

HER2 APP for IHC

Automated, Accurate and Objective

The HER2 APP from Visiopharm® is a part of the Oncotopix® Diagnostics product portfolio of CE-IVD labelled APPs. The HER2 APP is a digital analysis tool that has been CE-marked for in-vitro diagnostic use in Europe, and has shown to provide reliable diagnostic decision support (ref 1). With the Oncotopix® Diagnostics workflow the analysis is seamlessly integrated into existing LIS platforms, allowing pathologist to review and sign-off pre-analyzed specimens.

NordiQC Co-Validated performance

The HER2 APP for IHC has been validated on data from 176 NordiQC member laboratories, showing a sensitivity of 99.2% and a specificity of 100% when correlated to FISH (ref. 1). From 6 independent studies containing in total 1441 samples it was shown HER2 IHC APP delivered 63% fewer inconclusive (2+) results than manual scoring (ref. 2). This translates into a significant cost savings on reflex testing, and shorter turn-around-times for pathologists, oncologists and patients on inconclusive cases (ref. 2).

The performance of the APP analysis has been optimized with respect to HER2 gene-amplification and according to the guidelines of the American Society of Clinical Oncology/College of American Pathologists (ASCO/CAP).



CE IVD

Apply HER2 APP, Breast Cancer to:

- **Reduce** the number of inconclusive (2+) cases and the need for reflex testing
- **Shorten** turn-around-time on inconclusive patient cases
- **Get patented** algorithm performance, which correlates strongly to FISH testing
- **Be more efficient** with a CE-IVD validated tool to simply review and sign-off
- **Enhance** productivity for the pathologist

Clinical Application and Performance Data

The HER2 APP, Breast Cancer can be used to lower the amount of inconclusive (2+) cases needing to go to FISH test. The APP is based on current guidelines and includes analysis of invasive tumor cells and determines the completeness of the positive membrane staining. The HER2 APP performs an overall assessment of the degree of circumferential membrane staining and staining intensity within the invasive tumor region of interest. This APP is based on the same principle and offers a computer driven consistent, reliable and objective way of performing HER2 IHC Analysis and increases laboratory productivity.

The CONNECT technology from Visiopharm® is a patented approach to identify brown pixel intensity in cell membrane staining as well as size of structures. The algorithm uses the "chicken-wire" structure of the membrane present in cases with 3+ HER2 IHC staining. Based on the CONNECT technology the HER2 protein expression can be translated into the classical 0, 1+, 2+, and 3+ scores.

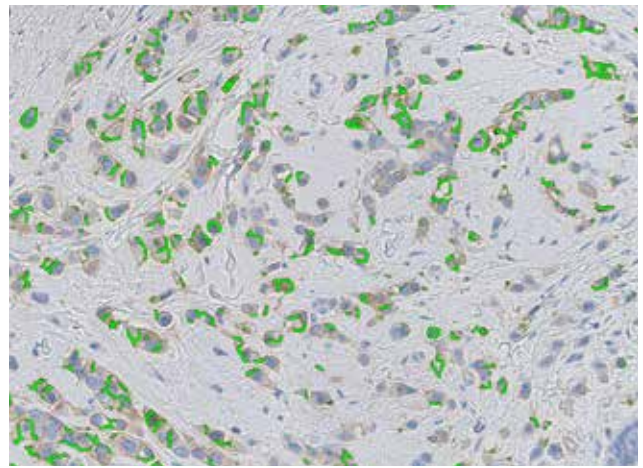


Image analyzed area of a HER2-IHC 1+ staining. Breast tissue.

HER2 APP, Breast Cancer
Reduces inconclusive (2+) cases

Across 6 studies (1441) samples
2+ cases were reduced by 63%

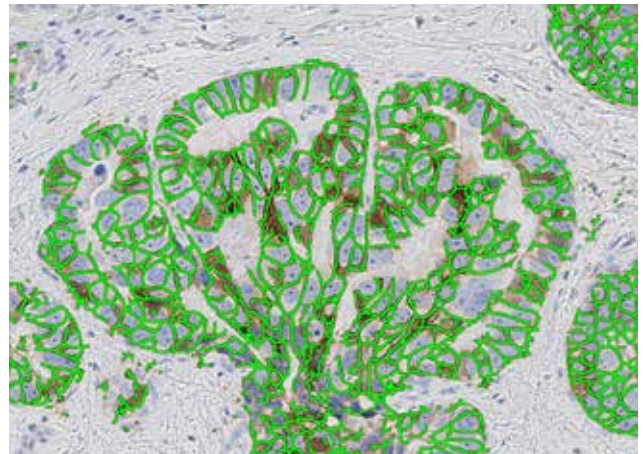


Image analyzed area of a HER2-IHC 3+ staining. The algorithm uses the "chicken-wire" structure of the 3+ HER2 membrane-staining in breast cancer tissue.

Clinical Validation Details

Sensitivity towards FISH 94.0% (613/652) [ref.2]
Specificity towards FISH 98.9% (1318/1333) [ref.2]

Slide Scanners	HAMAMATSU, GE/OMNYX, LEICA/APERIO
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Stain Vendors	DAKO/Agilent, VENTANA/ ROCHE, LEICA
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References

1. Brüggmann A, Eld M, Lelkaitis G, Nielsen S, Grunkin M, Hansen JD, Foged NT, Vyberg M. Digital image analysis of membrane connectivity is a robust measure of HER2 immunostains. Breast Cancer Res Treat Apr 22. [Epub ahead of print]. 2011
2. Package Insert for Visiopharm HER2 APP, Breast Cancer, 6th Edition 2016

Covered by US and European patents: US 8,731,845 and EP 2,327,040

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