



INIFY Prostate Screening

Power to the pathologist!



ContextVision

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Today's pathologists face an ever-increasing workload. By providing support tools that fully explore the advantages of new digital technology – while drawing on the very latest breakthroughs in AI and deep learning – we at ContextVision aim to empower you in your everyday workflow.

Innovation, technical know-how and professionalism have always been the cornerstones of ContextVision's enduring market leadership.

Our first product – **INIFY Prostate Screening** – is an AI-based and CE-marked decision support tool that suggests and outlines suspected cancer areas in digital H&E whole-slide images of prostate biopsy samples.

INIFY Prostate Screening provides pathologists with valuable decision support when identifying cancer in prostate biopsies. It makes room for **smarter**, more **accurate** and **faster** decisions, is proven to be **robust** across different labs and scanners, and is **adaptable** to individual workflows and user needs. INIFY Prostate Screening builds on the **resilient** foundation of innovation, technical know-how and professionalism that has been a trademark of ContextVision for the last 30 years.



Detailed outlined annotation performed by **INIFY Prostate Screening**

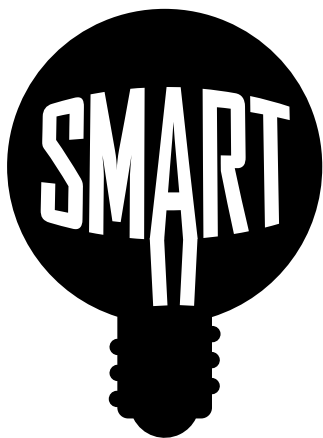


Testimonials from Ospedale Cannizzaro in Catania, Italy, where INIFY Prostate Screening is fully integrated in the digital workflow since 2018, show excellent results and user satisfaction.

“We have been involved in the development of INIFY Prostate Screening and can assure it fits laboratory needs. A prototype version of the product has been used daily for two years in our fully digital pathology workflow here in Catania, and I can testify that it is really easy to use, saves time and helps highlight suspicious areas for cancer.”

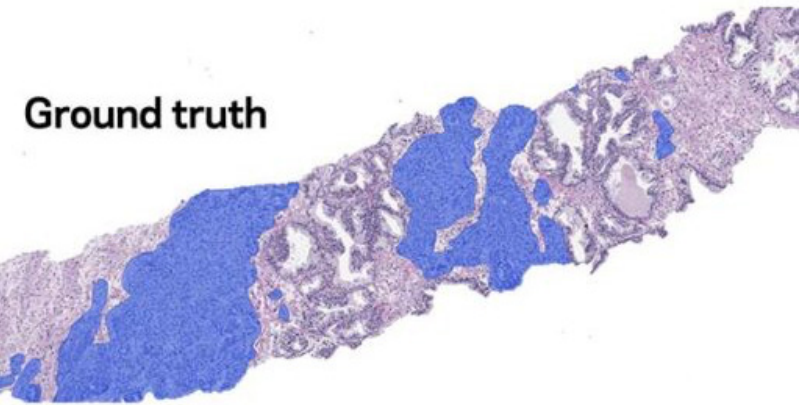
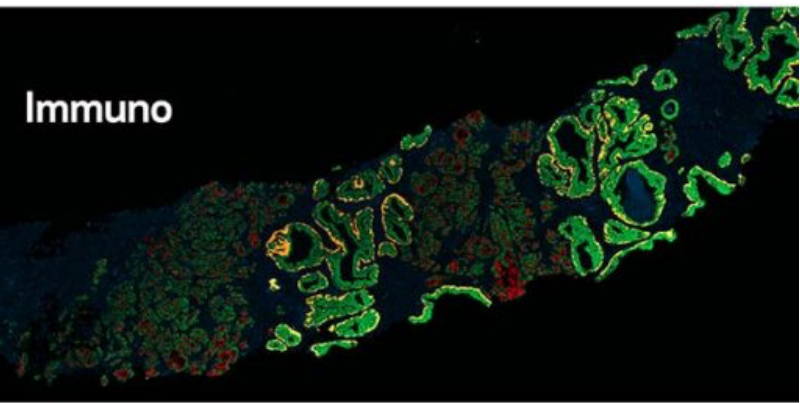
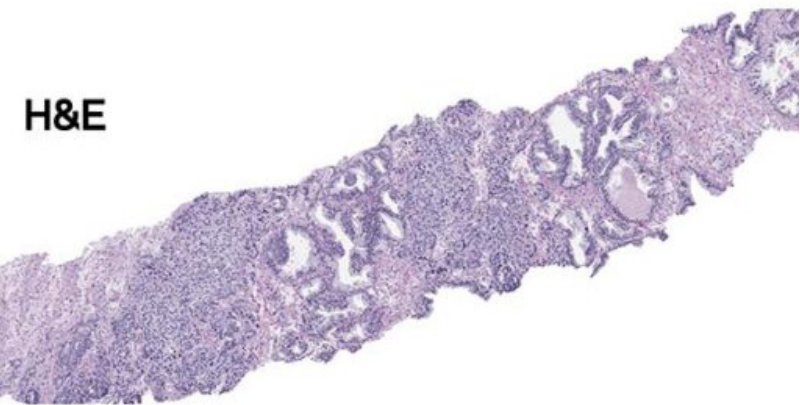
DR. FILIPPO FRAGGETTA
CHIEF PATHOLOGIST AT THE PATHOLOGY UNIT
OF CANNIZZARO HOSPITAL

Smart



An algorithm is only as smart as its underlying training data. The predicting AI-based engine in INIFY Prostate Screening is built on deep learning algorithms that are carefully trained and fine-tuned by Context-Vision’s skilled research team, resulting in proprietary high-performance algorithms with pixel-level accuracy¹.

Our unique and patented MasterAnnotation^{II} method has been used to create the training data on which the predicting engine is built. Using multiplex immunofluorescent staining, it identifies and highlights suspicious cancer areas and other structures with great accuracy, on a pixel level; these are then quality assured by certified pathologists. This minimizes the risk of subjectivity, which is otherwise a known challenge.

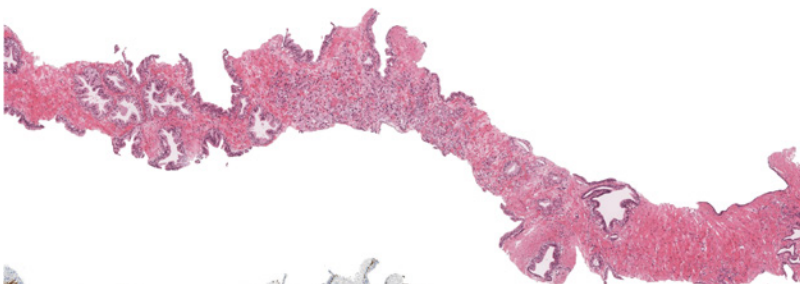


Accurate



For ContextVision it has been essential to take accuracy far beyond case or slide level. In INIFY Prostate Screening, pathologists are presented with impressive detail. Our algorithm predicts on sub-micron level, and suspicious cancer areas are identified and outlined with high accuracy – down to cell-cluster level – minimizing the risk of missing small cancer areas.

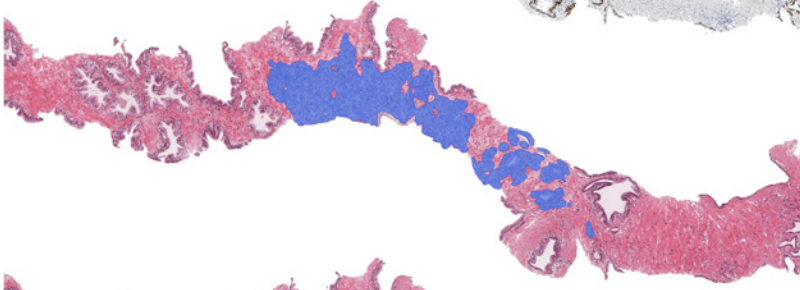
Whole slide images displaying our workflow for generation of test data:



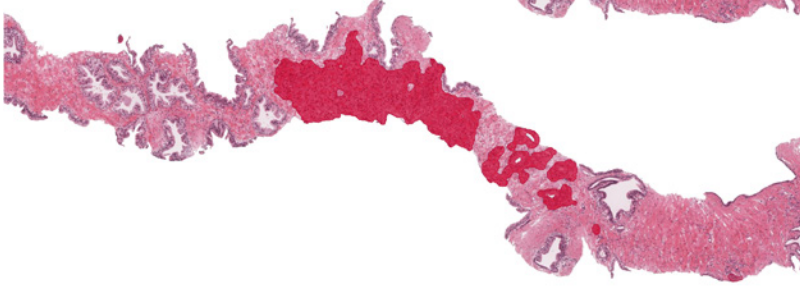
H&E original image



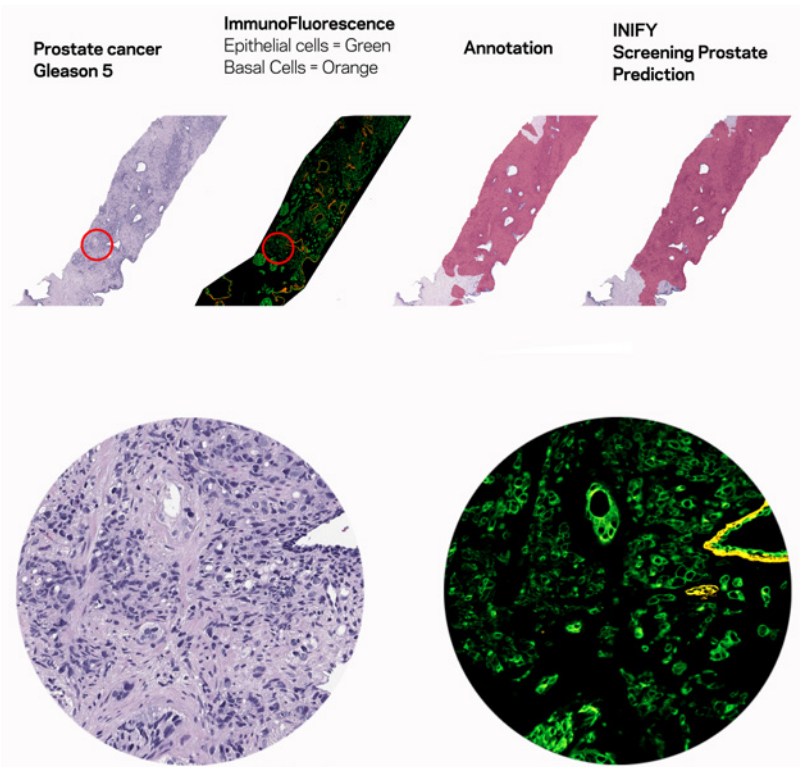
IHC on consecutive slide displaying dark brown basal cells = healthy glands, light brown AMACR = cancer area



Pathologist annotation based on the IHC, outlined in blue, used as ground truth



INIFY prediction, in red, shows a perfect match compared to the IHC-verified ground truth



In a pixel-level performance study, INIFY Prostate Screening was used to analyze whole-slide images with different Gleason scores, stained at five different labs and scanned with three different brands of scanners. When compared to ground truth, INIFY Prostate Screening predicted suspicious cancer areas with a very high pixel-level sensitivity on whole slide images from malignant biopsies^{III}. This means that even small clusters of suspicious cancer cells were identified.

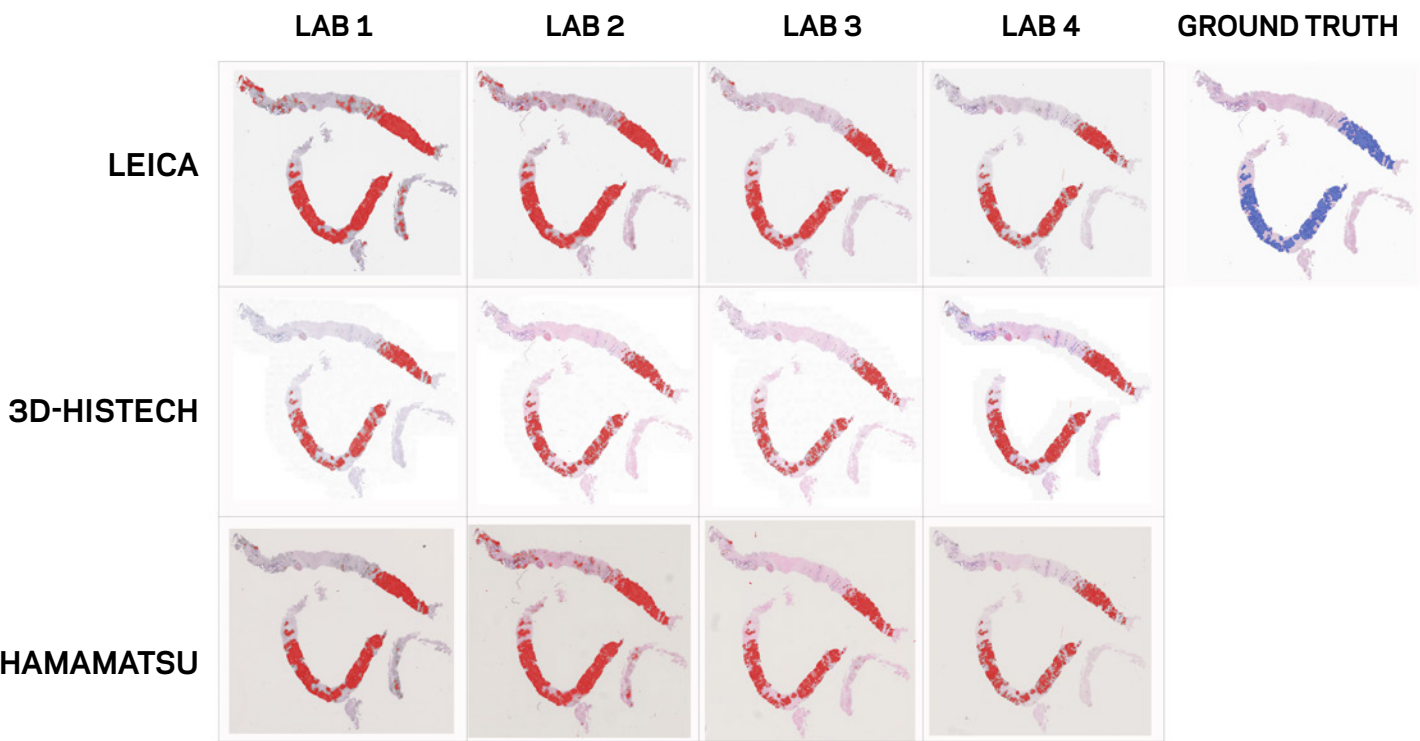
Figure shows an example of a cluster of Gleason 5 pattern, spread in the stroma of the prostate.

Robust



Different scanners have small variations in image resolutions, compression and white balancing when scanning whole slide images. These variations can sometime create problems when applying an AI algorithm. In our algorithm training, we have used data from patients all over the world, stained at numerous different labs and scanned with different scanners.

INIFY Prostate Screening’s algorithms stand up impressively to known differences between labs, enabling a plug-and-play approach. Tests have been performed on slides stained at different labs as well as scanned on different scanners, with impressive results, see below^{IV}.



Fast



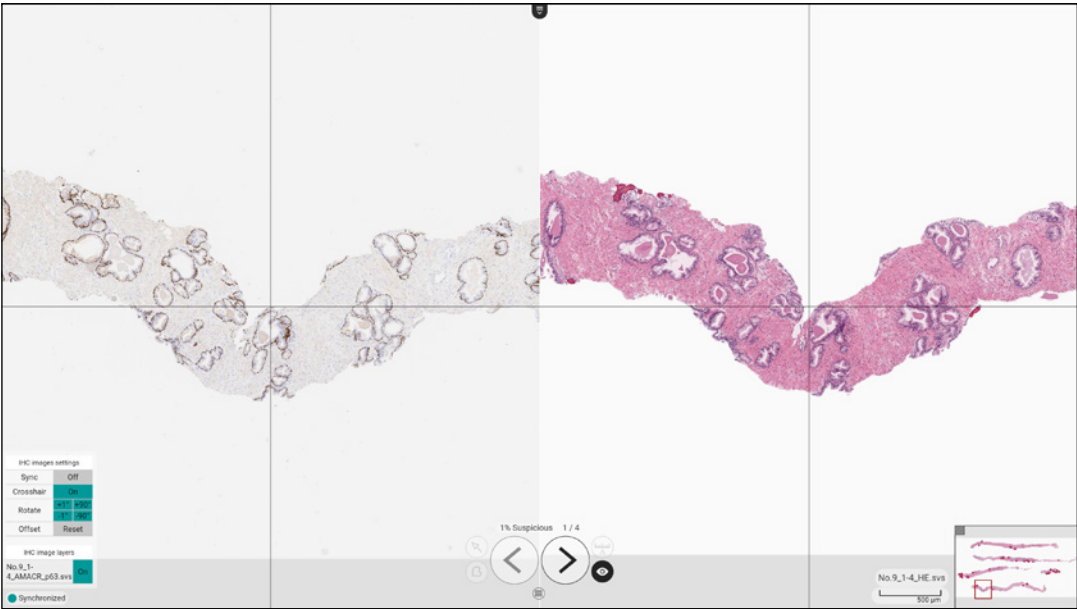
INIFY Prostate Screening is designed to help pathologists make the most of their valuable time.

The INIFY viewer combines powerful performance and speed with a user-friendly, intuitive interface and a broad range of useful tools and time-saving features^V.

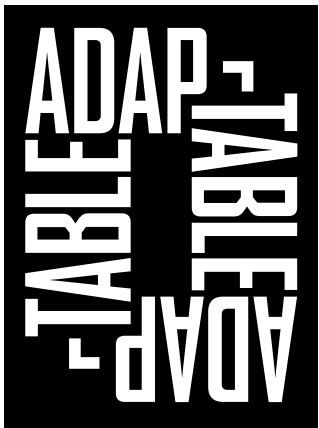
All slides are analyzed and ready to be examined before the case is opened. Those with the most suspicious areas are presented first, with an automatic calculation of the suspicious cancer area percentage in each slide.



Additional time-saving features include the side-by-side view of immunohistochemistry slides and H&E-stained slides – and the easy-to-use tool for measuring length of both total tissue and suspicious cancer.



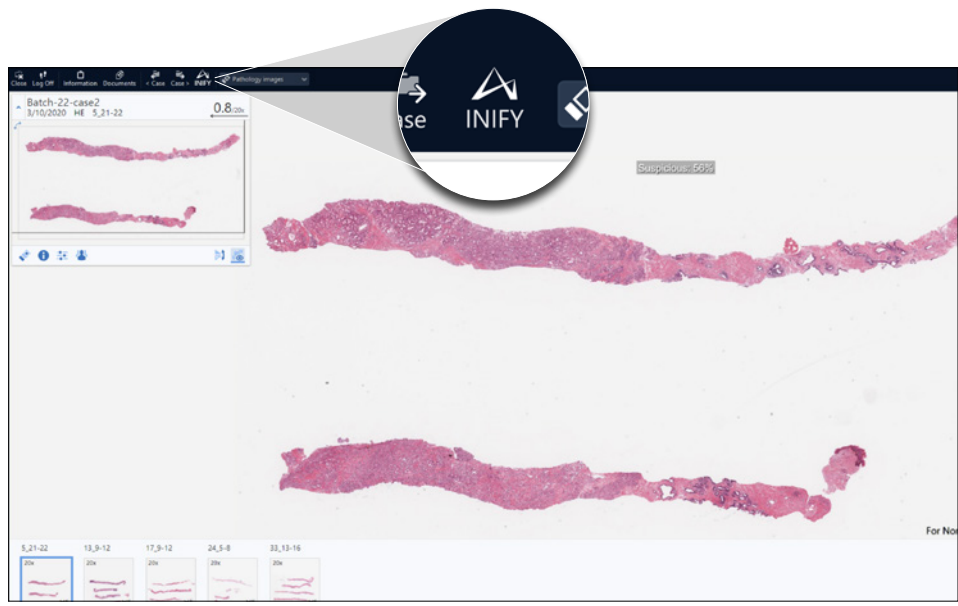
Adaptable



Thanks to the powerful, user-friendly INIFY viewer – offering a wide range of features – pathologists can review and adjust predictions generated by the algorithms.

To ensure a smooth fit into the clinical workflow, INIFY Prostate Screening is made to be adaptable to the clinic’s existing LIS/PACS system.

Below is an example of how it looks when integrated with Sectra’s digital pathology solution. Here, cases that have been processed by INIFY are displayed in the Sectra viewer, together with the percentage of predicted suspicious areas per slide. A click in the Sectra viewer launches the INIFY viewer with its full functionality and power, allowing predicted suspicious areas to be reviewed in detail and modified if necessary, giving full control to the pathologist.



INIFY Prostate Screening is also available for integration with Tesi PATHOX LIS.



Resilient



Innovation, technical know-how and professionalism – these are the cornerstones of ContextVision’s enduring market leadership for the last 30 years.

Today, ContextVision’s state-of-the-art solutions for medical imaging are used in over 300,000 systems worldwide.

We entered the digital pathology market from a very strong platform, as a successful and profitable business with healthy financials.

ContextVision has been a trusted long-term partner to leading manufacturers all over the world for many years.

You can rely on us to be here, now and in the future, to further our customer relationships and provide long-term support.

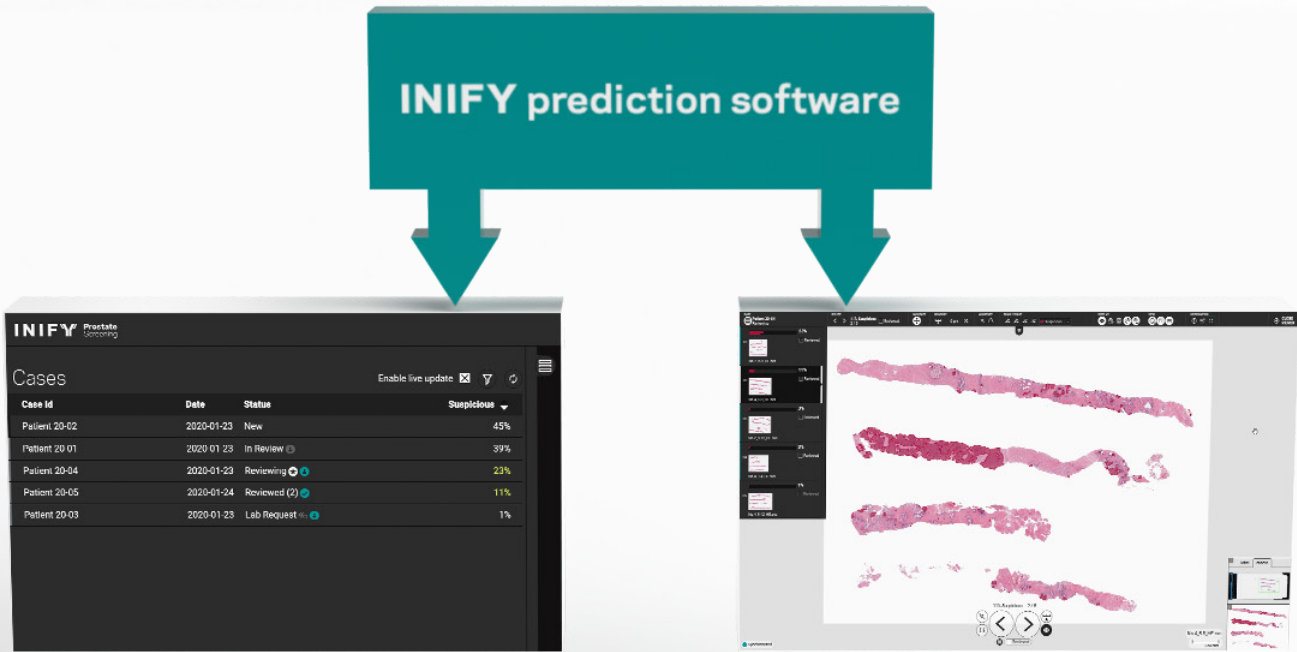


Installation & integration



INIFY Prostate Screening consists of three parts

- 1 THE PREDICTION SOFTWARE** (the engine)
Predicts and annotate suspicious areas.
- 2 INIFY CASE MANAGER**
Calculates suspicious areas and sorts the cases.
- 3 INIFY VIEWER**
Sorts the slides within a case. The viewer is designed for today's pathologists' needs with a range of useful features.



Intended use

- ContextVision's Decision Support Tool, INIFY Prostate Screening, is a Computer Aided Detection (CAdE) Software which analyses digital H&E whole slide images of prostate biopsy samples, then suggests and outlines areas that contain glandular tissue without basal cells as well as areas with intraductal cancer, i.e. "suspicious" areas, in each image.
- Glands without basal cells is typical for pathological tissue containing the most common prostate cancer type, acinar prostatic carcinoma.
- INIFY Prostate Screening can sort a working list to organize cases, and slides within each case, with the largest outlined areas on top, and measures % and outlined area against tissue area.
- The sorting function can be altered if the hospital has other preferences, e.g. date of examination.
- INIFY Prostate Screening is intended to present image-related information that is interpreted by trained medical professionals, primarily pathologists.
- INIFY Prostate Screening does not directly generate diagnosis. The pathologist takes the final decision on clinical status.



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INIFY Prostate Screening is CE-marked according to EU Invitro Diagnostic Device Directive 98/79/EEC.

INIFY® is a registered trademark of ContextVision AB

ⁱ Verification record, COV01-847168749-2311

ⁱⁱ Patent US 10,572,996

ⁱⁱⁱ Performance report, COV01-847168749-2541

^{iv} Verification record, COV01-847168749-2311

^v Usability engineering file, COV01-847168749-616

WWW.INIFY.COM

If you have any questions, comments or
suggestions, don't hesitate to get in touch!
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INIFY Prostate
Screening

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