

FoundationOne® Specimen Guidelines

BELOW ARE SPECIMEN GUIDELINES TO HELP 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 specimen less than 6 months old preferred).
Metastasis biopsy or primary tumour acceptable (choose site with highest percent tumour or largest tumour focus).

YES } **MUST** use post-targeted therapy specimen.

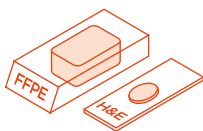
ACCEPTABLE SAMPLES

- Formalin-fixed, paraffin embedded (FFPE) specimens, including core needle biopsies, fine-needle aspirates and effusion cytologies.
- Tissue should be FFPE. 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 tissue.** When decalcification is required, EDTA is recommended. Do not use strong acids (e.g. hydrochloric acid, sulfuric acid, picric acid).

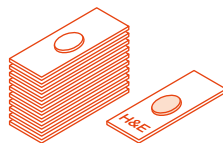
1 SAMPLE TYPES

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

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



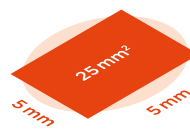
OR



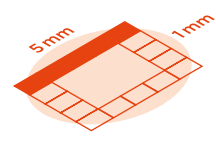
2 SAMPLE SIZE SURFACE AREA

Optimal: 25 mm²
If sending slides, provide 10 unstained slides cut at 4-5 microns thick.

Minimal: 5 mm²
For small (<25 mm²) or impure samples, additional unstained slides may be needed to extract sufficient DNA for testing.



OR



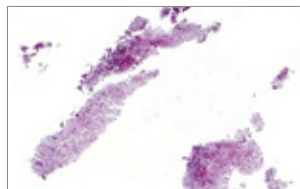
3 TUMOUR NUCLEI PERCENTAGE

Optimal: 30% Minimal: 20%

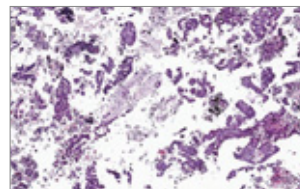
Percent tumour nuclei = number of tumour cells divided by total number of all cells with nuclei.*



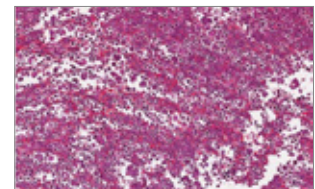
Resection



Small Biopsy



Fine Needle Aspiration (Cell Block)



Fluid Exfoliative Cytology (Cell block)

* For liver specimens, minimal 40% of tumour nuclei is required. Since polyploidy is a common characteristic of hepatocytes, twice as many tumour cells would be needed to obtain enough tumour DNA for analysis.

SHIPPING INSTRUCTIONS

- Place the samples, FoundationOne® Requisition Form, pathology report, and any other attachments into the FoundationOne® Specimen Kit.
- Place the Specimen Kit (including samples and paperwork) into the provided shipping pack and seal the shipping pack. Ensure any export documentation (Commercial Invoice) is completed and included in the shipping pack.
- Complete the pre-printed shipping labels (if necessary) and apply to shipping pack.
- Ship sealed shipping pack to: **Accessioning, Foundation Medicine, Inc. 150 Second Street Cambridge, MA 02141**, by dropping the package at your site's designated FedEx pick up location, or call to request a pick up. The local FedEx contact number is indicated on the top of the shipping pack.

LOCAL AND REGIONAL CONTACT

Please refer to your country
for local contact details.

For more information, contact
our APAC Customer Services team:
APAC.foundation@roche.com



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1, Kim Seng Promenade #15-07/11,
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