SELECTING THE MOST REPRESENTATIVE PROSTATE TUMOR BLOCK

A. Choose the tumor-containing biopsy block with the greatest amount of highest grade carcinoma (longest linear measurement).
B. Neutral buffered formalin is the preferred fixative. Alternative fixatives are not recommended.
C. For prostate submissions, radical prostatectomy specimens are not accepted.
D. Only the minimum required tissue will be accessed and the block will be returned upon report generation.
E. While both blocks and unstained slides are accepted, blocks are preferred.

SPECIMEN PREPARATION INSTRUCTIONS

BLOCKS

1. Follow your laboratory’s standard practice guidelines for the processing of fixed paraffin embedded (FPE) tissue.
2. Apply one S barcode label, obtained from the inner top lid of the Oncotype DX® Specimen Kit, to each block (See photo, left).
3. Place the tumor block in the small plastic bag and seal the bag.
4. Do not submit an H&E slide when you are submitting tumor blocks. Genomic Health® will prepare an H&E slide on site.
5. Secure the specimen in the foam insert inside the Oncotype DX Specimen Kit.
6. Include a frozen ice pack (provided with the Oncotype DX Specimen Kit) on top of the foam insert and seal the secondary containment bag.

NOTE: The ice pack included with the kit should be frozen overnight for best use.

UNSTAINED SLIDES

NOTE: Follow your laboratory’s standard practice guidelines for the processing of FPE tissue.
To reduce cross-contamination:
• Use a new section of the microtome blade (or a new blade) between cases.
• Clean the water bath between cases (e.g., using a clean Kimwipe).
• Wear clean gloves during the cutting and mounting process.

1. Prepare eight 5 μm serial unstained slides with one 5 μm serial section on each slide.
   A. Use charged glass slides (standard 1” x 3” or 25mm x 75mm size).
   B. Ensure the sections on each slide are oriented similarly.
   C. Allow the slides to air dry. Do not place the slides on a hot plate.
   D. Do not place cover slips on the unstained slides.
2. Label the slides as follows:
   A. Apply one S barcode label, obtained from the inner top lid of the Oncotype DX Specimen Kit, to each slide (See photo, right).
   B. Hand number the serially sectioned unstained slides (1-8) to indicate the order in which they were cut. Unnumbered slides will be rejected.
3. Once the slides are dry, insert them into slide carriers and place one S barcode label from the Oncotype DX Specimen Kit on the outside of each slide carrier. Place the slide carriers in the Oncotype DX Specimen Kit for shipping.
4. Seal the large secondary containment bag and close the box using the tab.

MATERIALS AND EQUIPMENT:

1. Oncotype DX Requisition Form
2. Copy of Pathology Report
3. Oncotype DX Specimen Kit containing the patient specimen
4. FedEx® US Airbill pre-printed with Genomic Health shipping information
5. FedEx® Clinical Pak, Large — a plastic over wrap used to ship the specimen to Genomic Health
6. FedEx® adhesive airbill pouch for the FedEx® Airbill

REQUISITION FORM AND SUPPORTING MATERIALS:

1. Complete one Oncotype DX Specimen Kit and Requisition Form for each patient and each primary tumor (if applicable). Extra S barcode labels should be left in the Oncotype DX Specimen Kit and should NOT be used for another patient or primary tumor.
2. Before shipping, make a copy of the Oncotype DX Requisition Form and retain it for your records.
3. Place the Oncotype DX Requisition Form, a copy of the pathology report, and relevant patient insurance materials in the Oncotype DX Specimen Kit, between the box and the large secondary containment bag.