

FoundationOne®CDx can help you determine next steps for the care of your patients by detecting the 4 classes of genomic alterations.* Below are Specimen Guidelines to help ensure successful genomic profiling.†

Selecting the Best Specimen from Multiple Options

Has the patient been treated with targeted therapy?

NO

Use recurrence or original resection (most recent material preferred). Metastasis biopsy or primary tumour acceptable (choose site with highest percent tumour or largest tumour focus).

YES

MUST use post-targeted therapy specimen, if available.

Acceptable Samples

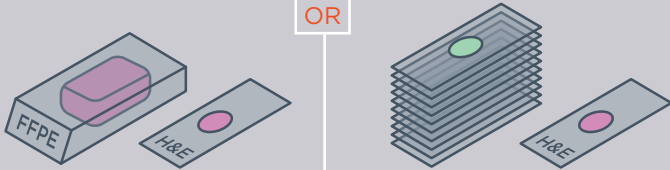
- FFPE specimens, including core needle biopsies, fine-needle aspirates and effusion cytologies.
- Tissue should be formalin-fixed, paraffin embedded. Use standard fixation methods to preserve nucleic acid integrity. 10% neutral-buffered formalin for 6-72 hours is industry standard. **DO NOT** use other 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).

1 SAMPLE TYPES

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

OR

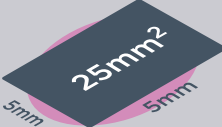
10 unstained slides (positively charged and unbaked at 4-5 microns thick) + 1 original (not recut) H&E Slide.



2 SAMPLE SIZE SURFACE AREA

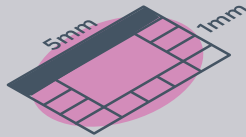
Optimal: 25 mm²

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



Minimal: 5 mm²

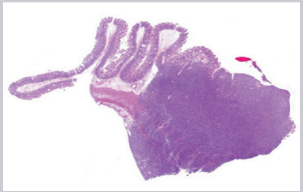
For small (<25mm²) or impure samples, additional unstained slides may be needed to extract sufficient DNA for testing.



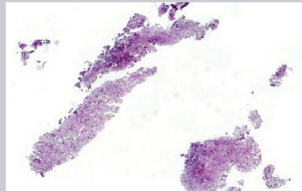
3 TUMOUR NUCLEI PERCENTAGE

Optimal: 30% Minimal: 20%

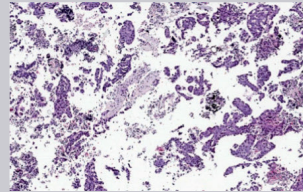
Percent tumour nuclei = number of tumour cells divided by total number of all cells with nuclei.†



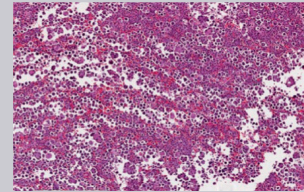
Resection



Small Biopsy



Fine Needle Aspiration (Cell Block)



Fluid Exfoliative Cytology (Cell block)

* Liver specimens may require additional tumour.

Shipping Instructions

1. Place the samples, FoundationOne®CDx Requisition Form, pathology report, insurance information, and any other attachments into the FoundationOne® Specimen Kit.
2. Place the specimen kit (including samples and paperwork) into the provided shipping pack and seal the shipping pack.
3. Ensure commercial invoice in triplicate is initialed and included in the shipping pack.
4. Ship sealed shipping pack to: Accessioning, Clinical Laboratory Foundation Medicine, Inc. 150 Second Street Cambridge, MA 02141
5. Drop the package at your site's designated FedEx pick up location or call FedEx at 1-800-463-3339 to request a pick-up.

† Frampton *et al.* Development and validation of a clinical cancer genomic profiling test based on massively parallel DNA sequencing. *Nature Biotech* 2013 Nov.

If you require this information in an accessible format, please contact Roche at 1-800-561-1759.