Advancing Cancer Diagnostics
Improving Lives

Validating Aperio LV1 IVD Live View Solution for Rapid, On-Screen Diagnosis

A REMOTE, LIVE VIEW, DIGITAL PATHOLOGY SYSTEM FOR ON-SCREEN DIAGNOSIS

Aperio LV1 IVD is a compact, economic digital pathology platform that enables remote live view of microscope slides in 15 seconds or less. It also features digital slide scanning at up to 40x true optical magnification. A clinical validation study was carried out to determine if Aperio LV1 IVD is suitable for diagnostic use on H&E slides, both frozen section and formalin-fixed, paraffin-embedded (FFPE). Studies with three consulting pathologists found high concordance between microscope review and on-screen diagnosis, using both Aperio LV1 IVD live view and whole slide images (WSI).

VALIDATION ON ROUTINE CASELOAD WAS CARRIED OUT BY EXPERT PATHOLOGISTS

A total of 326 cases were chosen to represent routine workflow, including cases that often require 40x magnification for review, and which closely reflected the diversity of cases and diagnoses found in general practice. One representative H&E slide was selected from each case, for a total of 326 slides – 163 frozen section, and 163 FFPE slides.

Three experienced pathologists took part in the two-part study. The first part looked at slides under 20x magnification (n=240), while the second part examined slides under 40x magnification (n=86), Each part of the study was carried out in three phases.

Phase 1: Conventional microscope read, followed by at least a 2-week wash-out period.

Phase 2: Aperio LV1 IVD live view read, followed by at least a 2-week wash-out period.

Phase 3: Aperio LV1 IVD scanned WSI read, and review by pathologists to confirm that all relevant tissue had been captured by Aperio LV1 IVD during scanning.

For Phases 2 and 3, slides were re-numbered and presented to pathologists in a unique, randomized order. At each phase, the pathologists reviewed the slides and recorded their diagnoses to a data table. Using the microscope read as gold standard, an expert adjudicator compared the live view and WSI reads from each pathologist against the microscope read, and marked each live view / WSI diagnosis as “Concordant”, “Minor Discordance” (minor change in diagnostic threshold or different diagnosis with no clinical significance), or “Major Discordance” (improper rendering of a diagnosis as malignant or benign).

APERIO LV1 IVD IS 99% CONCORDANT WITH MICROSCOPE REVIEW

Statistical analysis was carried out to determine the level of concordance between digital methods and microscope review, using a 95% confidence level. Results are shown here:

20x Study (N=240)	Live View concordance w/ microscope	WSI concordance w/ microscope
Frozen Section	98%	98%
FFPE	99%	99%
Overall	99%	99%

40x Study (N=86)	Live View concordance w/ microscope	WSI concordance w/ microscope
Frozen Section	98%	98%
FFPE	99%	98%
Overall	99%	98%

From these results, we can see that reviews made using Aperio LV1 IVD are highly concordant with conventional microscope, with 99% concordance overall. We can conclude that Aperio LV1 IVD is suitable for on-screen diagnosis of frozen section and FFPE H&E slides, using both live view functionality and whole slide image capture.

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