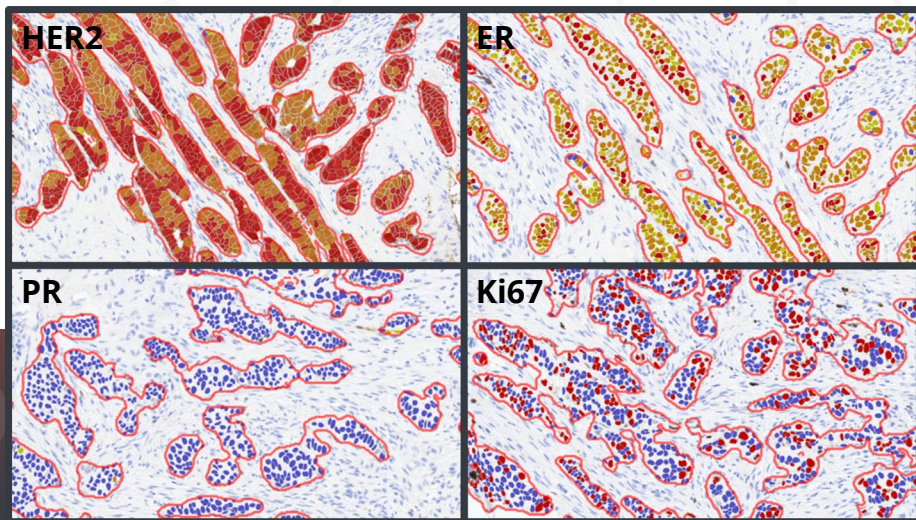


# BREAST IHC AI

HALO Clinical AI Solutions



Breast IHC AI is a suite of algorithms that analyzes the expression of breast cancer biomarkers through whole slide image (WSI) scoring of IHC-stained FFPE tissue sections in invasive primary breast carcinoma. It is seamlessly integrated into the CE-IVDR marked HALO AP® diagnostic digital pathology platform. Breast IHC AI is For Research Use Only and not intended for clinical diagnostic use.

powered by **indica labs**

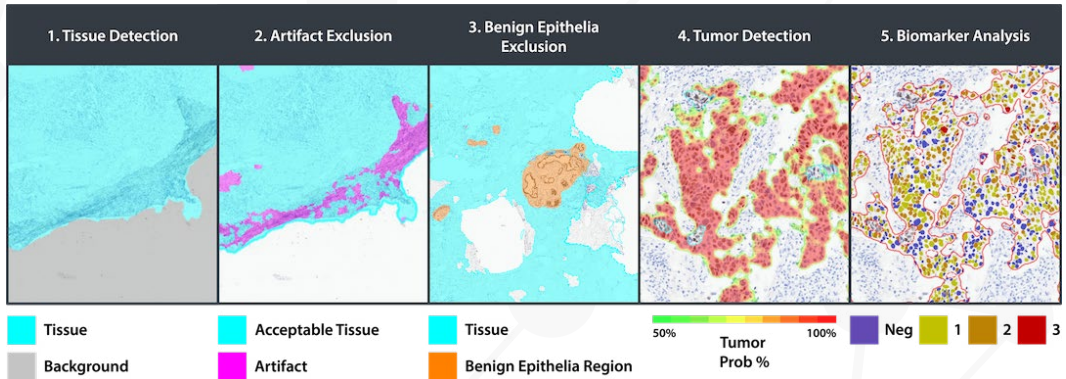
# Put AI to work in your anatomic pathology laboratory

## Inputs

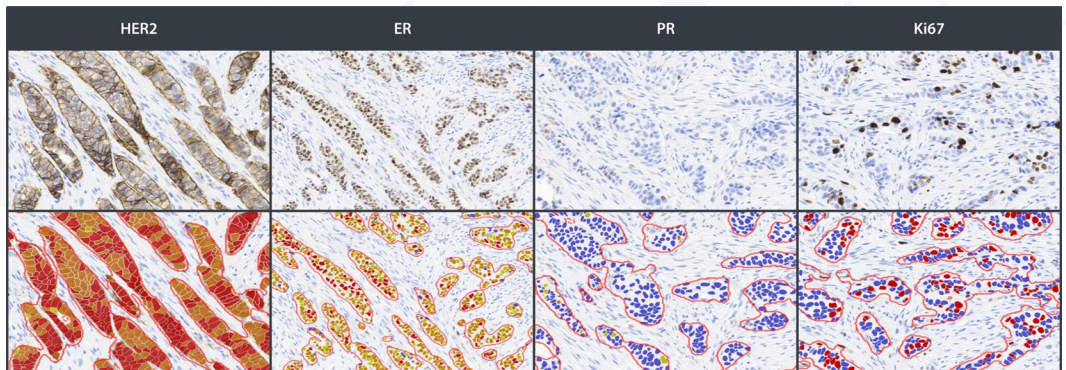
- + Resections, excisions, and/or biopsies from primary invasive breast cancer

## Supported Scanners

- + Hamamatsu NanoZoomer S360
- + Leica Aperio GT 450



## Key Output Metrics



- + HER2 score
- + Percent HER2 1+, 2+, and 3+ positive cells

- + Allred score
- + Intensity score
- + Percent weak, moderate, and strongly positive cells

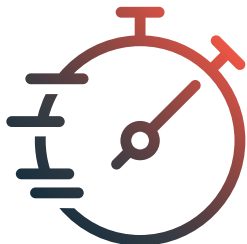
- + Allred score
- + Intensity score
- + Percent weak, moderate, and strongly positive cells

- + Percent positive cells



## **STANDARDIZE BIOMARKER EVALUATION**

Breast IHC AI allows you to standardize your reporting, reducing variability in the IHC evaluation process.



## **MORE EFFICIENT WORKFLOW**

By automating time-consuming manual tasks, Breast IHC AI significantly reduces the workload for pathologists and researchers. This efficiency boost allows for faster decisions without compromising accuracy.



## **COMPLEMENT YOUR EXPERTISE**

Breast IHC AI serves as an additional tool to aid your analyses. By handling tedious tasks and providing consistent, standardized measurements, it frees you to apply your expertise where it's needed most, in the interpretation of results to make informed decisions.

# DECREASE VARIABILITY IN YOUR BREAST BIOMARKER ANALYSIS

## Accurate Comparative Studies

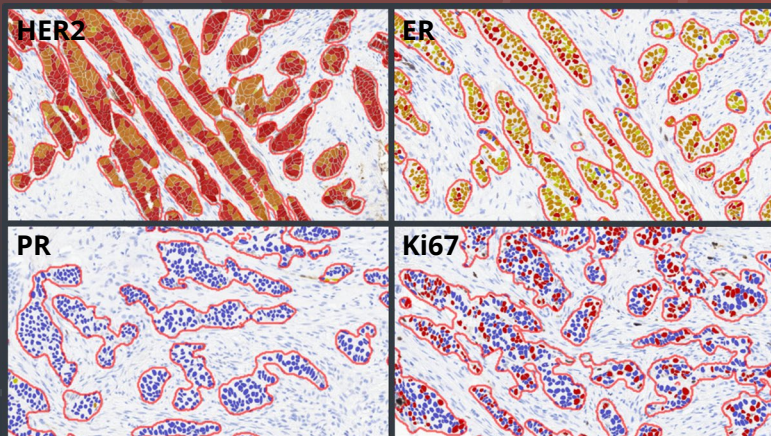
By eliminating inter-observer variability through automated analysis, Breast IHC AI allows for accurate comparisons between groups.

## Focus on the Most Challenging Cases

By automating breast cancer biomarker analysis, pathologists are free to invest their time into analyzing the most time-consuming, challenging cases, such as those with borderline expression.

## Seamlessly Integrated into HALO AP®

Breast IHC AI deploys seamlessly in HALO AP, where users can take advantage of a wide variety of tools for further analysis, collaboration, and research.



Breast IHC AI assists pathologists in arriving at more reproducible breast biomarker expression analysis in invasive breast carcinoma cases.

# PERFORMANCE & VALIDATION

## Internal Validation

### 3 Expert Pathologists vs. Breast IHC AI

Clinical scores compared for agreement and consensus on slides previously unseen to algorithm.

Biomarker	% Agreement with Pathologists' Mode
ER	100%
PR	85%
HER2	85%
Ki67	95%

Biomarker	Fleiss' Kappa
ER	0.91
PR	0.78
HER2	0.74
Ki67	0.82

## External Validation

### Institute 1 – Hamamatsu S360 Scanner

Comparing Breast IHC AI to clinical score using slides previously unseen to algorithm.

Biomarker	% Agreement with Clinical Data
ER	94%
PR	90%
HER2	84%
Ki67	82%

### Institute 2 – Aperio GT 450 Scanner

Comparing Breast IHC AI to clinical score using slides previously unseen to algorithm.

Biomarker	% Agreement with Clinical Data
ER	91%
PR	91%
HER2	83%



## AUTOMATE YOUR BREAST IHC ANALYSIS

Breast IHC AI accurately detects invasive tumor regions and tumor cells within breast cancer tissue and demonstrates high clinical agreement when scoring routine diagnostic IHC. Breast IHC AI can support pathologists by improving workflow efficiency and standardizing results.

### Ready to learn more?

Contact us to schedule a demo of Breast IHC AI and HALO AP®.



HALO AP® is CE-IVDR marked for in-vitro diagnostic use in Europe, the UK, and Switzerland. HALO AP is For Research Use Only in the US and is not FDA cleared for clinical diagnostic use. In addition, HALO AP provides built-in compliance and certifications with FDA 21 CFR Part 11, ISO 13485:2016, HIPAA, and GDPR.

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