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Artificial intelligence determined reference value “rAIght value” included in virtual histopathology EQA scheme:

Comparison of participating pathologists and a trained image analysis algorithm

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Labquality in a nutshell

We are quality makers – a team of experienced experts in healthcare and health-tech quality.

Our services:

- Clinical research (CRO) and regulatory services for medical device, IVD and pharmaceutical companies
- External quality assessment (EQA) services for clinical laboratories and POCT sites
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- Labquality Days congress

We operate globally and have offices in Finland, Sweden, Germany, and Poland.

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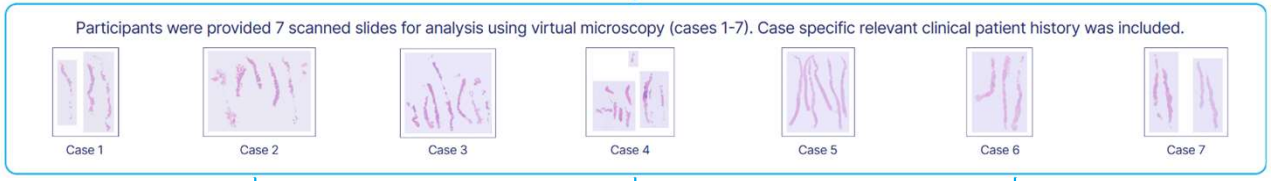
Histopathology EQA 2x / year

Round 2-2023: prostate cancer



Participants: 150 from 15 countries

Expert evaluation

Scheme expert Marita Laurila

AI whole slide imaging model

rAIght value

6542 / Histopathology, virtual microscopy

Samples: Virtual images of at least 5 slides of miscellaneous tissue. Brief case histories and instructions are provided.

Type: Digital sample

Examinations: Observations and diagnoses.

Additional information: Topics may vary annually.
Try the virtual microscopy technology demo.

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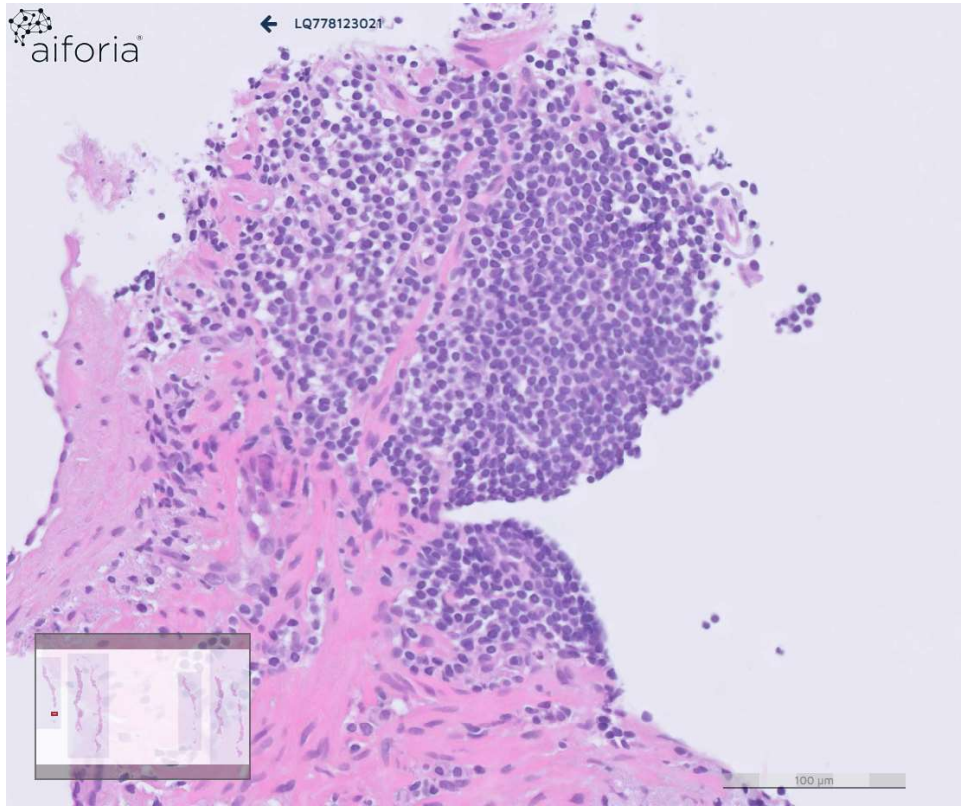
Background

- Prostate cancer is the second most common occurring cancer among men
  - According to WHO, there were more than 1.4 million new cases of prostate cancer in 2020 (1)
- Correct identification of prostate cancer is important to help patients correctly and on time.
- Analysis of biopsies is time-consuming and prone to interobserver variability (2)



1. Cancer Today - IARC. (2023, February 2nd). Online analysis table. WHO. https://gco.iarc.fr/today/
2. Melia J. et al. A UK-based investigation of inter- and intra-observer reproducibility of Gleason grading of prostatic biopsies. Histopathology. 2006 May;48(6):644-54

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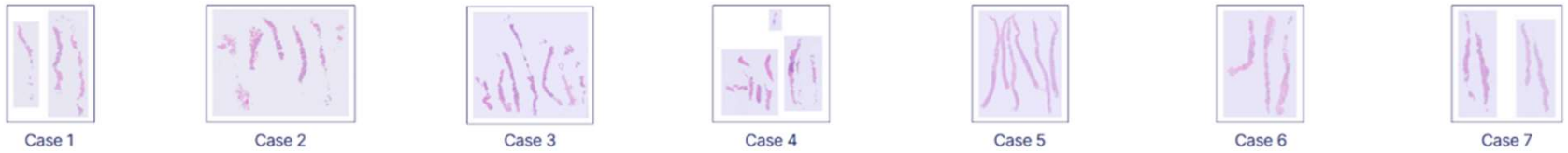
Gleason scoring



- The pathologist evaluates the biopsies to figure out the malignancy of the cancer
- The histological classing is used to predict the disease and to evaluate the needed care
- Prostate cancer samples are evaluated with the Gleason score and Gleason grade group.
- There might be several places for the cancer cells and the cancer cells can be different (heterogeneous)

  → Gleason scoring takes into account the multifocality and heterogeneity of prostate cancer

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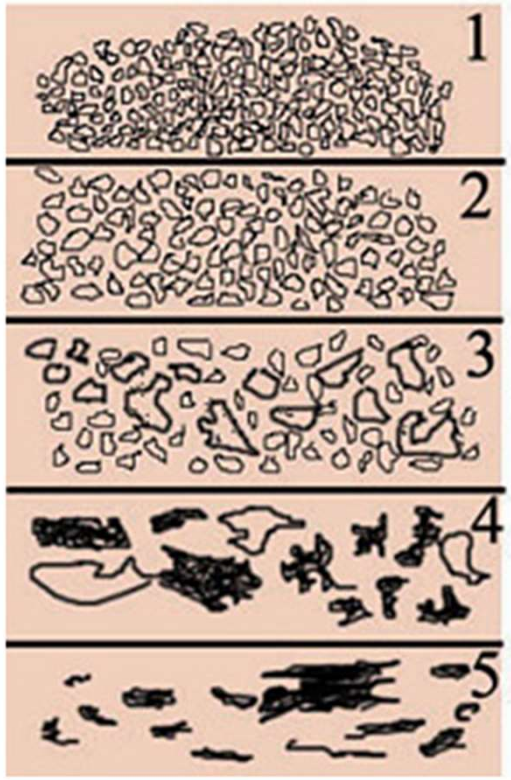
Gleason scoring

- The biopsies are graded from 1-5 for the most common and most aggressive grades
- The most common and most aggressive grades are added together
- This is the overall Gleason score for the sample.



1. Small, kind glands
2. More space between glands
3. Infiltrative growth of cells on gland borders
4. Irregular cellmass, only few glands
5. No glands, piles of cells

Kind

Bad

https://www.suomalaineneturauhassyopa.fi/diagnostiikka/luokittelu/

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Most common vs. Most aggressive

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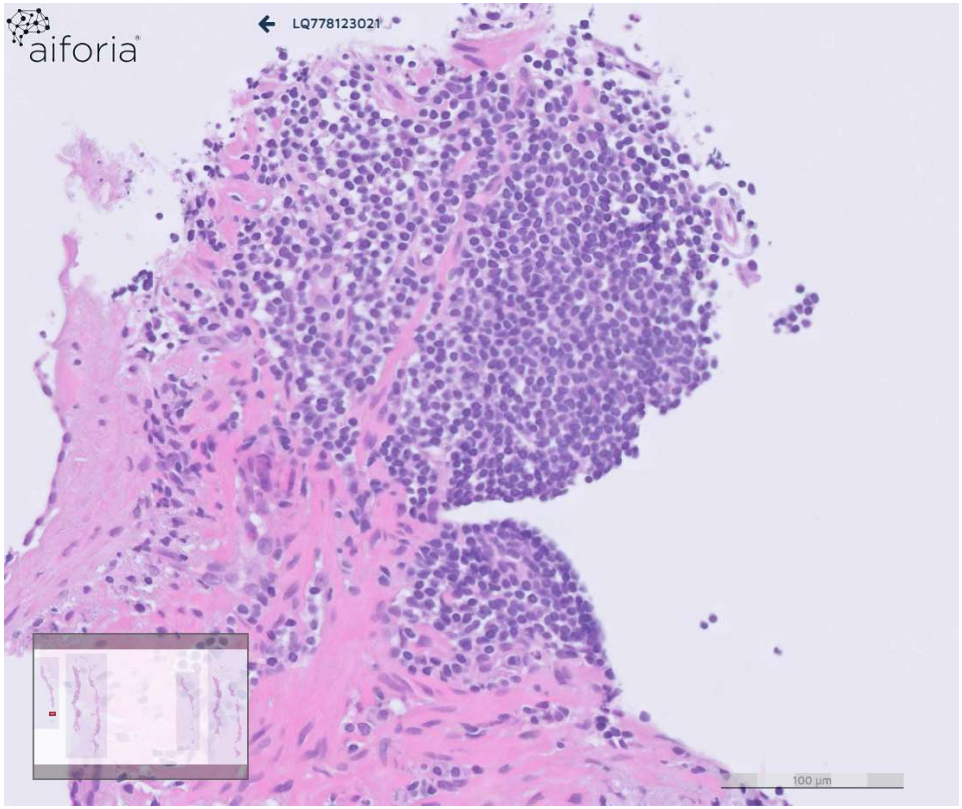
Grade Group



The overall Gleason score determines the Grade Group (GG) from 1 to 5

5 is the most aggressive.

Risk Group*	Gleason Score	Grade Group
Low/Very Low	Gleason Score ≤ 6	Grade Group 1
Intermediate Favorable/Unfavorable	Gleason Score 7 (3 + 4)	Grade Group 2
	Gleason Score 7 (4 + 3)	Grade Group 3
High/Very High	Gleason Score 8	Grade Group 4
	Gleason Score 9-10	Grade Group 5

*The 2014 International Society of Urological Pathology (ISUP) Consensus Conference on Gleason Grading of Prostatic Carcinoma. Epstein JI, et al. Am J Surg Pathol. 2016;40(2):244-52.

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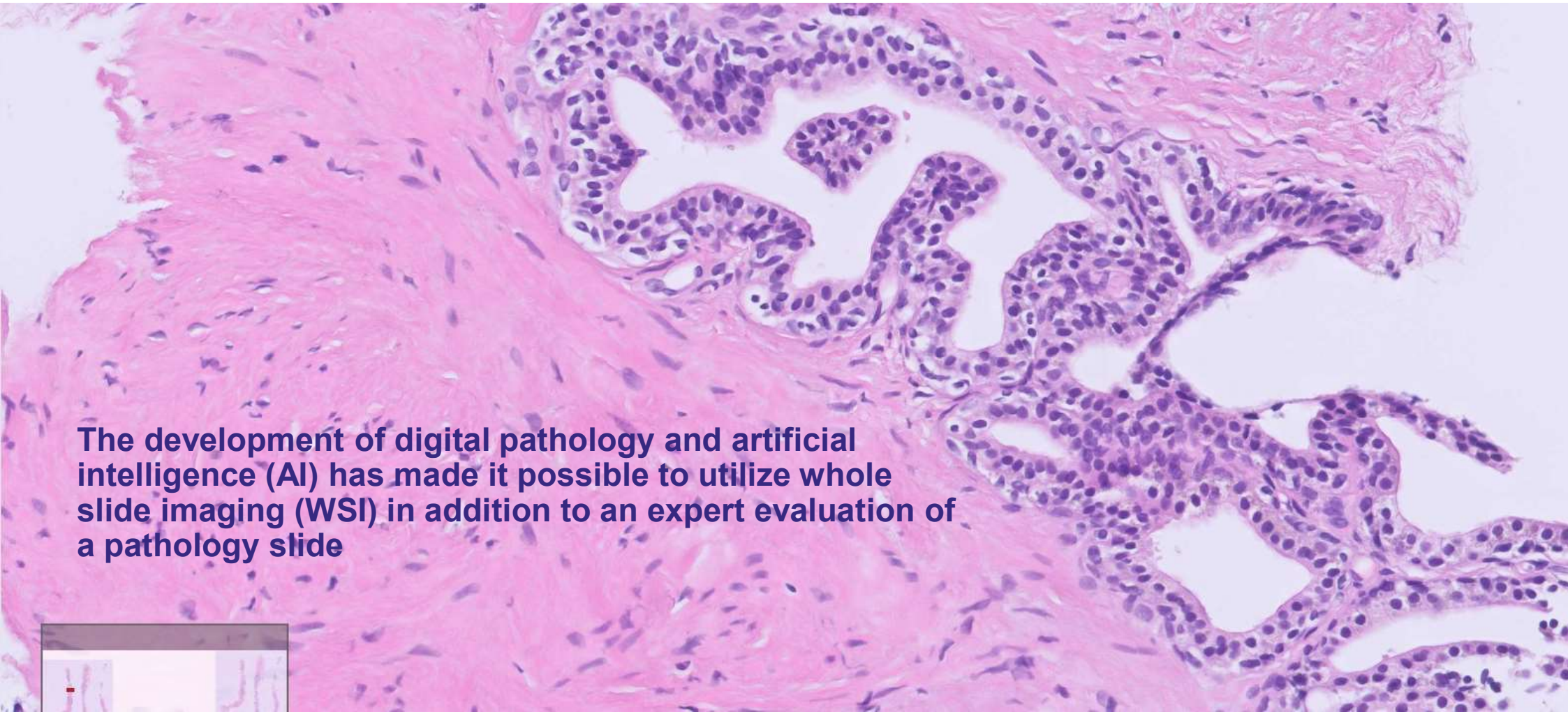

The development of digital pathology and artificial intelligence (AI) has made it possible to utilize whole slide imaging (WSI) in addition to an expert evaluation of a pathology slide

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Co-operation with Aiforia® Clinical AI Model

Aiforia has produced a cloud-based deep learning AI model for prostate cancer.

Neural networks have been trained to detect and classify tumor epithelium. Aiforia's clinical suite for prostate cancer is a CE-marked software product.

The model produces automated image analysis with a quantitative Gleason grade score and grade group from a whole slide view

In this poster we compare the visual interpretation of the participating pathologists, the expert interpretation and the rAIght value

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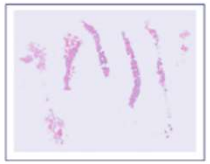
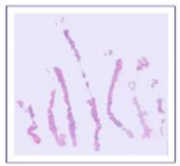
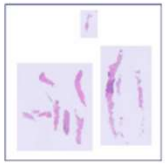
Participants were provided 7 scanned slides for analysis using virtual microscopy (cases 1-7). Case specific relevant clinical patient history was included.


Case 1


Case 2


Case 3


Case 4


Case 5


Case 6


Case 7

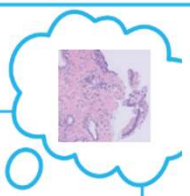
Altogether 148-150 pathologists from 15 countries participated in this EQA round.

The evaluation of the participant performance was based on a reference diagnosis by the scheme expert.

Pathologists were requested to grade the samples according to Gleason Grading:

- most common Gleason score
- most aggressive Gleason score
- Grade Group (GG).

In this study, only GG results were used.



Aiforia AI model produces a "rAIgth value" according to Gleason Grading for comparison.

Comparison of results by pathologists and "rAIght value" in the final report as additional information and an introduction to how AI could be used and further developed to ease the workload of pathologists in the future.

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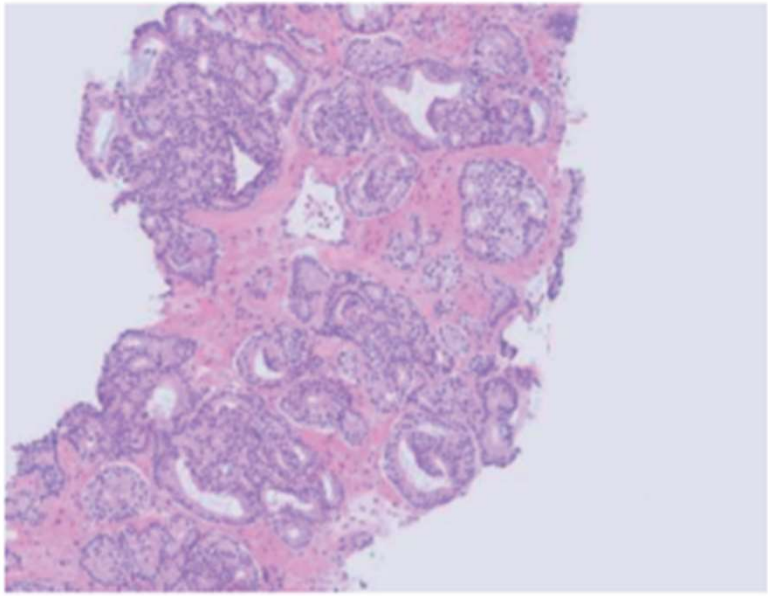
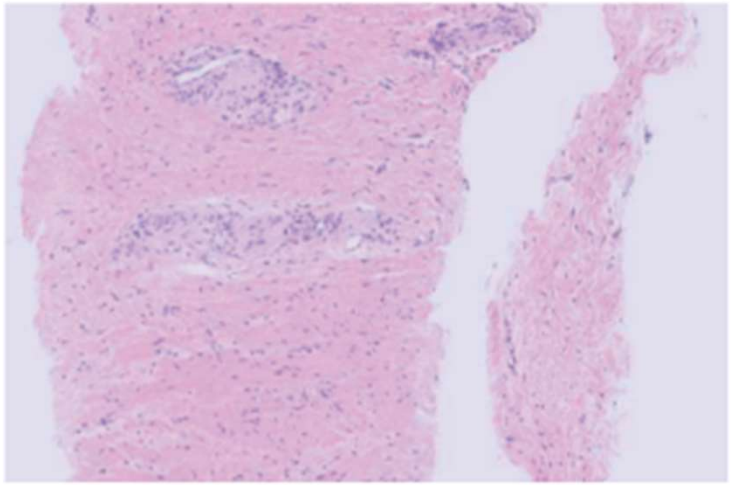
Cases	How many agreed with the rAIght value (%)	Risk group by participants	Risk group by AI	Results
1	47	Intermediate	Intermediate	The AI-produced results were in alignment with the results reported by the participants
2	82	Low/Very low	Low/Very low	The AI-produced results were in alignment with the results reported by the participants
3	28	Intermediate	Intermediate	the majority (49%) of the participants graded it to GG2 and whereas 28% graded it to GG3 which was the AI-produced grading.
4	19	Intermediate	High	Graded to GG3 by 55 % of the Participants, AI determined it to be GG5. 19 % agreed.
5	19	High/Very high	Intermediate	Most discrepancy among the participants with grading varying roughly even from GG2-5 and 19% graded it to GG2 which was the AI-grading.
6	90	No evidense of malignancy	No evidense of malignancy	The AI-produced results were in alignment with the results reported by the participants
7	32	Low/Very low	Intermediate	Graded as GG1 by 61% of the participants whereas AI-produced grading was GG2 agreeing with 32% of the participants.

Case	Risk group by participants	Risk Group by rAIght value
1	Intermediate	Intermediate
2	Low/Very low	Low/Very low
3	Intermediate	Intermediate
4	Intermediate	High
5	High/Very High	Intermediate
6	No evidence of malignancy	No evidence of malignancy
7	Low/Very low	Intermediate



Case 1 representing a sample where the risk group was graded Intermediate by most of the participants and the "rAIght value".



Case 6 represening a sample where no evidence of malignancy was found by the majority of participants and he "rAIght value".

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Conclusions

In this study, the grading of the samples differs somewhat between the participants and the AI model, however, there is also variability in Gleason scoring and GG between the participants indicating that there are challenges in making a diagnosis.

In all 7 cases, both the participants and the AI model graded the clinical outcome of the samples such that the patient could have received similar treatment.

Artificial intelligence tools can support the user's visual interpretation and assist the pathologist in making a diagnosis.

As AI models are able to analyze the WSIs quickly, they can help to reduce the workload of the medical professionals.

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Next rAIght value will be produced in 2025

Breast cancer pathology

AI tools are coming into use in pathology laboratories, several suppliers available such as Aiforia, HumanBytes, IndicaLabs, Proscia


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Thank you
Labquality Team Pia Eloranta and Heidi Berghäll
Aiforia Team Juuso Juhila and Anniina Wester
Scheme expert Marita Laurila from Fimlab Laboratories
LABQUALITY DAYS
6-7 February 2025
International Congress on Quality in Laboratory Medicine and Health Technology
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