



AI IN PRIMARY DIAGNOSIS:

The Beginning of a Beautiful Friendship!

Richard Nicholson, Commercial Director, UK & Nordics

Trusted Cancer Diagnostics for All



Clinical grade, AI-based
solution for cancer diagnosis



Accuracy



Efficiency



Insights

Galen™ Suite: AI-supported Cancer Diagnosis



Available in multiple workflows:

- Supporting case review during primary diagnosis
- AI-powered second reads on all cases



Multi tissue detection:

Prostate, breast & gastric



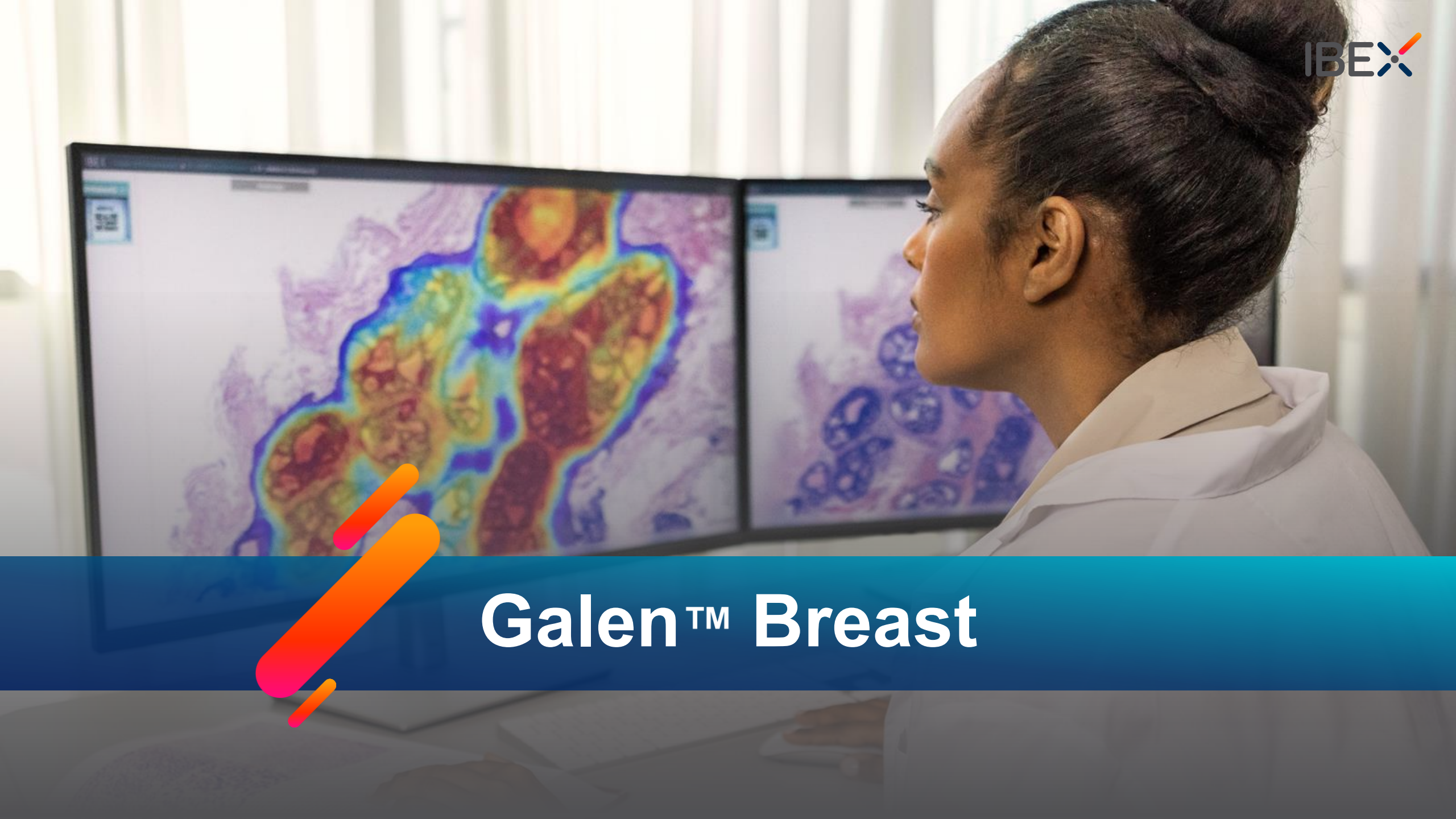
AI-based diagnostic tools: case prioritization worklist, slide viewer, IHC preordering, cancer heatmaps, grading, measurements, non-cancer findings, AI-driven reporting



Open API for AI-integration: scanning, workflow & LIS



Deployed at labs worldwide & used
by pathologists in everyday practice



Galen™ Breast

The most powerful and comprehensive AI solution for breast diagnosis

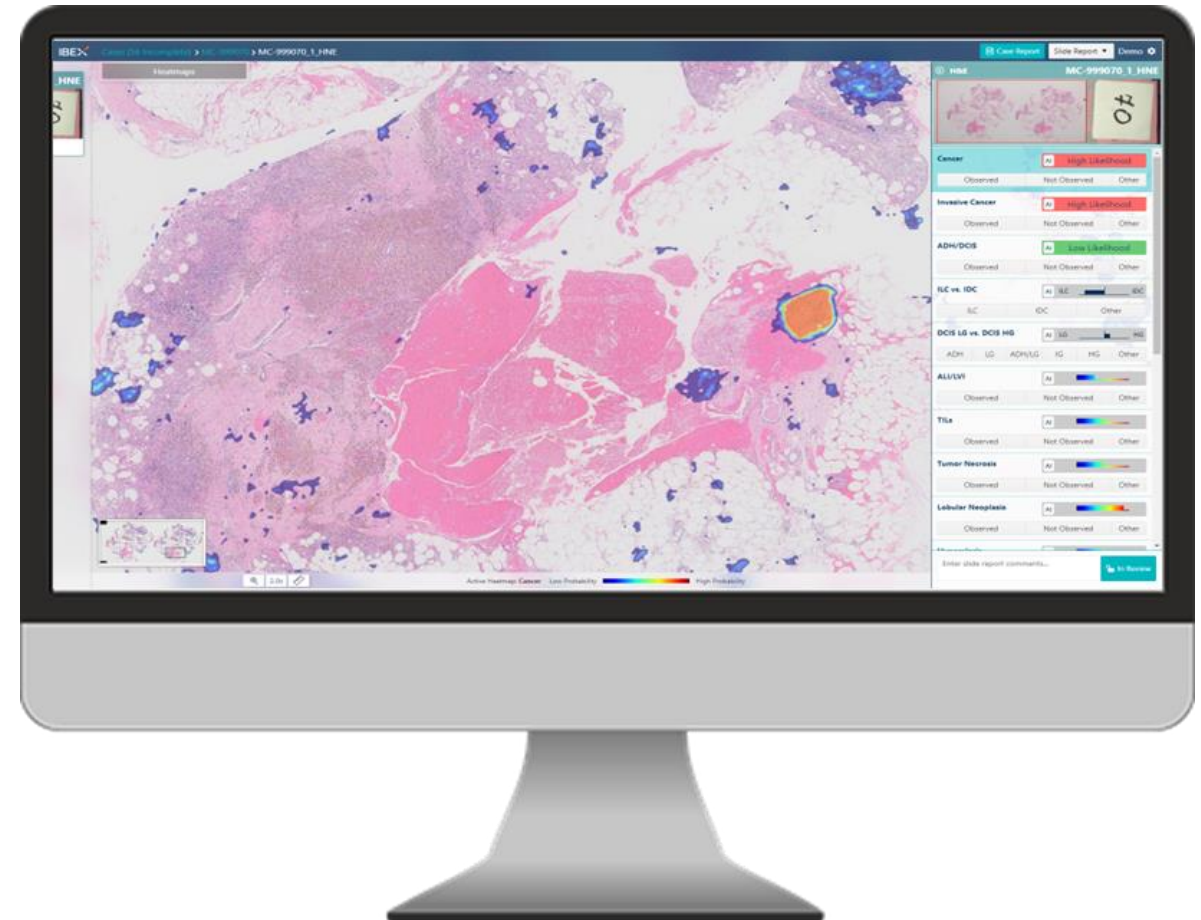
- **Trained** on >130K manual annotations in >2,000 slides, selected by clinical findings and other criteria
- Rigorously **validated** in large-scale multi-site studies
- **Deployed** and used in routine clinical practice since 2019

H&E

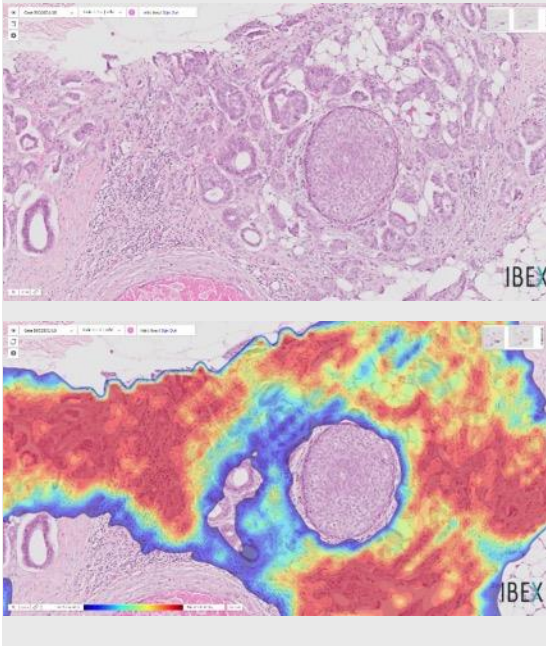
- AI identifies **51 morphological features**, including: Invasive cancer (+special subtypes), DCIS (+grading), TILs, ALI, lobular neoplasia, microcalcifications, hyperplasia, CCC, biphasic tumors, ...

IHC (breast panel) – *In development*

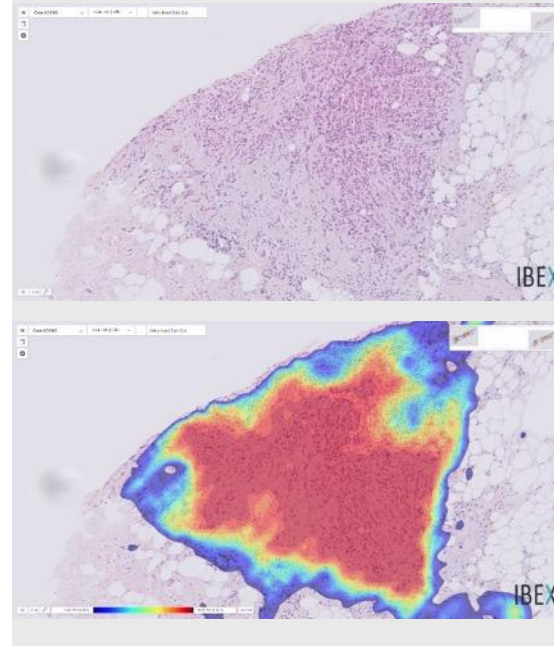
- **Fully automated quantification:** AI detects invasive cancer, identifies tumor cells, classifies their staining pattern and provides a slide-level score
- Apps: **Her2, Ki67, ER, PR**



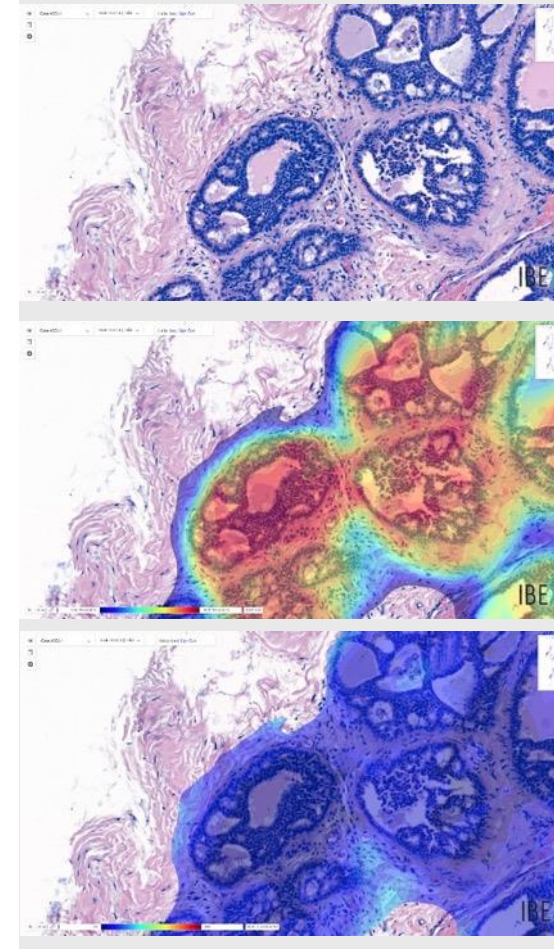
IDC



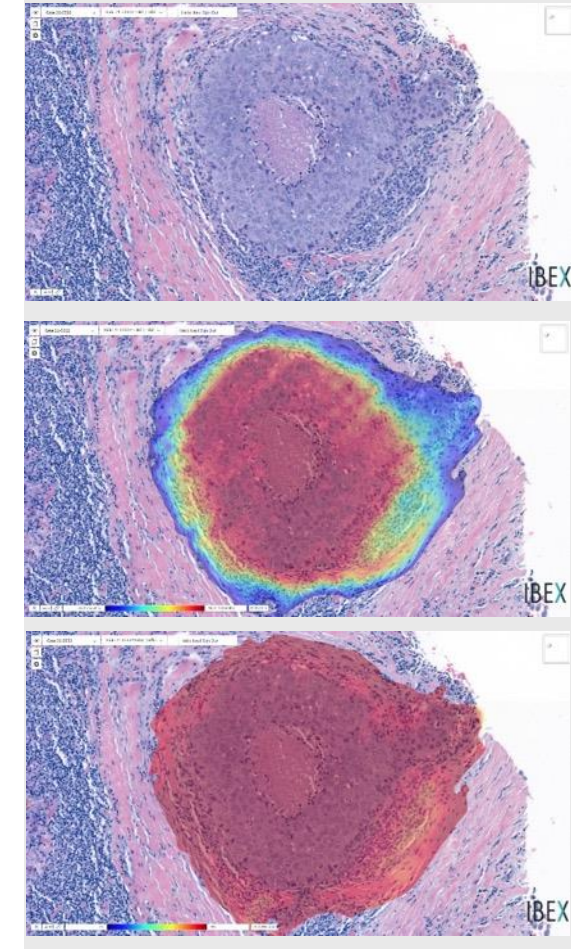
ILC



DCIS (low grade)



DCIS (high grade)

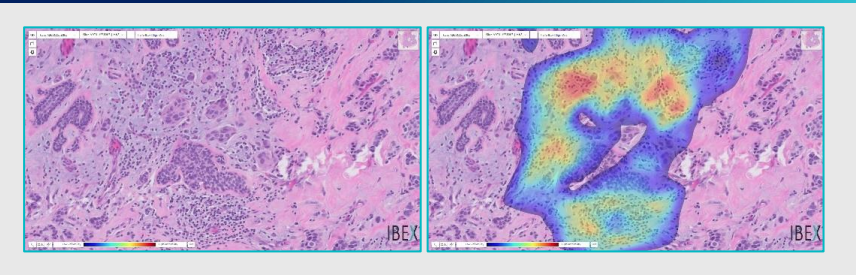


AI accurately **detects** & grades **multiple types** of invasive & in- situ breast cancer

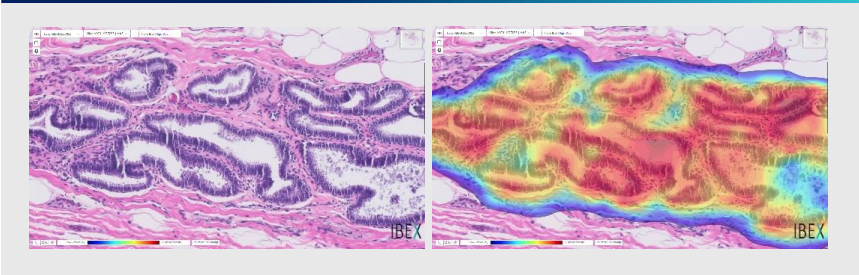
Galen™ Breast: More Than Just Cancer



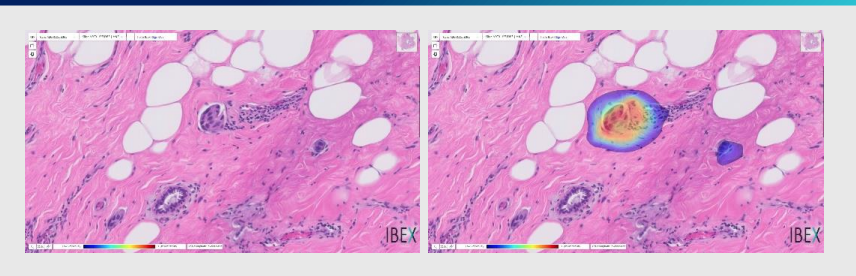
TILs



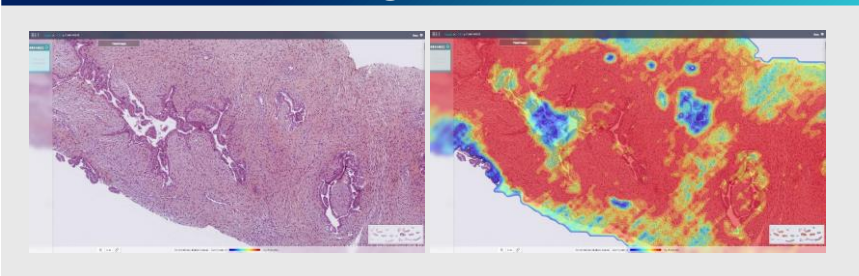
Columnar Cell Change



ALI



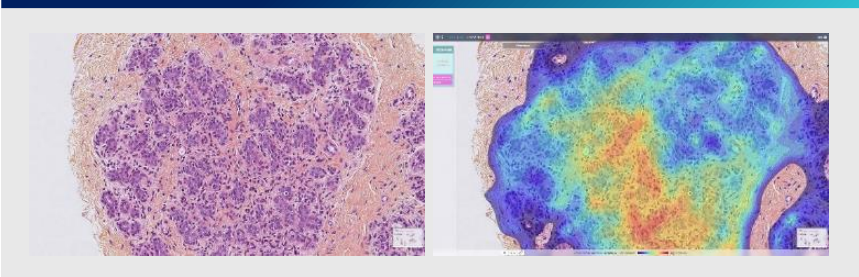
Phyllodes Tumor grade I



Microcalcifications



Adenosis



Additional features

Angiolymphatic involvement	Biphasic tumor	Tumor infiltrating lymphocytes
Hyperplasia	Inflammation	Fibrocystic change
Elastosis	Tumor necrosis	Normal ducts & lobules
Stromal changes	Lobular neoplasm	Sclerosing adenosis

and many more...

The Broadest Range of
Detection Capabilities
Available In the Field

How Can AI Help in the Practice of Breast Pathology?



Improve Quality

- **AI decision support** - Highlight clinically important lesions and other morphological features in primary diagnostic workflow
- **AI Diagnostic QA** - Provide second a read before final sign out to ensure clinically significant lesions have not been missed
- **AI Quantification of IHC**



Improve workflow & reduce TAT

- Prioritisation of cases
- Pre-order receptor IHC's for invasive cancers and DCIS
- Pre-order additional levels (e.g., for calcifications)
- Eliminate need for IHC for some cases

Galen™ Breast: AI-powered Accuracy

Validation and real-world clinical application of an artificial intelligence algorithm for breast cancer detection in biopsies

Judith Sandbank^{1,2}, Guillaume Bataillon^{3,7}, Alona Nudelman¹, Ira Krasnitsky², Rachel Mikulinsky², Lilach Bien², Lucie Thibault³, Anat Albrecht Shach⁴, Geraldine Sebag², Douglas P. Clark², Daphna Laifenfeld^{2,8}, Stuart J. Schnitt^{5,6}, Chaim Linhart², Manuela Vecsler^{1,2} and Anne Vincent-Salomon^{1,2,9}

Detection	AUC	Specificity	Sensitivity
Invasive Breast Cancer	0.990	93.6%	95.5%
DCIS	0.980	93.8%	93.2%
IDC vs ILC	0.973	92.7%	92.9%
IG / HG DCIS vs. ADH / LG DCIS	0.921	84.8%	84.1%

- * A multi-site study of 436 breast biopsies (841 H&E/HES slides): 156 invasive, 135 DCIS/ADH, 145 benign¹
- * Cohort enriched with rare subtypes
- * Multiple scanning systems and staining platforms
- * The study **successfully validated** the performance of Galen Breast:
 - **Very high performance** for invasive carcinoma & DCIS detection
 - AI differentiated well between subtypes/grades of invasive & in-situ cancers

1) Vincent-Salomon et al, npj Breast Cancer 2022

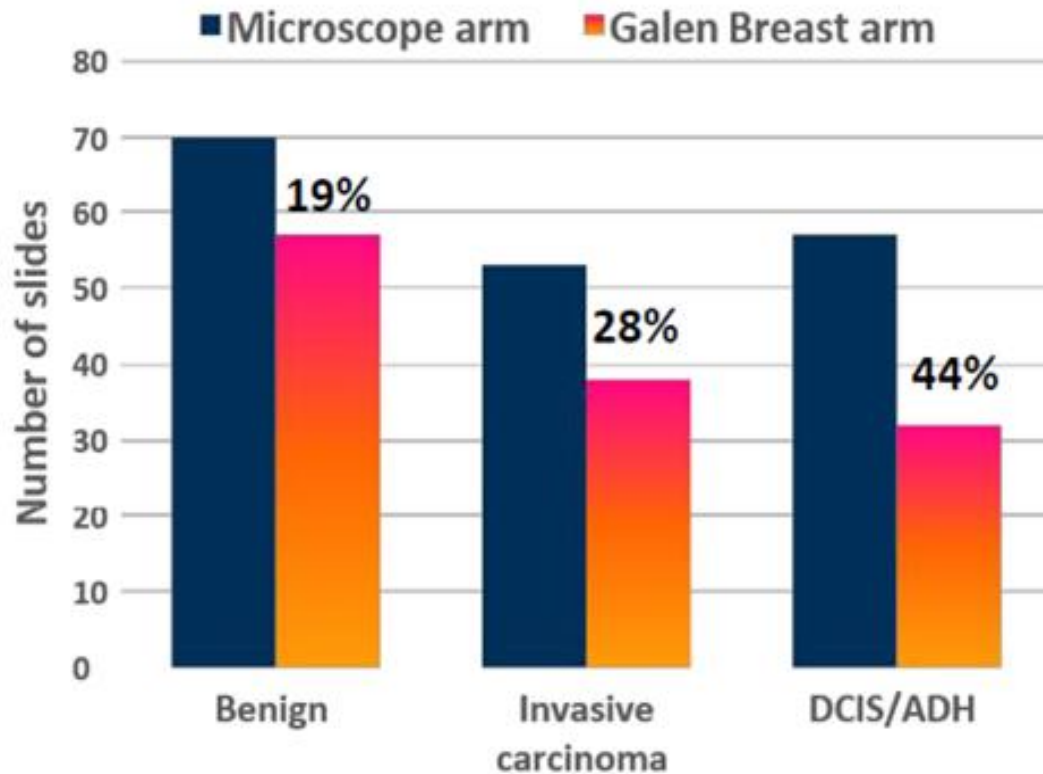
Galen™ Breast: AI-powered Diagnostic QC

Case ID	Date	Tissue	Diagnosis	No. of Slides	Alerts	Assigned to
CP-009005	2022-08-10	prostate	Adenocarcinoma; Gleason:3+3	5	2	Pathologist
AH-000358	2022-08-10	prostate	Benign	14	1	Pathologist
MP-003392	2022-08-10	prostate	Benign	15	2 1	Pathologist
MP-013130	2022-08-10	prostate	MALT lymphoma	16	2	Pathologist
UL-060880	2022-08-10	prostate	Benign	12	2	Pathologist
MP-003278	2022-08-10	prostate	Benign	15	1	Pathologist
MP-003316	2022-08-10	prostate	Benign	14	1	Pathologist
MC-999070	2022-08-09	breast	Benign	1	1	Pathologist
MC-117463	2022-08-09	breast	Benign	9	2	Pathologist
MP-004485	2022-08-09	breast	Benign	12	1	Pathologist
CP-000098	2022-08-09	breast	Benign	17	4	Pathologist
AH-001561	2022-08-10	prostate	Adenocarcinoma; Gleason:3+3; PNI	14		Pathologist
CP-000026	2022-08-10	prostate	Adenocarcinoma; Gleason:3+3	3		Pathologist
HP-000708	2022-08-10	prostate	Adenocarcinoma; Gleason:3+3	8		Pathologist
HP-049771	2022-08-10	prostate	Adenocarcinoma; Gleason:4+5	6		Pathologist
HP-051168	2022-08-10	prostate	Benign	6		Pathologist
MP-003300	2022-08-10	prostate	Benign	6		Pathologist

- * Alerts raised for 363 slides (4.2%) originally dx'ed as benign and for 126 slides (15.1%) originally diagnosed as DCIS/ADH
- * 75% required no change after pathologist re-review
- * 25% led to additional sections or stains

Galen™ Breast: AI for Primary Diagnosis

30% Reduction in IHC Ordering²



- * Multiple studies of Galen Breast in primary diagnosis (485 cases collectively)
- * Parallel arms comparing pathologists with AI to pathologists with microscope
- * Galen Breast was found to help pathologists **improve diagnostic quality and efficiency**:
 - Improved overall accuracy (by 29%)¹
 - Improved sensitivity for invasive cancer¹
 - Reduced IHC ordering (by 30%)²

1) Unpublished data from clinical studies. Subject to further analysis

2) Sandbank et al. Presented at USCAP 2022

Heatmaps

HNE



HNE



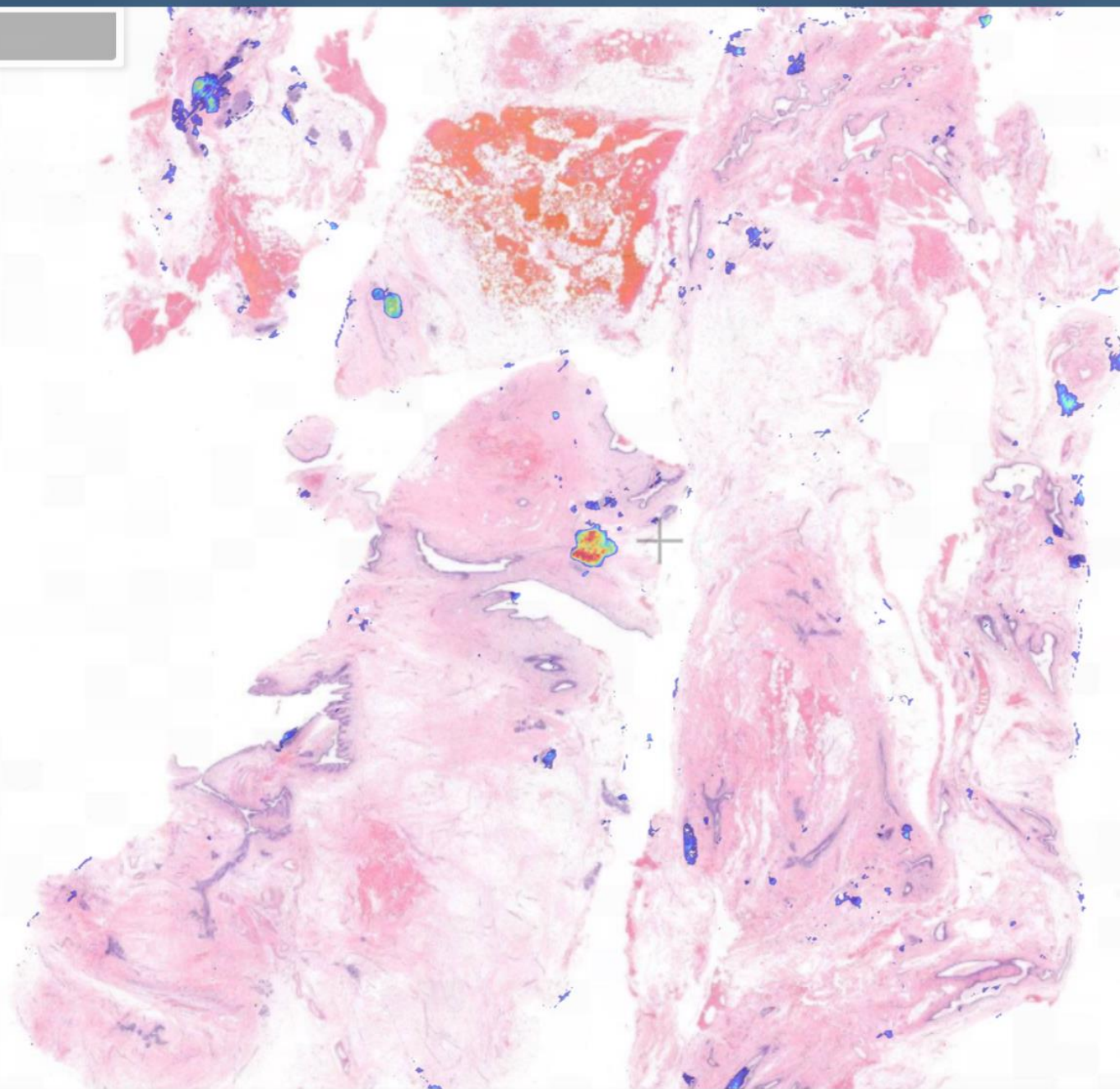
3G7



13_63



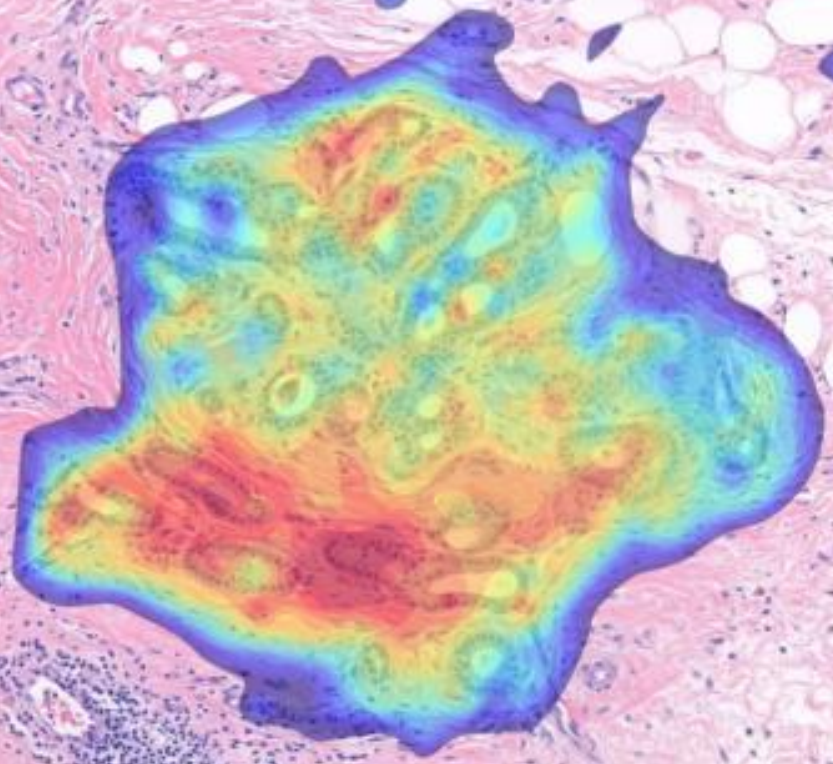
R-312

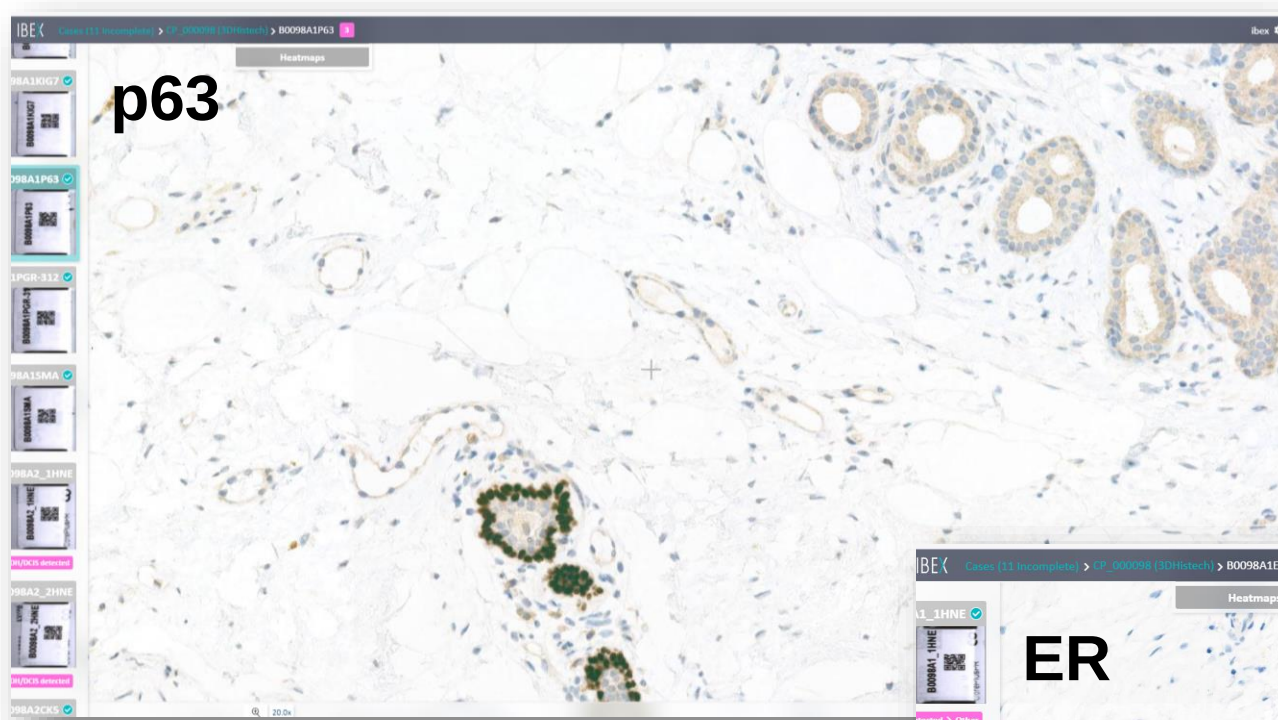


0.4x

Active Heatmap: **Cancer** Low Probability High Probability

Quality Assurance is Important: After IBEX AI - **Cancer Detected**





**Invasive ductal carcinoma,
grade 1**



Case Prioritisation, Triage & IHC Pre-ordering



Breast

	Case ID	Date ↑	Tissue	No. of Slides	Findings	Assigned to
	MP-004417	2022-05-23	breast	15	Cancer Invasive Cancer ADH/DCIS	Pathologist
	MC-999070	2022-05-25	breast	3	Cancer Invasive Cancer ADH/DCIS	Pathologist
	MP-004402	2022-05-25	breast	8	Cancer Invasive Cancer	Pathologist
	MC-117463	2022-05-25	breast	9	Cancer Invasive Cancer	Pathologist
	CP-000030	2022-05-25	breast	1	Cancer Invasive Cancer	Pathologist
	MP-004354	2022-05-25	breast	3	Cancer Invasive Cancer	Pathologist
	CP-000014	2022-05-25	breast	1	Cancer Invasive Cancer	Pathologist
	MP-004485	2022-05-25	breast	12	Cancer Invasive Cancer ADH/DCIS	Pathologist
	MP-009618	2022-05-25	breast	6	Cancer Invasive Cancer ADH/DCIS	Pathologist
	MP-004357	2022-05-25	breast	4	Cancer ADH/DCIS	Pathologist
	MC-023811	2022-05-25	breast	6	Cancer ADH/DCIS	Pathologist
	MC-999170	2022-05-25	breast	3	Cancer ADH/DCIS	Pathologist
	MC-008566	2022-05-25	breast	13	Cancer ADH/DCIS	Pathologist
	MC-134340	2022-05-25	breast	1		Pathologist
	MC-032851	2022-06-07	breast	2		Pathologist
	KM-000040	2022-06-07	breast	9		Pathologist
	CP-000098	2022-06-07	breast	17		Pathologist
	IC-000129	2022-06-07	breast	1		Pathologist
	MC-045262	2022-08-16	breast	1		Pathologist

Small foci of IDC detected with Galen Breast AI



IBEX

Cases (55 Incomplete) > MC-999170 > MC-999170_1_HNE

HNE

Heatmaps

041

2_IHC

3_IHC

10.0x

100%

H&E

MC-999170_1_HNE

041

Cancer

AI High Likelihood

Observed Not Observed Other

Invasive Cancer

AI High Likelihood

Observed Not Observed Other

ADH/DCIS

AI Low Likelihood

Observed Not Observed Other

ILC vs. IDC

AI ILC IDC

ILC IDC Other

DCIS LG vs. DCIS HG

AI LG HG

ADH LG ADH/LG IG HG Other

ALI/LVI

AI

Observed Not Observed Other

TILs

AI

Observed Not Observed Other

Tumor Necrosis

AI

Observed Not Observed Other

Lobular Neoplasia

AI

Observed Not Observed Other

Hyperplasia

AI

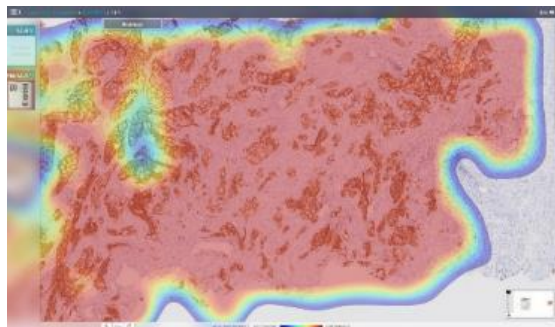
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In Review

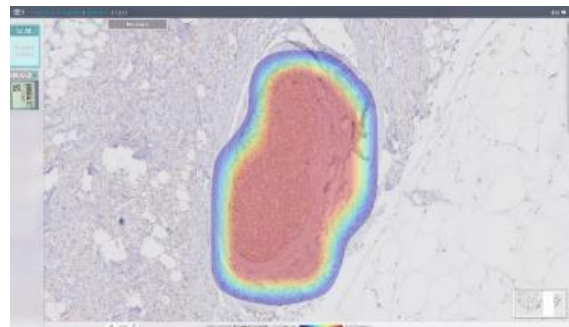
Active Heatmap: ILC vs. IDC

ILC IDC

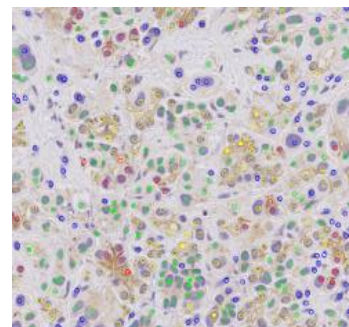
IHC analysis: Deep Quantification



Invasive cancer



DCIS



HER2 Cell Detection

- Not invasive
- Not stained
- Faint incomplete
- Moderate incomplete
- Intense incomplete
- Faint complete
- Moderate complete
- Intense complete

Innovative Technology

- * Fully automated analysis pipeline – pathologist does not need to mark ROI
- * “Transfer Learning” - technology utilizes Ibex’s powerful H&E algorithms to train Deep Learning models for IHC
- * Technology combines patch-level classification (e.g., to detect invasive cancer & DCIS) with cell detection models (e.g., to count stained vs. non-stained cells)

First application: HER2

- * Automatically identifies invasive breast cancer
- * Detects & classifies invasive tumor cells
- * Scores slide according to ASCO/CAP guidelines

Next Solutions

- * Ki67 and ER/PR – full breast panel analysis
- * IHC quantification apps are integrated in the Ibex platform for full support of breast tissue analysis

Deep Quantification is a novel technology for automated, accurate & objective AI-based quantification of IHCs, complementing Ibex’s H&E solutions

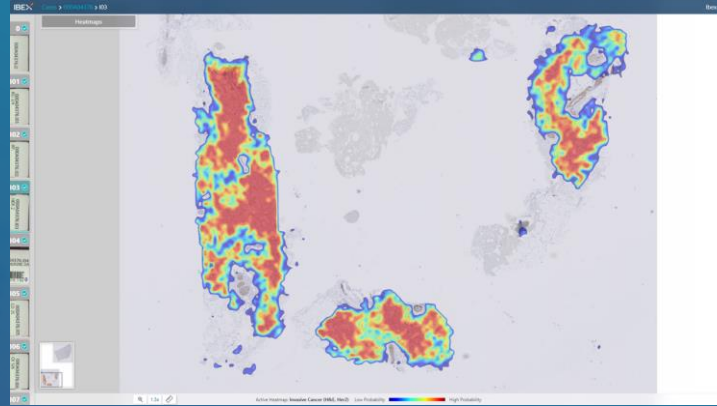
Galen™ Breast HER2



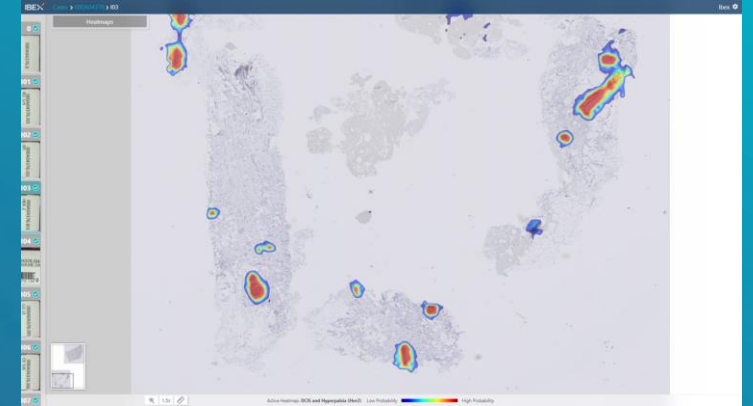
HER2



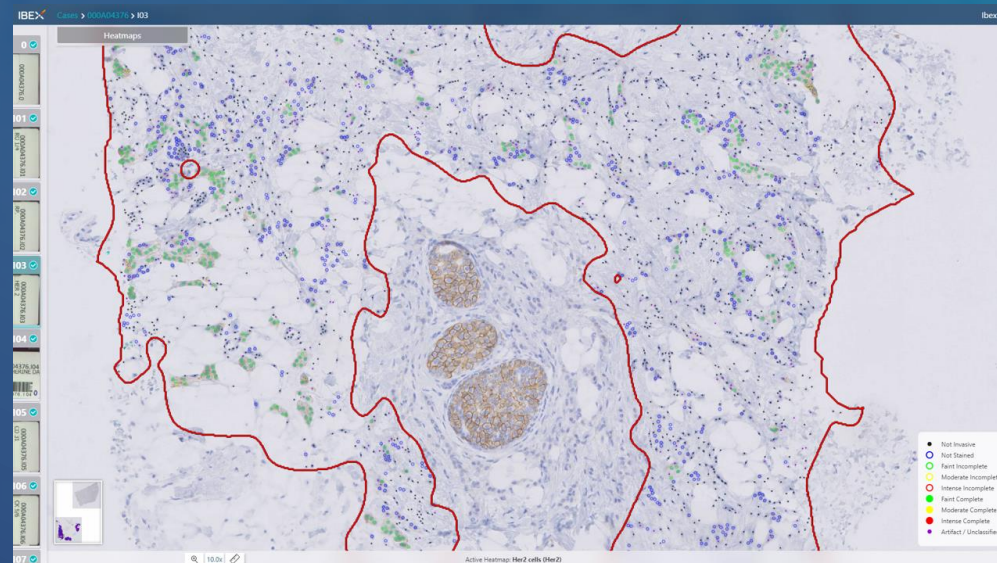
Invasive Ductal Carcinoma



DCIS

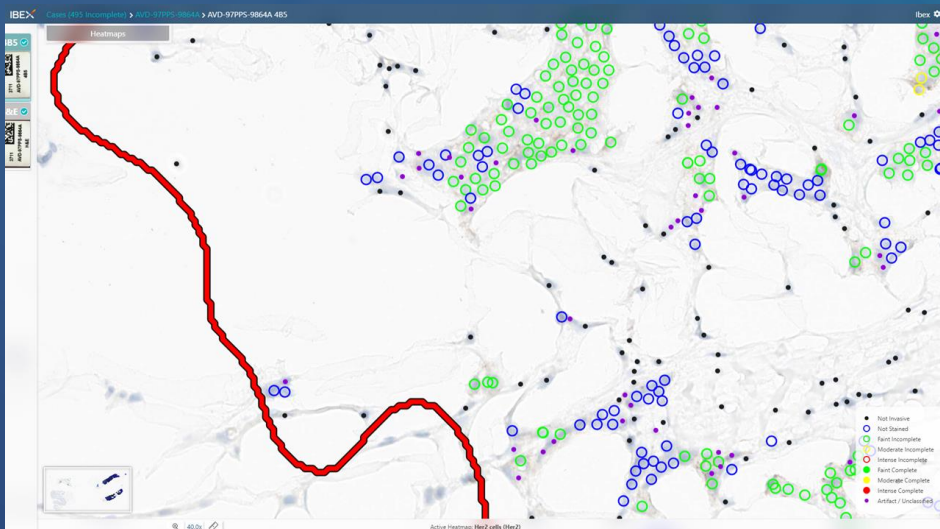
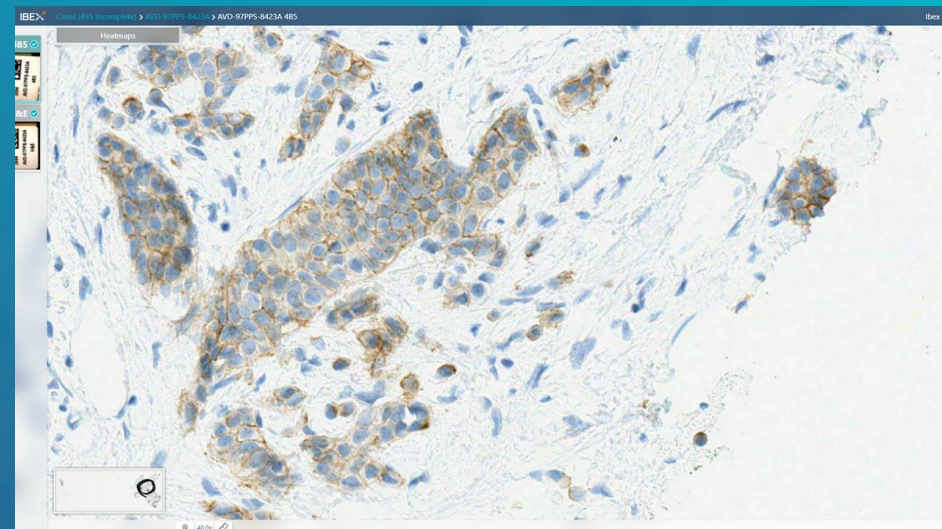
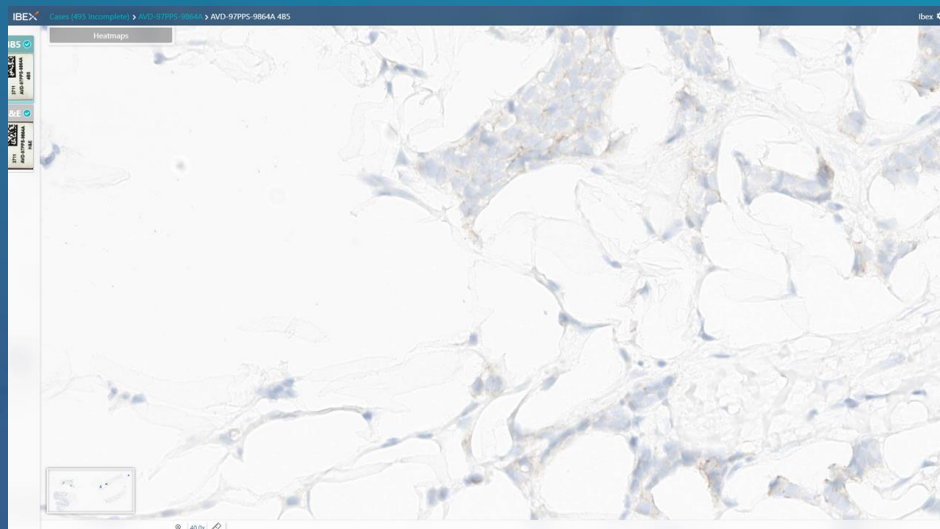


AI-powered
HER2 Pattern
1+ Scoring

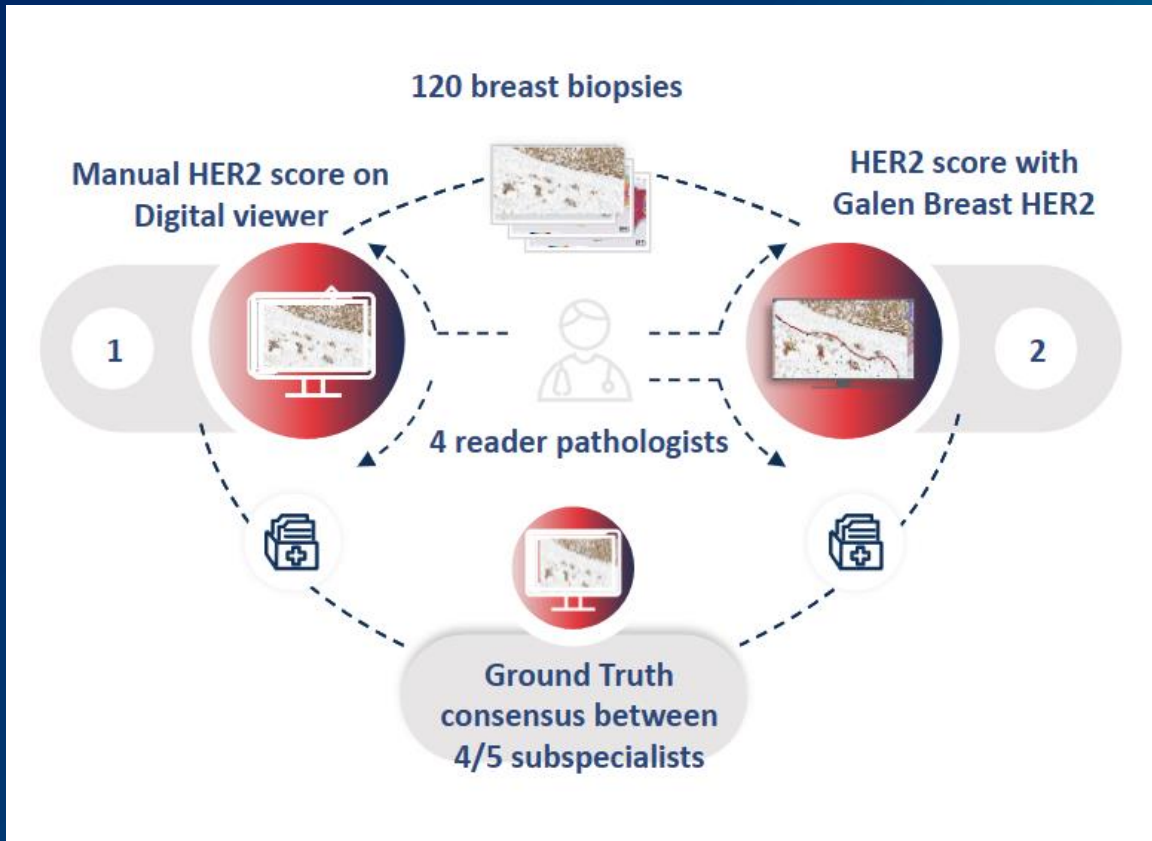


Galen™ Breast HER2: Accurate scoring of faint and moderate incomplete cells

AI-powered
HER2
Pattern 1+
Scoring



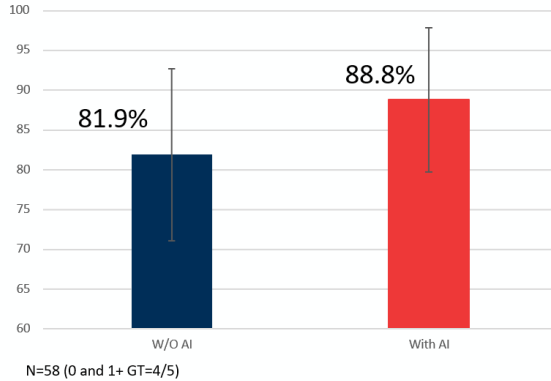
Galen™ Breast HER2: AI for Primary Diagnosis



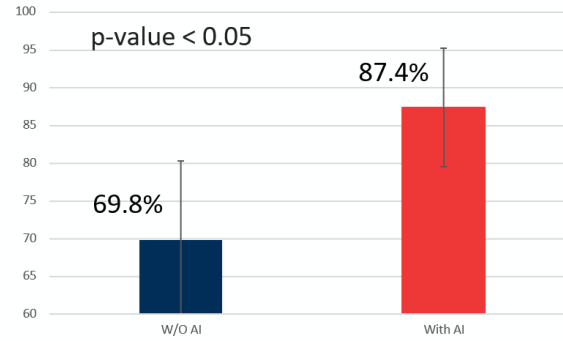
- * 120 arbitrary HER2 IHCs from multiple labs, scanners, and antibodies
- * Diagnosis distribution of 70.8% IDC, 22.5% ILC, 1.7% IDC+ILC, 5% metaplastic (enriched for special subtypes)
- * Ground truth (GT) by 5 Breast expert pathologists
- * Two parallel arms with a crossover design with 4 pathologist readers interpreting HER2 IHCs with and without AI
- * Typical distribution of HER2 scores (original scores):
 - * HER2 0 - 30%
 - * HER2 1+ - 32%
 - * HER2 2+ - 20%
 - * HER2 3+ - 15%

Galen™ Breast HER2: AI for Primary Diagnosis

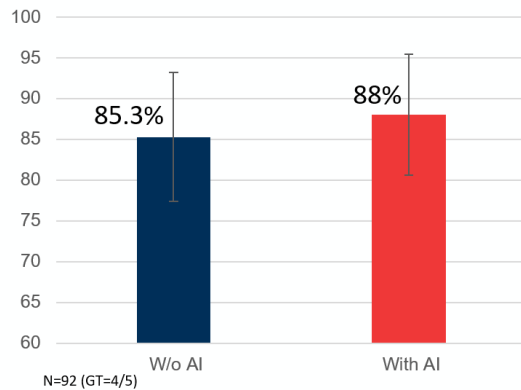
Average agreement with GT



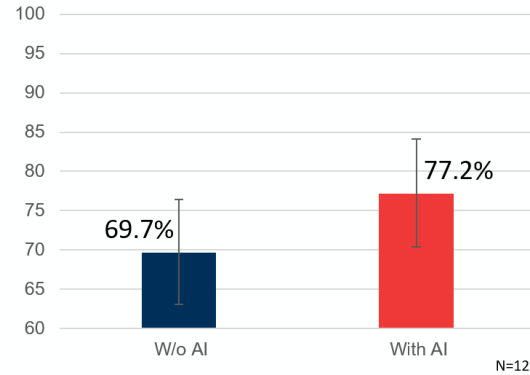
Inter-observer agreement



Average agreement with GT



Inter-observer agreement



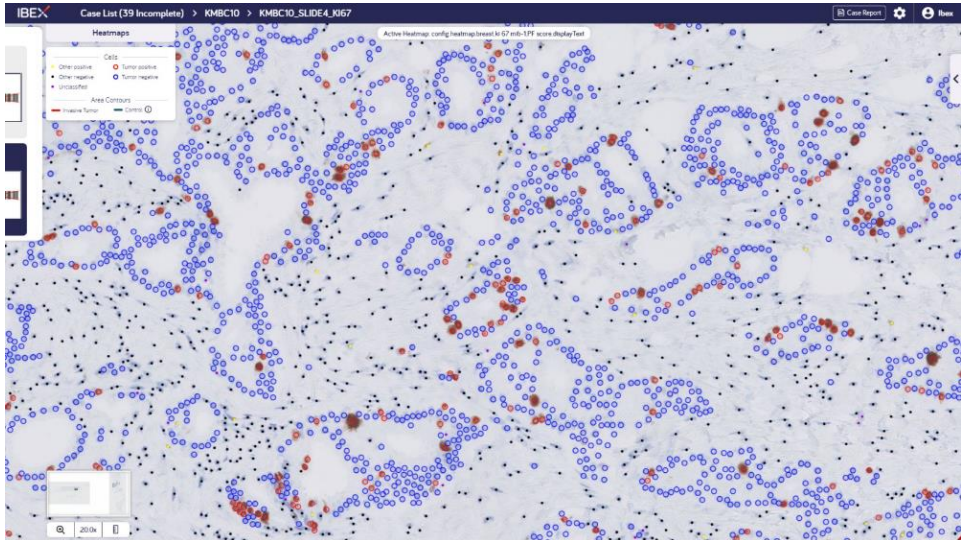
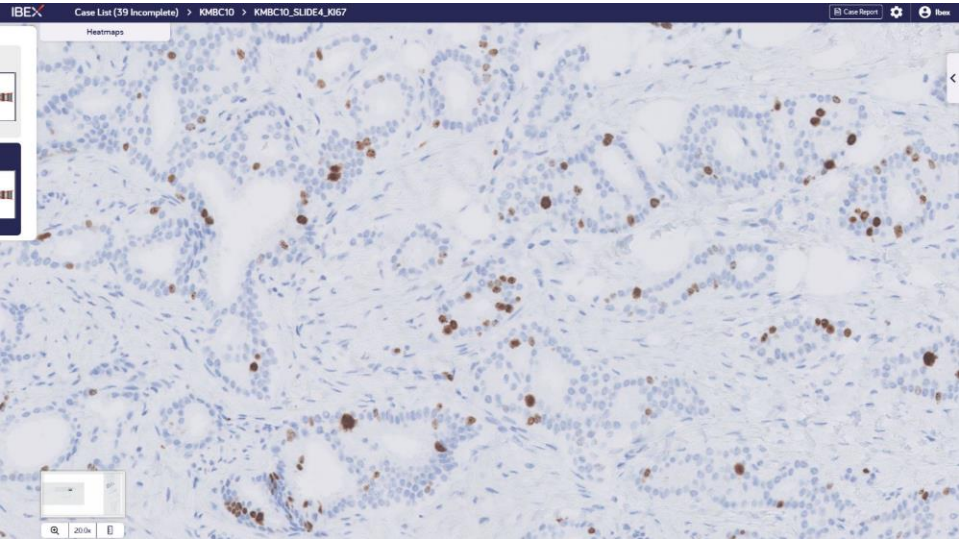
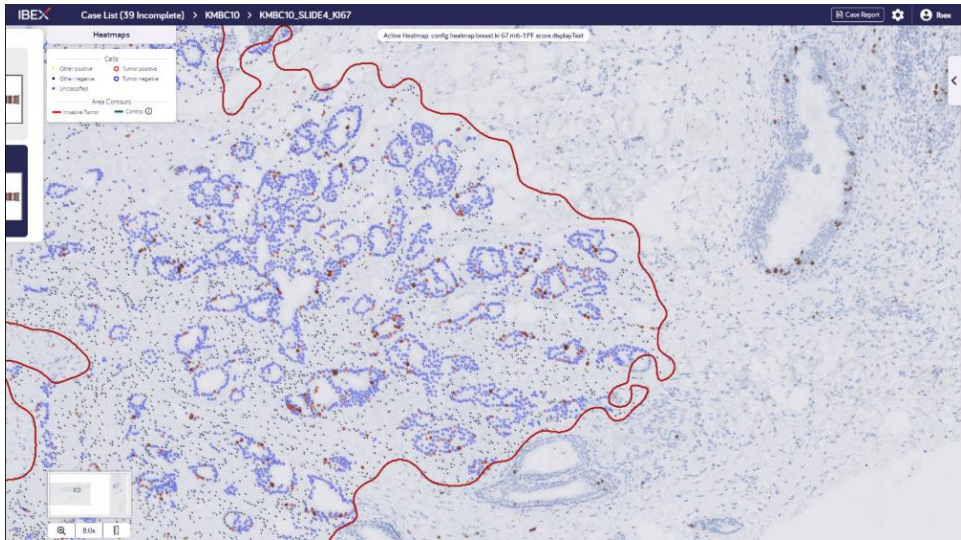
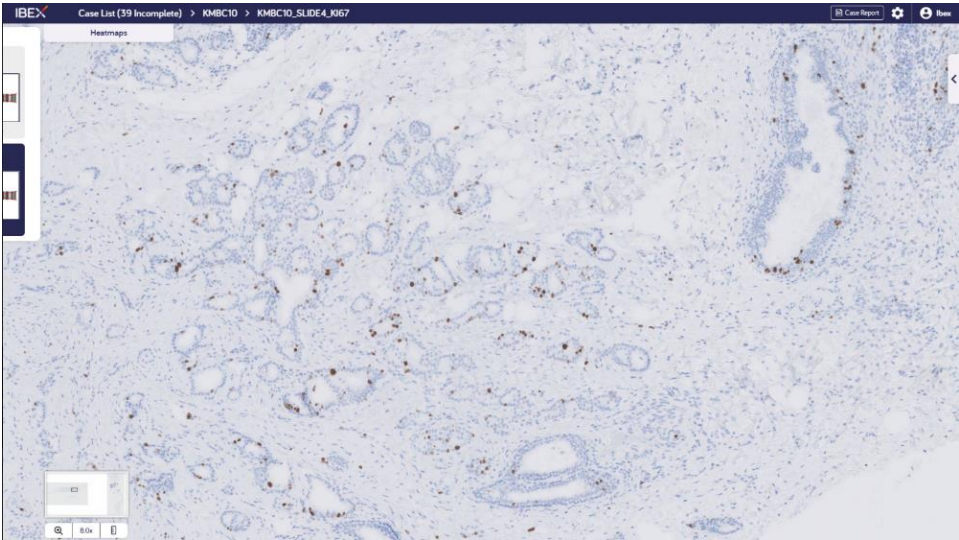
Pathologists' Performance for HER2 0 and 1+

- ✱ Higher agreement with GT and higher inter-observer concordance for pathologists with AI vs. without AI for cases with GT HER2 0 or 1+

Overall Pathologists' Performance with & without AI

- ✱ Higher inter-observer concordance and similar agreement with GT for pathologists with AI vs. W/O AI

Galen™ Breast Ki67: Example

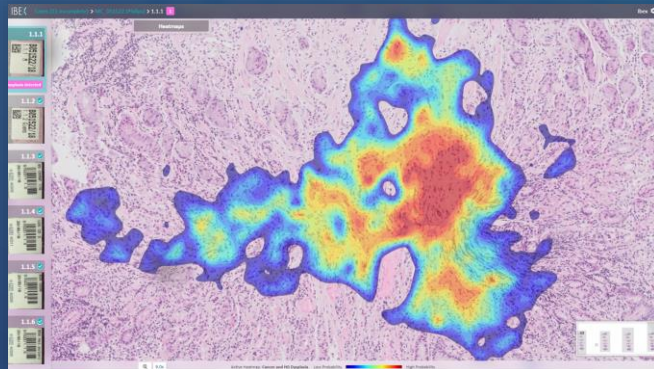
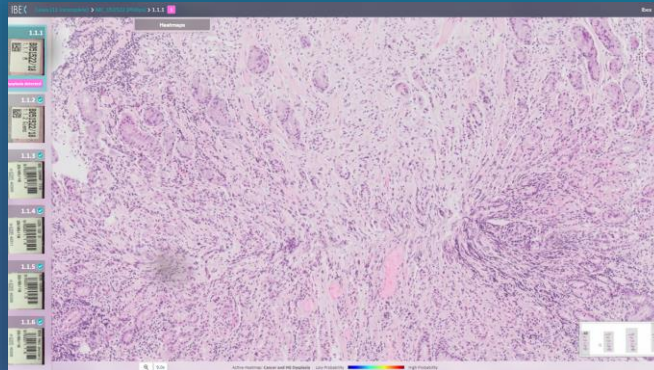




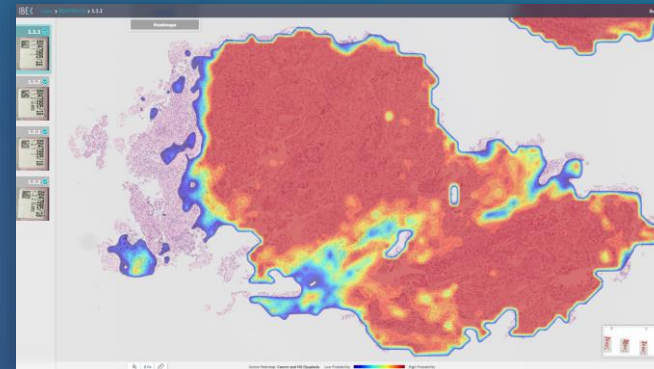
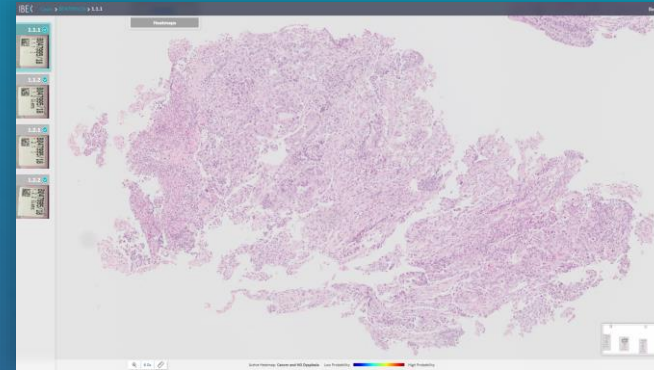
Galen™ Gastric

Galen™ Gastric: More Than Just Cancer

Gastric Cancer



High Grade Dysplasia

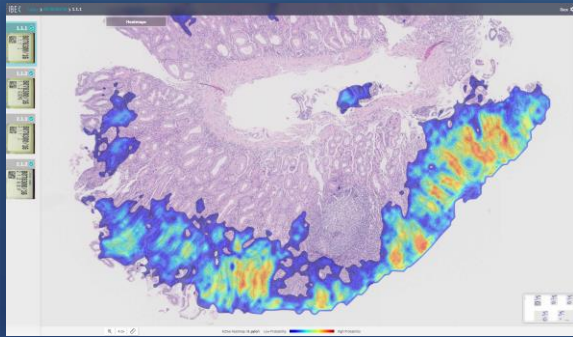
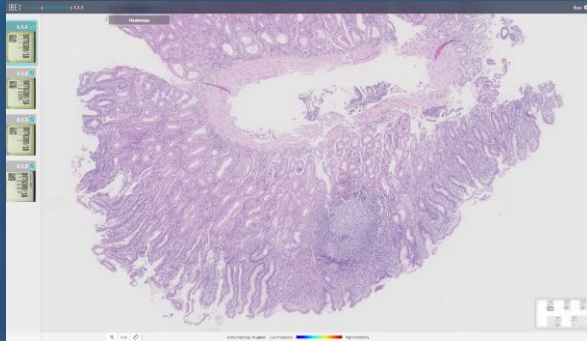


The only AI solution for the GI tract

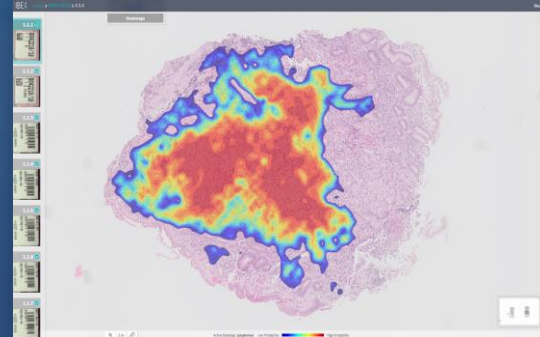
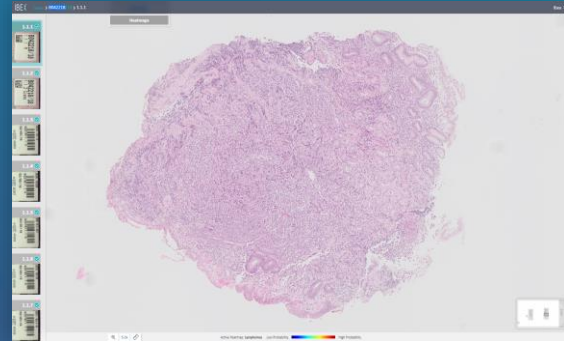
Galen™ Gastric: More Than Just Cancer



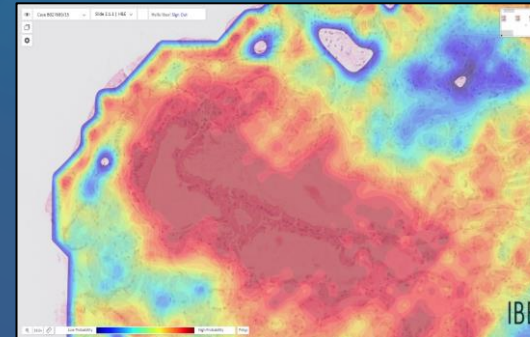
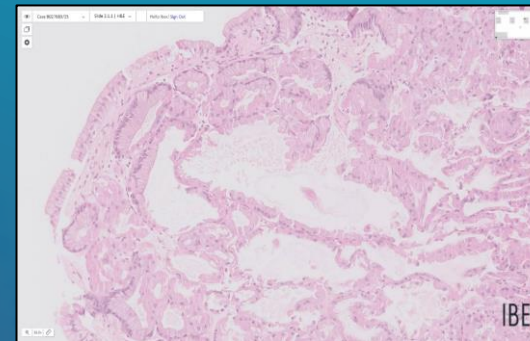
H. Pylori



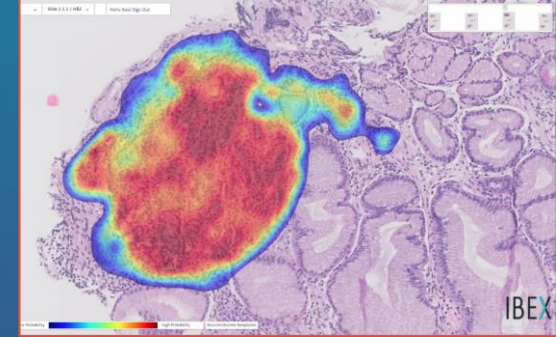
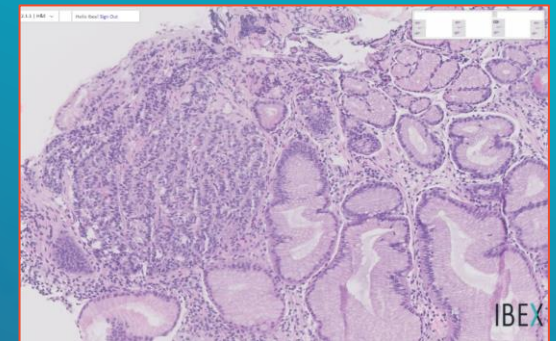
Lymphoma



Polyps



Neuroendocrine



The only AI solution for the GI tract



How Can AI Help in the Practice of GI Pathology?



Improve Quality

- **AI decision support** - Highlight clinically important lesions and other morphological features in primary diagnostic workflow
- **AI Diagnostic QA** - Provide second a read before final sign out to ensure clinically significant lesions have not been missed



Improve workflow & reduce TAT

- Screening tool
- Prioritisation / Triage of cases
- Pre-order IHC's / Addition Stains
- Eliminate need for IHC for some cases

Galen™ Gastric: AI-powered Cancer Detection

Detection	AUC	Specificity	Sensitivity
Carcinoma/ HG Dysplasia	0.994	97.3%	96.7%
Helicobacter pylori	0.966	91.7%	91.4%

- * Study of 1,845 gastric biopsies (810 H&E/HES slides): 82 carcinomas/HG dysplasia /HG lymphoma, 112 H. pylori cases 1
- * Galen Gastric goes beyond cancer detection and enables detection of lymphomas, neuroendocrine neoplasms, intestinal metaplasia, adenoma, LG dysplasia and more
- * Ibex AI can drive a more cost-effective workflow by detecting H.pylori and reducing turnaround time and stain ordering

1) Sandbank et al. Presented at USCAP 2022

Galen Gastric: AI for Primary Diagnosis

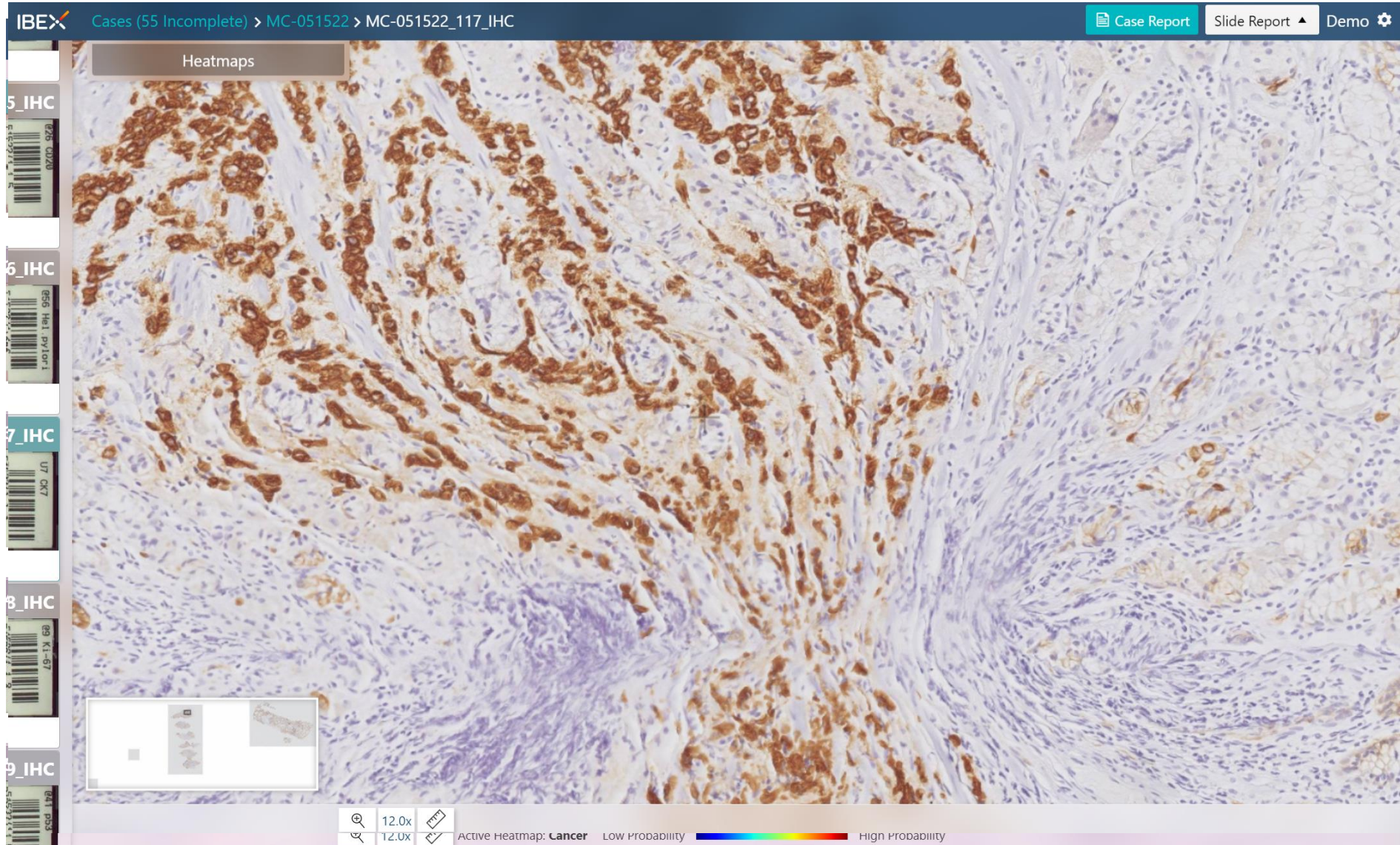
Arm	Agreement Rate	Major Discrepancy Rate	Sensitivity Cancer Detection
Digital review (SOC)	82.52%	17.48%	94.17%
Galen Gastric	86.99%	13.01%	91.67
Difference		-25%	

1) Rodriguez-Justo et al. Presented at ECP 2023

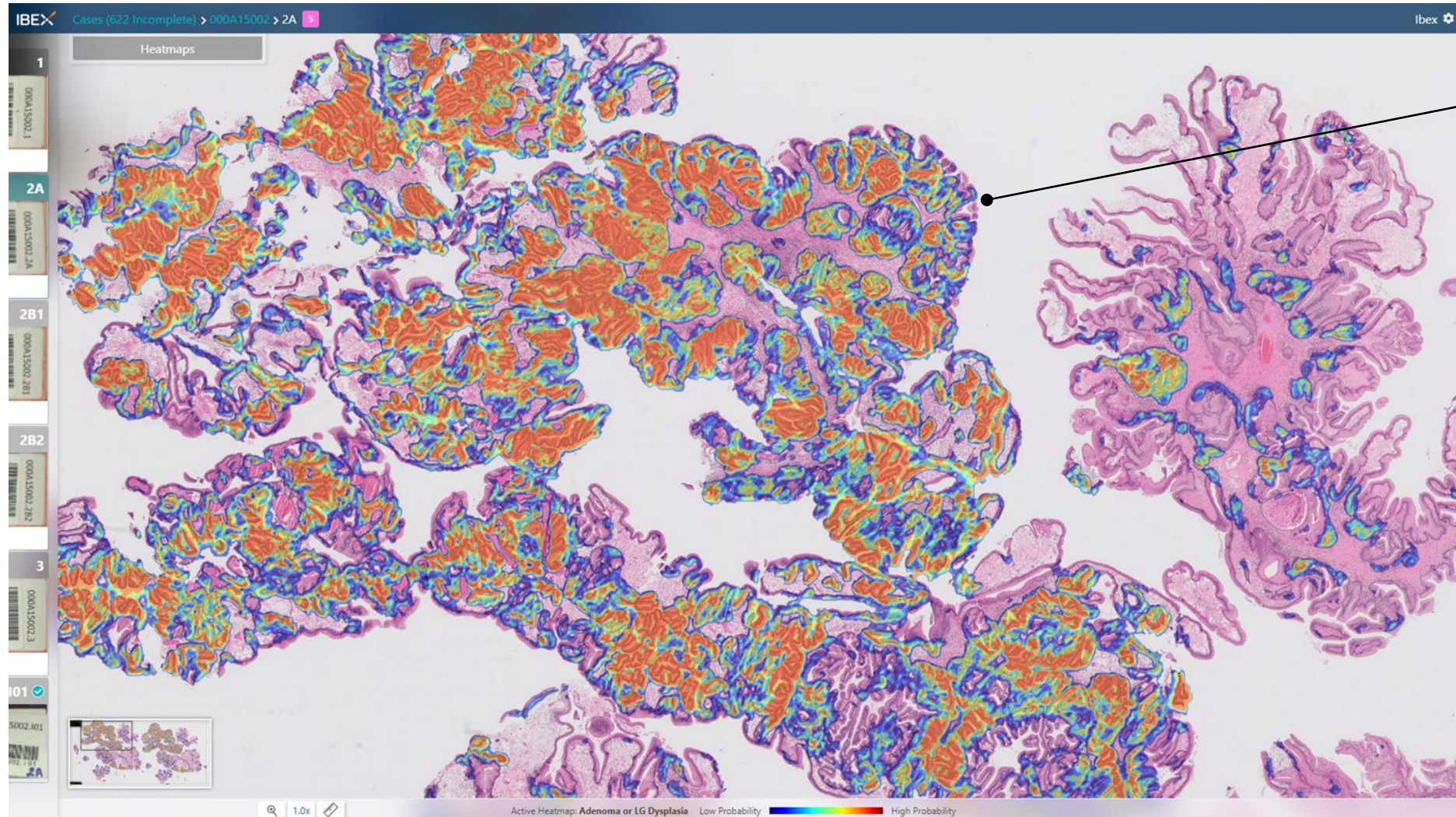


- * Multi-Site Multi Reader Study on Artificial Intelligence-Assisted Primary Diagnosis of Gastric Biopsies (235 cases collectively)
- * Parallel arms comparing pathologists with AI to pathologists with microscope
- * Galen Gastric was found to help pathologists **improve diagnostic quality**:
 - Improved overall accuracy (by 25%)¹
 - Lowered the major discrepancy rate in all pathologies measured inc. Carcinoma, HG Lymphoma, H.Pylori, LG Lymphoma, LG Dysplasia, Neuroendocrine lesions.
 - Improved sensitivity for gastric cancer¹

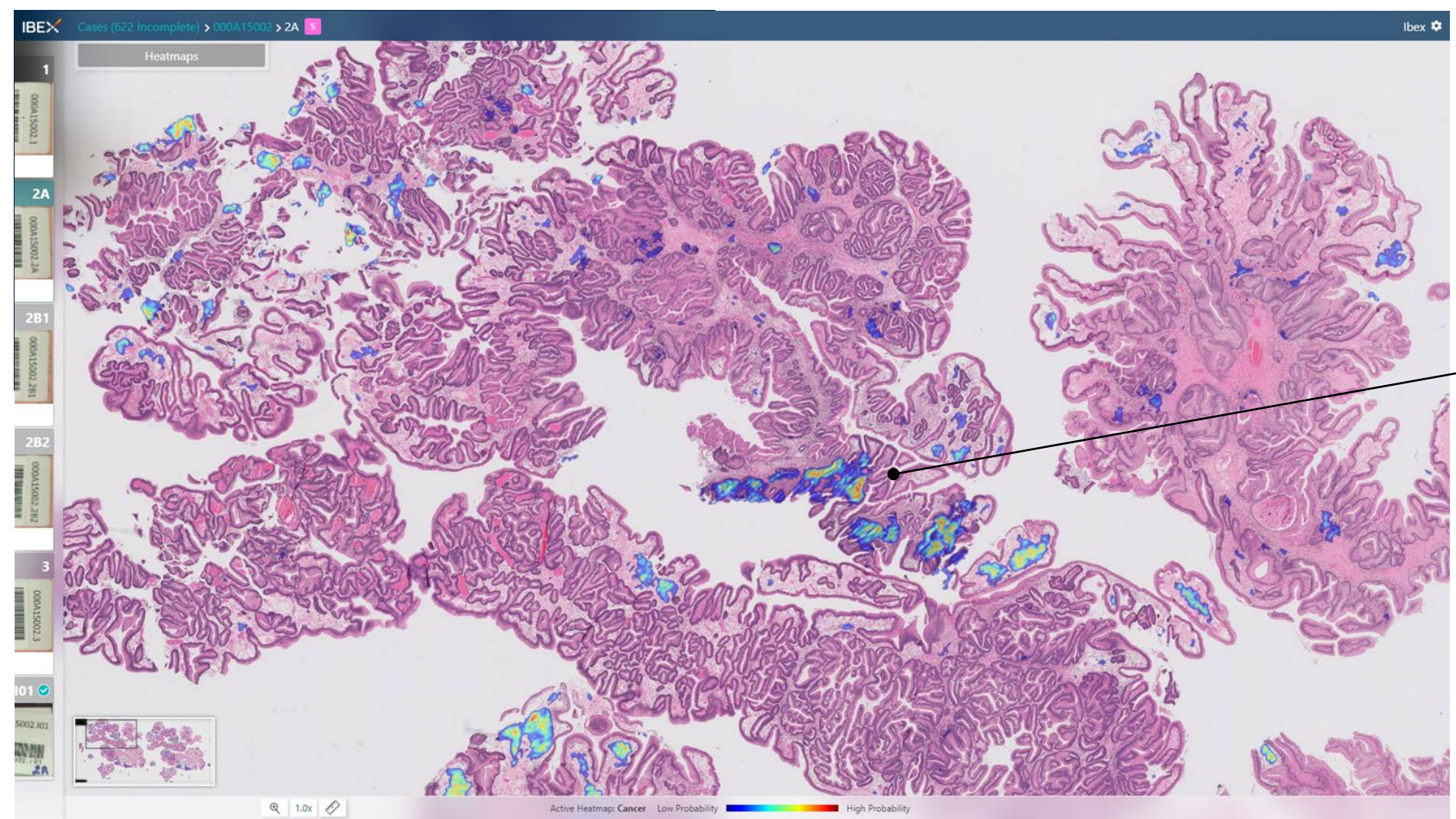
Example of Gastric Cancer Missed on the Microscope and Detected Using Galen Gastric



Example of HG Dysplasia Missed on the Microscope and Detected Using Galen Gastric

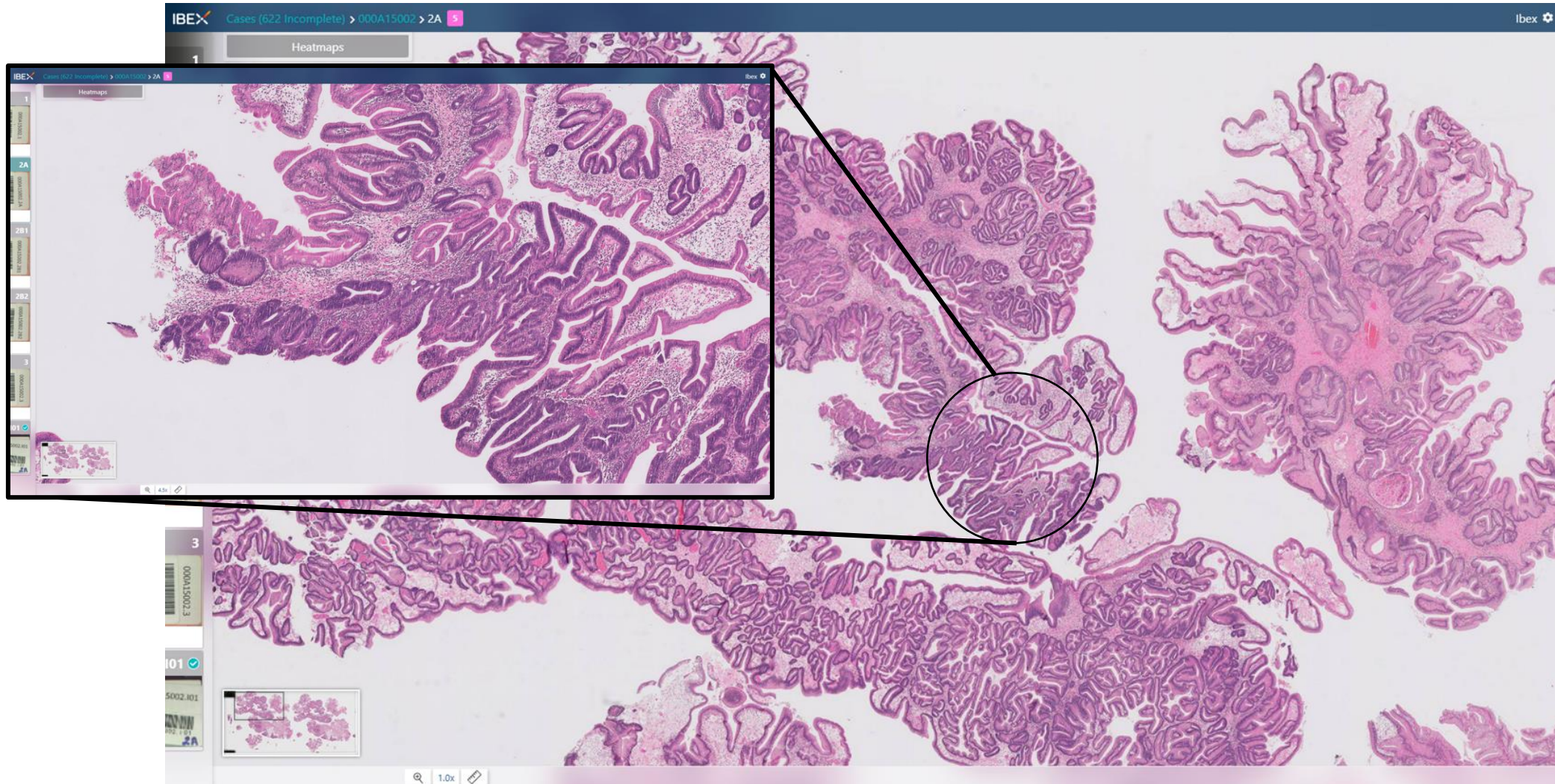


Example of HG Dysplasia Missed on the Microscope and Detected Using Galen Gastric

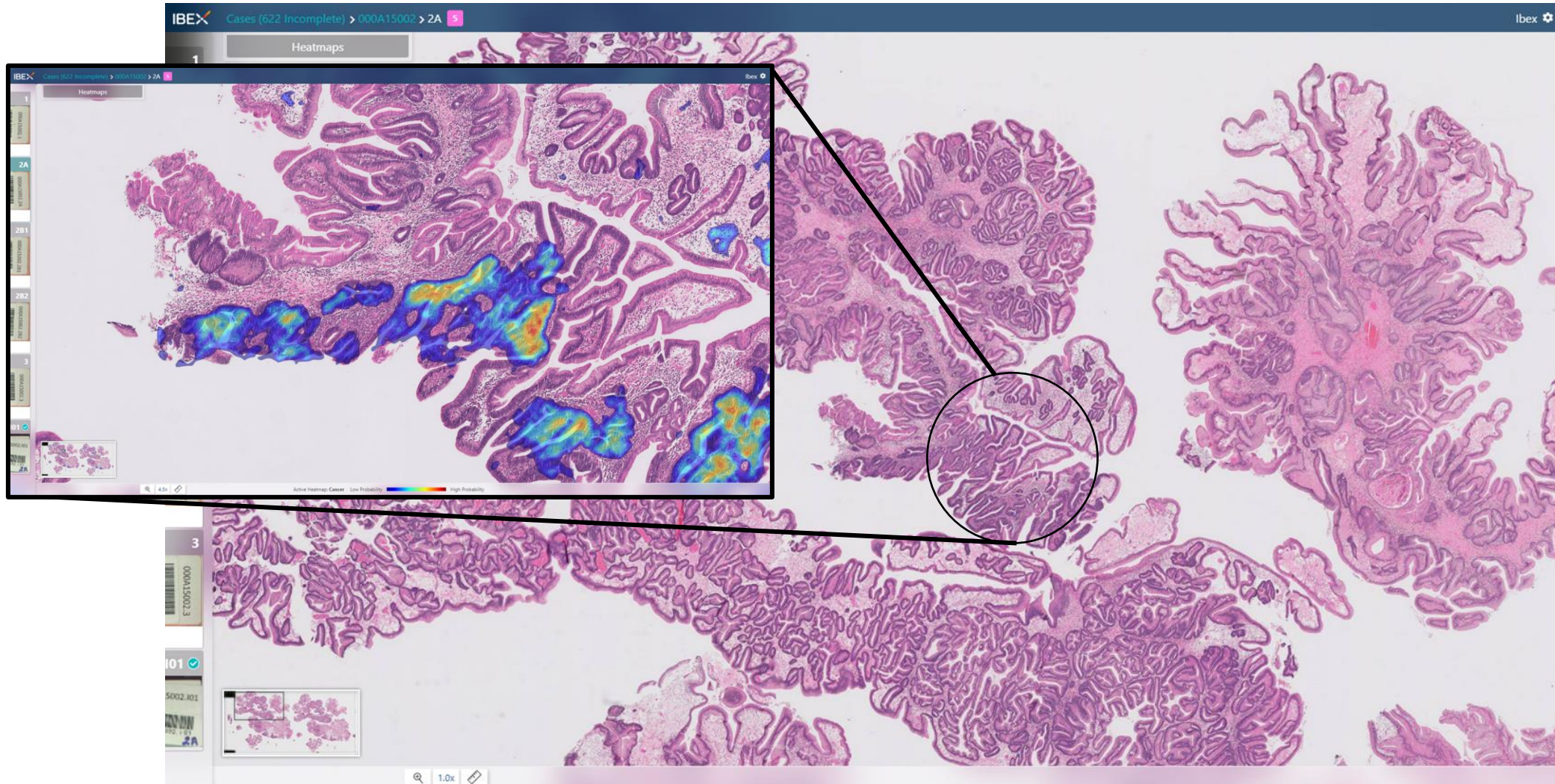


HG
Dysplasia

Example of HG Dysplasia Missed on the Microscope and Detected Using Galen Gastric

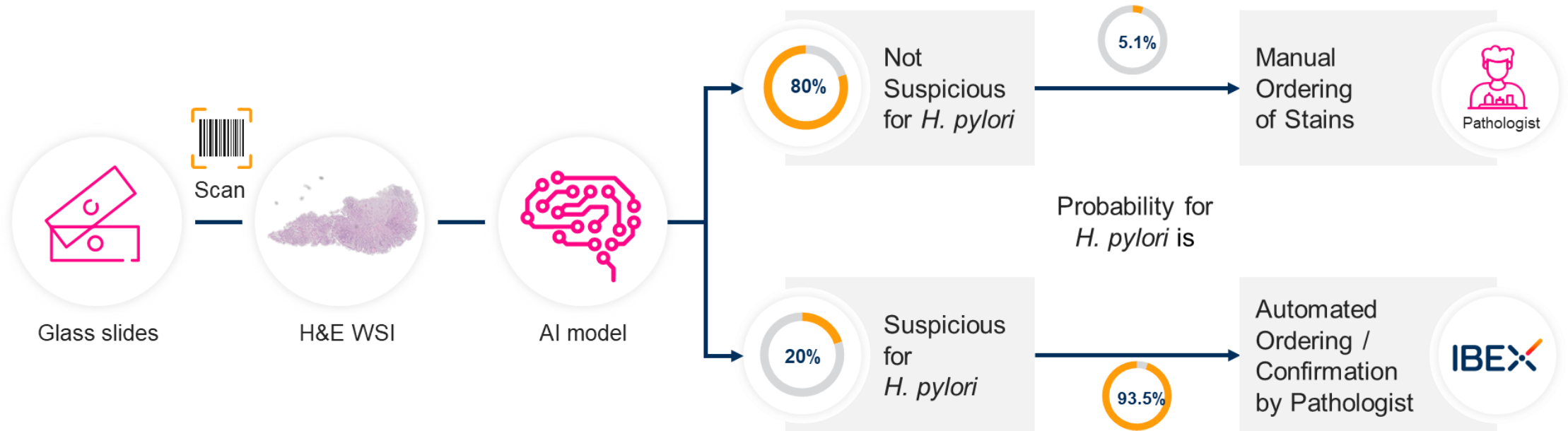


Example of HG Dysplasia Missed on the Microscope and Detected Using Galen Gastric





Optimised Workflow for Helicobacter Pylori detection



- * Galen Gastric can support optimization of H. pylori workflow:
- * Automatic screening for H. pylori diagnosis, streamlining H.pylori-IHC stain ordering, and reducing pathologists review and turnaround time (TAT)
- * Implementation of a comprehensive and efficient quality control process for increased diagnostic accuracy

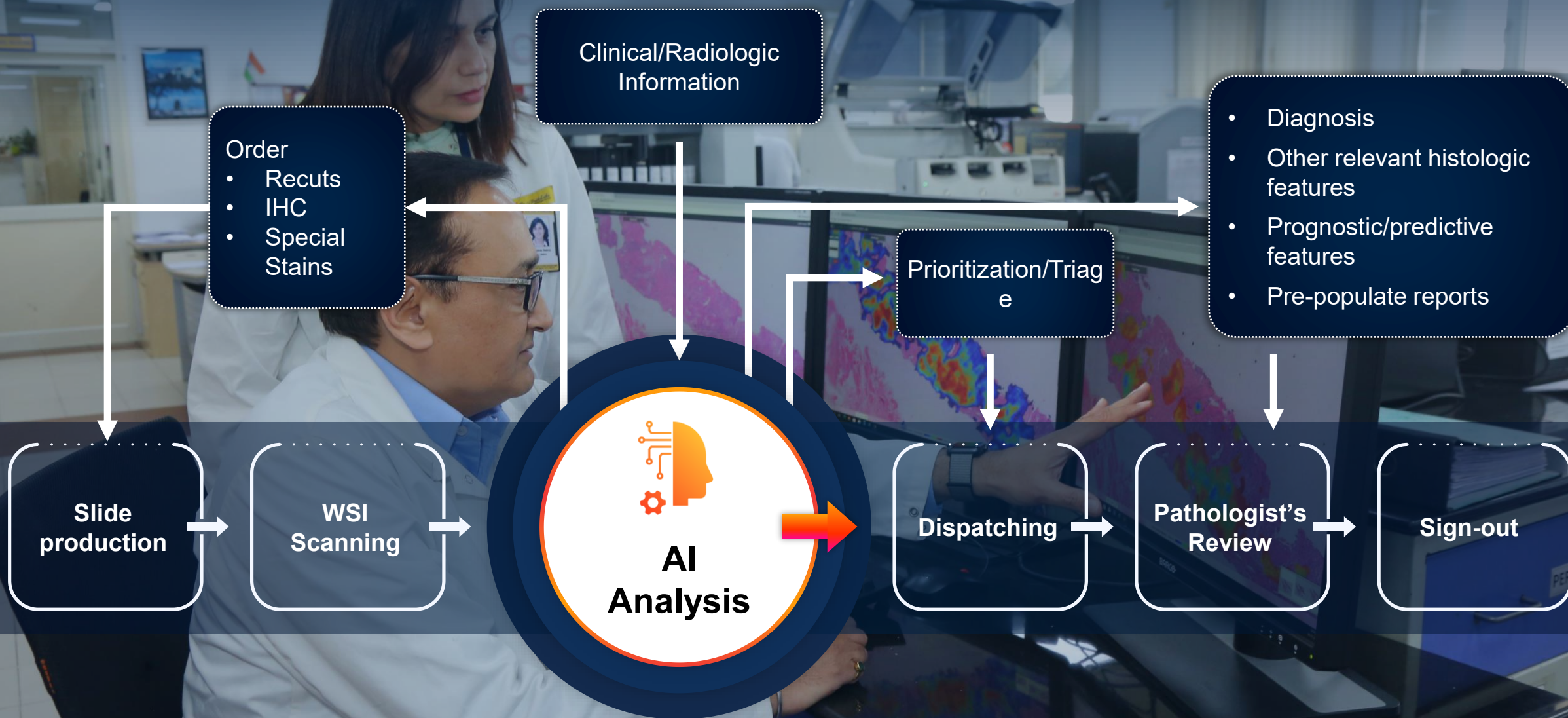
Screening, Triage & case Prioritisation



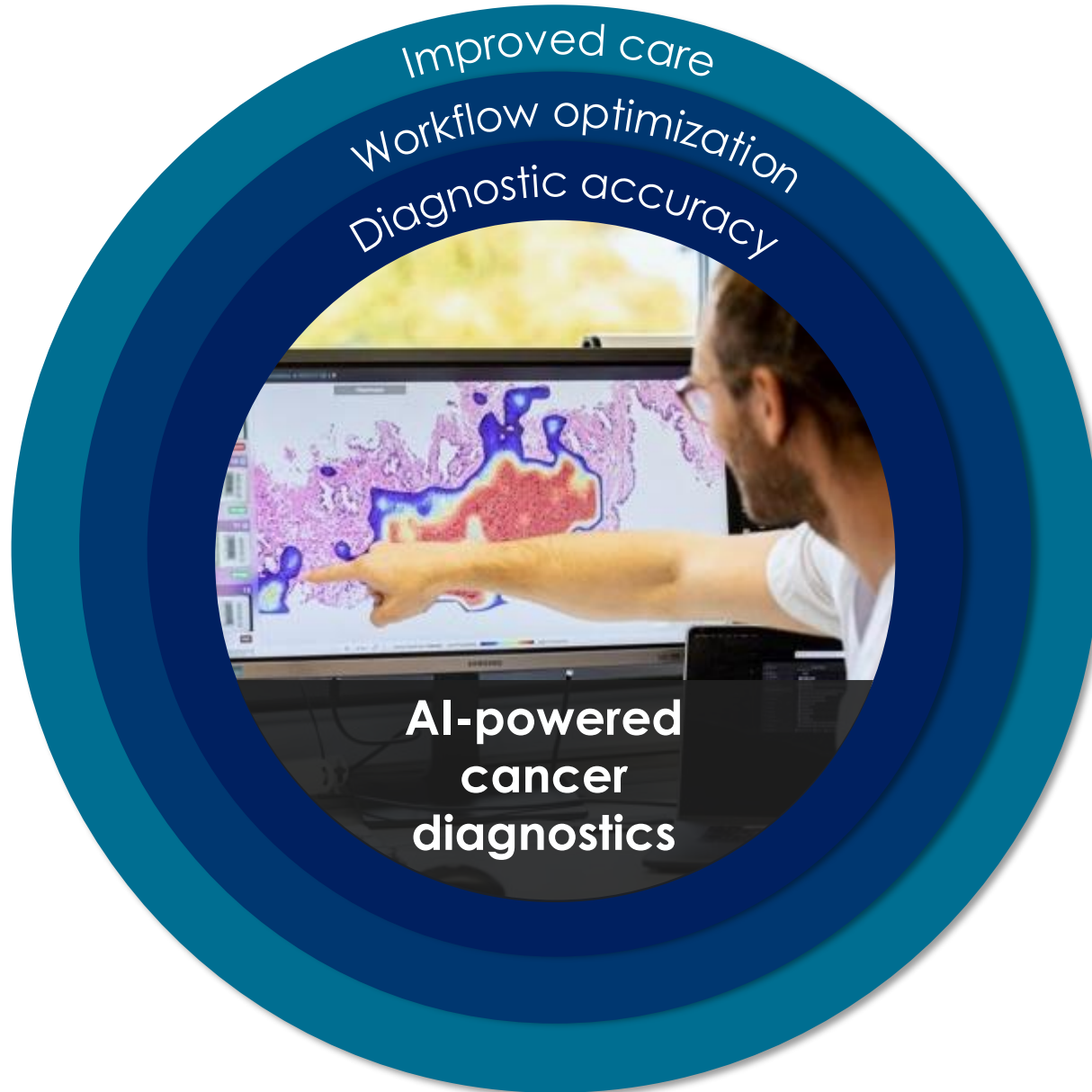
Gastric

	Case ID	Date ↓	Tissue	No. of Slides	Findings	Assigned to
	MP-015049	2022-06-06	gastric	2	HGD/Ca/HG Lymph	Pathologist ▼
	CP-001083	2022-06-06	gastric	2	Hp Gastritis	Pathologist ▼
	CP-001067	2022-06-06	gastric	2	Hp Gastritis	Dr. Gregory ▼
	MC-051522	2022-06-06	gastric	16		Dr. Gregory ▼
	MC-033320	2022-06-05	gastric	2		Pathologist ▼
	MC-037797	2022-06-01	gastric	12		Pathologist ▼
	MC-052165	2022-05-24	gastric	11		Pathologist ▼
	MC-000070	2022-05-24	gastric	8		Pathologist ▼
	MP-013449	2022-05-24	gastric	2		Pathologist ▼
	MP-014705	2022-05-24	gastric	15		Pathologist ▼
	MP-014818	2022-05-24	gastric	4		Pathologist ▼
	MP-014842	2022-05-24	gastric	7		Pathologist ▼
	MP-014855	2022-05-24	gastric	5		Pathologist ▼
	MP-014788	2022-05-24	gastric	2		Pathologist ▼
✓	MC-014967	2022-08-16	gastric	2		Dr. Doe ▼

The AI Driven Workflow of the Future



Revolutionising Cancer Diagnosis With AI



- Improved **accuracy**
- **Reduced error rate** and nearly eliminated missed cancers
- Improved **productivity**
- Shorter **turnaround** times
- Reduction of **IHC ordering**
- Improved **IHC quantification**: accuracy, subjectivity, reproducibility
- Ready for integration with scanning platforms, pathology workflow and lab information software
- Improved **lab workflows** with AI insights: Breast IC/DCIS detection, TILS, ALI, microcalcifications & more...
- **Reduced physician burnout** with better working experience and alleviated workloads

IBEX  THANK YOU

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