WHITE PAPER

Experience Speed to Quality in Digital Pathology Scanning

Advancing with the latest standards in digital pathology

Proven technology for improved workflow efficiency and patient care are set to define digital pathology and increase overall adoption. With the call for more rigorous controls, manufacturers of digital pathology devices are being held to the highest standards of quality, security, and patient safety.

Leica Biosystems Aperio GT 450 DX is a high-throughput, continuous load slide scanner, designed to meet the needs of busy clinical laboratories. Its automated, hands-off design helps Histotechnicians deliver rapid results with confidence, while centralized management through the Scanner Administration Manager (SAM DX) enables IT Professionals to scale digital pathology operations easily and securely.

To ensure that the Aperio GT 450 DX meets user needs a Design Validation study[1] was carried out to test the performance and usability of the scanner and SAM DX software.

Aperio GT 450 DX has been validated through robust user testing

The design validation study took place across three independent laboratories with a total of twelve users, split between slide scanning and IT administration roles. A series of test scenarios were carried out to validate that the Aperio GT 450 DX performs as expected under laboratory conditions.

Validation by Histotechnicians used a set of approximately 75[2] typical coverslipped FFPE slides, in a mix of H&E, IHC, and ISH as shown in Table 1, provided by each of the testing sites and labeled with barcodes by Leica Biosystems. Product performance metric requirements were tested as follows:

• System shall have a first-time scan success rate of 98% for FFPE tissue histology slides stained with H&E.
• System shall encompass all stained portions of the tissue at 98% success rate for FFPE H&E stained slides and 90% for FFPE IHC.
• System shall handle ≥99.9% of glass slides successfully without damage.
• System shall successfully decode the identified barcode types at a rate of 99%.

All of these performance end points were successfully validated during the study.

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No. slides	Stain	Body site
5	H&E	Colon
5	H&E	Prostate
5	H&E	Lung
5	H&E	Breast
5	H&E	Liver/Kidney
5	H&E	Skin
5	H&E	Brain
5	H&E	Pancreas
5	H&E	Thyroid
5	ER	Breast
5	PR	Breast
5	HER2	Breast
5	Ki67	Breast
5	P53	Breast
2 or 5[3]	Brightfield ISH	Miscellaneous

Table 1: Slides used for Histotechnician validation

In addition, the Histotechnician users validated ease of use of the Aperio GT 450 DX, by performing a series of test scenarios following one hour of user training on Aperio GT 450 DX operation.

- 100% of users were able to correctly load slides and racks, and perform standard scanner functions, following one hour of user training on Aperio GT 450 DX operation.
- 100% of users could accurately determine status of racks and slides during scanning, using the Aperio GT 450 DX console touchscreen.
- 100% of users could successfully perform a visual assessment of tissue finder coverage when viewing scanned slide macro-images on the Aperio GT 450 DX console touchscreen.

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Validation by IT Professionals involved performing a series of test scenarios using Aperio SAM DX software interface, following 1 hour of user training, to measure ease of use of SAM DX.

- 100% of users were able to remotely assess Aperio GT 450 DX scanner status.
- 100% of users were able to review Aperio GT 450 DX scanner statistics across selected time periods.
- 100% of users could successfully create new SAM DX user accounts with appropriate permissions.
- 100% of users could successfully create and assign new user PIN settings for Aperio GT 450 DX scanners.
- 100% of users were able to switch between SVS and DICOM image format output on Aperio GT 450 DX scanners.

Proven digital pathology for diagnostic excellence

Aperio GT 450 DX enables anatomic pathology laboratories to scale up digital pathology operations, increasing throughput in high volume clinical workflows.

This study validates that Aperio GT 450 DX meets user needs, setting a high standard for quality and supporting patient-centric care.

1. VP-0622 Aperio GT 450 DX Design Validation
2. Three test sites utilized 75, 75, and 72 slides respectively.
3. One test site utilized 2 ISH slides due to availability restrictions.

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