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:** 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:** 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