

Background

Digital pathology systems allow pathologists to read digital slides on a computer monitor, but is this equivalent to using a microscope?

To be widely accepted for clinical use, digital pathology systems need to be cleared/approved by the Food and Drug Administration (FDA) and performance studies must demonstrate the performance of this new technology to the clinical community.

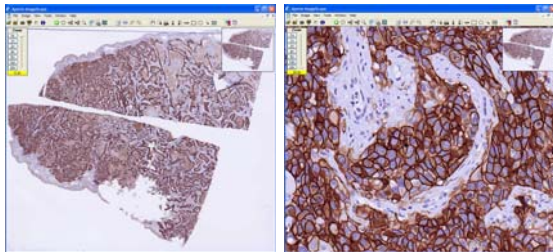
Digital pathology systems vary in performance and each application has its own performance requirements, thus requiring evaluation of the different systems for the different applications.

This study demonstrates the performance of Aperio Technologies Inc.'s Digital Pathology Platform, the first (and currently only) FDA cleared system for reading digital slides on a computer monitor with limitation to Immunohistochemistry (IHC) and Human Epidermal Growth Factor Receptor 2 (HER2).

IHC is an important clinical application. Using a digital pathology system for image analysis applications provides a great ease-of-use. Image analysis can be run efficiently with the push of a button while reading digital slides on a computer monitor, all integrated in the same workflow.

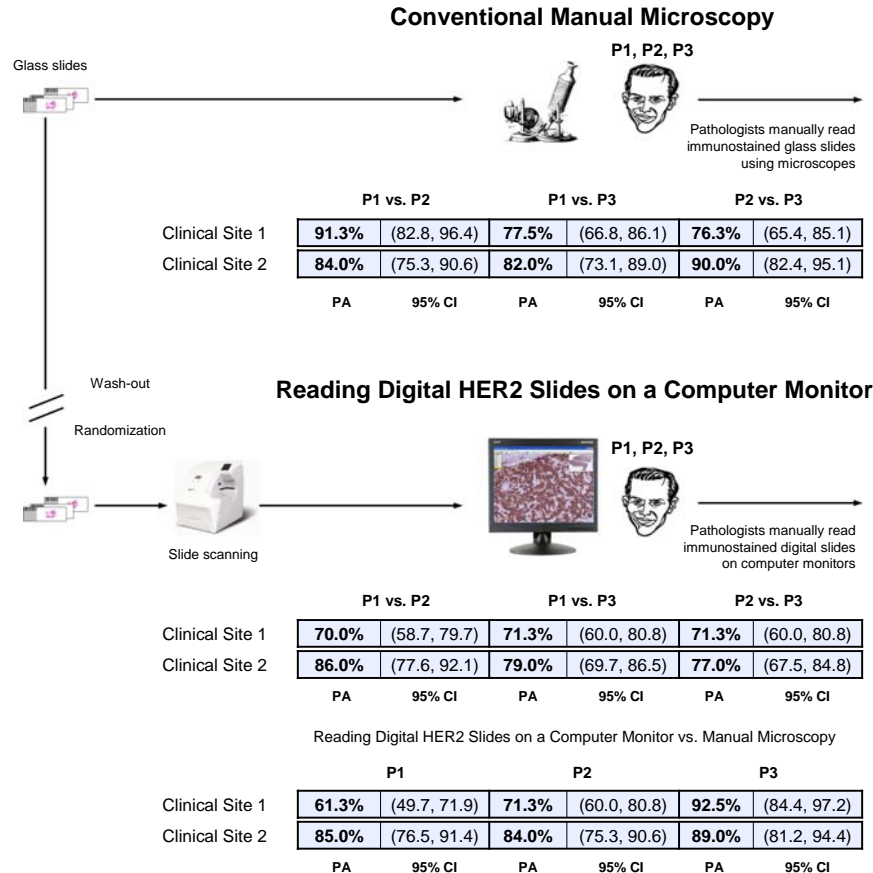
Reading Digital HER2 Slides on a Computer Monitor

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



HER2 digital slide shown to "fit screen" and at 20X on a computer monitor.

A Multi-Site Performance Study using 180 HER2 Stained Breast Specimens



Design

A multi-site performance study was conducted at Emory University Hospital and Quest Diagnostics Nichols Institute. Reading digital IHC HER2 slides on a computer monitor using Aperio Technologies Inc.'s Digital Pathology Platform (ScanScope® XT slide scanner and Spectrum™ digital pathology information management system) was compared to conventional manual microscopy.

180 formalin-fixed, paraffin-embedded breast tissue specimens immunohistochemically stained using Dako's HercepTest™ were assayed; 80 specimens with almost equal HER2 score distribution were from clinical site 1, and 100 routine specimens were from clinical site 2.

At each site, 3 pathologists performed a blinded read of the glass slides using a conventional light microscope, and reporting the HER2 score (0, 1+, 2+ or 3+) for each slide. The glass slides were then scanned using a 20X objective 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 their computer monitor, again reporting the HER2 score for each slide.

Result

Each of the methods: manual microscopy and reading digital HER2 slides on a computer monitor were evaluated separately and comparatively between methods using Percent Agreement (PA) along with an exact 95% Confidence Interval (CI) of a trichotomous categorization of the HER2 scores combining 0 and 1+ and leaving 2+ and 3+ uncombined.

Comparable percent agreement values were obtained for manual microscopy and for reading digital HER2 slides on a computer monitor.

Proficiency training is important. As with any change of instrument we could observe an unintended but systematic change in diagnostic performance. Adoption of digital pathology might eliminate this problem in the future as the acquisition and viewing of digital slides can be calibrated consistently for all pathologists.

Conclusion

This performance study has demonstrated that reading digital HER2 slides on a computer monitor using Aperio Technologies Inc.'s Digital Pathology Platform is a substantial equivalence to conventional manual microscopy and therefore can be used as an alternative to a conventional microscope.