

ONCOTYPE MAP™ PAN-CANCER TISSUE SPECIMEN SUBMISSION GUIDELINES

SELECTING THE MOST REPRESENTATIVE >15% 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 required fixative. Tissues processed in other fixatives SHOULD NOT be submitted.

SPECIMEN PREPARATION INSTRUCTIONS

BLOCKS

1. Follow standard practice guidelines for the processing of formalin-fixed paraffin embedded (FFPE) tissue.
2. Label the block with an additional patient-specific identifier (e.g., specimen accession number, patient medical record number, etc.). All specimens require two (2) patient-specific identifiers for processing.
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. Exact Sciences will prepare an H&E slide on site.
5. Secure the specimen in the foam insert inside the Oncotype MAP Pan-Cancer Tissue Specimen Kit.
6. Include a frozen ice pack (provided within the Oncotype MAP Pan-Cancer Tissue Specimen Kit). The ice pack included with the kit should be frozen overnight for optimal use or a minimum of four (4) hours.



UNSTAINED SLIDES

1. Calculate the number of slides needed for NGS and IHC (see FFPE Sample Submission).
(e.g., specimen accession number, or order number). All specimens require two (2) patient-specific identifiers for processing.
2. Prepare appropriate number of 4 µm serial unstained slides with one (1) 4 µm serial section on each slide.
 - a. Use charged glass slides (standard 1" x 3" or 25 mm x 75 mm 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.
3. Label the slides as follows:
 - a. Label the slides with a patient-specific identifier

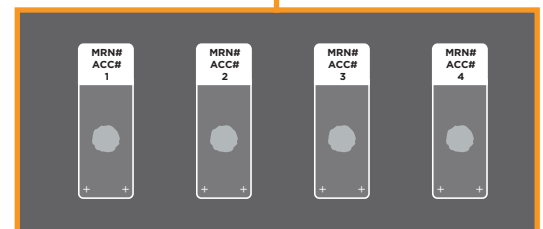
- b. Hand-number the serially sectioned unstained slides (1-4) to indicate the order in which they were cut.
4. Once the slides are fully dry, insert them into slide carriers. Place the slide carriers in the Oncotype MAP Pan-Cancer Tissue Specimen Kit for shipping.
 5. Seal the large secondary containment bag.

Follow your laboratory's standard practice guidelines for the processing of formalin-fixed paraffin embedded (FFPE) 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.

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*See Specimen Rejection Criteria and Testing Priority on reverse

UNSTAINED SLIDES

FFPE Sample Submission:

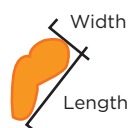
Preferred Method

- Verify tissue is as large as a grain of rice (3 mm²).
- Send whole block

 Actual Size

Alternate Method

- Measure tissue (length x width) in mm
Area = _____ X _____ = _____mm²
 - If <10 mm², send whole block
 - If ≥10 mm², send 4µm slides as below:
- | | | | | | | | | |
|-----|---|-----|---|-----|---|-------------|---|-----------------|
| 1 | + | 1 | + | 1 | + | _____ | = | _____ |
| H&E | | NRC | | NGS | | # of IHC(s) | | Slides Needed** |



**If HER2 Equivocal, five (5) additional slides required for FISH.

SPECIMEN REJECTION CRITERIA

A specimen will be rejected for NGS when:

1. It contains <15% tumor cells after dissection, or
2. It is not of sufficient size as described in FFPE Sample Submission; or
3. It is not FFPE; or
4. It is a decalcified specimen for NGS testing (exception: EDTA is acceptable) and a decalcified specimen may be contraindicated in some IHCs.

TESTING PRIORITY

NGS is run first, then IHCs are run in the order listed until complete or the block is exhausted. Specify in notes if a different priority is required. MSI may require higher % tumor. MMR will be substituted if MSI isn't possible.

SHIPPING INSTRUCTIONS

1. Place the Oncotype MAP Requisition Form, a copy of the pathology report, and relevant patient demographics and insurance materials in the Oncotype MAP Pan-Cancer Tissue Kit.
2. Place the Oncotype MAP Specimen Kit into the FedEx® Clinical Pak. DO NOT include any patient identifiers on the Specimen Kit.
3. The airbill is pre-printed with Exact Sciences shipping information for your convenience.
BE SURE TO MARK SERVICE AS "PRIORITY OVERNIGHT"
SHIP TO: Exact Sciences
445 N. 5th Street, Suite 300
Phoenix, AZ 85004
CONTACT CUSTOMER SERVICE AT 866-662-6897 WITH ANY QUESTIONS
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 standard FedEx pickup, call 800-GO-FEDEX (800-463-3339) to arrange pick up.
7. To order additional kits, email Customer Service at oncotypemap@exactsciences.com

**QUESTIONS? CONTACT CUSTOMER SERVICE AT
1-866-662-6897 or oncotypemap@exactsciences.com**

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