

Pathology

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Former Standard and Guidance	Revised Standard and Guidance
Not applicable New Standard	<p>Pathology Standard of Practice 1 (PA S1): Whole Slide Imaging</p> <p>The use of whole slide imaging (WSI) must be validated to ensure the digital image(s) includes all cellular material and/or tissue fragments that would be visible on a glass slide such that a licensed pathologist is able to render a result from the digital images. The validation must be approved by the laboratory director.</p> <p>Guidance -</p> <p>Digital pathology that utilizes any algorithm, including artificial intelligence or machine learning models, to aid the pathologist in diagnosis may require approval from the Food and Drug Administration.</p> <p>The resolution of the remote viewing device (e.g., monitor) must be comparable to the highest resolution obtained by the scanning equipment such that resolution meets the laboratory and manufacturers specified criteria determined to be sufficient for the pathologist to render their diagnosis or findings.</p>

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Former Standard and Guidance	Revised Standard and Guidance
Not applicable New Standard	<p>Pathology Standard of Practice 2 (PA S2): Quality Control of Whole Slide Imaging</p> <p>The laboratory must have a mechanism to rescan images at the request of the reading pathologist.</p>