

BREAST & COLON PATHOLOGY GUIDELINES

SELECTING THE MOST REPRESENTATIVE BREAST OR COLON TUMOR 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).
- 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 tumor block in the small plastic bag and seal the bag.
- Do not* submit an H&E slide when you are submitting tumor blocks. Genomic Health will prepare an H&E slide on site.
- Secure the specimen in the foam insert inside the Oncotype DX Specimen Kit.
- Include a frozen ice pack (provided with the Oncotype DX Specimen Kit) on top of the foam insert and seal the secondary containment bag.

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

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).
 - 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 Order Form and Statement of Medical Necessity and retain it for your records.
- Place the Oncotype DX Requisition Form, a copy of the pathology report, and relevant patient insurance materials in the Oncotype DX Specimen Kit.
- Place the Oncotype DX Specimen Kit into the FedEx® Clinical Pak.
- Complete the FedEx US Airbill. The airbill is pre-printed with Genomic Health shipping information.
- Seal the Clinical Pak by removing the plastic adhesive protector from the white strip and secure.
- Place the package in the designated FedEx pickup location at your site.
- If your site does not have standard FedEx pickup, call 800-GO FEDEX (800-463-3339) to arrange for pick up.
- To order additional kits, email Customer Service at customerservice@genomichealth.com.

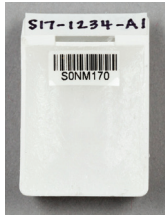
PROSTATE PATHOLOGY GUIDELINES

SELECTING THE MOST REPRESENTATIVE PROSTATE TUMOR BLOCK

- Choose the tumor-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).
- 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 tumor block in the small plastic bag and seal the bag.
- Do not* submit an H&E slide when you are submitting tumor blocks. Genomic Health will prepare an H&E slide on site.
- Secure the specimen in the foam insert inside the Oncotype DX Specimen Kit.
- Include a frozen ice pack (provided with the Oncotype DX Specimen Kit) on top of the foam insert and seal the secondary containment bag.

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

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 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).
 - 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 Order Form and Statement of Medical Necessity and retain it for your records.
- Place the Oncotype DX Requisition Form, a copy of the pathology report, and relevant patient insurance materials in the Oncotype DX Specimen Kit.
- Place the Oncotype DX Specimen Kit into the FedEx® Clinical Pak.
- Complete the FedEx US Airbill. The airbill is pre-printed with Genomic Health shipping information.
- Seal the Clinical Pak by removing the plastic adhesive protector from the white strip and secure.
- Place the package in the designated FedEx pickup location at your site.
- If your site does not have standard FedEx pickup, call 800-GO FEDEX (800-463-3339) to arrange for pick up.
- To order additional kits, email Customer Service at customerservice@genomichealth.com.