

# BREAST & COLON PATHOLOGY GUIDELINES

## SELECTING THE MOST REPRESENTATIVE BREAST OR COLON TUMOUR BLOCK

- Choose the one block with the greatest amount/area of the highest grade carcinoma, morphologically consistent with the submitting diagnosis.
- Formalin is the preferred fixative. Tissues processed in other fixatives should not be submitted.
- Hemorrhage, necrosis, and adipose tissue do not need to be minimized. They contain little RNA and thus do not significantly impact this assay.
- For breast carcinoma submissions, microinvasive carcinomas (one or more foci < 0.1 cm) are not acceptable samples.
- For DCIS submissions, total mastectomy specimens are not appropriate samples.

## SPECIMEN PREPARATION INSTRUCTIONS

### BLOCKS



- Follow your laboratory's standard practice guidelines for the processing of fixed paraffin embedded (FPE) tissue.
- Apply one S barcode label, obtained from the inner top lid of the Oncotype DX® Specimen Kit, to each block (see photo).
- Apply one S barcode label in the designated area on the requisition form to associate the specimen with the requisition form.
- Label the block with an additional patient-specific identifier (e.g., specimen accession number, patient medical record number, etc.). All specimens require two patient-specific identifiers for processing.
- Place the tumour block in the small plastic bag and seal the bag.
- Do not* submit an H&E slide when you are submitting tumour blocks. Genomic Health will prepare an H&E slide on site.
- Secure the specimen in the foam packaging inside the Oncotype DX Specimen Kit.
- Include the gel pack (provided in the Oncotype DX Specimen Kit), preferably frozen, on top of the foam packaging, and seal the secondary containment bag.

### UNSTAINED SLIDES

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.



- Prepare **fifteen** 5 µm serial unstained slides with one 5 µm serial section on each slide.
  - Use charged glass slides (standard 1" x 3" or 25 mm x 75 mm size).
  - Ensure the sections on each slide are oriented similarly.
  - Allow the slides to air dry. Do not place the slides on a hot plate.
  - Do not place cover slips on the unstained slides.
- Label the slides as follows:
  - Apply one S barcode label, obtained from the inner top lid of the Oncotype DX Specimen Kit, to each slide (see photo).
  - Apply one S barcode label in the designated area on the requisition form to associate the specimen with the requisition form.
  - Label the slides with an additional patient-specific identifier (e.g., specimen accession number, patient name, date of birth, hospital number, or order number). All specimens require two patient-specific identifiers for processing.
  - Hand-number the serially sectioned unstained slides (1-15) to indicate the order in which they were cut.
- Once the slides are dry, insert them into slide carriers. Place the slide carriers in the Oncotype DX Specimen Kit for shipping.
- Seal the large secondary containment bag.

## SHIPPING INSTRUCTIONS

- Before shipping, make a copy of the Oncotype DX Requisition Form and retain it for your records.
- Place the Oncotype DX Requisition Form, specimen, copy of pathology report and relevant documents inside the Oncotype DX Specimen Kit.
- Load Oncotype DX Specimen Kit in the FedEx® Large Clinical Pak.
- Place the completed FedEx International Air Waybill and 3 copies of the commercial invoice in the clear document pouch located on the FedEx Clinical Pak.
- Use only street addresses (no P.O. boxes) when completing the waybill.
- Seal the Clinical Pak by removing the plastic adhesive protector from the white strip and secure.
- All FedEx shipping charges are covered by Genomic Health.
- Contact Customer Service to order additional kits:  
**Europe, Middle East, Africa:** [EuropeanSupport@genomichealth.com](mailto:EuropeanSupport@genomichealth.com)  
**Asia Pacific, Latin America, Canada:** [International@genomichealth.com](mailto:International@genomichealth.com)

# PROSTATE PATHOLOGY GUIDELINES

## SELECTING THE MOST REPRESENTATIVE PROSTATE TUMOUR BLOCK

- Choose the tumour-containing biopsy block with the greatest amount of highest grade carcinoma (longest linear measurement).
- Formalin is the preferred fixative. Tissues processed in other fixatives should not be submitted.
- For prostate submissions, radical prostatectomy and transurethral resection of the prostate (TURP) specimens are not accepted.
- While both blocks and unstained slides are accepted, blocks are preferred.
- The block will be returned promptly upon report generation.

## SPECIMEN PREPARATION INSTRUCTIONS

### BLOCKS



- Follow your laboratory's standard practice guidelines for the processing of fixed paraffin embedded (FPE) tissue.
- Apply one S barcode label, obtained from the inner top lid of the Oncotype DX® Specimen Kit, to each block (see photo).
- Apply one S barcode label in the designated area on the requisition form to associate the specimen with the requisition form.
- Label the block with an additional patient-specific identifier (e.g., specimen accession number, patient medical record number, etc.). All specimens require two patient-specific identifiers for processing.
- Place the tumour block in the small plastic bag and seal the bag.
- Do not* submit an H&E slide when you are submitting tumour blocks. Genomic Health will prepare an H&E slide on site.
- Secure the specimen in the foam packaging inside the Oncotype DX Specimen Kit.
- Include the gel pack (provided in the Oncotype DX Specimen Kit), preferably frozen, on top of the foam packaging, and seal the secondary containment bag.

### UNSTAINED SLIDES

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.



**IMPORTANT: UNNUMBERED SLIDES WILL BE REJECTED**

- Prepare **eight** 5 µm serial unstained slides with one 5 µm serial section on each slide.
  - Use charged glass slides (standard 1" x 3" or 25 mm x 75 mm size).
  - Ensure the sections on each slide are oriented similarly.
  - Allow the slides to air dry. Do not place the slides on a hot plate.
  - Do not place cover slips on the unstained slides.
- Label the slides as follows:
  - Apply one S barcode label, obtained from the inner top lid of the Oncotype DX Specimen Kit, to each slide (see photo).
  - Apply one S barcode label in the designated area on the requisition form to associate the specimen with the requisition form.
  - Label the slides with an additional patient-specific identifier (e.g., specimen accession number, patient name, date of birth, hospital number, or order number). All specimens require two patient-specific identifiers for processing.
  - Hand-number the serially sectioned unstained slides (1-8) to indicate the order in which they were cut. Unnumbered slides will be rejected.
- Once the slides are dry, insert them into slide carriers. Place the slide carriers in the Oncotype DX Specimen Kit for shipping.
- Seal the large secondary containment bag.

## SHIPPING INSTRUCTIONS

- Before shipping, make a copy of the Oncotype DX Requisition Form and retain it for your records.
- Place the Oncotype DX Requisition Form, specimen, copy of pathology report and relevant documents inside the Oncotype DX Specimen Kit.
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