VISIOPHARM®

Breast Cancer Analysis

Diagnostic APPs for biomarker assessment

Standardizing breast cancer diagnosis

A precise diagnosis must deliver certainty, and certainty emerges from objective and reproducible results. Visiopharm's diagnostic APPs have been validated on thousands of tissue sections and deliver the precision and reproducibility needed for decision making.

Our CE-IVD APPs for AI-based image analysis can replace manual steps in your diagnostic workflow. Developed with pathologists and rigorously tested for each indication, the list of applications is constantly growing. The AI-based APPs for breast cancer biomarkers can help pathologists obtain more standardized, unbiased quantifications for biomarkers used in breast cancer diagnosis.

CE-IVD APPs for breast cancer
For a given region of interest, assess:

Estrogen receptor (ER)
Percentage of positive cells and Allred score.

Progesterone receptor (PR)
Percentage of positive cells and Allred score.

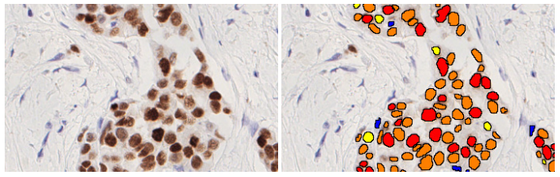
HER2
Her2 score according to guidelines[2] and Her2 connectivity score

Ki-67
Proliferation index.

Visiopharm's breast cancer APPs

CE 2797

The CE-IVD marked APPs to detect breast cancer biomarkers help the pathologists to achieve more consistent readings of the tumor landscape for better informed decision making

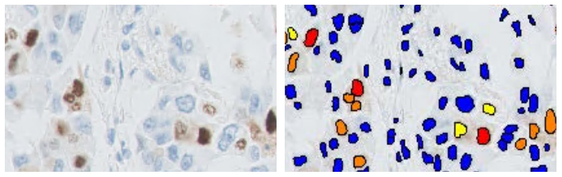


Estrogen Receptor

(APP# 90002)

Biological significance:
Assessment of ER status in tumors is a predictive marker for responsiveness to hormone therapy. According to The American Society of Clinical Oncology/College of American Pathologists (ASCO/ CAP), patients' ER status should be determined on all invasive breast cancers and recurrent breast cancers [1].

APP performance:
Validated at 5 different clinical sites on full tissue sections, biopsies, and TMA samples, this APP can be used to determine the positive percentage of ER positive cells in the respective regions as well as the Allred Score (= Proportion Score + Intensity Score).

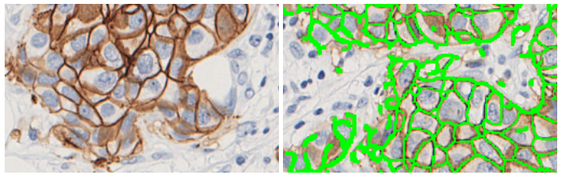


Progestrone Receptor

(APP# 90003)

Biological significance:
Assessment of PR status in tumors is a predictive marker for responsiveness to hormone therapy. According to The American Society of Clinical Oncology/College of American Pathologists (ASCO/ CAP), patients' PR status should be determined on all invasive breast cancers and recurrent breast cancers [1].

APP performance:
Validated at 4 different clinical sites on biopsies and TMA samples, this APP can be used determine the positive percentage of PR positive cells in the respective regions as well as the Allred Score (= Proportion Score + Intensity Score).

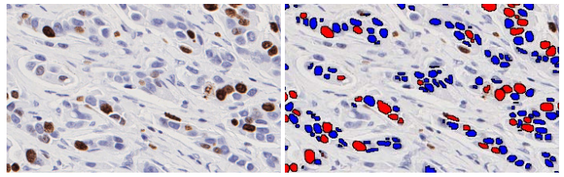


HER2

(APP# 90007)

Biological significance:
HER2 is a central biomarker in invasive breast cancer. The HER2 status has both important prognostic implications and is predictive for the patient's response to HER2-targeted treatment. According to the guidelines of the American Society of Clinical Oncology/College of American Pathologists (ASCO/CAP), the HER2 status must be determined by genetic and/or protein expression analysis of breast tissue sections using immunohistochemistry (IHC) and/or in situ hybridization (ISH) [2].

APP performance:
Validation in 7 studies on more than 2000 breast cancer cases confirmed high correlation of the Her2 score to FISH testing.



Ki-67

(APP# 90004)

Biological significance:
Ki-67 is a nuclear marker of cell proliferation. The percentage of positive nuclei in the tumor tissue using IHC staining is often used as a prognostic or predictive marker and can support treatment discussions [3].

APP performance:
Validated at 3 clinical sites on full tissue sections and TMA as well as compared with the average results from 126 NordiQC membership labs, this APP detects and classifies nuclei as positive or negative and returns an average proliferation index for the entire region of interest.

Clinical Validation Details

Agreement (95% CI) 99% (96.6 - 99.9%)

Clinical Validation Details

Agreement (95% CI) 94.7% (91.0 - 97.1)

Clinical Validation Details

Sensitivity toward FISH 93.9% (613/652)
Specificity toward FISH 98.9% (1317/1332)

Clinical Validation Details

Agreement (95% CI) 89.5% (84.1 - 93.6%)

Our apps work with a broad range of stain vendors and slide scanner.

CE-IVD APPs are for in vitro diagnostic use in Europe. Not for sale in the USA.

1) Stålhammar G., Fuentes Martinez N., Lippert M et al. Digital image analysis outperforms manual biomarker assessment in breast cancer. Mod Pathol. 2016 Feb 26.

2) Wolff AC et al., Human Epidermal Growth Factor Receptor 2 Testing in Breast Cancer: American Society of Clinical Oncology/College of American Pathologists Clinical Practice Guideline Focused Update. J Clin Oncol. 2018 Jul 10;36(20):2105-2122.

3) Dowsett M, Nielsen TO, A'Hern R, et al. Assessment of Ki67 in breast cancer: recommendations from the International Ki67 in Breast Cancer working group. J Natl Cancer Inst. 2011 Sep 29.

Digital workflow optimization

Realize the full potential of digital analysis for breast cancer tissues from sample preparation to diagnosis.

BIOPSY

Tissue preparation
Automated slide staining

The digital pathology workflow begins with efficient and reliable staining. Using an automated IHC and ISH solution from a trusted provider supports your lab by delivering fast, complete, consistently stained cases, ready for digitization.

Digital slide scanning
Automated slide staining

Implementing digital slide scanning allows high-resolution capture of whole slides at high speed, allowing more efficient use of the pathologists' time while preserving the crucial information from the original slides in digital format.

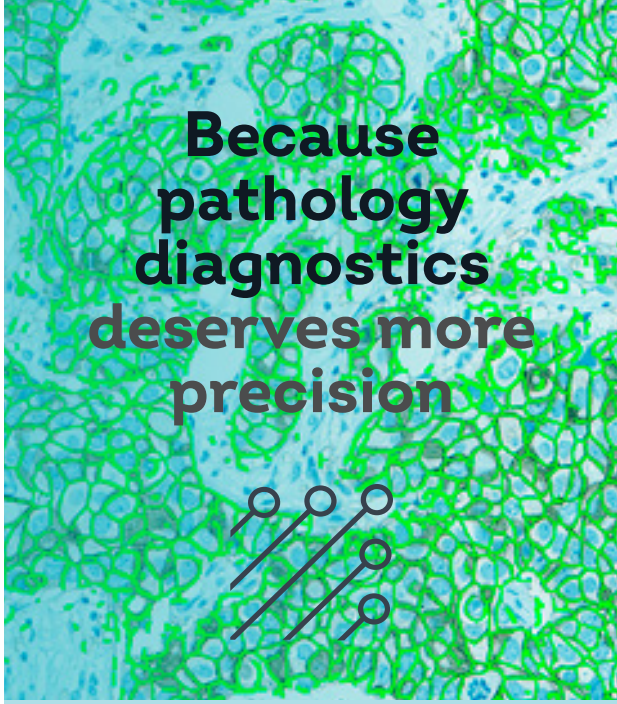
AI-driven image analysis
Visiopharm's APP center

Visiopharm's CE-IVD APPs based on AI for image analysis can automate steps in your diagnostic workflow. Developed with pathologists and rigorously tested for each indication, access the entire portfolio of diagnostic APPs with convenient subscription-based software editions.

Access and sharing of results
Visiopharm's data management

With digital data management and storage, you get a scalable solution that makes it possible to easily review and handle your information across an entire lab, institute, hospital, or region.

DIAGNOSIS



Decision support for pathologists

CE-IVD APP results are presented as an overlay on the images for easy review. All virtual slides associated with a patient case are automatically registered and presented to the pathologist. Benefit from digital image analysis for objective, quantified and standardized analysis.

Help compensate the shortage of pathologists

CE-IVD APPs allows your qualified staff to handle all technical aspects of image analysis in a standardized way, with low inter-operator variability. The results are then sent to the laboratory information system for final pathologist review.

High reproducibility and accuracy

For our breast cancer markers we have documented repeatability and reproducibility in diagnostic readings.

Scan with confidence

In Europe we offer various in vitro diagnostic use slide scanners to meet your slide throughput. Visiopharm's Oncotopix® Scan by Hamamatsu deliver fast and reliable whole slide imaging, ready for image analysis.

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