

Specimen Instructions

FoundationOne® can help you determine next steps for the care of your patients by accurately detecting all classes of genomic alterations. Below are specimen instructions to help ensure successful genomic profiling.

Selecting the best specimen from multiple options:



Has the patient been treated with targeted therapy?

YES Use post-targeted therapy specimen, if available.

NO Use recurrence or original resection (most recent material preferred). Metastasis biopsy or primary tumor acceptable (choose site with highest percent tumor or largest tumor focus).



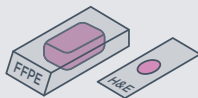
Acceptable Samples

- Formalin-fixed paraffin embedded (FFPE) specimens, including core-needle biopsies, fine-needle aspirates, and effusion cytologies.
- Use standard fixation methods to preserve nucleic acid integrity. 10% neutral-buffered formalin for 6–72 hours is industry standard. **DO NOT** use other fixatives (Bouins, B5, AZF, Holland's).
- Do not decalcify. When decalcification is required, EDTA is recommended. Do not use strong acids (e.g., hydrochloric acid, sulfuric acid, picric acid).

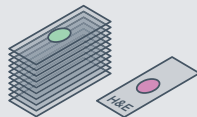
SAMPLE SIZE

1 When feasible, please send the block + 1 original (not recut) H&E slide.

10 unstained slides (positively charged and unbaked at 4–5 microns thick) + 1 original (not recut) H&E Slide.



OR



SURFACE AREA

2 **OPTIMUM: 25 mm²**

If sending slides, provide 10 unstained slides cut at 4-5 microns thick.

MINIMUM: 5 mm²

For small (<25 mm²) or impure samples, additional unstained slides may be needed to extract sufficient DNA for testing.

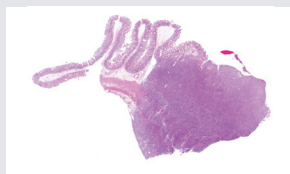


TUMOR CONTENT

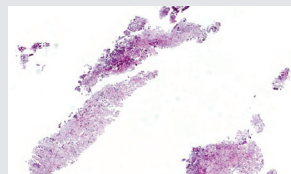
3 **OPTIMUM: 30% TN** **MINIMUM: 20% TN**

Percent tumor nuclei (%TN) = number of tumor cells divided by total number of all cells with nuclei

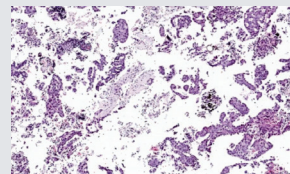
Note for liver specimens: higher tumor content may be required because hepatocyte nuclei have twice the DNA content of other somatic nuclei



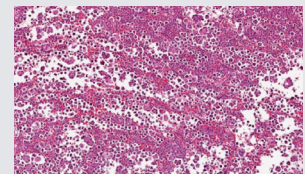
Resection



Small Biopsy



Fine-Needle Aspiration
(Cell Block)



Fluid Exfoliative Cytology
(Cell Block)

See reverse for shipping instructions.

Shipping Instructions

1. Place the samples, FoundationOne requisition form, insurance information, and any other attachments into the FoundationOne Specimen Shipping Kit.
2. Place the specimen shipping kit (including samples and paperwork) into the provided FedEx shipping pack, first ensuring that primary specimen containers (e.g. blocks, slides) are labeled with two patient-specific identifiers. Seal the shipping pack.
3. Complete the pre-printed shipping labels (if necessary) and apply to shipping pack.
4. Call 800.463.3339 to request a pick-up or drop the package at your site's designated FedEx pick-up location and ship sealed shipping pack to:

Foundation Medicine, Inc.
150 Second Street
Cambridge, MA 02141
Phone: 888.988.3639