NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Artificial Intelligence technologies to assist histopathology for prostate cancer diagnosis ID6684

Draft scope

Draft remit and evaluation objective

To appraise the clinical and cost effectiveness of artificial intelligence technologies to assist histopathology for the diagnosis of prostate cancer within its marketing authorisation for diagnosing prostate cancer.

Background

Prostate cancer is the most common type of cancer in men in the UK, and the second most common cause of cancer death in males in the UK (after lung cancer) (NICE NG131, 2021). Each year in the UK more than 64,000 men are diagnosed with prostate cancer and more than 12,000 will die from the disease (Prostate Cancer UK, 2026). It is estimated that 1 in 6 to 8 men in the UK will get prostate cancer at some point in their lives. Prostate cancer mainly affects men over 50, and risk increases with age (Prostate Cancer UK 2024) with the most common age of diagnosis at 65 to 69 years of age (NICE CKS, 2026) This number has been increasing over the last 10 years, which may be due to an ageing population and the increased uptake of Prostate Specific Antigen (PSA) testing (Cancer Research UK, 2019; National Collaborating Centre for Cancer, 2019). While adenocarcinoma accounts for 95% of prostate cancers, other rare and often more aggressive types exist. These include neuroendocrine tumours (such as small cell carcinoma) transitional cell (urothelial) carcinoma, squamous cell carcinoma and sarcomas, which arise from different cell types in the prostate (CRUK, 2025).

Clinical pathway

People with suspected prostate cancer are usually seen within the primary care setting first. While most people with prostate cancer are asymptomatic (NICE CKS, 2026), symptoms that may cause suspicion of prostate cancer include unexplained:

- lethargy
- lower back or bone pain
- erectile dysfunction
- visible haematuria

- anorexia/weight loss (NICE, CKS 2026)

Screening for prostate cancer is currently not recommended in the UK (UKNSC, 2026). Any asymptomatic man aged 50 and over can make an appointment with their GP to discuss testing for prostate cancer (DoH, 2016). Those groups considered higher risk for prostate cancer, including people with a family history of prostate cancer or people of Black African or Caribbean background are encouraged to discuss with their GP from the age of 45 (Prostate Cancer UK, 2025).

Before offering testing for prostate cancer appropriate information and advice should be offered to enable the person to make an informed choice about proceeding with testing. This includes information on the benefits and limitations of an initial blood test to measure their prostate-specific antigen, known as PSA testing. PSA testing provides information on whether prostate-specific antigen levels are elevated from normal age-related thresholds but do not give an indication of the cause. Given the high prevalence of prostate cancer in the over 80s, the Academy of Medical Royal Colleges has published best practice guidance which states that in men over 80 without signs of metastatic disease, the benefit of PSA testing is uncertain and should only be performed after an appropriate shared decision-making process (Academy of Medical Royal Colleges, 2024). A digital rectal examination (DRE) may be considered and discussed to allow assessment of the prostate for signs of prostate cancer, including; a hard gland, sometimes with palpable nodules or benign enlargement (smooth, firm, enlarged gland). This is typically offered if PSA levels are not raised.

If PSA levels are above the age-specific reference range or DRE is abnormal, NICE recommend a referral is made using a suspected cancer pathway (NICE CKS, 2026). NICEs Guidelines on prostate cancer recommends that people with suspected clinically localised prostate cancer who are able to have radical treatment, should be offered multiparametric MRI (mpMRI) as the first line investigation. This approach aims to improve the detection accuracy of clinically significant cancer and reduce the need for biopsy in those with non-suspicious mpMRIs *(*NHSE, Rapid diagnostic pathway, 2022). Results of the mpMRI should be reported using a 5-point Likert scale. The decision of whether to proceed with a prostate biopsy considers this MRI Likert score alongside PSA density and additional risk factors (such as age, family history and ethnicity) (GIRFT Urology, 2024). An mpMRI influenced prostate biopsy should be offered to people whose Likert score is 3 or more. Those with score of 1 or 2 should discuss the risks and benefits of a prostate biopsy as part of a shared decision making (NICE NG131, 2021).

There is more than one type of prostate biopsy, transrectal ultrasound-guided biopsy (TRUS) and transperineal ultrasound-guided biopsy (NICE NG131, 2021). GIRFT recommend that local anaesthetic transperineal (LATP) biopsy in an outpatient setting should be the standard approach (GIRFT, 2024). This is due to the reduced risk of infection in the transperineal biopsy. This approach involves sampling 6 to 8 sites from the prostate using a transperineal route under local anaesthetic (NICE

NG131, 2021). If available, lesions located on mpMRI should be targeted, with a maximum of 4 cores (GIRFT, 2024). Alternatively, a template biopsy can be carried out under a general anaesthetic which involves taking transperineal core biopsies using a grid system involving systematically sampling across 2 or 3 core sites meaning over 50 core biopsies are taken. Tissue cores are immediately placed in a preservative (formalin) to “fix” the cellular structure before being transported to the histopathology laboratory.

Histological pathway

Samples are logged and prepared for processing in paraffin wax blocks. A microtome is used to slice them into ultra-thin sections which are mounted onto glass slides and stained, typically with Haematoxylin and Eosin (H & E), to make cellular structures visible under a microscope. Prostate cores are particularly thin with a tendency to curve and/or fragment so additional care must be taken when preparing these tissues (RCPath, 2024). These stained histopathology whole slides, referred to as whole slide images (WSIs) are examined microscopically by a consultant histopathologist to look for architectural and cytological abnormalities. If cancer is found the pathologist assigns a Gleason Score to indicate how aggressive the cells in each gland or cluster appear. With 1 representing well-differentiated, benign-appearing tissue, and GP 5 indicating poorly differentiated, highly aggressive carcinoma. An International Society of Urological Pathology (ISUP) Grade group classification system is also used to provide more differentiation in intermediate risk categories to support clinical decision making.

The Royal College of Pathologists have clear published datasets for histopathological reporting on individualised cancers to standardise reporting methods (RCPath, 2024). For prostate cancer, core items to be reported on include but are not limited to:

- Clinical data (PSA, MRI findings, number and site of prostatic biopsies and type of biopsy)
- Macroscopic pathology data (number of cores or fragments and location)
- Microscopic pathology data (histological type of prostate cancer, number of positive cores per side, longest length of tumour, presence of invasive cribriform, presence of perineural invasion, presence of extra prostatic extension, Gleason score, Grade group, percentage pattern and representative percentage for molecular studies.)

If the diagnosis is unclear following initial review the pathology lab may request additional immunocytochemistry (ICC/IHC) testing. This specialised laboratory technique uses antibodies to identify specific proteins within tissue samples highlighting specific prostate cancer markers.

The reporting times vary significantly depending upon tissue type, case complexity additional testing and referrals for second opinion or on to specialist centres which can increase workload, costs, and lead to diagnostic delays.

The Royal College of Pathologists (RCPath, 2024) standards specify that diagnostic cytology and histopathology cases should be reported, confirmed, and authorised within 7 to 10 calendar days of the procedure (with expectations that 80% of cases are completed within 7 days and 90% within 10 days). NHS England's best practice timed pathways recommend that men referred with suspected prostate cancer receive the mpMRI and, where indicated, a biopsy within 9 days of GP referral, with pathology results reported within a further 5 days, creating a 14 day turnaround from referral to biopsy result, as reinforced in GIRFT Urology guidance (2024). More broadly, NHS England's Faster Diagnosis Standard was introduced to ensure that patients are informed whether they have cancer or cancer is excluded within 28 days of an urgent referral This standard currently requires providers to meet a 75% threshold, rising to 80% by March 2026 (FDS, 2022).

Treatment

According to NICE Guidelines (NG131), treatment decisions should consider tumour characteristics including type, size, grade, and stage as well as PSA level, Gleason score or Grade Group, and imaging findings to determine the individual's risk category and guide shared decision-making. A multidisciplinary team typically reviews each case to ensure that treatment plans reflect both clinical needs, disease severity and individual circumstances including comorbidities and preferences. Options may include active surveillance, radical prostatectomy, or radiotherapy for localised disease, and hormone therapy or chemotherapy for more advanced cancer.

Early diagnosis substantially improves outcomes. Nearly all individuals diagnosed with prostate cancer at the earliest stage survive at least five years, whereas survival drops to around 49% when the disease is diagnosed at the latest stage (NICE CKS, 2025).

Unmet need

Prostate cancer, the second most common cancer overall, is the leading diagnosis among men (Prostate Cancer UK, 2025). To expedite cancer diagnoses and improve patient experience, NHS England (NHSE) established the Faster Diagnosis Framework and Standards. However, pathology departments in the country vary in their set up, including differences in subspecialisation for different conditions and digital adoption in laboratories both of which may contribute to variability in review procedures, review times and the quality of reporting. Additionally the demand for pathology services is growing rapidly, both in volume and complexity, while trained pathologist workforce is shrinking (RCPath, 2025) putting pressure on service delivery and subsequent patient safety. A Royal College of Pathologists 2025 workforce census found that 47% of pathologists are aged 50 and over and that 60% of consultant pathologists in the UK are typically working beyond their contracted

hours each week. Most pathologists do not believe current staffing levels are adequate to ensure long-term stability of pathology services and to meet growing demand.

In response to workforce shortages, the Royal College of Pathologists 2025 to 2028 workforce strategy aims to transform current models of working for pathology. This includes developing best practice recommendations on automation, digital and AI to improve the efficacy and efficiency of workflows. The Royal College of Pathologists position statement on the use of digital pathology and AI supports that there is an increasing body of research and interest in use of AI for assisting pathologists in diagnosis, and potential to transform working models which could improve healthcare. Key benefits highlighted in this statement include the potential for AI to introduce efficiencies into pathology services by freeing highly trained pathologists from more routine and repetitive work and improve accuracy or consistency in pathology diagnosis. A GIRFT 2025 summary of diagnostics findings and recommendations supported innovation in AI for pathology, and this aligns with the broader NHS long term plan commitment to introducing AI to increase efficient NHS services, including those committed to faster diagnosis of disease. Standardised reporting using AI may also reduce variability linked to local workforce constraints and support more equitable diagnostic quality across regions.

The technologies

Technologies that use artificial intelligence (AI) for histopathology analyse digitised images of tissue samples, called whole slide images (WSI). These technologies propose to automate a range of tasks that are usually done by one or more consultant histopathologists. Technologies typically provide diagnostic overlays, measurements and prompts for histopathologist reviews to improve accuracy and speed up review times.

Uses of the technologies vary driven by differences in technology features and across different pathology laboratory set ups but typically include the detection and quantification of prostate cancer, including grading (according to Gleason grade), measurement and identification of clinical features, highlighting suspicious areas to assist in prioritising and reviewing the workload, measuring the tumour length and proportion of disease per core and detecting perineural invasion if present. In some cases, prompting or ordering additional immunohistochemistry (IHC) testing may be beneficial. The technologies may offer accurate, efficient and timely results to assist in diagnosing prostate cancer and support achieving the Faster Diagnosis Standard 28-day target more consistently. Use of the technologies could also reduce inter-observer variability, improve reporting quality standards and consistency across centres, facilitating equitable access across the country.

All technologies identified to be in scope for this assessment are presented in Table 1. Technologies included in the scope analyse digitised whole slide images from prostate needle core biopsies that have been stained with H&E. Technologies included in scope should, in line with RCP datasets (2024), as a minimum;

- detect prostate cancer
- grade the prostate cancer detected, according to Gleason grading
- measure tumour length and proportion of tumour per core
- have appropriate regulatory approval or be in the process of obtaining this and be available to the NHS or be in the process of this.

Place of the technologies in the pathway

Technologies should be used in a digital pathology workflow for formalin-fixed paraffin-embedded (FFPE) human prostate core needle biopsy specimens which have been stained with Haematoxylin and Eosin (H&E). Once the slide is ready it is loaded into a digital pathology scanner which uses high-quality optical microscopes to capture the tissue into a whole slide image (WSI) ready for analysis.

The AI technologies in scope offer the analysis of the digitised WSI for the detection of prostate cancer.

Centres may use these AI technologies in different ways depending on analysis type and individual laboratory practices (for example, as triage, first or second read). The assessment will consider these alternatives if and where appropriate.

Some AI technologies may also be used for analysis on resected or excised tissues from the prostate or lymph nodes to understand more about the size, type, stage and grade of cancer to inform management. Costs and effects of technologies in these use cases will not be assessed as part of the scope of this assessment.

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Table 1. Technologies proposed to be in scope

Technology and Company name	Indication for use	Detection	Grading and measurements	Additional features (including PNI)	Infrastructure	Regulation	NHS use
Aiforia Clinical Suite for Prostate cancer Aiforia	Indicated for digitalised WSIs of prostate tissue from needle core biopsies of men aged over 18 with suspected prostate cancer	Yes Aiforia Prostate Cancer Biopsy module automatically detects prostate cancer	Yes Aiforia Prostate Cancer Biopsy assists in grading using Gleason grading score. Measures lengths of tumour and tissue biopsy to support reporting of disease extent per core.	Yes Aiforia Prostate cancer PNI (perineural invasion) detects perineural invasion from foci of cancer Aiforia Prostate cancer G4 cribriform detects Gleason grade 4 cribriform patterns Aiforia Clinical suite viewer is software interface used to view the AI analysed images	Cloud based software as a service platform. Integrates with existing digital pathology systems	All CE-IVD Class C Aiforia Clinical Suite is MHRA registered and Aiforia Prostate Cancer Biopsy MHRA registration in development	Yes
AIRAProstate AIRA Matrix Private Limited	Indicated for digitalised WSIs of prostate tissue from needle core biopsies of men aged over 40 with suspected prostate cancer	Yes AIRA prostate first categorises prostate tissue as either benign or suspicious for cancer.	Yes For tissues identified as suspicious for cancer, the software provides the Gleason grade grouping identified using colour coded overlays.	Yes Detection and quantification of cribriform pattern in grade 4 foci Detection of perineural invasion The system presents the analysis as an overlay during the review process.	Digital software application offering both cloud and on premises solutions that integrate with existing digital pathology systems.	CE-IVD marked	Yes

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Technology and Company name	Indication for use	Detection	Grading and measurements	Additional features (including PNI)	Infrastructure	Regulation	NHS use
			Core length and tumour length measurements	Automated report creation			
Cells- IA Cells IA technologies Laboratories ROVI	Indicated for digitalised WSIs of prostate tissue from needle core biopsies of men aged over 18 with suspected prostate cancer	Yes Automated identification of areas of malignant tumour in prostate tissue samples to provide a preliminary diagnosis	Yes Approximate tumour grading	Unknown	Cloud based digital pathology platform that integrates with existing digital pathology systems	CE marking not available	Unknown
DeepDx Prostate Deep Bio	Indicated for digitalised WSIs of prostate tissue from needle core biopsies of men aged over 18 with suspected prostate cancer	Yes Detects and localises areas of interest	Yes Using coloured overlays based on Gleason patterns. The proportions of Gleason patterns out of the total tumour area and tumour to tissue ratios are automatically quantified to assist in scoring and	Yes Deep Bio detects and reports on perineural invasion Identifies cribriform patterns and intraductal carcinoma Measurements can be recalculated in real time as	Digital software application offering both cloud and on premises solutions that integrate with existing digital pathology systems	CE- IVD marked	Unknown

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Technology and Company name	Indication for use	Detection	Grading and measurements	Additional features (including PNI)	Infrastructure	Regulation	NHS use
			automatically measures tissue and tumour lengths.	user annotations are made. This can work alongside Deep Dx Viewer to provide multiple image control functions and management features for Deep Dx			
HALO Prostate AI Indica Labs	Indicated for digitalised WSIs of prostate tissue from needle core biopsies of men aged over 18 with suspected prostate cancer	Yes Provides cancer detection and localisation	Yes Completes Gleason grading and measurement of tumour size	Yes Detects and reports on the presence of perineural invasion and intraductal carcinoma	Digital software application offering both cloud and on premises solutions that integrate with existing digital pathology systems	CE -IVD marked	Yes
Ibex Prostate (formerly known as Galen Prostate) Ibex Medical Analytics	Indicated for digitalised WSIs of prostate tissue from needle core biopsies of men aged over 18 with suspected prostate cancer	Yes Detects and highlights suspicious areas of cancer detection on a slide	Yes The software grades cancer, according to Gleason scores Automatically calculates tissue and tumour length	Yes Detects presence of perineural invasion Detects cribriform patterns Can automatically pre order immunohistochemistry (IHC) tests for suspicious or difficult areas	Digital software application offering predominantly cloud as well as on premises solutions that integrate with existing digital pathology systems	CE -IVD marked	Yes

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Technology and Company name	Indication for use	Detection	Grading and measurements	Additional features (including PNI)	Infrastructure	Regulation	NHS use
OptraScan Prostate cancer biomarker analysis algorithm OptraSCAN Inc	Indicated for digitalised WSIs of prostate tissue from needle core biopsies of men aged over 18 with suspected prostate cancer	Yes Prostate Cancer Biomarker Analysis Algorithm, automates the evaluation of key biomarkers automatically identifying and flagging cancerous tissue	Yes Completes Gleason Grading Measure total length of biopsy core and percentage or length within the core	Yes The system presents the analysis as an overlay during the review process	Cloud based digital pathology service. Integrates with digital pathology systems	CE -IVDR marked	Unknown
Paige Prostate Suite Tempus (formerly known as Paige.AI)	Indicated for digitalised WSIs of prostate tissue from needle core biopsies of men aged over 18 with suspected prostate cancer	Yes Paige prostate detect which identifies and flags areas of interest that are suspicious for adenocarcinoma	Yes Paige prostate grade and quantification evaluates any foci of cancer detected to produce primary and secondary Gleason grade prediction, as well as a percentage and linear measurement of tumour burden.	Yes Paige prostate perineural invasion identifies the presence or absence of perineural invasion (PNI) in the images and uses a slide overlay to indicate predicted locations of the focus of cancer more likely to harbour PNI. Detection and reporting on cribriform patterns	Software based AI system which can be deployed either as a cloud-based platform or directly within a hospitals IT infrastructure	CE IVDR marked	Yes

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Technology and Company name	Indication for use	Detection	Grading and measurements	Additional features (including PNI)	Infrastructure	Regulation	NHS use
Qai Prostate Grade iher2 qUANT QRITIVE	Indicated for digitalised WSIs of prostate tissue from needle core biopsies of men aged over 18 with suspected prostate cancer	Yes Provides automated analysis within Pantheon digital pathology platform by identifying prostate cancer and classifying into benign and malignant areas	Yes Completes Gleason grading, ISUP grade, digitally calculated metrics and annotations on the WSI. Quantitative summaries of tumour size and percentage for each tissue.	Yes Provides automated report creation	Digital software application offering both cloud and on premises solutions that integrate with existing digital pathology systems.	Pantheon has CE mark. Class C IVD certification Not currently UKCA or CE marked	Unknown
Virasight tumour detection Virasoft	Indicated for digitalised WSIs of prostate tissue from needle core biopsies of men aged over 18 with suspected prostate cancer	Yes Virasight tumour detection module detects and provides heatmaps for visualising tumoral region	Yes Provides Gleason grading	Yes An Image viewer and image management system that offers	Cloud based digital pathology platform that integrates with existing digital pathology	Virasight has CE certification Prostate analysis module does not currently have regulation available	Unknown

Decision Problem

Interventions	AI technologies that assist histopathology review of whole slide images of core needle prostate biopsies for the initial diagnosis of prostate cancer. These are proposed to include: • Aiforia • AIRA matrix • Cells IA technologies laboratories • Deep Bio • Ibex Medical Analytics • Indica Labs • OptraSCAN Inc • Qritive • Tempus • Virasoft
Population	Adults with suspected prostate cancer who have undergone a core needle biopsy
Subgroups	Subgroups may be considered where data permits. No subgroups have been identified currently.
Comparators	Histopathologist review of whole slide images of prostate biopsies without the use of AI
Outcomes	The outcome measures to be considered include: **Intermediate outcomes:** • diagnostic accuracy (sensitivity, specificity, positive predictive value, negative predictive value) • case review time / turnaround time (slide review time, time to report, time to diagnosis) • concordance between AI and pathologist review • need for / use of additional tests (repeat biopsies / immunochemistry) • need for second pathologist read • proportion of slides not appropriate for AI review • adverse events or technical failure • impact on clinical decision making

	Clinical outcomes
	• stage of cancer at detection
	• overall survival
	• time to initiate treatment
	• progression free survival
	• adverse effects of treatment, including under or overtreatment
	
	Patient reported outcomes
	• health-related quality of life
	• service user and carer acceptability, views and experience
	Other
	• User ease of use or user acceptability
	
	Resource use
	• cost of technology, considering
	  ○ procurement
	  ○ implementation
	  ○ ongoing running costs
	  ○ IT set up
	  ○ costs of updates
	  ○ costs of data storage
	  ○ cost of training
	• costs of second reads
	• costs of additional tests (for e.g. IHCs)
	• cost of managing cancer, related to missed cancers or overdiagnosis.

Setting	NHS histopathology services that use digital pathology for prostate cancer diagnosis
Economic analysis	The NICE reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year. The reference case stipulates that the time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared.

	Costs will be considered from an NHS and Personal Social Services perspective. The availability of any commercial arrangements for the intervention, comparator and subsequent treatment technologies will be taken into account. The availability of any managed access arrangement for the intervention will be taken into account.
Other considerations	Guidance will only be issued in accordance with the CE marking. **Digital infrastructure:** Infrastructure supporting digital pathology is a pre-requisite of the use of AI for histopathology. Current digital pathology usage is not widespread in the NHS and IT compatibility issues and capacity issues may be a potential barrier to the implementation of AI software in some NHS Trusts. Data security is essential when deploying AI technologies for histopathology as they require access to patient data. There may be challenges around confidentiality, integrity, and governance. Consideration should be made to issues such as data ownership and custodianship, risks of re-identification of depersonalised data, unauthorised access and system vulnerabilities, and consent and data sharing. Key to these concerns is the location of data storage and processing (e.g., on-site or cloud-based), and the security measures employed. Clinical pathways for these technologies vary across the devolved nations. **Technology features**: The validity of AI algorithms depends on the data on which it is trained. When available, information will be reported on the representativeness of training and validation datasets for the UK prostate cancer population. Caution is raised that cases with significant artefacts may reduce performance and interpretation of technologies. The quality of reporting for AI assisted biopsies should be audited as part of laboratory practice (RCPath, 2024). **Training:** Workforce training is required for the safe and optimal use of AI technologies in this pathway. Most technologies report to provide training delivery packages online alongside user guides, support services which should be used in conjunction with local competency sign offs. **Sustainability:** AI assisted workflows claim to increase efficiency and reduce waste associated with physical lab processes. **AI acceptability:** Work by the Academy of Medical Sciences suggests that patients strongly support the use of AI in healthcare provided it improves quality and frees up time. The

	Royal College of Pathologists advise there is a need for more engagement with patients about the potential use of AI in their healthcare in order to maintain broad public support (RCPath, 2024). From a user perspective, optimal integration with existing workflows is key to successful deployment of AI in laboratories **Technology effects:** These technologies may offer additional benefits for people with low-risk prostate cancer. The proposed improved accuracy and consistency in reporting across labs may further inform decision making for clinical management of low-risk prostate cancer, potentially reducing overtreatment. Evidence for this group will be considered if available.
Equality considerations	People with cancer are protected under the Equality Act 2010 from the point of diagnosis. **Sex**: prostate cancer is the most commonly diagnosed cancer in men in England (Prostate Cancer UK 2025) **Age:** Prostate cancer mainly affects men over 50, and risk increases with age (Prostate Cancer UK 2024) with the most common age of diagnosis at 65 to 69 years of age (NICE CKS, 2026) **Gender**: Some people may not identify as men but have a prostate. This includes trans women, non-binary people who were registered male at birth and some intersex people. Prostate cancer can affect trans women, as the prostate is usually conserved after gender-affirming surgery. The risk of developing prostate cancer may be lower in people who take testosterone blockers or antiandrogens, or who have had an orchidectomy, as these treatments reduce testosterone levels (Prostate Cancer UK 2025). **Ethnicity**: People from a Black African or Caribbean background are at higher risk of developing prostate cancer. People from a Black African or Caribbean background are also more likely to be diagnosed with prostate cancer at a younger age (Prostate Cancer UK 2024). **Deprivation**: cancer death rates are nearly 60% higher for those living in the most deprived areas of the UK compared with the least deprived. Those living in areas of higher deprivation are 29 % more likely to be diagnosed with late stage prostate cancer (PCUK, 2026). **Geography**: There is significant variation in histopathology laboratories across the countries due to differences in setup, workload, workforce capacity and the rate of digital adoption. People in Scotland and the North / Midlands of England are

	more likely to be diagnosed at a later stage compared to London (PCUK, 2023). **Disabilities**: There is some evidence to suggest people with learning disabilities are more likely to be diagnosed with late-stage diagnosis. **Inclusion health groups**: many inclusion health groups are at higher risk of late-stage diagnosis of prostate cancer because they may have challenges in registering and attending a GP. More detail is available in the: Equality impact assessment (2021) as part of the NICE Guideline on Prostate cancer: diagnosis and management (NG131) Disability, age, race, sex, and gender reassignment are protected characteristics under the Equality Act (2010) **The technological intervention:** If AI technologies can improve review turnaround times and the quality of diagnostic accuracy reporting as they propose this could help reduce variability across pathology labs and local workforce constraints, improving equity of access to timely diagnosis and management. The validity of AI algorithms depends on the data on which it is trained. When available, information will be reported on the representativeness of training and validation datasets for adults who have had core needle prostate cancer. If groups are not represented, the assessment will consider the potential to exacerbate or introduce health inequalities.
Related NICE recommendations	**Related Health Tech Guidance:** Transperineal biopsy for diagnosing prostate cancer (2023) NICE HealthTech guidance 680 MRI fusion biopsy systems for diagnosing prostate cancer (2023) NICE HealthTech guidance 678 Paige Prostate for prostate cancer (2021) Medtech innovation briefing, MIB280. **Related Health Tech Guidance in development:** Artificial intelligence technologies to help detect prostate cancer on multiparametric (mp) MRI. NICE Guidance. Publication date to be confirmed. **Related technology appraisals:**

	There are 24 published technology appraisals on prostate cancer and 4 in development. **Related NICE guidelines:** NICE's guideline on prostate cancer: diagnosis and management (2021) NICE guideline NG131 **Related NICE guidelines in development:** Prostate cancer: diagnosis and management (update) NICE guideline. Publication TBC Suspected Cancer: recognition and referral (update). NICE guideline. Publication expected March 2026 **Related quality standards:** Suspected cancer (2016) Quality standard 124 Last updated: 05 December 2017 Prostate Cancer (2015) Quality standard 12 Last updated: 30 December 2021

Questions for consultation

1. Is the proposed title for this assessment appropriate
2. Is the proposed population described appropriately? Please comment with respect to:
    a. Is it appropriate to include people who have previously been treated for prostate cancer?
    b. Are there any subgroups for whom you would expect the clinical and cost effectiveness of the intervention to differ?
3. Is the description of the intervention appropriate
    a. Are there any additional considerations you think should be captured in the minimum requirements of the technologies to be included in scope?
    b. Are there any technologies which you do not feel appropriate to be in scope and why?
    c. Are there any technologies you feel should be added to the scope and why?
4. Is the usage of AI technologies in the prostate cancer pathway appropriately described?
5. Is the comparator appropriate?
6. Are all the outcomes suitable for inclusion in the assessment? Are there any additional outcomes we should capture?
7. What level of evidence do you understand there is for the use of these technologies for initial diagnosis of prostate cancer?
8. Which of these technologies do you understand are currently in use in the NHS?
9. Do you consider that the use of AI technologies to support histopathology for prostate cancer can result in any potential substantial health-related benefits that are unlikely to be included in the QALY calculation?
   Please identify the nature of the data which you understand to be available to enable the committee to take account of these benefits.
10. Are there any other stakeholders NICE should be aware of for this topic?
11. NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that the proposed remit and scope may need changing in order to meet these aims. In particular, please tell us if, in addition to the equality considerations in the decision problem table, the proposed remit and scope:
    - could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which AI technologies to assist histopathology for prostate cancer diagnosis could be used
    - could lead to recommendations that have a different impact on people protected by the equality legislation than on the wider population, e.g. by making it more difficult in practice for a specific group to access the technology.
    - could have any adverse impact on people with a particular disability or disabilities
    - if there are any additional equality considerations, we should be aware of?
    - please tell us what evidence should be obtained to enable the committee to identify and consider such impacts.

Glossary of terms

Biopsy
A sample of tissue from the body to assist in diagnosis of disease

Core biopsy reporting categories
Biopsies are rated B1 (normal) to B5 (malignant) in the Royal College of Pathologists reporting proformas. B2 indicates a benign lesion, B3 indicates an atypia with uncertain malignant potential and B4 indicates a lesion suspicious for malignancy.

Histological grade
Histological grade is reported when carcinoma is identified. DCIS is graded as high, intermediate or low based on how abnormal the cells look. Invasive carcinoma is graded using the Elston and Ellis method, also known as Nottingham Grading. A score between 3 and 9 is reached by considering the percentage of the tumour that forms tubular gland (scored 1 to 3), how much the cancer cell nuclei differ from normal cells (scored 1 to 3), and mitotic count which is the frequency of dividing cells in the most active part of the tumour (scored 1 to 3). Total scores of 3 to 5 points indicates grade 1 tumour (low grade), 6 to 7 points indicates grade 2 tumour (intermediate grade) and 8 or 9 is grade 3 (high grade).

Histopathology
The microscopic examination of biological tissues to study, diagnose, and understand the manifestations of disease.

Immunohistochemistry (IHC) testing
This specialised laboratory technique uses antibodies to identify specific proteins within tissue samples highlighting specific prostate cancer markers.

Invasive cribriform
The presence of a cribriform growth is a specific morphological pattern seen in microscopic review of core biopsies. It is recognised as a specific high risk growth pattern. All Cribriform patterns, regardless of size, are classified as Gleason pattern 4. Prescence of invasive cribriform or intraductal carcinoma is a core data requirement for microscopic review of prostate core biopsies.

Perineural invasion
Is a pathological finding where cancer cells are seen surrounding and tracking along or invading the nerve sheath within the prostate gland. It is reported when malignant cells surround at least one third of a nerve’s circumference