

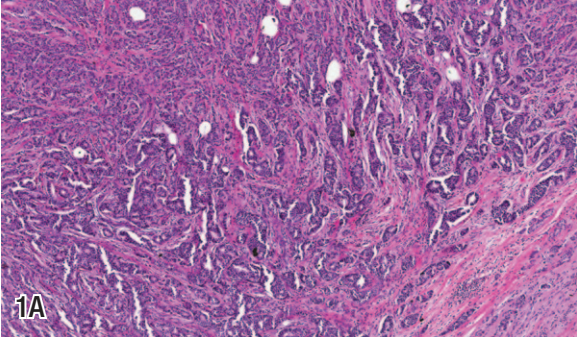
## RECOMMENDATIONS FOR SELECTING THE MOST REPRESENTATIVE TUMOR BLOCK

Select the paraffin-embedded tumor block with the greatest amount of carcinoma that is morphologically consistent with the submitting diagnosis.

- A. Choose the one block with the greatest amount/area of the highest grade carcinoma.
- B. Neutral buffered formalin is the preferred fixative. Alternative fixatives are not recommended.
- C. Hemorrhage, necrosis, and adipose tissue do not need to be minimized. They contain little RNA and thus do not significantly impact this assay.
- D. A pathologist at Genomic Health will review the H&E slide and, if necessary, perform manual microdissection consistent with clinical trial experience.
- E. For breast carcinoma submissions, microinvasive carcinomas (one or more foci < 0.1 cm) are not acceptable samples.
- F. For DCIS submissions, total mastectomy specimens are not appropriate samples.

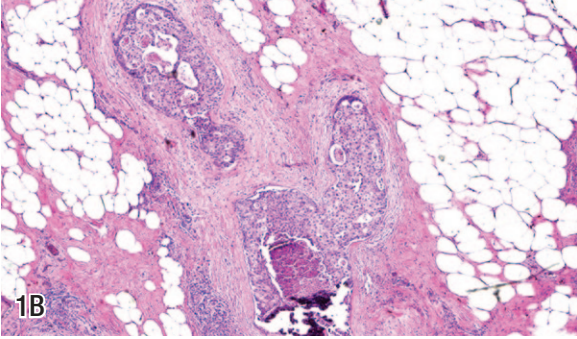
oncotype DX<sup>®</sup>  
Breast Cancer Assay

SATISFACTORY INVASIVE CARCINOMA



1A

SATISFACTORY DCIS



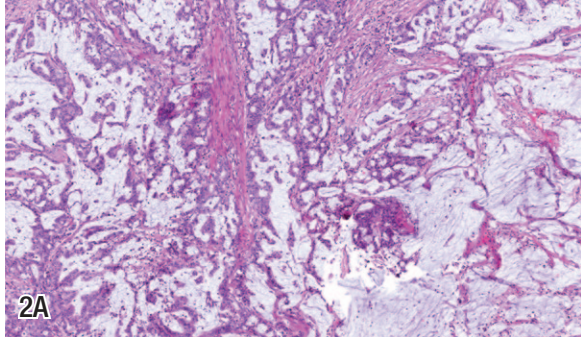
1B

**Figure 1A.** The block with the greatest area of invasive carcinoma is the preferred sample for the Oncotype DX Breast Cancer Assay for patients with invasive breast carcinoma.

**Figure 1B.** The block with the greatest area of DCIS is the preferred sample for the Oncotype DX Breast Cancer Assay for patients with DCIS.

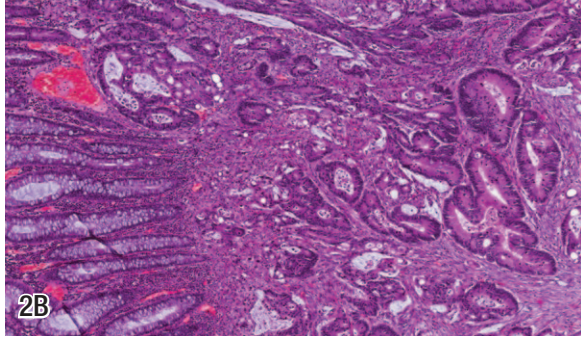
oncotype DX<sup>®</sup>  
Colon Cancer Assay

SATISFACTORY INVASIVE CARCINOMA



2A

SATISFACTORY INVASIVE CARCINOMA



2B

**Figure 2A.** The block with the greatest area of invasive colon carcinoma is the preferred sample for the Oncotype DX Colon Cancer Assay.

**Figure 2B.** The invasive carcinoma infiltrates around normal colonic epithelium requiring manual macrodissection by Genomic Health pathology for the Oncotype DX Colon Cancer Assay.

# SPECIMEN PREPARATION INSTRUCTIONS

## BLOCKS

To submit a tumor block:

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

## UNSTAINED SLIDES

To submit unstained slides:

**NOTES:** 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 fifteen 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 the 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 Figure 4)
  - B. Hand number the serially sectioned unstained slides (1-15) to indicate the order in which they were cut.
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.



Figure 3: Block

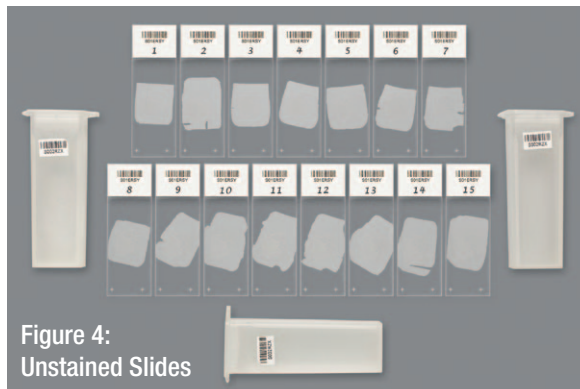


Figure 4:  
Unstained Slides

## DOMESTIC SHIPPING INSTRUCTIONS

### 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.

**REIMBURSEMENT:** Genomic Health is prepared to bill insurance plans directly on behalf of insured patients in the US whose physicians order the Oncotype DX Assay.

### SPECIMEN KIT AND SHIPMENT:

1. Place the Oncotype DX Specimen Kit into the FedEx® Clinical Pak.
2. Remove plastic adhesive protector from FedEx® airbill pouch and place on designated area on FedEx® Clinical Pak.
3. Complete the sender portion of the FedEx® Airbill, and insert into the FedEx® Airbill pouch. Remove the plastic adhesive protector to seal the Airbill pouch.
4. Seal the Clinical Pak by removing the plastic adhesive protector from the white strip and secure.
5. Place the package in the designated FedEx® pickup location at your site.
6. If your site does not have a standard FedEx® pickup please call 800-GO FEDEX (800-463-3339) to arrange for pick up.

**NOTE:** To order additional kits please e-mail Customer Service at [customerservice@genomichealth.com](mailto:customerservice@genomichealth.com) or call 866-ONCOTYPE (866-662-6897).

QUESTIONS? PLEASE CALL 866-ONCOTYPE (866-662-6897)

301 Penobscot Drive Redwood City, CA 94063 [www.oncotypedx.com](http://www.oncotypedx.com)

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