancer, 2022.

Disclosures: Richard Nicholson, Shaya Goodman, Ira Krasnitsky, Daniel Ignatov, Maya Grinwald, Dana Mevorach and Manuela Vecsler are employees of Ibex Medical Analytics and have an ownership interest in stock options.