

Turning  
images into  
knowledge...

...for confident  
decisions



## VirtualDoubleStaining™

Easy, Robust, and Automated Tumor/Stroma Separation

VirtualDoubleStaining™ (VDS) is a novel and patent protected method for automated, robust and verifiable tumor/stroma separation. The method has been developed and validated in collaboration with the NordiQC and thoroughly tested in practical clinical environments at major diagnostic pathology labs across Europe.

### The Devil is in the Data

Important clinical decisions are made by pathologists based on the assessment of biomarkers. It is well known that there is significant intra- and inter-reader variability associated with diagnostic reading and interpretation of biomarker expression. There is an urgent need to reduce or eliminate this type of variability for biomarkers to be used as prognostic and predictive markers. Data from thousands of tissue samples supports that image analysis for tumor area detection, combined with quantification of biomarker expression, provide significant improvements in both reproducibility and accuracy.

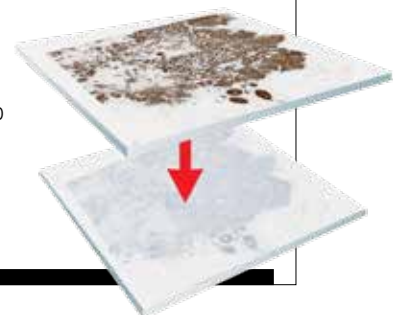
### Benefits of VirtualDoubleStaining™:

#### Improved data quality:

- Objective, verifiable detection of tumor to exclude proliferating lymphocytes
- Detect and exclude Ductal Carcinoma In Situ
- Can be based on manual outlining as well as fully automated quantitative image analysis

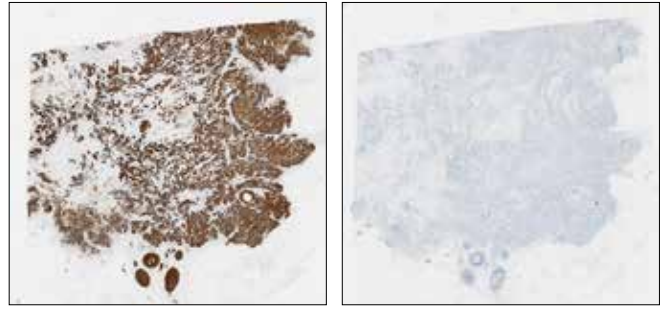
#### Fully automated Tumor/Stroma separation:

- Avoid time-consuming manual outlining of tumor areas
- Can be performed by lab technicians
- Pathologist can confirm or edit the result



## Virtual double staining is done in a few easy steps

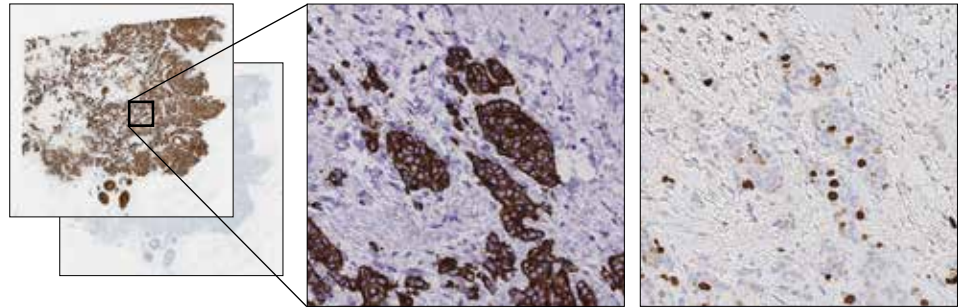
VDS builds on aligning two digitized serial sections; one stained with a tumor marker e.g. PCK, H&E, CK5/CK7+p63 etc. and another with a cancer biomarker e.g. Ki-67, ER, PR, etc. It can be used with single biomarker stains as well as cocktail biomarker stains.



2,5x magnified breast cancer sections stained for PCK and Ki-67, scanned at 20x.

## The two images are aligned

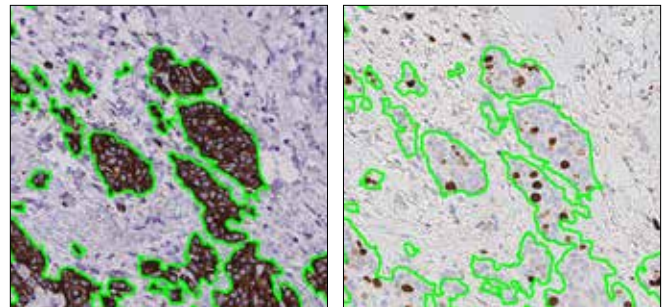
The Visiopharm's patented alignment software is used to create an overlay outlining the tumor cells.



20x magnified breast cancer sections stained for PCK and Ki-67, scanned at 20x.

## The tumor region is identified using image analysis

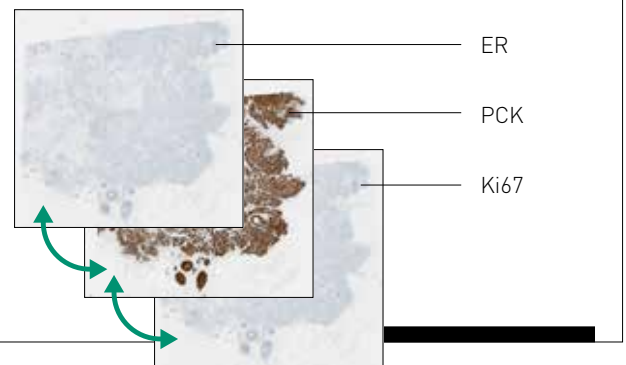
The outlined tumor region is then transferred to the section stained with the analytical biomarker to be analyzed with the relevant image analysis APP.



Same images as above now analyzed with VDS™ outlining regions of interest based on the PCK staining.

## Virtual Triple Staining

The tumor marker can also be virtually aligned with two slides creating a sandwich around the tumor marker. Allowing VirtualTripleStaining™.



The Visiopharm APPs for Breast Cancer Ki-67, ER and PR are validated for in vitro diagnostic use (CE IVD) in Europe utilizing the PCK VirtualDoubleStaining™ capability (ref. 1). All other VirtualDoubleStaining™ applications are for Research Use Only.

### References

1. Package Inserts for Visiopharm Ki-67 APP, Breast Cancer, ER APP, Breast Cancer and PR APP, Breast Cancer.

# VISIOPHARM®

Visiopharm A/S  
Agern Allé 24  
DK-2970 Hørsholm  
Phone: +45 8820 2088  
www.visiopharm.com  
Email: contact@visiopharm.com