Prolaris®

Prostate Cancer Prognostic Test

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Sample requirements for Prolaris

Formalin-fixed, paraffinembedded sections of localized prostatic adenocarcinoma biopsies

1. SELECTION OF TISSUE SAMPLE

a. The core with the greatest length of continuous tumor with highest gleason score should be chosen.

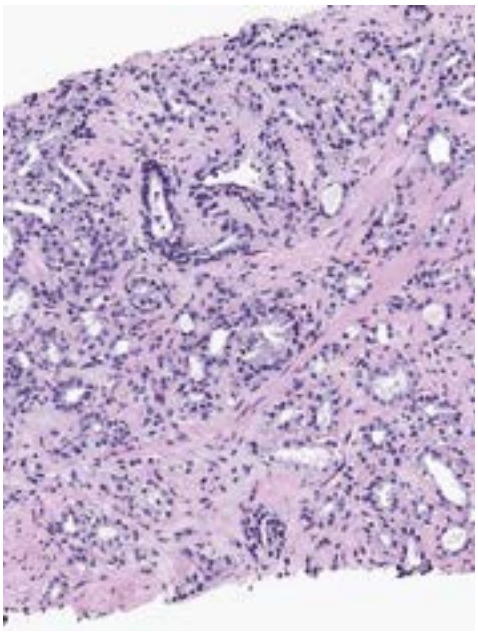
b. The core must contain at least 0.5 mm length of core with ≥60% tumor tissue. The proportion of the tumor should be determined by a pathologist based on Haematoxylin and Eosin (H&E) stained tissue sections according to local standard operating procedures.

c. Tissue blocks are prefered over slides.

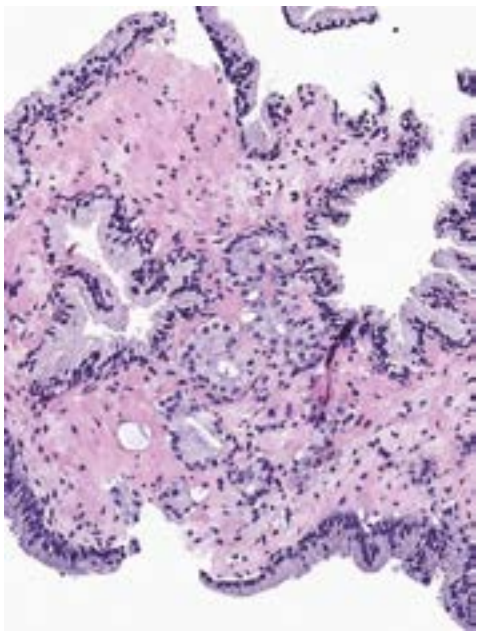
d. If the block cannot be sent, one H&E cut at 4-5 microns, plus five consecutive unstained 5-micron sections are needed.

Examples of acceptable and non-acceptable tumor densities

Acceptable example:
0.5 mm with **≥60%** tumor tissue



Unacceptable example:
0.5 mm with **<60%** tumor tissue



2. REQUIRED CLINICAL INFORMATION OF THE PATIENT

- Age of the patient in years at the time of biopsy
- Patient's PSA value (ng/mg) before the biopsy
- Number of positive cores. An ultrasound- or MRI- or DRE-targeted lesion that is biopsied more than once and demonstrates cancer (regardless of percentage core involvement or number of cores involved) counts as a single positive core.
- Number of taken cores
- Primary Gleason grade
- Secondary Gleason grade
- Clinical T stage

3. LIMITATIONS

This test is not validated for the analysis of transurethral resection of the prostate samples (TURP) or biopsies from patients with PSA levels >100 ng/ml or with prostate cancer stage pT3b or pT4. Performance characteristics of the Prolaris test have only been established for men with localized, newly diagnosed prostate cancer who are naive from any local (surgery, radiation therapy) or systemic treatment (ADT, chemotherapy) for their disease.

4. FIXATION

Tissue collection, fixation, paraffin embedding and storage of the tumor biopsy(ies) must be performed according to ISO 20166-1:2018 with the following restrictions:

1. 10% neutral buffered formalin must be used as a fixative (equals 4% formaldehyde).
2. The duration from biopsy removal until beginning of fixation should not exceed 1 hour.
3. The fixation time should not exceed 24 hours.

The FFPE tissue sections that are used for Prolaris testing should be cut directly after the section used for H&E staining.

Reference:

Cuzick J, et al. Prognostic value of a cell cycle progression signature for prostate cancer death in a conservatively managed needle biopsy cohort. BJC 2012;106(6):1095-109

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CE IVD This in vitro diagnostic medical device is CE-marked.
For use by healthcare professionals only.

Please refer to the instructions for use.

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