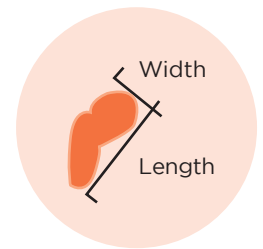


Specimen Submission Guidelines

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.



Acceptance criteria

- ≥ 15% malignant cells after dissection.
- Sufficient size as described to the right.
- FFPE sample.
- Is not decalcified or is decalcified with EDTA.

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 requires higher % tumor (≥ 20% optimal).

Preferred

Surface area: ≥ 10 mm²
Tumor content: ≥ 20%
Send whole block*

Acceptable

Surface area: 3 mm²
Tumor content: ≥ 15%
Send whole block



Verify tissue is as large as a grain of rice



*Block is preferred, but submitting 15 4-5 μm slides is acceptable for samples with ≥ 10 mm² if block not available.

Specimen preparation instructions

Blocks

1. 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.
2. DO NOT submit an H&E slide when you are submitting tumor blocks. Exact Sciences will prepare an H&E slide on site.
3. Include two patient-specific identifiers (e.g., specimen accession number, order number).
4. Include frozen ice pack. Freeze overnight or a minimum of 4 hours.

Slides

1. Prepare 15 4-5μm serial unstained, charged slides with one (1) serial section on each slide.
2. Hand number serially-sectioned slides in order cut (1-15).
3. Include two patient-specific identifiers (e.g., specimen accession number, order number).
4. Air dry slides. DO NOT bake slides. DO NOT coverslip.

Specimen Submission Guidelines

Shipping Instructions

1. Place sample into appropriate packaging:
 - For BLOCKS, place in the small plastic bag provided and seal. Secure the bag in kit foam insert. Include frozen ice pack.
 - 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 all supporting documents on top of specimen bag:
 - Requisition form
 - Pathology report
 - Patient demographics
 - Insurance materialsClose and seal the Oncomap™ kit.
4. Apply the priority overnight return shipping label pre-printed with Exact Sciences' shipping information to the outside of the Clinical Pak.
5. Place kit into the FedEx® Clinical Pak.
 - DO NOT include any patient identifiers on the specimen kit.
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.
 - If your site does not have standard FedEx pickup, call 800-GO-FEDEX (800-463-3339) to arrange pick up.
8. To order additional kits, email Customer Service at oncomap@exactsciences.com.

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