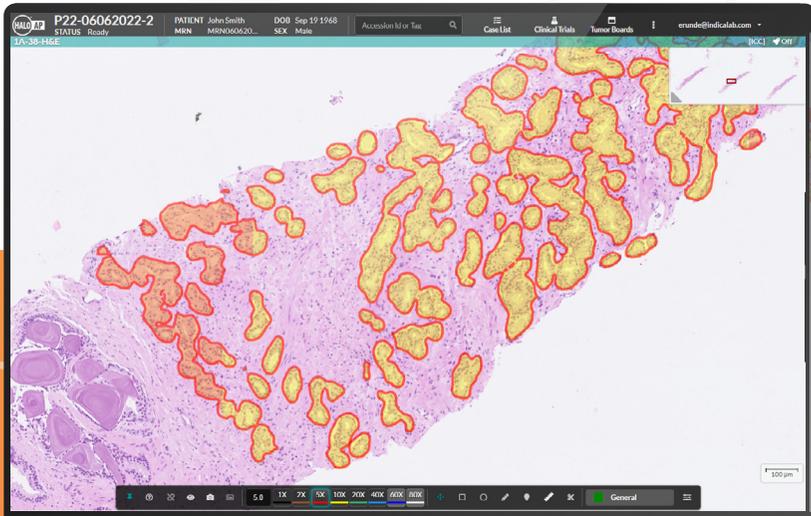


# HALO PROSTATE AI



A CE-IVD certified deep learning-based screening tool designed to assist pathologists in the identification and grading of prostate cancer in core needle biopsies.

powered by **indica labs**

The HALO Prostate AI algorithm automatically analyzes all appropriate case slides and notifies pathologists of cases with suspected findings directly in their native workflow.

## SEAMLESSLY INTEGRATED, AI-ENHANCED WORKFLOW

- + Exceptional clinical sensitivity and specificity
- + Deploy as a screening tool to support triage or use as a post-diagnostic QC-check
- + Speed up reporting times with image analysis masks
- + Share results with your LIS/LIMS system
- + Safeguard your patients' data by deploying in your own cloud or on-premise environment
- + Fully integrated into HALO AP®, the AI-powered, pathologist driven platform from Indica Labs for anatomic pathology workflows
- + Extend your image analysis capability with further integration of IHC image analysis from Indica Labs

### COMPREHENSIVE ANALYSIS RESULTS

- + Gleason Grading + Tumor Size
- + Cancer Detection and Localization



## **F A S T**

Reduce turnaround time and mitigate resource shortages to improve diagnostic speed and productivity.



## **I N T U I T I V E**

Access clear and easy-to-understand analysis results for review and incorporation into final diagnostic report.



## **A C C U R A T E**

HALO Prostate AI validation studies demonstrate negative predictive values 99% or higher.

# RETROSPECTIVE VALIDATION OF HALO PROSTATE AI AT TWO MAJOR EUROPEAN CLINICAL CENTERS

In a multi-site clinical validation study, HALO Prostate AI analyzed 4,973 whole slide images of prostate core biopsy tissue sections and high sensitivity, specificity, and negative predictive value for cancer detection were reported.

In a separate study, Gleason scores from HALO Prostate AI were compared against scores assigned by pathologists and high concordance was found in both cohorts.



UNIKLINIK  
KÖLN

Landeskrinikum   
WIENER NEUSTADT

# VALIDATION COHORTS

## + University Hospital Cologne, Germany

A prominent teaching hospital, host to Germany's largest academic pathology center

## + Landeskrankenhaus Wiener Neustadt, Austria

The teaching hospital of the Medical Universities of Vienna and Graz

## VALIDATION RESULTS: CANCER DETECTION

Cohort	Cores Analyzed	Scanner	Accuracy	Sensitivity	Specificity	Negative Predictive Value
1*	2,280	Hamamatsu	93.5%	97.5%	92.4%	99.2%
2**	2,022	Hamamatsu	93.7%	98.3%	92.0%	99.3%
3**	671	Leica	97.0%	97.1%	97.0%	99.0%

\*University Hospital Cologne, \*\*Landeskrankenhaus Wiener Neustadt

# GLEASON GRADING VALIDATION



9x Board-Certified GU Pathologists



1x Board-Certified General Surgical Pathologist

Cohort	Cores Analyzed	Average Quadratic Kappa	
		AI	Pathologist Range
1*	235	0.8	0.64 - 0.82
2**	165	0.7	0.65 - 0.75

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## Regulatory Compliance

Access HALO Prostate AI in HALO AP®, a case-centric digital pathology slide management, collaboration, and AI-powered quantitative analysis browser-based platform.

Seamlessly integrate with scanners and LIS/LIMS systems while providing built in compliance and certifications: CE-IVD, FDA 21 CFR Part 11, HIPAA, and GDPR.



HALO Prostate AI and HALO AP® are CE-marked for in-vitro diagnostic use in Europe and For Research Use Only in the USA.

info@indicalab.com | emea@indicalab.com | japan@indicalab.com | china@indicalab.com

USA +1 505 492-0979 | UK/EU +44 1789 765 721 | 日本 +81 (0)3 3525 4158 | 中国 +86 13761896143