

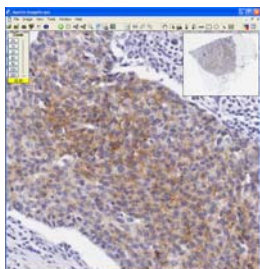
Background

Immunohistochemistry (IHC) image analysis systems today are intended to be used as an adjunct to manual microscopy. As this is an extra step outside the workflow of a pathologist this requires additional work by labs and pathologists.

Digital pathology systems allow running image analysis efficiently with the push of a button while reading digital slides on a computer monitor, all integrated in the same workflow. In a digital pathology solution for IHC the performance of reading digital IHC slides on a computer monitor becomes equally important to the performance of the IHC image analysis.

Digital IHC

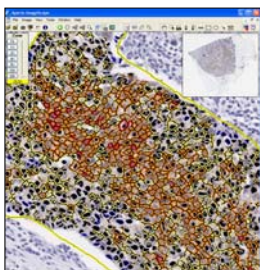
Reading Digital HER2 Slides on a Computer Monitor



Pathologists read digital slides on a computer monitor by panning and zooming through high quality whole slide images.

When pathologists identify a tumor region they can outline that region for analysis, run image analysis and review the results.

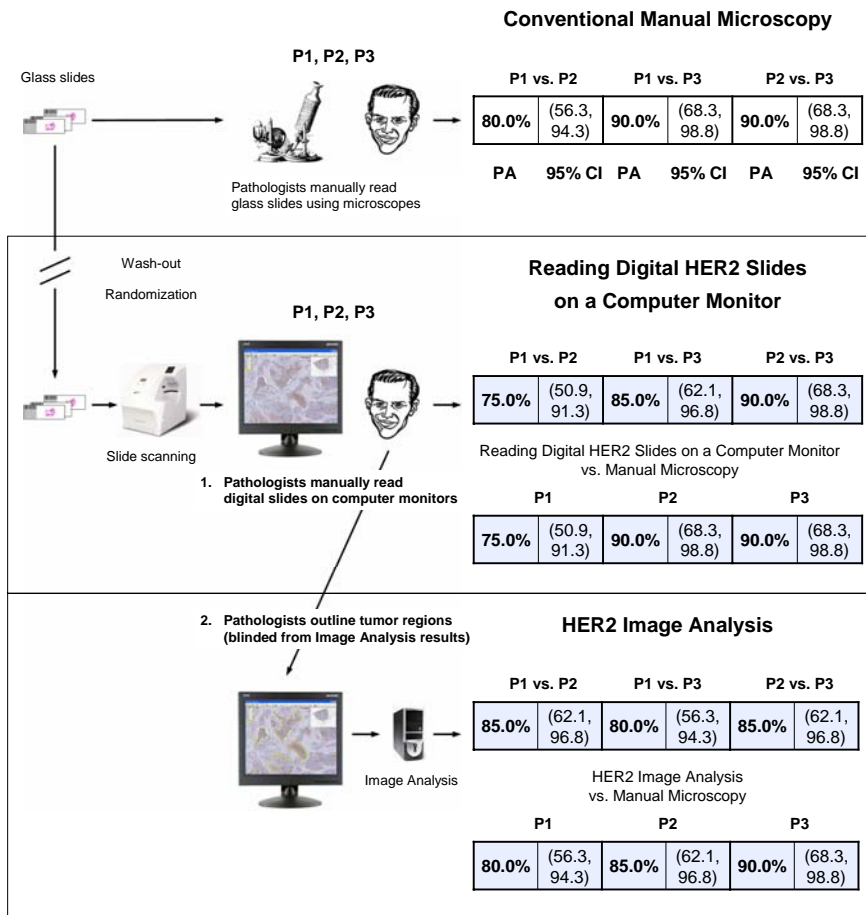
HER2 Image Analysis



HER2 Score: 2+

3+ Cells:	1.8%
2+ Cells:	31.9%
1+ Cells:	62.2%
0 Cells:	4.1%

A Feasibility Study using 20 HER2 Stained Breast Specimens



Design

Pathology Inc., a Medical Corporation, conducted a feasibility study to compare the performance of Aperio Technologies Inc.'s Digital Pathology Solution for IHC to manual microscopy evaluating both, the reading of digital HER2 slides on a computer monitor and the HER2 image analysis.

A set of 20 formalin-fixed, paraffin-embedded breast tissue specimens stained using Dako's HerceptTest™ with equal HER2 score distribution were assayed.

3 pathologists performed a blinded read of the glass slides using their microscopes. The slides were then scanned and randomized. After a wash-out period of over one week the same 3 pathologists performed another blinded read of the same slides, but this time of the digital slides on a computer monitor. At the same time, each pathologist also outlined a representative set of tumor regions to be analyzed by image analysis.

The algorithm itself was run in batch mode blinded from the pathologists to avoid influencing the pathologists in their choice of the tumor regions.

The algorithm was used with the provided default parameter set for Dako's HerceptTest. The algorithm reported the HER2 score for each of the 3 pathologists for each of the slides.

Result

Each of the methods: manual microscopy, reading digital slides on a computer monitor and image analysis were evaluated separately and comparatively between methods using Percent Agreement (PA) along with an exact 95% Confidence Interval (CI) of the dichotomous outcome of negative HER2 scores (0, 1+) vs. positive HER2 scores (2+, 3+).

The study showed comparable percent agreement values for manual microscopy and reading digital slides on a computer monitor.

The study showed comparable percent agreement values for manual microscopy and image analysis.

Conclusion

Aperio's Digital Pathology Solution for IHC provides an efficient workflow for pathologists allowing them to run image analysis while reading the digital slides on a computer monitor.

This feasibility study supports that reading digital HER2 slides on a computer monitor and HER2 image analysis using Aperio's Digital Pathology Solution for IHC are a substantial equivalence to conventional manual microscopy.