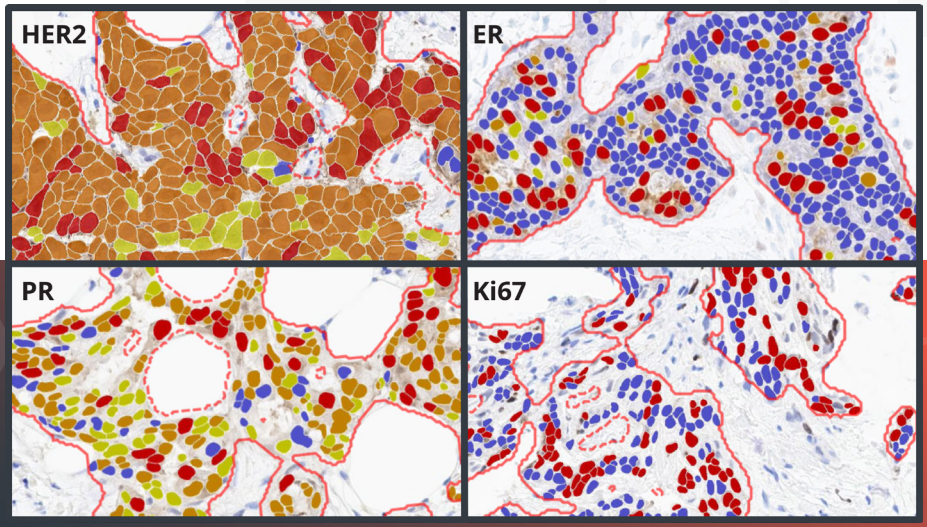
BREAST IHC AI

HALO Clinical AI Solutions

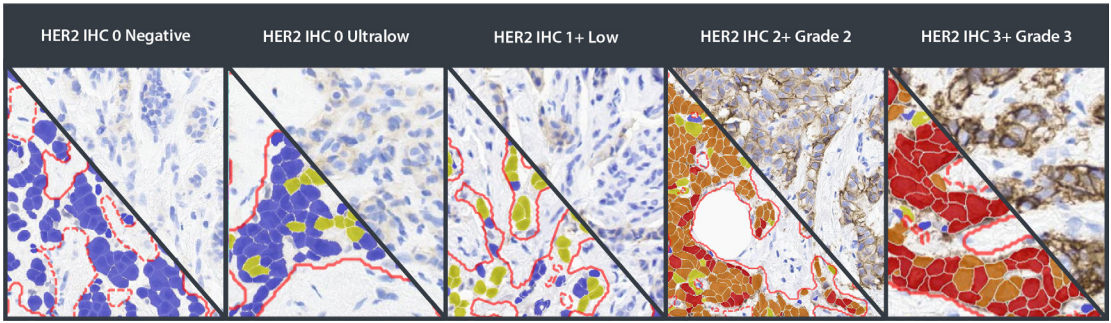
NOW DETECTING HER2 LOW AND ULTRALOW



Breast IHC AI is a suite of algorithms for breast cancer biomarker analysis in cases of invasive primary breast carcinoma. Each algorithm performs whole slide image scoring of IHC-stained tissue sections and includes an upgraded HER2 algorithm for detection of HER2 expression at any level, including low and ultralow. Breast IHC AI is seamlessly integrated into the CE-IVDR HALO AP® platform.

powered by indica labs

HER2 LOW AND ULTRALOW DETECTION IN BREAST CANCER



Breast IHC AI assists pathologists with reproducible HER2 expression analysis, including cases of ultralow and low expression levels.

DECREASE VARIABILITY IN YOUR BREAST BIOMARKER ANALYSIS

Accurate Comparative Studies

Automated analysis reduces inter-observer variability between pathologists and researchers, facilitating easy collaboration with consistent results.

Focus on Advancing Clinical Research

By automating breast cancer biomarker analysis, pathologists are free to invest their time in clinical research and medical advancements.

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.

Put AI to work in your anatomic pathology laboratory

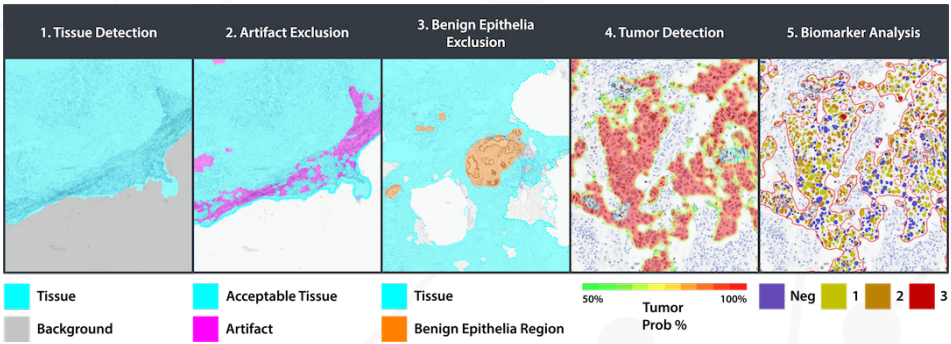
Inputs

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

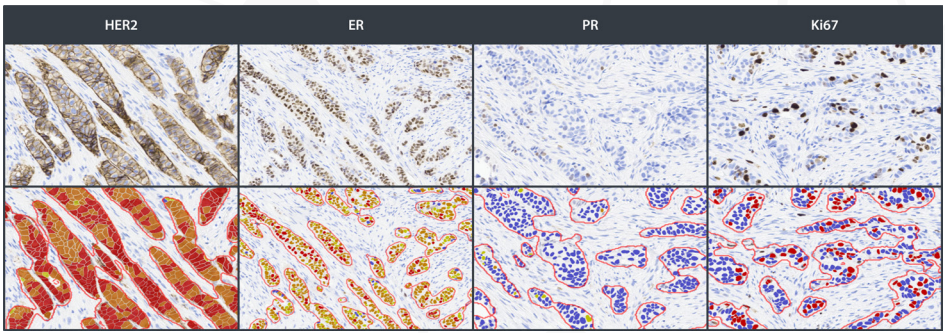
Compatible File Formats

+ Non-proprietary (JPG, TIF, OME. TIFF, DICOM [DCM*])
+ Leica (SVS, AFI, SCN, LIF)
+ Hamamatsu (NDPI, NDPIS)
+ Philips (iSyntax, i2Syntax)
+ 3DHistech (MRXS)
+ Nikon (ND2)
+ Akoya (QPTIFF, component TIFF)
+ Olympus / Evident (VSI)
+ Zeiss (CZI)
+ Ventana (BIF)
+ KFBIO (KFB, KFBF)

*whole slide images



Key Output Metrics



+ HER2 Grade: Negative, Ultralow, Low, 2+, 3+
+ HER2 Score: 0,1+,2+,3+
+ Percent positive

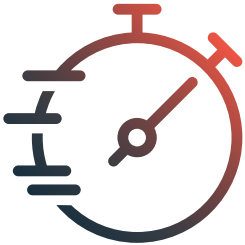
+ Allred score
+ Intensity score
+ Percent weak, moderate, and strongly positive cells

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

+ Percent positive cells

STANDARDIZE BIOMARKER EVALUATION

Breast IHC AI standardizes biomarker scoring and reduces interobserver variability in the IHC evaluation process, without compromising accuracy.



EFFICIENT WORKFLOWS

Automated biomarker evaluation reduces the workload for pathologists and researchers while delivering accurate and efficient results.

COMPLEMENT YOUR EXPERTISE

Breast IHC AI provides consistent, standardized measurements so you are free to apply your expertise where it's needed most, in the interpretation of results to make informed decisions.

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 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®.

Breast IHC AI is For Research Use Only and not intended for clinical diagnostic use. Breast IHC AI is accessed via the HALO AP® enterprise digital pathology platform.

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 USA and is not FDA cleared for clinical diagnostic use. In addition, HALO AP® provides built-in compliance with FDA 21 CFR Part 11, HIPAA, and GDPR.

indica labs

info@indicalab.com | emea@indicalab.com | japan@indicalab.com | china@indicalab.com

USA +1 505 492-0979 | UK/EU +44 (0) 333 090 1113 | 日本 +81 (0)3 4400 0466 | 中国 +86 13761896143