IBEX

Trusted Cancer Diagnostics For All

Pitch Symposium voor Pathologie

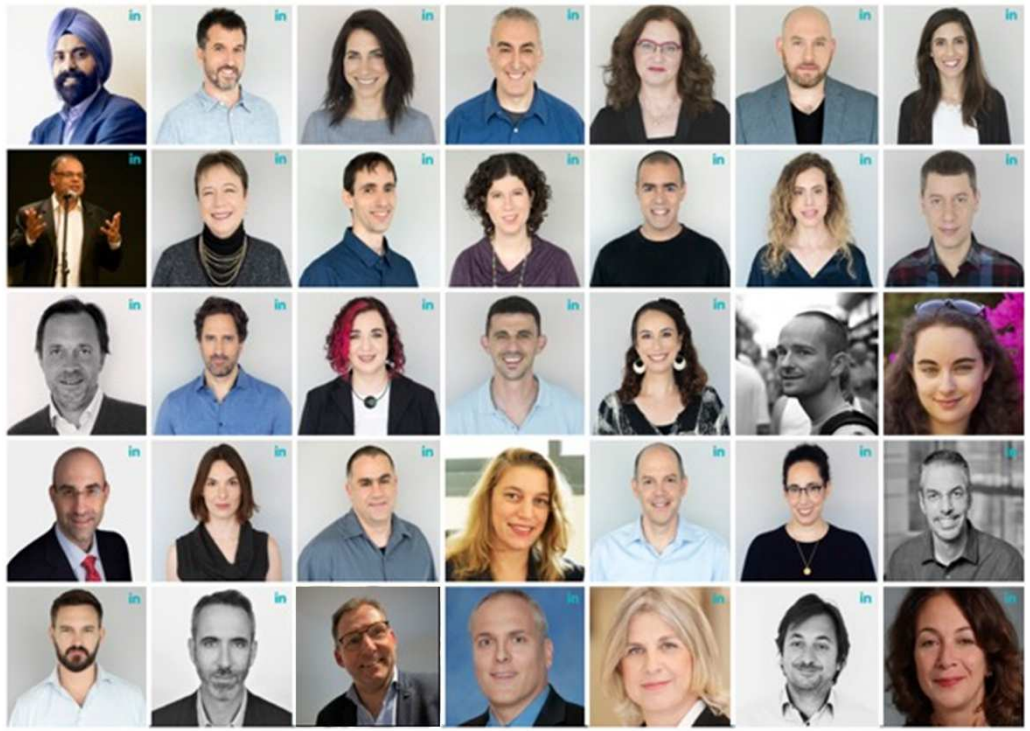
Olivier Poulin

December 2022

Ibex in a Nutshell

IBEX

- Ibex are the **pioneers of Clinical-grade AI** in pathology
- Live deployment in **routine clinical practice since April 2018**
- **Industry leading** technology & performance (**CE-IVD**), **FDA BDD**
- Solutions **today** for **Prostate**, **Breast** & **Gastric** (strong pipeline)
- Large data partnerships with **access to >7,000,000 slides**.
  Prostate developed on **dataset of >60,000 slides**
  Breast developed on **dataset of >150,000 slides**



Ibex is also the **most implemented AI company** with **live deployments** for routine clinical use in pathology

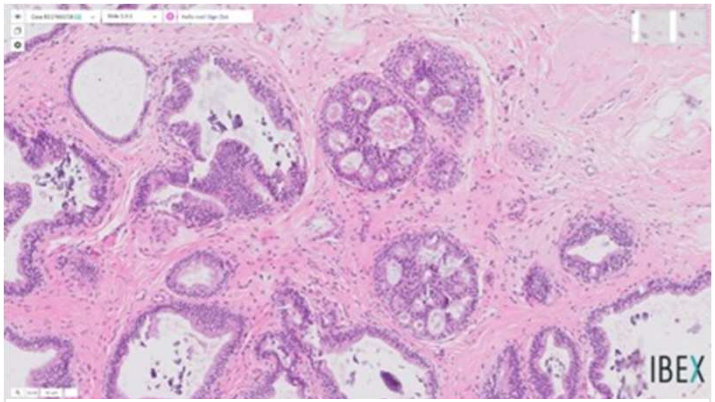
Ibex is revolutionizing cancer diagnostics with AI

The opportunity for Pathology

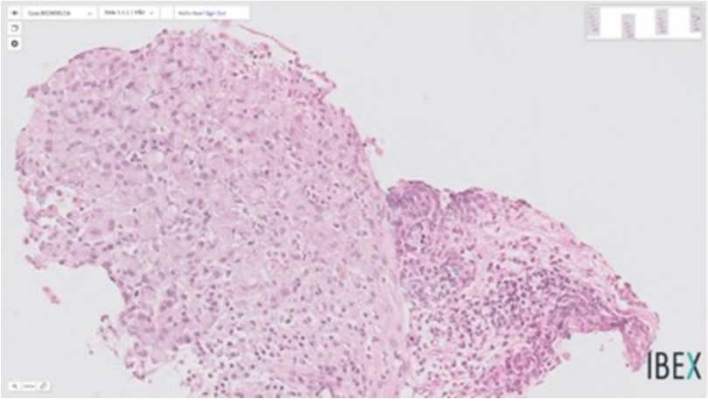
The opportunity

- Facilitate scalable growth
- Drive standardization
- Productivity of pathologists / create time
- Eliminate diagnostic discrepancies & contribute to structured reporting

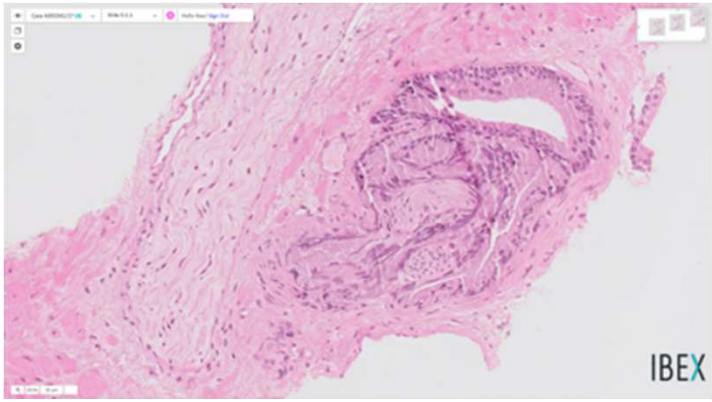
Misdiagnosis Is Not Uncommon



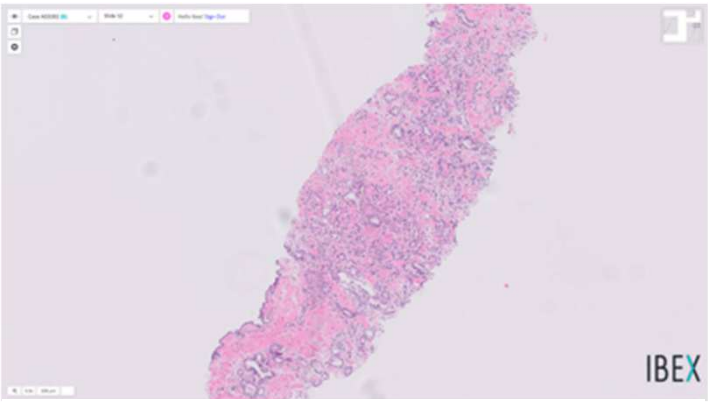
Tissue	Original Dx	IBEX Dx
Breast	**Benign**	



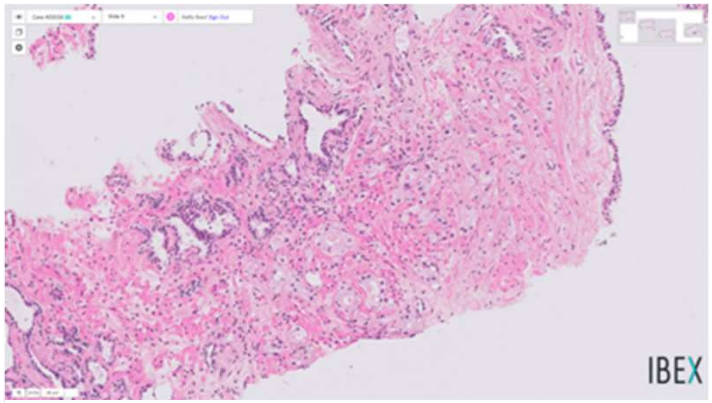
Tissue	Original Dx	IBEX Dx
Gastric	**Benign**	



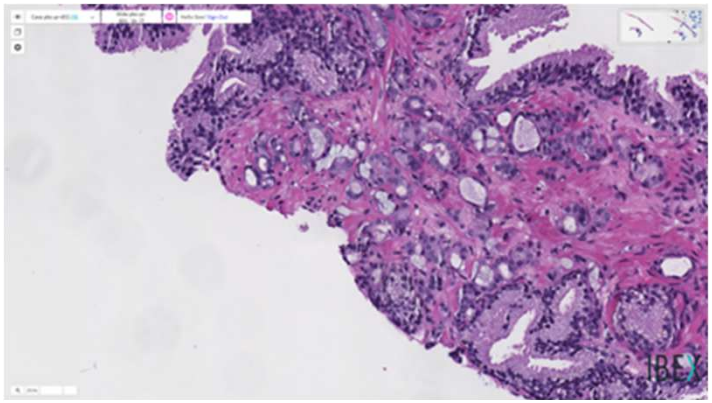
Tissue	Original Dx	IBEX Dx
Prostate	**Benign**	



Tissue	Original Dx	IBEX Dx
Prostate	**Benign**	

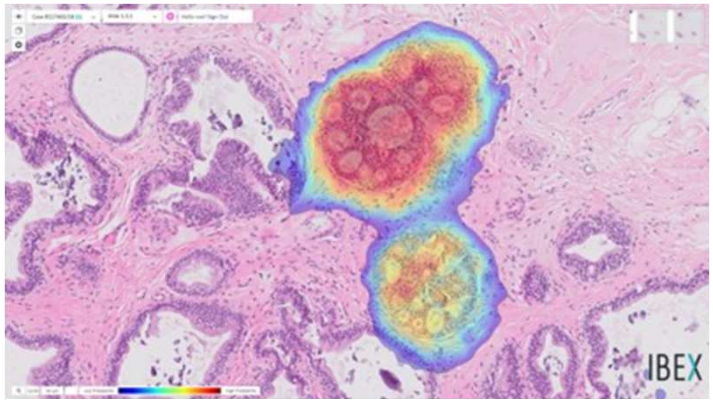


Tissue	Original Dx	IBEX Dx
Prostate	**Benign**	

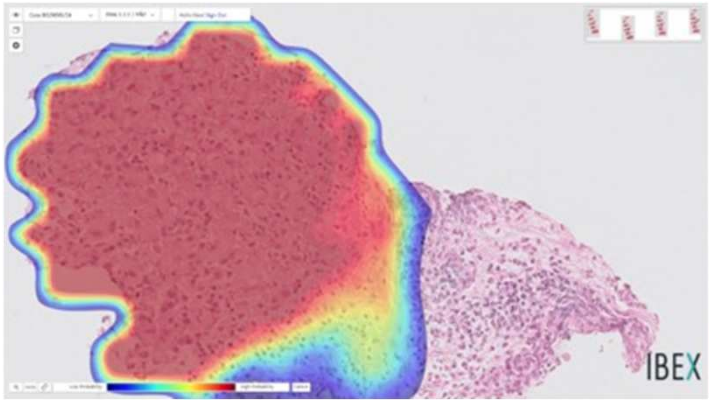


Tissue	Original Dx	IBEX Dx
Prostate	**ADC G3+3**	

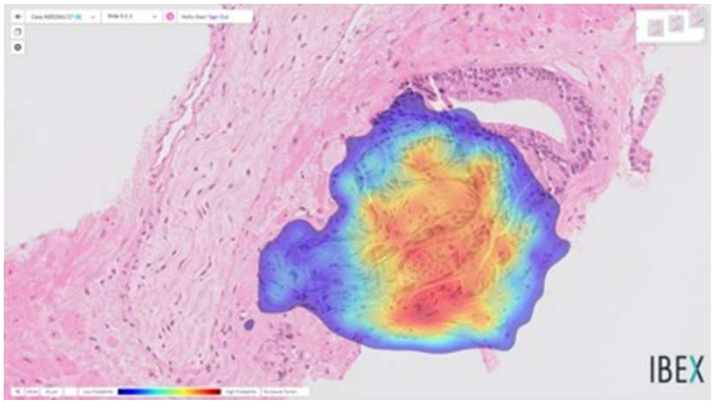
Misdiagnosis Is Not Uncommon



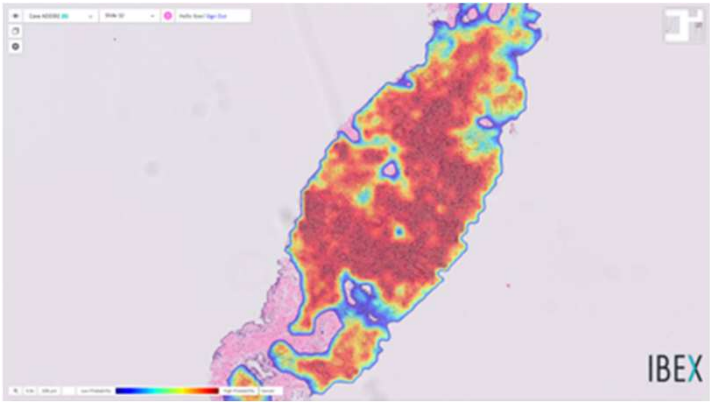
Tissue	Original Dx	IBEX Dx
Breast	**Benign**	**DCIS**



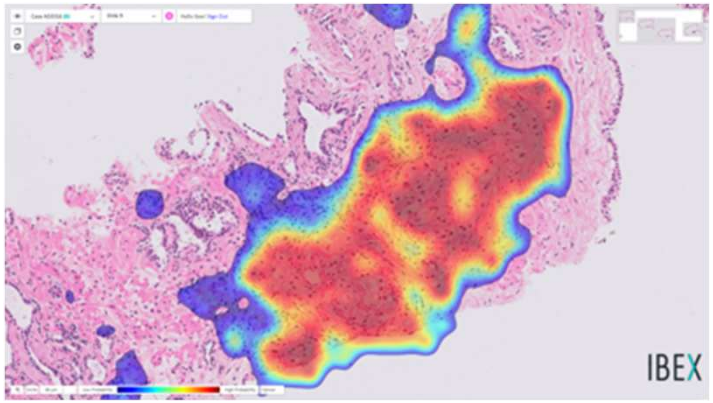
Tissue	Original Dx	IBEX Dx
Gastric	**Benign**	**PC Carcinoma**



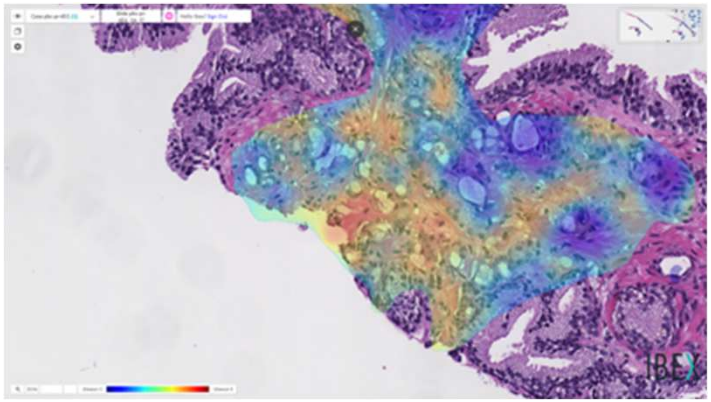
Tissue	Original Dx	IBEX Dx
Prostate	**Benign**	**ADC G4+3 PNI**



Tissue	Original Dx	IBEX Dx
Prostate	**Benign**	**ADC G4+3**



Tissue	Original Dx	IBEX Dx
Prostate	**Benign**	**ADC G4+3**



Tissue	Original Dx	IBEX Dx
Prostate	**ADC G3+3**	**ADC G4+3**

Clinical Excellence

IBEX

institut Curie | Maccabi The Best Healthcare Group in Israel

Galen™ Breast

Breast cancer detection[1]

Cancer type	AUC	SPEC	SENS
Invasive	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%

- **Very high accuracy levels**
- Multi site, blinded study
- 436 breast biopsies (841 slides)
- Multiple scanning systems and staining platforms
- Including rare cancer subtypes

UPMC LIFE CHANGING MEDICINE

Galen™ Prostate

Prostate cancer detection[2]

AUC	SPEC	SENS	# slides
0.99	98.5%	97%	1,627

Grading and more[2]

Test	Performance
G7+	AUC = 0.94
G5	AUC = 0.97
Perineural invasion	AUC = 0.96
Cancer size	Correlation = 0.88

- **First study to go beyond cancer detection**
- First study to report on AI used in routine practice in pathology

THE LANCET Digital Health

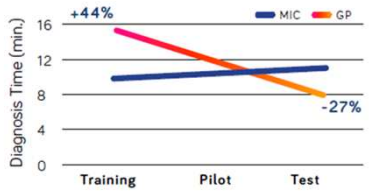
MEDIPATH Médecins pathologistes indépendants

Galen™ Prostate

Prostate cancer detection[3]

AUC	SPEC	SENS	# slides
0.997	95.6%	98.6%	860

Average diagnosis time[4]



- **Ibex AI helps pathologists perform significantly better** than with a microscope in primary diagnosis
- **37% productivity gains[4]**
- 32% less discrepancies with ground truth[5]
- 12% missed cancer rate when using a microscope[6]. Detected by AI

Maccabi The Best Healthcare in Israel

Galen™ Gastric

Cancer detection[7](AdC/HG dysplasia)

AUC	SPEC	SENS	# cases
0.994	97.3%	96.7%	1,845

H.pylori detection[7]

AUC	SPEC	SENS	# cases
0.966	91.7%	91.4%	691

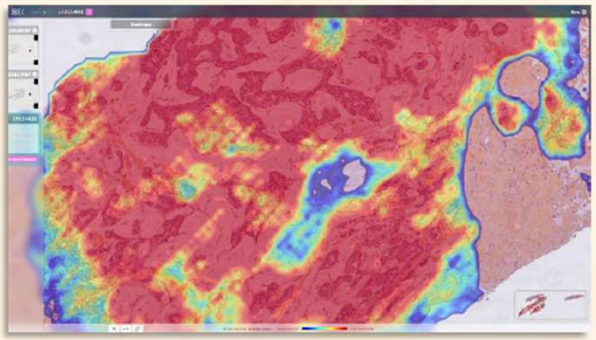
- **The only AI solution for the GI tract**
- Galen Gastric goes beyond cancer detection and enables detection of lymphomas, neuroendocrine neoplasms, intestinal metaplasia, adenoma, LG dysplasia and more
- **Ibex AI can drive a more cost-effective workflow** by detecting H.pylori and reducing turnaround time and stain ordering

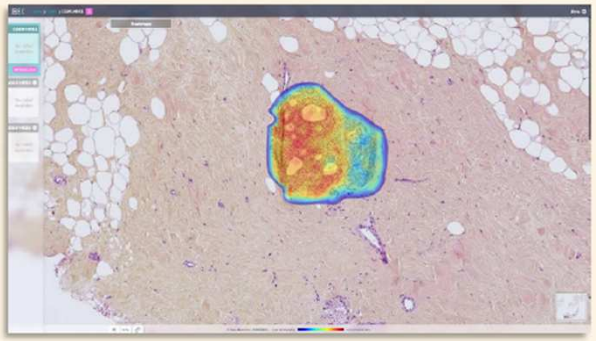
1) Vincent-Salomon et al. Presented at the European Congress of Pathology 2021 (CLICK TO WATCH) 2) Pantanowitz et al. THE LANCET Digital Health Aug 2020 (CLICK TO READ) 3) Amin et al. Presented at USCAP 2021 (CLICK TO WATCH) 4) Raoux et al. Presented at USCAP 2021 (CLICK TO WATCH) 5) Comperat et al. Presented at the European Congress of Pathology 2021 6) Laifenfeld et al. Presented at the European Congress of Pathology 2019 (CLICK TO READ) 7) Sandbank et al. Presented at USCAP 2022 (CLICK TO WATCH)

Galen Breast: Multi-site Validation Study

- Multi-site study of 436 breast biopsies (841 slides): 156 invasive, 135 DCIS/ADH, 145 benign
- Enriched with rare subtypes
- Multiple scanning systems and staining platforms
- Successfully validated the performance of Galen Breast:
  - **High performance for invasive carcinoma and DCIS detection**
  - **Differentiated well** between subtypes/grades of invasive and in-situ cancers

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%





Vincent-Salomon, et al, USCAP 2022

Ibex AI Performance: Invasive Carcinoma Detection

INVASIVE CARCINOMA DETECTION*

N=436 cases (156 invasive; 135 DCIS/ADH; 145 benign)

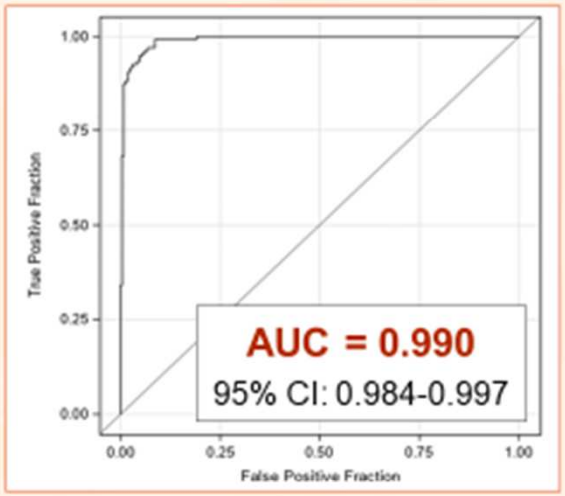
Performance		95% Confidence Limits	
Sensitivity	95.51%	91.03%	97.81%
Specificity	93.57%	90.07%	95.90%
PPV	89.22%	83.61%	93.07%
NPV	97.40%	94.73%	98.73%

PPV – positive predictive value; NPV- negative predictive value

*Note: The cohort was enriched with 34 rare cases, such as metaplastic, acinic cells, tubular, apocrine, mucinous and micropapillary carcinomas and others

Performance on consecutive biopsies is expected to be higher

ROC CURVE



AUC – area under the ROC curve; Galen Breast invasive probability score versus the ground truth diagnosis after discrepancy review

AI demonstrated **extremely high performance** in detecting **multiple types of invasive cancer**

Vincent-Salomon, et al, USCAP 2022

Ibex AI Performance: In Situ Carcinoma Detection

DCIS DETECTION[1]

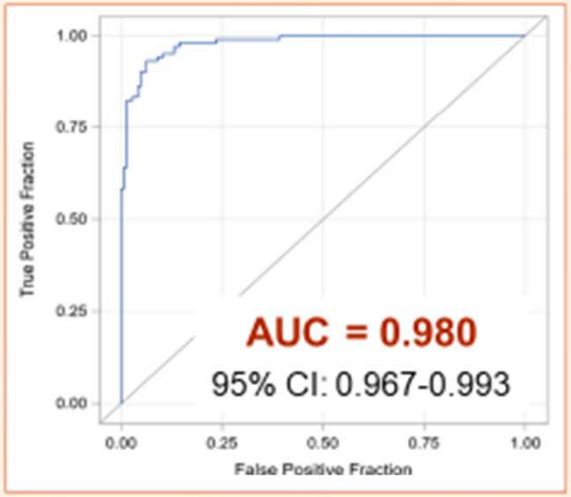
N= 248 cases (103 DCIS; 145 benign/other)

Performance		95% Confidence Limits	
Sensitivity	93.79%	88.63%	96.70%
Specificity	93.20%	86.63%	96.67%
PPV	91.4%	84.51%	95.43%
NPV	95.1%	90.24%	97.61%

*Note: The cohort was enriched with uncommon subtypes of DCIS (e.g., low-grade DCIS); Performance on consecutive biopsies is expected to be higher

[1]Performance for DCIS/ADH detection is AUC=0.949, Specificity=86.9%, Sensitivity=87.41%

ROC CURVE



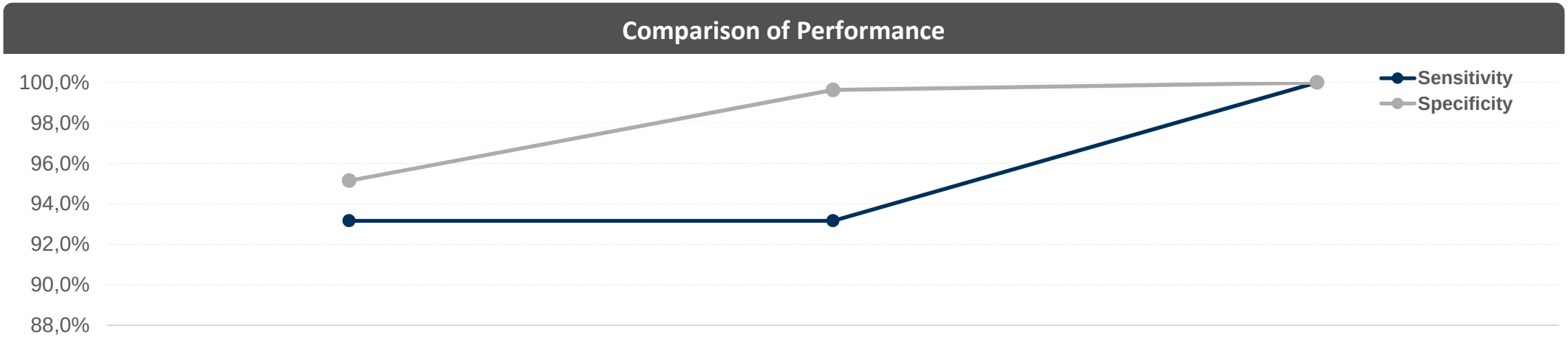
AUC – area under the ROC curve; Galen Breast in-situ probability score versus the ground truth diagnosis after discrepancy review

AI demonstrated **high performance** in detection of **DCIS** vs. benign

Vincent-Salomon, et al, USCAP 2022

Galen Breast Improves Pathologists' Accuracy on Invasive Cancer Detection

IBEX



	Galen Breast AI algorithm*	Pathologists on Microscope	Pathologists using Galen Breast
Sensitivity	93.2%	93.2%	100.00%
Specificity	95.2%	99.6%	100.00%
PPV	93.2%	99.0%	100.00%
NPV	97%	97.0%	100.00%

*Galen Breast algorithm analyzed H&E slides only

Note: These studies do not represent a typical case distribution in a lab, since certain indications were **enriched** in order to allow sufficient statistical power for various analyses; **Performance on consecutive biopsies is expected to be higher**

Sandbank J, et al, ECP 2022

Review with Galen Breast Led to 30% Reduction in IHCs Ordering

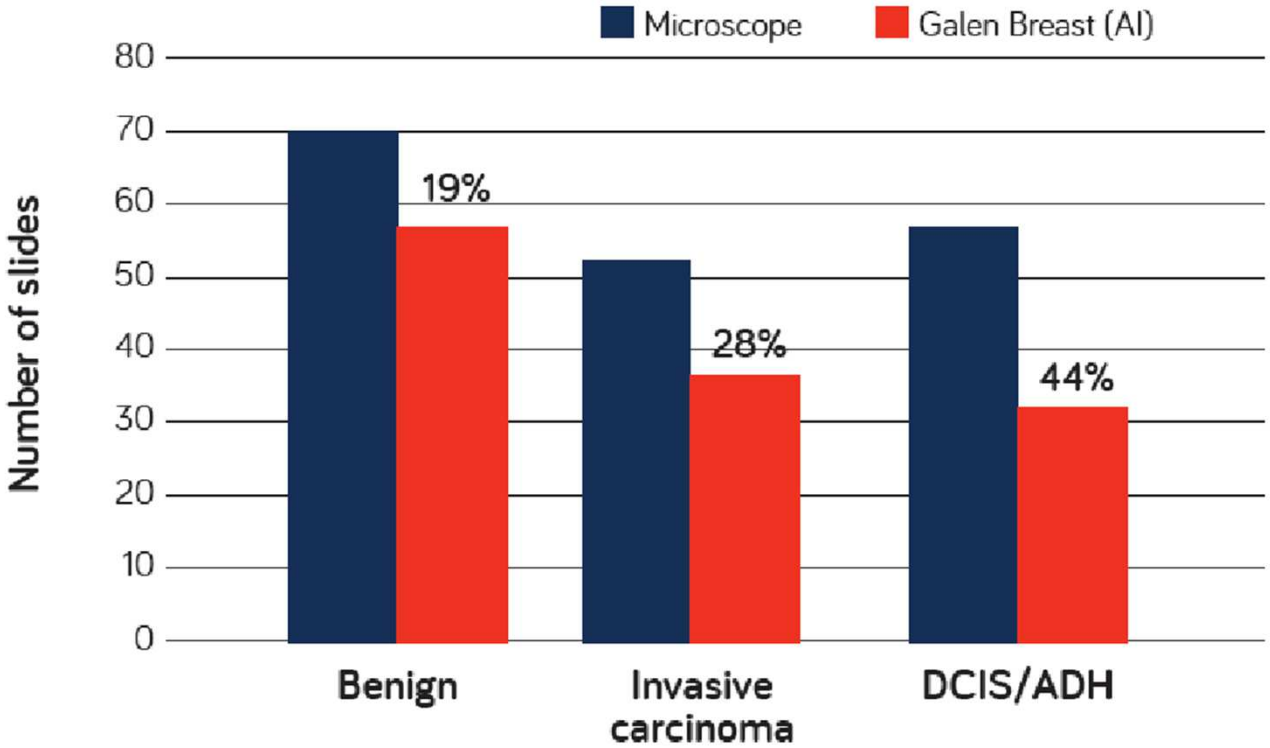


Figure 1. Amount of diagnostic IHCs ordered by pathologists in both arms

Sandbank J, et al, USCAP 2022

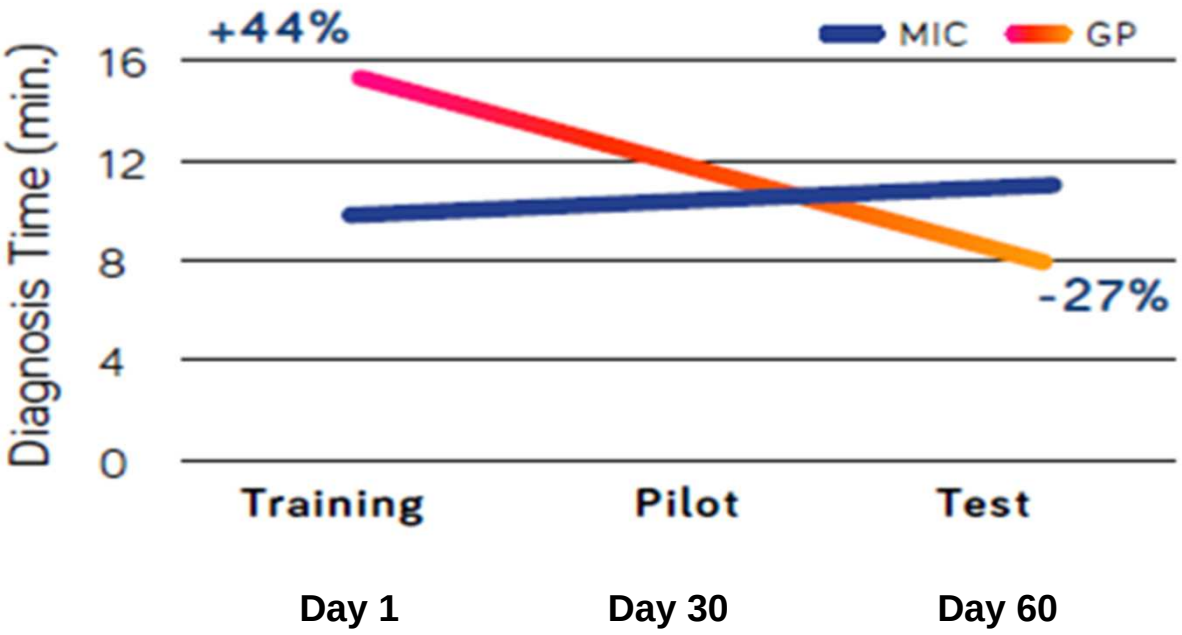
Improved Pathologists' Performance with Galen Breast

Major Discrepancy Rate Comparison of the Study Arms				
Arm	**Agreement Rate**	**Major Discrepancy Rate**	**95% Confidence Interval**	
Microscope vs GT	95.6%	**4.42%**	2.4%	6.5%
Galen Breast vs GT	96.9%	**3.12%**	1.4%	4.9%
Difference		**-29%**		

Galen Breast was found to help pathologists improve diagnostic quality:
29% lower major discrepancy rate

Sandbank J, et al, ECP 2022

Efficiency study at Medipath



- **37% productivity gains** in a non-integrated deployment
- **32% less discrepancies** with ground truth
- **no missed cancer** when using Galen Platform.

Galen™ Platform: AI-supported Cancer Diagnosis

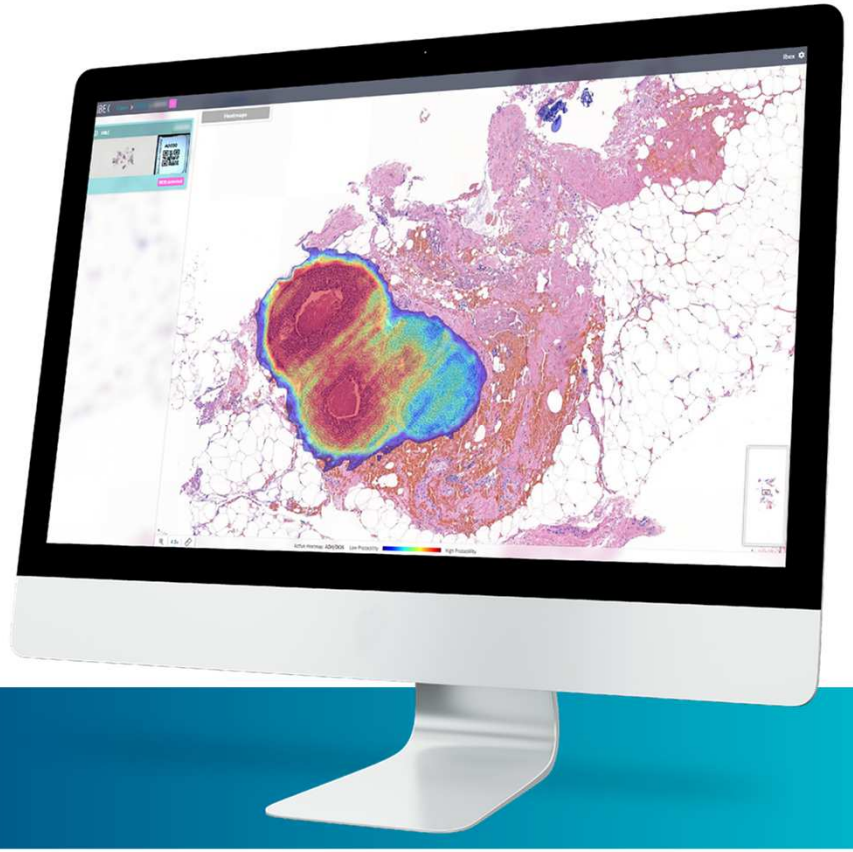
Slide production → Scanning → IBEX → Review

Available in multiple workflows:
- Supporting case review during **Primary diagnosis**
- AI-powered second reads on all cases

Real-time multi tissue detection: **prostate**, **breast** and **gastric**

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

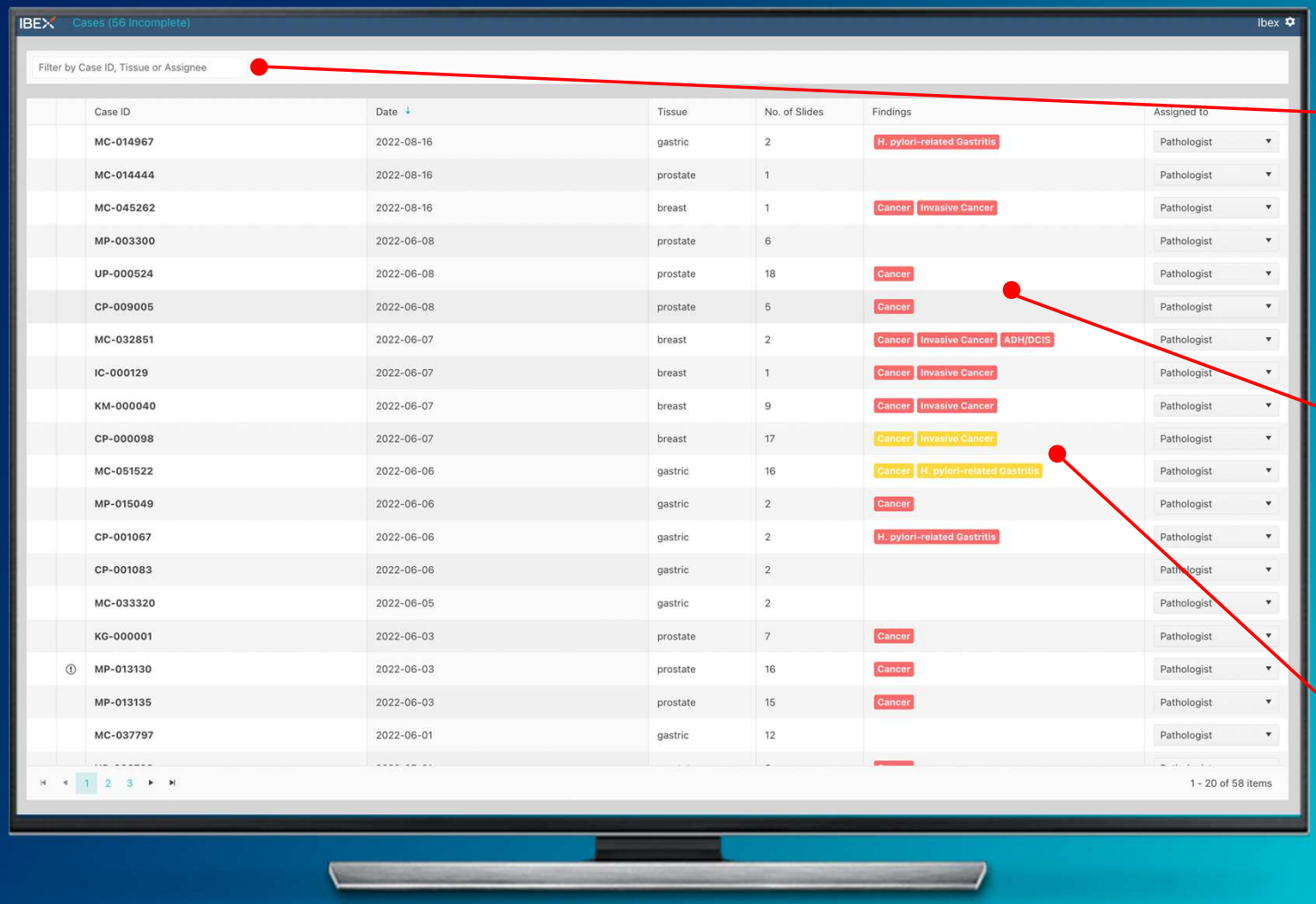
Open API for AI-integration with scanning, workflow and LIS systems



Deployed at labs worldwide and used by pathologists in everyday practice

The Galen platform is CE Marked and approved in additional territories. It is not FDA cleared and for Research Use Only (RUO) in the United States

Ibex Worklist: Quickly identify & prioritize work



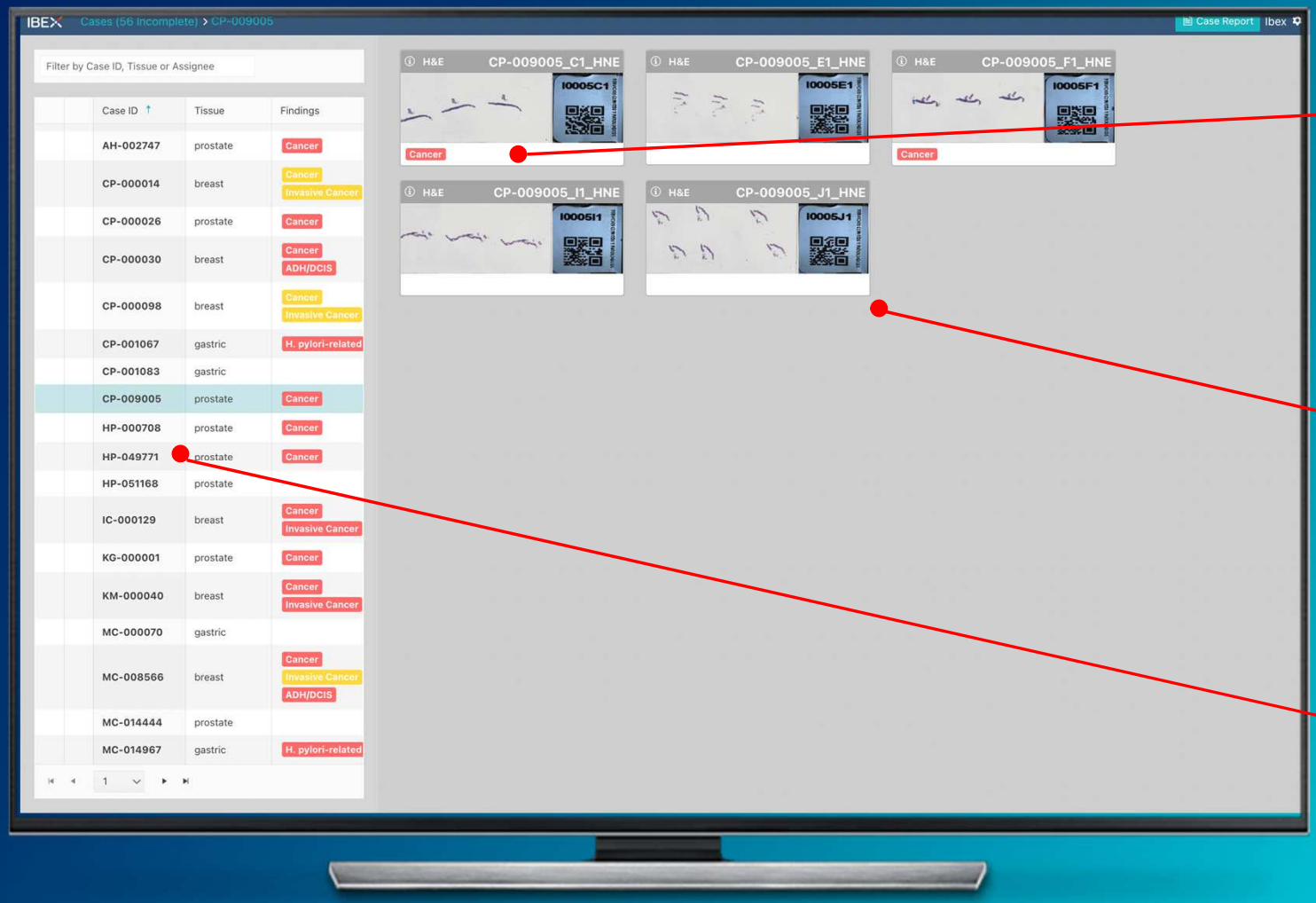
Case ID	Date	Tissue	No. of Slides	Findings	Assigned to
MC-014967	2022-08-16	gastric	2	H. pylori-related Gastritis	Pathologist
MC-014444	2022-08-16	prostate	1		Pathologist
MC-045262	2022-08-16	breast	1	Cancer, Invasive Cancer	Pathologist
MP-003300	2022-06-08	prostate	6		Pathologist
UP-000524	2022-06-08	prostate	18	Cancer	Pathologist
CP-009005	2022-06-08	prostate	5	Cancer	Pathologist
MC-032851	2022-06-07	breast	2	Cancer, Invasive Cancer, ADH/DCIS	Pathologist
IC-000129	2022-06-07	breast	1	Cancer, Invasive Cancer	Pathologist
KM-000040	2022-06-07	breast	9	Cancer, Invasive Cancer	Pathologist
CP-000098	2022-06-07	breast	17	Cancer, Invasive Cancer	Pathologist
MC-051522	2022-06-06	gastric	16	Cancer, H. pylori-related Gastritis	Pathologist
MP-015049	2022-06-06	gastric	2	Cancer	Pathologist
CP-001067	2022-06-06	gastric	2	H. pylori-related Gastritis	Pathologist
CP-001083	2022-06-06	gastric	2		Pathologist
MC-033320	2022-06-05	gastric	2		Pathologist
KG-000001	2022-06-03	prostate	7	Cancer	Pathologist
MP-013130	2022-06-03	prostate	16	Cancer	Pathologist
MP-013135	2022-06-03	prostate	15	Cancer	Pathologist
MC-037797	2022-06-01	gastric	12		Pathologist

Search & Sort for Cases to help manage workload

AI Findings: Allow pathologists to quickly identify urgent cases.

Identify challenging cases that require IHC to improve TAT

Case Overview: Quickly navigate slides in a case

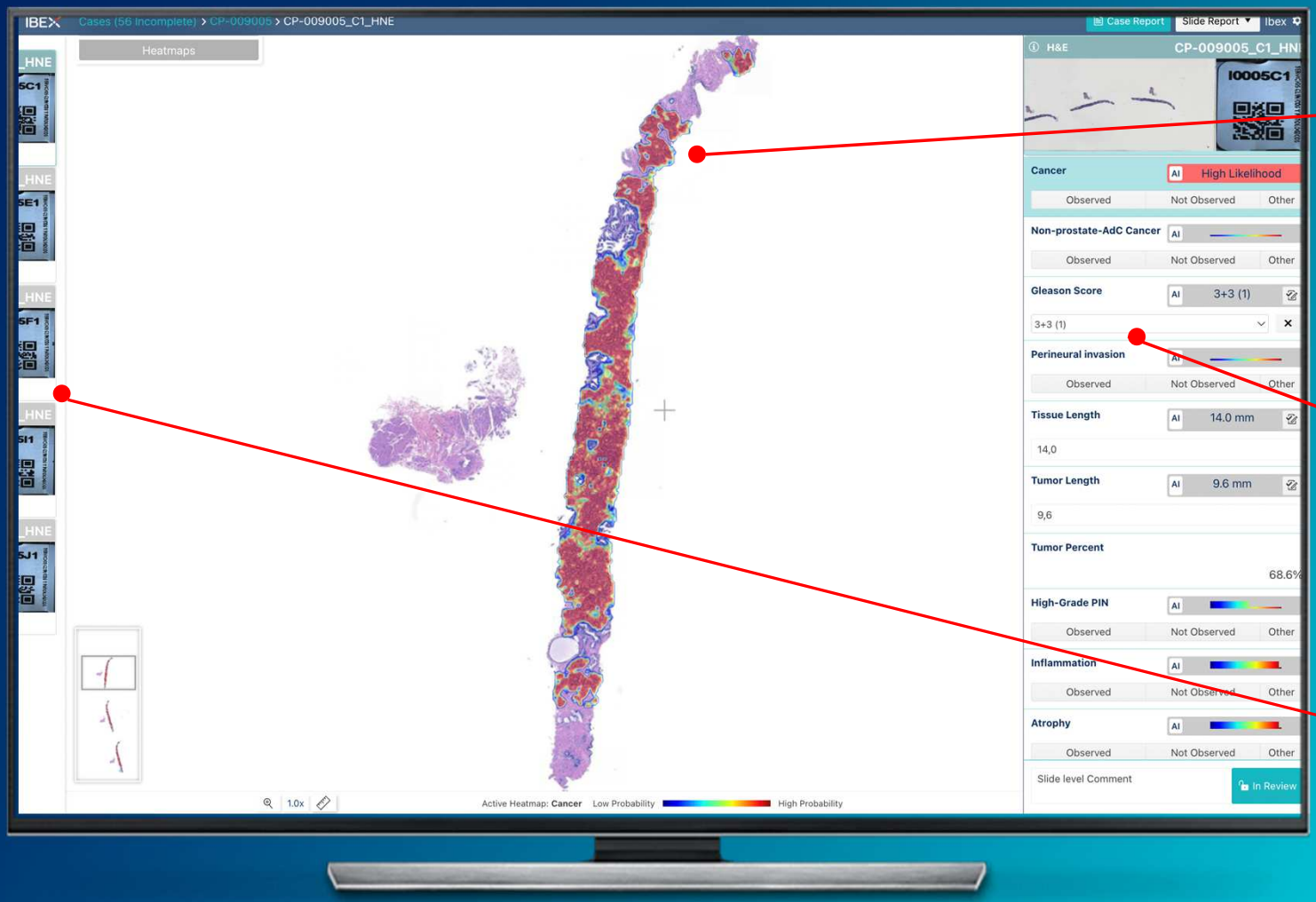


Identify slides where Ibex AI has identified important findings (e.g. Cancer)

Case overview of all slides in a case, including tissue area & barcode.

Maintain overview of entire worklist

Case Overview: Quickly navigate slides in a case



Web based viewer with Heatmaps identifying clinically important features

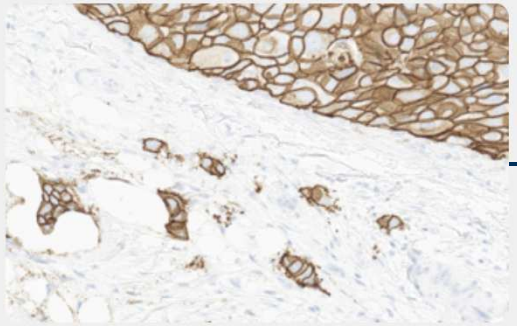
Reporting tool pre-populated with AI-based findings & measurements

Access to all other slides in the case

IBEX

Galen™ Breast

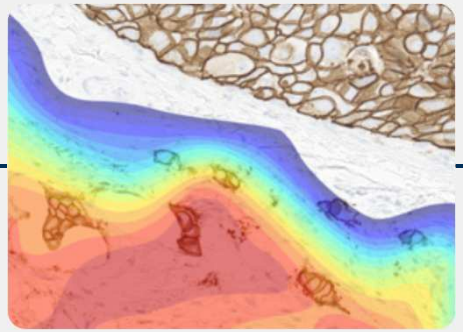
Her2 Algorithm Description



HER2 WSI

Regions Model

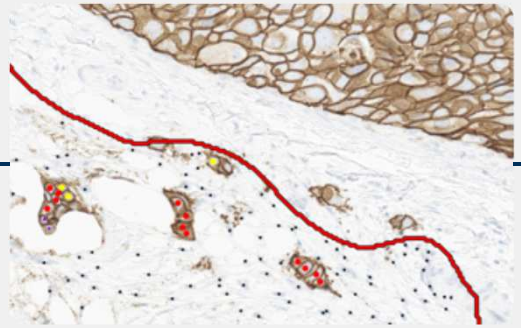
- 1,300 slides with auto-annotations
- 150 slides with manual annotations
- 10 classes



Invasive area detected

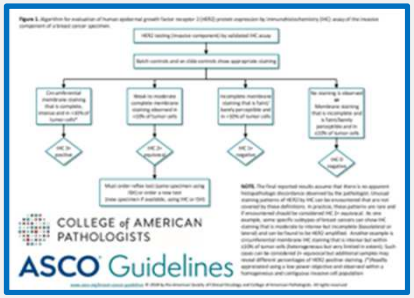
Cells Model

- 125,000 cells annotated
- 150 annotated slides
- 8 classes
- Object detection networks



Detected cells and staining pattern:
Intense Complete: 12 cells = 80%
Moderate Complete: 3 cells = 20%
...
...

ASCO/CAP guidelines



HER2 score: 3+

- Fully automated score
- Built-in quality control - does not score problematic or borderline slides (e.g., not enough tumor cells detected)

Thank you