

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.
- Neutral buffered formalin is the preferred fixative. Alternative fixatives are not recommended.
- 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, left).
- Apply one S barcode label in the designated area on the requisition form to associate the specimen with the requisition form.
- 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 25mm x 75mm 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 the 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, right).
 - Apply one S barcode label in the designated area on the requisition form to associate the specimen with the requisition form.



- 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 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.
- Seal the large secondary containment bag and close the box using the tab.

SHIPPING INSTRUCTIONS

MATERIALS:

- Oncotype DX Requisition Form
- Copy of Pathology Report
- Commercial Invoice necessary for shipping to the US.
- Oncotype DX Specimen Collection and Transportation Kit (Specimen Kit)
- S-Barcode labels located in the inside top flap of the Specimen Collection and Transportation Kit Box to associate the specimen with the requisition form.
- FedEx[®] International Air Waybill pre-printed with Genomic Health shipping information.
- FedEx[®] Large Clinical Pak, to ship specimen to Genomic Health.
- FedEx[®] adhesive clear airbill pouch for the FedEx[®] International Air Waybill.

All materials are included in the Oncotype DX Specimen Kit. Contact Customer Service to order additional kits.

REQUISITION FORM AND SUPPORTING MATERIALS:

- Complete one Requisition Form for each patient.
- 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.
- Kits cannot be sent to P.O. Boxes.

All FedEx shipping charges are covered by Genomic Health.

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).
- Neutral buffered formalin is the preferred fixative. Alternative fixatives are not recommended.
- For prostate submissions, radical prostatectomy 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, left).
- Apply one S barcode label in the designated area on the requisition form to associate the specimen with the requisition form.
- 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 **eight** 5 µm serial unstained slides with one 5 µm serial section on each slide.
 - Use charged glass slides (standard 1" x 3" or 25mm x 75mm 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, right).
 - Apply one S barcode label in the designated area on the requisition form to associate the specimen with the requisition form.



IMPORTANT: UNNUMBERED SLIDES WILL BE REJECTED

- 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 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.
- Seal the large secondary containment bag and close the box using the tab.

SHIPPING INSTRUCTIONS

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