

Hormone Receptor (ER/PR) APPs for IHC

Automated, Accurate and Objective

The Hormone Receptor (ER/PR) APP from Visio-pharm® is a part of the Oncotopix® Diagnostics product portfolio of CE-IVD labelled APPs. The hormone receptor analysis algorithm for Oncotopix® supports the pathologist with highly reproducible quantification of biomarker expression for Estrogen (ER) and Progesterone Receptor (PR) protein without compromising diagnostic sensitivity and specificity. The APP can be configured to provide positive ratio, H-Score and/or Allred score.

The ER/PR APP can be combined with Virtual Double Staining (VDS) for verifiable identification of stroma, Ductal Carcinoma In-Situ (DCIS), and elimination of background staining in stroma. This makes it possible for a laboratory technologist to handle the technical aspects of the analysis.

The performance of ER/PR APPs for IHC are optimized to ASCO/CAP guidelines and NordiQC co-validated.



CE IVD

Apply ER/PR APPs, Breast Cancer to

- **Optimize intra- and inter-operator repeatability** with automated computerized reading
- **Enhance productivity** and turn-around-time through automation
- **Easy to integrate** with local LIS
- **Reduce inter- and intra-observer variability** in interpretation
- **Be more efficient** with a CE-IVD validated tool to simply review and sign-off

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Clinical Application and Performance Data

The reporting of ER and PR based on current guidelines, requires manual counting of 500-1,000 cells. Apart from subjectivity and the concomitant lack of reproducibility, this is tedious and a very time consuming task. Furthermore, there are no universally agreed-upon guidelines for choosing intensity cut-offs to determine when a given nucleus is ER and PR positive.

The CE-IVD ER/PR analysis algorithms offer automated and objective analysis of whole slide digital images acquired by a digital slide scanner. The image analysis is performed within tumor regions that can either be identified automatically with VirtualDoubleStaining™ or manual outlining.

With the Oncotopix® diagnostic workflow the analysis can seamlessly be integrated to existing LIS platforms, allowing a simplified review and sign-off on pre-analyzed specimens.



Clinical Validation Details

Agreement 95% CI	ER 99.3% (97.4-99.9%) [ref. 1] PR 95.5% (92.0-97.7%) [ref. 1]
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Slide Scanners	HAMAMATSU, GE/OMNYX, LEICA/APERIO, 3DHISTECH
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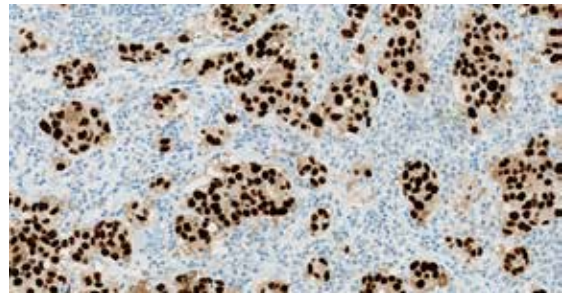
Stain Vendors	DAKO/Agilent, VENTANA/ ROCHE, LEICA
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References

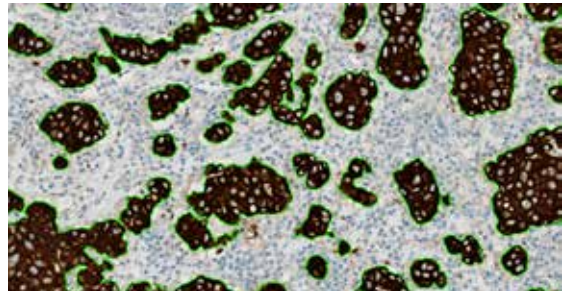
1. Package Inserts for Visiopharm ER APP, Breast Cancer, 4th Edition 2016 and PR APP, Breast Cancer, 4th Edition 2016

1



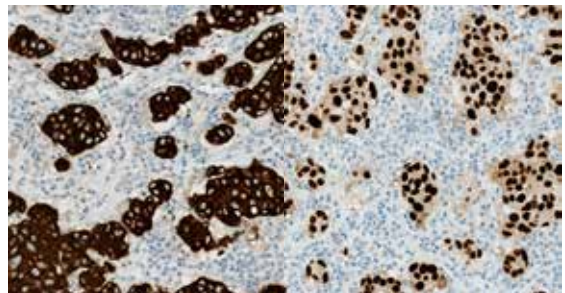
ER stained breast tissue at 20X magnification.

2



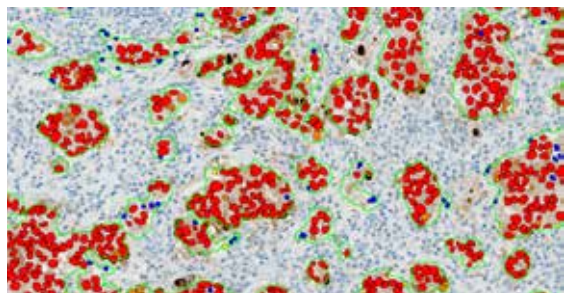
Serial section of the same 20X image as shown in figure 1, stained with the tumor marker.

3



The images in figure 1 and 2 are aligned for perfect cell-to-cell alignment.

4



The Oncotopix® ER/PR algorithm automatically eliminates stroma and analyzes the ER/PR samples.

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