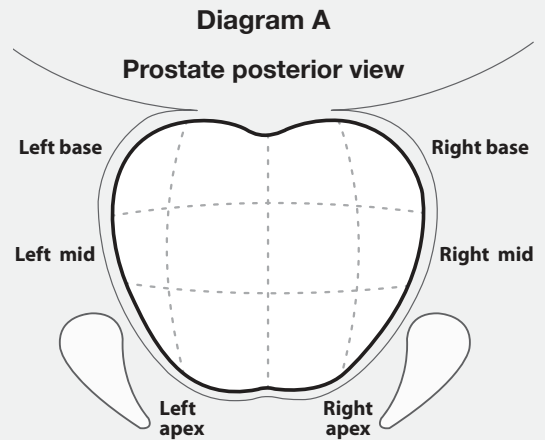


Specimen Requirements

ConfirmMDx is a tissue test that helps physicians determine if a patient is at higher or lower risk for prostate cancer and which men can safely avoid repeat biopsy.

Slide Requirements:

Specimen Requirements for Slides:	All biopsy cores collected must be submitted*
Specimen Location Requirements: (see Diagram A)	One left prostate biopsy core and one right prostate biopsy core, plus at least six additional cores from any prostate location
Labeling Instructions:	Label each slide with your specimen identification number
Specimen Volume:	Prefer 40µm (minimum 20µm) of FFPE tissue from each biopsy core. One slide with four sections at 10µm each preferred. Multiple sections can be placed on one slide.
Slide Requirements:	Unstained biopsy core sections on unbaked, positively charged slides.
Storage Requirements:	Maintain slides at room temperature
Special Instructions:	Please include pathology report with mapping location of each prostate biopsy core and completed test requisition form



Block Requirements:

Specimen Requirements for FFPE Tissue Blocks:	All biopsy cores collected must be submitted*
Specimen Location Requirements: (see Diagram A)	One left prostate biopsy core and one right prostate biopsy core, plus at least six additional cores from any prostate location
Labeling Instructions:	Label each block with your specimen identification number
Storage Requirements:	Maintain blocks at room temperature
Special Instructions:	Please include pathology report with mapping location of each prostate biopsy core and completed test requisition form

Turnaround Time:

7 to 10 business days from receipt of specimens

Patient Eligibility:

A patient with a cancer-negative prostate biopsy including benign, HGPIN, atypical, atypia, and/or ASAP histopathology findings are eligible. Specimens must have been collected within 30 months from date of receipt at MDxHealth.

Cause for Specimen Rejection:

- Patient with a previous diagnosis for prostate cancer
- Insufficient amount of tissue
- Specimens fixed in Bouin's Solution
- Broken and/or stained slides
- Specimens older than 30 months
- Seminal vesicle biopsy cores

*Accepted fixatives include 10% neutral buffered formalin, AZF (acetic acid zinc formaldehyde), Prefer, and BBC BiopsyFix. Contact Client Services for a complete list of accepted fixatives.

†Maximum of 24 months for Medicare

Questions?
Contact Client Services

866.259.5644
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