

REGULATORY RELEVANCE

Determine testing data required to demonstrate performance equivalence between WSI viewer devices

ABSTRACT

In this study, a software program, the Image Viewer Integrity Evaluation System (IVIES), was developed to compare two image viewers on the pixel level and report any measured color differences. Four freely available image viewers were inspected with the test method. The results show that some of the viewers rendered the whole slide images differently compared with the factory image viewer.

BACKGROUND

A WSI system used in digital pathology consists of the scanner, image viewer, and display components. Recently, some independent image viewers were submitted by third-party companies to replace the factory image viewer component used in the predicate device. To demonstrate substantial equivalence between the former and the latter, sponsors were expected to provide bench testing data for review. However, the sponsors frequently did not test their image viewers adequately for image quality.

RESEARCH QUESTION

Do different WSI viewers generate identical images for the same WSI file?

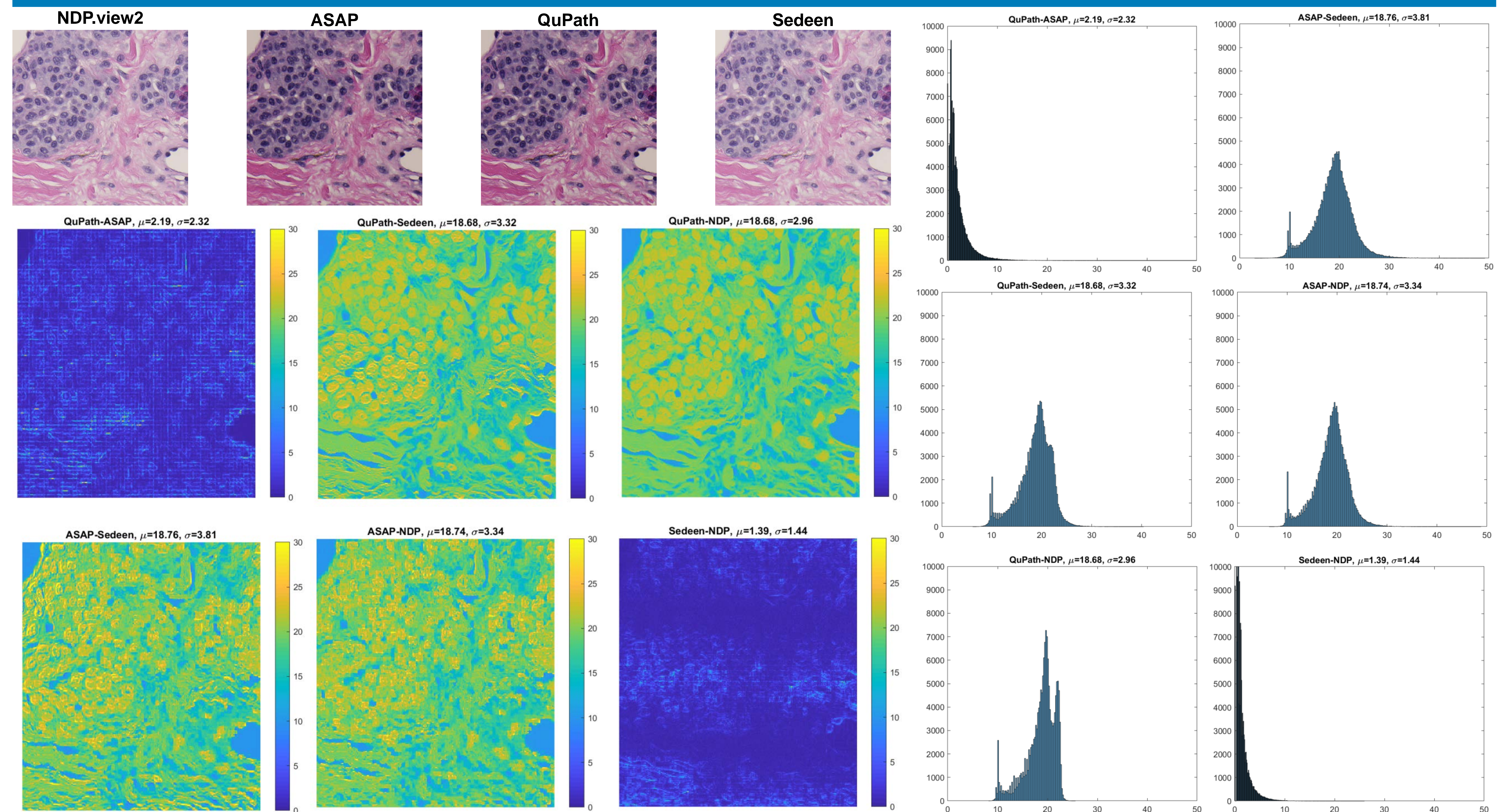
METHODOLOGY

- Use different viewers to open the same WSI
- Use a keyboard/mouse event generator to interact with the viewers to obtain the ROI
- Capture the screenshot in Windows
- Run registration; check registration accuracy
- Calculate color difference ΔE for each pixel
- Report statistics – mean, std, histogram, boxplot

SUBJECTS

- *NDP.View2* from Hamamatsu – reference
- *Sedeen* from PathCore – DICOM WG26 chair
- *QuPath* from Queen's U
- *ASAP* from Redboud U

RESULTS



FINDINGS

- NDP.view2 and Sedeen generated similar images
- ASAP and QuPath generated similar images
- Large color differences between the two groups
- Use of color profile is questionable
- JPEG compression artifacts are prominent when comparing certain pairs of viewers.
- Blank/void areas remains very similar between viewers.

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