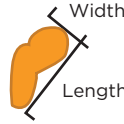

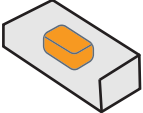
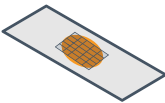
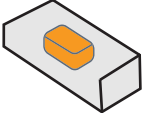


ONCOTYPE MAP™ PAN-CANCER TISSUE SPECIMEN SUBMISSION GUIDELINES

BEGIN BY 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.
- Estimate tissue surface area as width x length
- Send block/slides with largest tissue area to maximize success
- Formalin is the required fixative. Tissues processed in other fixatives SHOULD NOT be submitted.



Sample Submission Criteria	Preferred	Acceptable
Surface Area	≥ 10 mm ²	3 mm ² → Verify tissue is as large as a grain of rice. 
Tumor Content	≥ 20%*	15%
Specimen Type	Tissue blocks are greatly preferred because they provide additional flexibility for macrodissection and scant samples	
	<p>Send whole block OR calculate number of slides required as below. Typically 8-10 slides are needed for both NGS and IHC.</p> $1_{\text{H\&E}} + 1_{\text{NRC**}} + 1_{\text{NGS}} + \frac{\text{\# of IHC(s)}}{\text{\# of IHC(s)}} = \text{Slides Needed}^\dagger$	Send whole block
	 	

* In cases where the tumor percent is less than 20% after macrodissection, we need an additional 4 slides for MMR IHC
 ** Negative reagent control (NRC) slide required for PD-L1 (SP142) IHC

† For cases where slides are submitted, additional levels or a tissue block may be requested to perform microdissection.
 If HER2 equivocal, send 5 additional slides for FISH.

SPECIMEN PREPARATION INSTRUCTIONS

BLOCKS

- Follow standard practice guidelines for processing of formalin-fixed paraffin-embedded (FFPE) tissue. Consider using 10% neutral buffered formalin (10% NBF). Samples fixed in non-buffered formalin or 40% formalin may perform very poorly.
- DO NOT submit a H&E slide when you are submitting tumor blocks. Exact Sciences will prepare a H&E slide on site.
- Include two patient specific identifiers (e.g. specimen accession number, order number).
- Include frozen ice pack. Freeze overnight or a minimum of 4 hours.

SLIDES

- Calculate the number of slides needed for NGS and IHC.
- Prepare appropriate number of 4-5 μm serial unstained, charged slides with one (1) serial section on each slide.
- Hand number serially sectioned slides in order cut (1-4)
- Include two patient specific identifiers (e.g. specimen accession number, order number).
- Air dry slides. DO NOT coverslip.

*See Specimen Rejection Criteria and Testing Priority on reverse

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 (protocol available upon request) 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 (20% optimal). MMR will be substituted if MSI isn't possible.

SHIPPING INSTRUCTIONS

1. Place sample into appropriate packaging:
 - a. For BLOCKS, place in the small plastic bag provided and seal. Secure the bag in kit foam insert. Include frozen ice pack.
 - b. For SLIDES, place in slide carriers provided. Secure in kit foam insert.
2. Place complete foam insert into specimen bag and place in kit.
3. Place the Oncotype MAP Requisition Form, a copy of the pathology report, patient demographics and insurance materials on top of the specimen bag. Close and seal the Oncotype MAP Pan-Cancer Tissue Kit.
4. Place the Oncotype MAP Specimen Kit into the FedEx® Clinical Pak. DO NOT include any patient identifiers on the Specimen Kit.
5. Apply the priority overnight return shipping label pre-printed with Exact Sciences' shipping information to the outside of the Clinical Pak.
6. Seal the Clinical Pak by removing the plastic adhesive protector from the white strip and secure.
7. Place the package in the designated FedEx pickup location at your site.
8. If your site does not have standard FedEx pickup, call 800-GO-FEDEX (800-463-3339) to arrange pick up.
9. 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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