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REVIEW ARTICLE

Comparative Performance Evaluation of FDA-Cleared Whole Slide Imaging Scanners: A Scientific Review

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Abstract

Digital pathology systems are revolutionizing histopathological diagnostics by enabling automated analytics from high-resolution digital images of the entire tissue specimen placed on the surface of a glass slide. Novel applications such as remote diagnosis or workload balancing in large hospitals are becoming a reality. Although there are many manufacturers who market whole slide imaging (WSI) scanners, only six devices to date have undergone the rigorous U.S. Food and Drug Administration (FDA) review process and secured indications for making a primary diagnosis from surgical slides in routine clinical practice. To date, no WSI scanner has been cleared by the FDA for assessing frozen sections and only one WSI scanner has been cleared for assessing cytological specimens. This white paper presents a comparative analysis for the six FDA-cleared surgical pathology WSI scanners: Epredia E1000 Dx Digital Pathology Solution (K241717), Philips IntelliSite Pathology Solution (PIPS) (DEN160056), Hamamatsu NanoZoomer S360MD (K213883), Leica Aperio AT2 DX (K190332), Leica Aperio GT 450 DX (K232202) and Roche VENTANA DP 200 (K232879, K242783). Data presented in tables 1-10 show that the Epredia E1000 Dx demonstrated the lowest rescans, lowest discordance rates and highest inter-site agreement, suggesting overall superior consistency. These tables further show that the Philips PIPS, the Hamamatsu NanoZoomer and the Leica Aperio AT2 DX systems scored well on most metrics, but the Philips PIPS exhibited the worst slide rescan rates and the Aperio AT2 DX exhibited the slowest scanning rate. Data presented in table 3 show that the Leica GT Aperio 450 DX demonstrated better precision and reproducibility metrics compared to the Roche Ventana DP 200/600 system, but this scanner exhibited the poorest discordance for anus/perianal, breast, lung and skin tissue subspecialties per table 9 and the worst overall discordance rates between digital and conventional microscopy reads per table 2. Three of the six WSI scanners (Epredia E1000 Dx, Philips PIPS, Roche VENTANA DP 200/600) include a built-in FDA cleared Image Management System (IMS) to allow enterprise level scalability and workflow integration.

Introduction

Whole slide imaging systems are classified in the USA under 21 CFR 864.3700 as Class II medical devices and manufacturers must meet all the testing requirements listed in this regulation. In Europe, there are no explicit testing requirements, but WSI scanners are required to comply with the General Safety and Performance Requirements (GSPR) of the In Vitro Diagnostic Regulation (IVDR) to gain the coveted CE mark. Other jurisdictions have similar regulatory requirements though data gathered to satisfy the USA regulations can often be used in support of regulatory applications globally.

WSI scanners facilitate automatic acquisition of high-resolution digital images of formalin-fixed paraffin-embedded (FFPE) tissue slides for diagnostic review. The FDA has cleared several such systems, each undergoing rigorous validation for technical performance (bench testing at component and system level, evaluation of inter-system and intra-system precision, inter-site reproducibility), clinical accuracy, and human factors engineering. Multi-site, blinded performance studies have been conducted by manufacturers involving thousands of clinical cases, a wide variety of tissue types and a multitude of tissue stains. The results from these studies have then

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been critically reviewed by the FDA. Indubitably, FDA cleared WSI scanners are distinct from non-FDA cleared devices. Nevertheless, we're not aware of any scientific guideline published to date that makes this distinction when making recommendations for locally validating WSI scanners. For example, the current College of American Pathologists guideline [1] recommends that each pathologist should establish an intra-observer concordance of at least 95% when comparing diagnoses made from a traditional microscope and a WSI (with a minimum of a 2-week washout period between observations) using a minimum of 60 diagnostic slides. Each highly time-constrained pathologist is, therefore, required to undergo superfluous duplicative validation effort when adopting FDA cleared WSI scanners into routine clinical practice. We remain optimistic that guideline authoring committees will acknowledge this deficiency and provide appropriate updates in the near future to improve WSI adoption.

Digital pathology has emerged as a transformative technology in diagnostic medicine, enabling pathologists to interpret high-resolution digital images of entire histological slides rather than relying solely on manual digitization of select field-of-views (FOVs) from conventional microscopes. This paradigm shift offers numerous advantages, including improved workflow efficiency, workload balancing, remote consultation capabilities, and enhanced opportunities for image analysis and artificial intelligence integration. As the adoption of WSI systems accelerates, regulatory oversight becomes critical to ensure that these devices meet stringent standards for diagnostic accuracy, reproducibility, and safety. Furthermore, scientific guidelines need to keep pace with the ever-changing technological environment.

In the USA, FDA clearance under the 510(k) or De Novo pathways signifies that a device is substantially equivalent to a legally marketed predicate, or for a novel device, that it has demonstrated acceptable clinical performance, safety and efficacy. This clearance process involves rigorous validation of technical, analytical, and clinical performance. For pathologists, laboratory directors, and healthcare institutions, FDA clearance provides assurance that a digital pathology system can be safely and effectively integrated into routine diagnostic workflows without the need for local validation in a manner similar to adoption of radiological devices.

The rationale for the comparison presented in this paper stems from the growing need for evidence-based selection of digital pathology systems for clinical deployment. Institutions must consider not only the overall concordance rates but also organ-specific discordance trends, human factors usability, and system architecture. For example, while some systems may excel in general diagnostic consistency, others may offer superior performance in subspecialty areas such as dermatopathology or gynecologic pathology. Additionally, because workloads and specific needs of facilities can vary dramatically, considerations of slide capacity, first-time slide scan success rate, slide throughput, deployment scalability and integration with hospital information systems must also be acknowledged. This analysis provides stakeholders with a comprehensive understanding of how each system performs across diverse tissue types and diagnostic scenarios, thereby informing procurement decisions and clinical implementation strategies.

System Overviews

A clear understanding of device specifications is essential for interpreting the comparative performance of WSI systems, as these parameters directly influence image quality, diagnostic reliability, and operational fit within clinical workflows. Side-by-side comparison of key technical attributes for each FDA-cleared WSI scanner discussed in this review is provided in table 1. By summarizing specifications such as objective magnification, numerical aperture, pixel resolution, image quality, optical methodologies, and slide handling capacity, this overview highlights the unique features and operational capabilities that distinguish each platform. While all systems provide similar digital image resolution, the Epredia E1000 Dx and the Leica Aperio GT450 achieve these values at a native resolution. Additionally, the slide capacities range dramatically from as few as 6 slides on the Roche Ventana DP200 up to 1000 slides for the Epredia E1000 Dx, though the slide capacity for the Roche device was increased to 240 slides via a follow-up FDA submission and the device was renamed DP600. The Hamamatsu S360MD, Leica Aperio GT 450 and the Epredia E1000 Dx are the systems of choice if scanning speed is the most important selection criterion.

A further aspect for consideration is how well WSI scanners interconnect with a hospital's laboratory information systems (LIS) and electronic health record (EHR) systems. Most manufacturers provide native image viewers with their WSI systems to allow the user to view, pan, zoom, and annotate high-resolution scanned images. However, this basic single-user oriented functionality does not permit enterprise-wide workflow management tasks such as network storage/retrieval of digital images, data security and compliance, integration with LIS and EHR systems to streamline case tracking, and for the real-time sharing and annotation of slides amongst pathologists for workload management and collaboration. For scalability at large hospitals and enterprise laboratories (deployment of multiple scanners at multiple sites) and interoperability with standalone AI enabled analytics software, some manufacturers provide a built-in FDA cleared comprehensive IMS as shown in table 1.

Table 1: Description of individual device specifications.

	Epredia E1000 Dx Digital Pathology Solution	Philips IntelliSite Pathology Solution	Hamamatsu NanoZoomer S360MD	Leica Aperio AT2 DX	Leica Aperio GT 450 DX	Roche Ventana DP 200/600
Objective Lens	20x, NA 0.8	20x,NA 0.75	20x, NA 0.75	20x, NA 0.75	40x, NA 0.65	20x, NA 0.75
WSIs Resolution@40x mode [µm/pixel]	0.24	0.25	0.23	0.25	0.26	0.25
Slide Capacity [# of slides]	1,000	300	360	400	450	6/240
WSIs Formats	MRXS; DICOM	iSyntax	NDPi	SVS	SVS; DICOM	BIF ; DICOM
Scanning Rate* [slides/hour]	72 slides/ hour	60 slides/ hour	82 slides/ hour	20 slides/ hour	81 slides/ hour	51 slides/ hour
Image Viewer	Native	Native	Native	Native	Native	Native
FDA Cleared IMS	Native	Native	3rd Party	3rd Party	3rd Party	Native

*Based on 40x scan for 15 mm x 15 mm scan area

Performance Metric Evaluations

All FDA cleared WSI scanners underwent their respective blinded, multi-site clinical performance studies to demonstrate that viewing, reviewing, and diagnosing from digital images of surgical pathology slides using WSI systems was non-inferior to using a conventional brightfield microscope. The results from these studies tabulated the difference in major discordance rates between manual digital (MD) and manual optical (MO) modalities when compared to the reference sign-out diagnosis. This section presents a detailed summary of overall performance metrics for each scanner system. Notably, all scanners met or exceeded the FDA's acceptance criteria for use in primary diagnosis, affirming their safety, reliability and suitability for clinical deployment. Users should seek similar information from non-FDA cleared devices or should plan to gather such performance data by themselves if not readily available from the manufacturer.

A summary of discordance rates from manual digital (MD) and manual optical (MO) observations is presented in table 2 for all six FDA cleared WSI scanning systems. Comparative analysis of discordance metrics provides insight into system-level variability and the degree of alignment between digital and optical modalities. Observed differences in discordance rates are further delineated by the absolute and relative metrics, enabling a nuanced assessment of diagnostic consistency across platforms.

Absolute difference in discordance between manual digital and manual optical ranged from a low of 0.11% for the Epredia E1000 Dx to a high of 2.48% for the Leica Aperio GT 450 WSI scanner. Discordance rate for reading digital images varied from a low of 2.54% for the Epredia E1000 Dx to a high of 8.00% for the Roche Ventana DP 200. Even though the Aperio GT 450 is the only FDA cleared WSI system with a 40X objective, curiously, it has the worst diagnostic accuracy (worst MD-MO discordance of 2.8% and second worst digital discordance of 6.14%) as shown in table 2. Furthermore, table 2 shows that the Epredia E1000 Dx appears to offer the best diagnostic accuracy of all the six FDA cleared WSI scanners if this is the most important selection criterion.

A summary of results from the precision and reproducibility studies, including agreement rates between multiple scanners, sites, and readers is presented in table 3. While all scanners successfully demonstrated high levels of reproducibility across each category, the Ventana DP 200 showed the lowest agreement levels across all metrics. The Epredia E1000 Dx demonstrated the highest inter-reader agreement of 97.5%.

Comparative analysis of publicly reported manual rescanning rates across different WSI scanners is shown in table 4. By detailing both the total number of slides scanned, and the corresponding rescan rates, the results offer a quantifiable assessment of scanner performance and reliability. Additionally, the breakdown of rescan events according to specific causes-such as tissue or label detection errors and image quality or incomplete tissue issues-enables a nuanced understanding of the operational strengths and limitations of each platform. Such comparative data are essential for laboratories seeking to optimize workflow efficiency and minimize manual intervention, ultimately supporting more robust WSI adoption and improved diagnostic consistency.

The Epredia E1000 Dx experienced no tissue/label detection errors whereas the Philips PIPS scanner experienced the highest rate of 2.3% as shown in table 4. Overall, the Epredia E1000 Dx system exhibited the lowest non-slide related rescan rate of 0.2% compared to 3.9% for the Philips scanner. Data for the remaining three FDA cleared WSI scanners were not publicly available.

Another important consideration for the end-users is the behavior of the WSI scanner when it encounters a slide that does not scan properly. Some scanners simply stall at that location, pending operator intervention. The Epredia E1000 Dx system deposits the problematic

Table 2: Comparative discordance rates from FDA performance study evaluations.

System	Digital Discordance (MD)		Optical Discordance (MO)		Absolute Difference (MD-MO)
	# of Reads	%	# of Reads	%	% Different
Epredia E1000 Dx Digital Pathology Solution	3,897	2.54%	3,881	2.65%	0.11%
Philips PIPS Ultra-Fast Scanner	7,964	4.9%	7,961	4.6%	0.4%
Hamamatsu NanoZoomer S360MD	7,997	3.5%	7,998	3.1%	0.4%
Leica Aperio AT2 DX	7,509	3.73%	7,522	3.28%	0.45%
Leica Aperio GT 450 DX	3,549	6.14%	3,631	3.66%	2.48%
Roche Ventana DP 200	7,562	8.00%	7,562	7.39%	0.61%

Table 3: Summary of precision and reproducibility agreement percentages for each system.

System	Intra-System Agreement (%)	Inter-System/Site Agreement (%)	Intra-Reader Agreement (%)	Inter-Reader/Site Agreement (%)
Epredia E1000 Dx	96.9	95.1	96.3	97.5
Philips PIPS	92.0	93.8	*n.a.*	90.2
Hamamatsu S360MD	94.5	92.4	*n.a.*	93.4
Leica Aperio AT2 DX	97.9	96.0	95.0	94.2
Leica Aperio GT 450 DX	97.1	96.3	93.5	91.7
Roche VENTANA DP 200	90.3	89.3	88.1	90.1

Table 4: Reported rates* of manual rescanning.

	# of Slides	Total Rescan	Slide-related Issue	Scanning/Image Related Issue		
				Tissue/Label Detection Error	Image Quality or Incomplete Tissue	Total
Epredia E1000 Dx Digital Pathology Solution	1,796	5.8%	5.6%	0.0%	0.2%	0.2%
PIPS UFS	3,390	6.0%	2.1%	2.3%	1.6%	3.9%
Leica Aperio AT2 DX	2,119	1.8%	*n.a.*	1.0%	0.8%	1.8%

*Systems for which published data on rescan rates was not publicly available were omitted from the table.

Table 5: E1000 Dx major discordance percentages distributed by specific organ/tissue type.

Epredia E1000 Dx Major Discordance			
Organ/Tissue Type	**Digital (MD)**	**Optical (MO)**	**Difference (MD-MO)**
Adrenal	1.3%	0.0%	1.3%
Anal/Perianal	4.0%	2.7%	1.3%
Appendix	0.0%	0.0%	0.0%
Bladder	3.2%	2.3%	0.9%
Brain	4.3%	2.9%	1.4%
Breast	0.6%	1.1%	-0.6%
Colorectal	0.0%	0.7%	-0.7%
Gallbladder	5.0%	5.1%	-0.1%
GE Junction	2.0%	0.0%	2.0%
Gynecological	7.3%	10.1%	-2.8%
Hernia/Peritoneum/Omentum	1.7%	3.3%	-1.7%
Kidney	4.4%	2.2%	2.2%
Liver/Bile Duct	1.5%	3.0%	-1.5%
Lung	2.4%	4.3%	-2.0%
Lymph Node	1.8%	3.2%	-1.4%
Pancreas	0.0%	0.0%	0.0%
Parathyroid	0.0%	0.0%	0.0%
Prostate	0.0%	0.0%	0.0%
Salivary Gland	2.7%	2.7%	0.0%
Skin	3.4%	1.7%	1.7%
Soft Tissue	1.1%	1.1%	0.0%
Stomach	2.4%	1.0%	1.4%
Thyroid	5.6%	7.8%	-2.2%

slide into a separate basket and continues to scan the remaining slides without user intervention.

Organ-level data presented in table 5 [2] for the Epredia E1000 Dx scanner showed consistently low manual digital discordance across most tissues, with gynecological cases being an exception (7.3%). The manual optical discordance (MO) rate for these cases, however, was (10.1%), suggesting that pathologists were able to interpret these digital slides, as well as, if not superior to conventional microscopy. These results in combination with metrics described in preceding sections underscore the system's strength in diagnostic accuracy and reproducibility, making it particularly suitable for high-throughput and subspecialty applications. Its strength appears to be diagnostic accuracy; its limitation may be isolated tissue-specific discordance.

The Philips PIPS demonstrated varying levels of discordance across tissue types as shown in table 6 [3] with the largest discordance reported in Prostate (12.0%) and Bladder (7.3%) tissues, respectively. These high rates of discordance also appear in the corresponding conventional microscopy readings, which is suggestive of slide/stain preparation difficulties rather than contributions from the WSI scanner. Overall, the PIPS scanner demonstrated consistent performance across all precision and reproducibility metrics, with intra-system, inter-system, and inter-reader agreement rates all above 90.0% (Table 3). Notably, the Philips PIPS scanner reported the highest percentage of non-slide related rescans (3.9%) compared to any of the systems listed in table 4.

Overall metrics for precision and reproducibility (Table 3) for the Hamamatsu NanoZoomer S360MD were reasonable, not the best but certainly not the worst. Major discordance rates across tissue or organ types are shown in table 7 [4] with the largest digital discordance rates reported in respiratory tissue (10.3%). The corresponding conventional microscopy reads also exhibited the highest discordance in this tissue type. More worryingly, discordance rates for digital reads in gastroesophageal junction (6.0%) and bladder (6.3%) tissues were not as high when read through conventional microscopy.

The Leica Aperio AT2 DX exhibited better overall precision and reproducibility metrics compared to the Roche Ventana DP 200 as shown in table 3. Major discordance across tissue or organ types is shown in table 8 [5]. Consistent with other scanners, bladder tissue exhibited the highest discordance rate for digital reads (10.4%) but this WSI scanner struggled with skin tissue compared to the Philips PIPS. Overall, this scanner's strength appears to be precision and reproducibility, but it has the slowest scanning speed of just 20 slides per hour as shown in table 1.

The Leica Aperio GT 450 DX exhibited comparable intra-system agreement (97.1%) and inter-system agreement (96.3%) to the Epredia E1000Dx and Aperio AT2 DX systems as shown in table 3, indicating strong consistency. Organ-level analysis presented in table 9 [6] revealed higher discordance rates in certain tissues, such as bladder (14.79%), which is consistent with other scanners. However, unique to this system, is how poorly it handled anus/perianal, breast, lung and skin tissues. In all these subspecialties, the Aperio GT 450 DX exhibited a discordance difference rate > 4% for digital reads compared to conventional microscopy. This is by far the worst subspecialty discordance of the

Table 6: PIPS major discordance percentages distributed by specific organ/tissue type.

PIPS Ultra-Fast Scanner Major Discordance			
Organ/Tissue Type	**Digital (MD)**	**Optical (MO)**	**Difference (MD-MO)**
Breast	4.2%	4.3%	-0.2%
Prostate	12.0%	11.3%	0.8%
Respiratory	3.5%	4.2%	-0.7%
Colorectal	1.7%	1.0%	0.7%
GE Junction	2.0%	1.3%	0.7%
Stomach	0.8%	0.5%	0.3%
Skin	4.9%	4.7%	0.3%
Lymph Node	0.3%	0.8%	-0.5%
Bladder	7.3%	6.1%	1.3%
Gynecological	6.3%	5.2%	1.2%
Liver/Bile Duct	4.6%	5.6%	-1.0%
Endocrine	6.5%	4.7%	1.8%
Brain/Neuro	6.2%	5.8%	0.4%
Kidney	2.5%	1.0%	1.5%
Salivary Gland	2.0%	3.0%	-1.0%
Peritoneal	0.0%	0.0%	0.0%
Gallbladder	0.0%	0.0%	0.0%
Appendix	0.0%	0.0%	0.0%
Soft Tissue	0.0%	0.0%	0.0%
Perianal	1.0%	2.0%	-1.0%

Table 7: Hamamatsu NanoZoomer S360MD major discordance percentages distributed by specific organ/tissue type.

Hamamatsu NanoZoomer S360MD Major Discordance			
Organ/Tissue Type	**Digital (MD)**	**Optical (MO)**	**Difference (MD-MO)**
Breast	5.3%	4.8%	0.6%
Prostate	1.2%	1.8%	-0.7%
Respiratory*	10.3%	9.8%	0.5%
Colorectal	0.7%	0.5%	0.2%
GE Junction	6.0%	3.5%	2.5%
Stomach	1.5%	0.8%	0.8%
Skin	5.7%	4.6%	1.1%
Lymph Node	1.8%	1.8%	0.0%
Bladder	6.3%	4.3%	2.0%
Gynecological	3.5%	3.5%	0.0%
Liver/ Bile Duct	2.0%	1.5%	0.5%
Endocrine	4.5%	3.3%	1.3%
Brain/Neuro	0.8%	0.4%	0.4%
Kidney	0.5%	1.5%	-1.0%
Salivary Gland	1.0%	1.5%	-0.5%
Hernial/Peritoneal+	0.0%	0.0%	0.0%
Gallbladder+	0.0%	0.0%	0.0%
Appendix#	5.0%	0.0%	5.0%
Soft Tissue Tumors#	1.3%	0.0%	1.3%
Anus/Perianal	2.0%	3.5%	-1.5%

Table 8: Leica Aperio AT2 DX major discordance percentages distributed by specific organ/tissue type.

Leica Aperio AT2 DX Major Discordance			
Organ/Tissue Type	**Digital (MD)**	**Optical (MO)**	**Difference (MD-MO)**
Anus/perianal	3.95%	2.79%	1.16%
Appendix	0.00%	0.00%	0.00%
Bladder	10.40%	9.47%	0.93%
Brain/neuro	3.09%	2.54%	0.55%
Breast	4.29%	3.53%	0.76%
Colorectal	2.46%	2.46%	0.00%
Endocrine	4.04%	4.57%	-0.53%
Gastroesophageal junction	3.69%	3.16%	0.54%
Gallbladder	0.00%	0.00%	0.00%
Gynecological	4.28%	3.18%	1.10%
Hernia/peritoneal	0.00%	0.00%	0.00%
Kidney	1.14%	1.69%	-0.56%
Liver/bile duct	1.59%	0.53%	1.06%
Lung	5.24%	3.68%	1.55%
Lymph node	1.09%	1.87%	-0.78%
Prostate	3.00%	3.44%	-0.44%
Salivary gland	0.55%	1.69%	-1.14%
Skin	4.74%	2.72%	2.03%
Soft tissue	4.23%	4.83%	-0.60%
Stomach	3.15%	2.09%	1.06%

six FDA cleared WSI scanners, see tables 5-10. Overall, the scanner's strength appears to be high throughput, precision and a 40X objective lens; its limitation may be organ-specific variability and diagnostic accuracy (second worst MD discordance of 6.14% and worst overall MD-MO discordance of 2.8% per table 2.

The Roche VENTANA DP 200 showed the lowest precision, with intra-system agreement at 90.3%, inter-system at 89.3%, and inter-reader at 90.1% (Table 3). These figures indicate acceptable but comparatively lower reproducibility. The observed major discordance rate of 8.0% for digital reads (Table 2) is the highest among the six systems, suggesting potential limitations in diagnostic accuracy for certain organ systems as shown in table 10 [7]. Despite this, the system met FDA non-inferiority criteria, affirming its clinical viability. Its strength is in broad accessibility and integration, while its limitation is variability in reader agreement and low slide capacity.

Conclusion

This paper serves to highlight that FDA cleared WSI scanners have undergone extensive testing, and that

Table 9: Leica Aperio GT 450 DX major discordance percentages distributed by specific organ/tissue type

Leica Aperio GT 450 DX Major Discordance			
Organ/Tissue Type	**Digital (MD)**	**Optical (MO)**	**Difference (MD-MO)**
Anus/Perianal	7.26%	3.23%	4.03%
Appendix	0.00%	0.00%	0.00%
Bladder	14.79%	12.87%	1.93%
Brain/Neuro	2.90%	6.02%	-3.13%
Breast	7.62%	3.61%	4.01%
Colorectal	2.18%	1.42%	0.76%
Endocrine	6.47%	3.53%	2.94%
GE Junction	2.91%	4.65%	-1.74%
Gallbladder	0.00%	0.00%	0.00%
Gyn	5.22%	4.69%	0.53%
Hernial/Peritoneal	0.00%	0.00%	0.00%
Kidney, Neoplastic	3.13%	1.03%	2.09%
Liver/BD	4.55%	1.39%	3.16%
Lung	7.11%	2.02%	5.09%
Lymph Node	2.76%	2.27%	0.49%
Prostate	6.80%	4.03%	2.76%
Salivary gland	1.43%	1.37%	0.06%
Skin	10.57%	2.87%	7.70%
Soft Tissue Tumor	6.90%	3.41%	3.49%
Stomach	3.97%	3.27%	0.71%

Table 10: Roche Ventana DP 200 major discordance percentages distributed by specific organ/tissue type*.

Roche Ventana DP 200 Major Discordance			
Organ/Tissue Type	**Digital (MD)**	**Optical (MO)**	**Difference (MD-MO)**
Anus/ Perianal	7.0%	4.3%	2.7%
Appendix	1.6%	0.0%	1.6%
Bladder	14.1%	12.2%	1.9%
Brain/ Neurological	5.7%	7.6%	-1.9%
Breast	9.0%	6.8%	2.2%
Colorectal	6.8%	7.0%	-0.2%
Endocrine	8.7%	7.9%	0.8%
GE Junction	9.3%	8.5%	0.8%
Gallbladder	0.0%	0.0%	0.0%
Gynecological	10.4%	10.4%	0.0%
Hernial/ Peritoneal	0.0%	0.0%	0.0%
Kidney, Neoplastic	3.8%	5.1%	-1.3%
Liver/ Bile duct, Neoplastic	3.0%	1.5%	1.5%
Lung/ Bronchus/ Larynx /Oral Cavity/ Nasopharynx	10.6%	7.7%	2.9%
Lymph Node	2.9%	2.2%	0.7%
Prostate	6.6%	7.1%	-0.5%
Salivary Gland	4.7%	5.2%	-0.5%
Skin	10.4%	10.6%	-0.2%
Soft Tissue Tumors	3.4%	6.9%	-3.5%
Stomach	7.6%	6.4%	1.2%

the results have been critically reviewed independently by the FDA to establish clinical safety and efficacy. This provides the end-user assurance and confidence when adopting these systems into routine clinical usage without further local validation of discordance rates. FDA cleared WSI scanners are distinct from all other similar devices on the market worldwide. It is hoped that current scientific guidelines are updated soon to reflect this reality when making recommendations for local validation.

The comparative analyses presented here allow the end-user too readily and conveniently compare performance metrics such as precision, resolution, scanning capacity, scanning rate, reproducibility, rescan rates, clinical discordance, scalability, interoperability and integration with hospital LSIs and EHRs. Organ-specific data highlight variability in discordance across tissue types, emphasizing the importance of system selection based on diagnostic context. The Epredia E1000 Dx demonstrated the lowest rescans, lowest

discordance rates and highest inter-site agreement, suggesting superior consistency. The Philips PIPS, the Hamamatsu NanoZoomer and the Leica Aperio AT2 DX systems scored admirably on most metrics, but the Philips PIPS is the worst offender for slide rescans per table 4 and the Aperio AT2 DX exhibits the slowest scanning rate per table 1. The Leica GT Aperio 450 DX demonstrated better precision and reproducibility metrics compared to the Roche Ventana DP 200/600 as shown in table 3. It is the only FDA cleared WSI scanner with a 40X objective lens, yet it exhibited the poorest discordance for anus/perianal, breast, lung and skin tissue subspecialties per table 9 and, the worst overall discordance rates between digital and conventional microscopy reads per table 2.

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Contribution

All authors contributed equally.

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