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FOUNDATIONONE®CDx

Instructions

FoundationOne®CDx Specimen Guideline

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?

Yes	MUST 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).

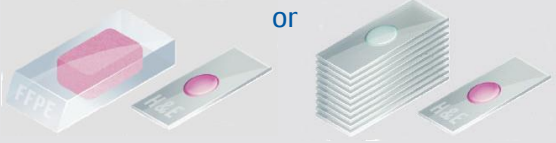
Acceptable Samples

- FFPE specimens, including core needle biopsies, fine-needle aspirates and effusion cytologies.
- Das 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 decal. When decalcification is required, EDTA is recommended. Do not use strong acids (e.g. hydrochloric acid, sulfuric acid, picric acid).

1 Sample Size

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.



2 Sample Size Surface Area

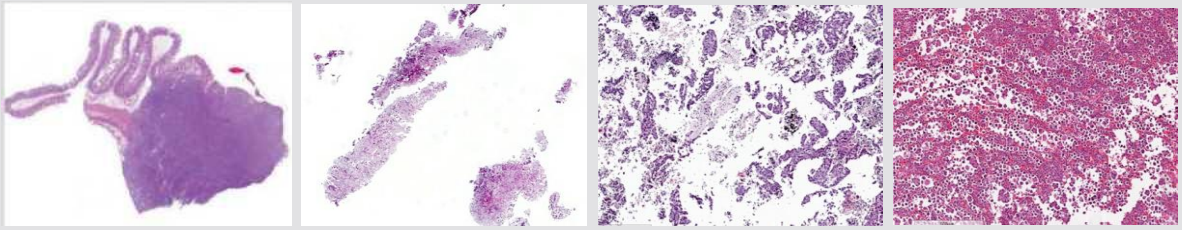
Optimal: 25 mm^2
If sending slides, provide 10 unstained slides cut at 4-5 microns thick.

Minimal: 5 mm^2
For small (<25mm2) or impure samples, additional unstained slides may be needed to extract sufficient DNA for testing.

3 Tumor Nuclei Percentage

Optimal: 30% Minimal: 20%

Prozentsatz Percent tumor nuclei = number of tumor 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 tumor.