

CADTH Reference List

# Digital Pathology Technology for Histopathological Diagnosis

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## Key Message

- One evidence-based guideline was identified regarding the use of digital pathology technology.

## Research Question

1. What are the evidence-based guidelines regarding the use of digital pathology technology?

## Methods

### Literature Search Methods

A limited literature search was conducted by an information specialist on key resources including MEDLINE, the Cochrane Database of Systematic Reviews, the international HTA database, the websites of Canadian and major international health technology agencies, as well as a focused internet search. The search strategy comprised both controlled vocabulary, such as the National Library of Medicine's MeSH (Medical Subject Headings), and keywords. The main search concept was digital pathology. Search filters were applied to limit retrieval to health technology assessments and guidelines. Where possible, retrieval was limited to the human population. The search was also limited to English-language documents published between January 1, 2016 and February 25, 2021. Internet links were provided, where available.

### Selection Criteria and Summary Methods

One reviewer screened literature search results (titles and abstracts) and selected publications according to the inclusion criteria presented in Table 1. Full texts of study publications were not reviewed. The Overall Summary of Findings section was based on information available in the abstracts of selected publications. Open-access, full-text versions of evidence-based guidelines were reviewed when abstracts were not available and relevant recommendations were summarized.

## Result

One relevant evidence-based guideline was identified regarding the use of digital pathology technology.<sup>1</sup>

Additional references of potential interest that did not meet the inclusion criteria are provided in Appendix 1.

**Table 1: Selection Criteria**

Criteria	Description
Population	Individuals of all ages requiring histopathology
Intervention	Digital pathology (e.g., telepathology, whole slide imaging), algorithms for dedicated morphometric analysis, algorithms employing artificial intelligence/machine learning, natural language processing, and novel microscopic techniques (e.g., multispectral, Fourier transform infrared and other infrared spectroscopy, and second harmonic generation imaging)
Comparator	Not applicable
Outcomes	Recommendations regarding best practices
Study designs	Evidence-based guidelines

## Overall Summary of Findings

One evidence-based guideline<sup>1</sup> was identified regarding the use of digital pathology technology. The authors of this guideline recommend the use of quality controls when using whole slide imaging systems to ensure they are operating normally and that the tests results are reliable.<sup>1</sup> In addition, the guideline recommends the use of immediate action if a system defect is identified, given the potential risk for serious errors in the test results.<sup>1</sup> Please see the full guideline for further details regarding recommendations for validation techniques.

## Reference

### Guidelines and Recommendations

1. Chong Y, Kim DC, Jung CK, et al. Recommendations for pathologic practice using digital pathology: consensus report of the Korean Society of Pathologists. J. 2020 Nov;54(6):437-452. [Medline](#)

## Appendix 1: References of Potential Interest

### Previous CADTH Reports

2. Hill S, Walter M. Artificial intelligence for classification of lung nodules: clinical utility, diagnostic accuracy, cost-effectiveness, and guidelines. (CADTH rapid response report: summary of abstracts). Ottawa (ON): CADTH; 2019: <https://www.cadth.ca/sites/default/files/pdf/htis/2019/RB1411%20AI%20Lung%20Cancer%20Final.pdf> Accessed 2021 Mar 8.
3. Mason J, Morrison A, Visintini S. An overview of clinical applications of artificial intelligence. (CADTH issues in emerging health technologies; issue 174). Ottawa (ON): CADTH; 2018: [https://www.cadth.ca/sites/default/files/pdf/eh0070\\_overview\\_clinical\\_applications\\_of\\_AI.pdf](https://www.cadth.ca/sites/default/files/pdf/eh0070_overview_clinical_applications_of_AI.pdf) Accessed 2021 Mar 8.

### Guidelines and Recommendations

#### *Methodology Not Specified*

4. Office of Product Evaluation and Quality (OPEQ), Center for Devices and Radiological Health (CDRH). Enforcement policy for remote digital pathology devices during the coronavirus disease 2019 (COVID-19) public health emergency. Guidance for industry, clinical laboratories, healthcare facilities, pathologists, and Food and Drug Administration staff. Rockville (MD): U.S. Food and Drug Administration (FDA); 2020: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-remote-digital-pathology-devices-during-coronavirus-disease-2019-covid-19-public> Accessed 2021 Mar 9.
5. The Digital Pathology Committee of the Royal College of Pathologists. Guidance for remote reporting of digital pathology slides during periods of exceptional service pressure. London (UK): The Royal College of Pathologists; 2020: <https://www.rcpath.org/uploads/assets/626ead77-d7dd-42e1-949988e43dc84c97/RCPath-guidance-for-remote-digital-pathology.pdf> Accessed 2021 Mar 9.
6. Center for Devices and Radiological Health. Technical Performance Assessment of Digital Pathology Whole Slide Imaging Devices. Guidance for Industry and Food and Drug Administration Staff. Rockville (MD): U.S. Food and Drug Administration (FDA); 2016: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/technical-performance-assessment-digital-pathology-whole-slide-imaging-devices> Accessed 2021 Mar 9.
7. Cross S, Furness P, Igali L, Snead D, Treanor D. Best practice recommendations for implementing digital pathology. London (UK): The Royal College of Pathologists; 2018. <https://www.rcpath.org/uploads/assets/f465d1b3-797b-4297-b7fedc00b4d77e51/Best-practice-recommendations-for-implementing-digital-pathology.pdf> Accessed 2021 Mar 9.  
See: Quality Assurance and Calibration, page 13; Imaging Analysis, page 14.

#### *Alternative Outcome*

8. Reznick RK, Harris K, Horsley T, Hassani MS. Task Force Report on artificial intelligence and emerging digital technologies. Ottawa (ON): Royal College of Physicians and Surgeons of Canada; 2020. <https://www.royalcollege.ca/rcsite/health-policy/initiatives/ai-task-force-e> Accessed 2021 Mar 9.  
See: Summary of Findings and Recommendations, page 34 to 36.

### Conference Proceedings

9. van Leenders G, van der Kwast TH, Grignon DJ, et al. The 2019 International Society of Urological Pathology (ISUP) Consensus Conference on Grading of Prostatic Carcinoma. *Am J Surg Pathol.* 2020 08;44(8):e87-e99. [Medline](#)

### Review Articles

10. Garcia-Rojo M. International clinical guidelines for the adoption of digital pathology: a review of technical aspects. *Pathobiology.* 2016;83(2-3):99-109. [Medline](#)

### Additional References

11. McGenity C, Treanor D. Guidelines for clinical trials using artificial intelligence - SPIRIT-AI and CONSORT-AI. *J Pathol.* 2021 Jan;253(1):14-16. [Medline](#)
12. College of American Pathologists. Upcoming CAP guidelines. [2021]: <https://www.cap.org/protocols-and-guidelines/upcoming-cap-guidelines> Accessed 2021 Mar 9.  
See: Validating Whole Slide Imaging for Diagnostic Purposes in Pathology.