

Specimen Instructions

The Foundation Medicine® FoundationFocus™ CDx BRCA assay is a companion diagnostic to Clovis Oncology's drug Rubraca®, a poly (ADP-ribose) polymerase (PARP) inhibitor therapy for the treatment of advanced ovarian cancer. Specimens that are found to have a deleterious BRCA alteration in their tumor tissue (tBRCA+) may be eligible for treatment with Rubraca® therapy.



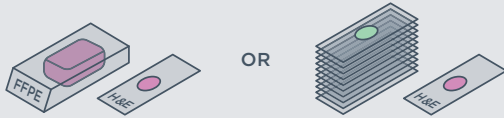
Acceptable Samples

- Formalin-fixed, paraffin embedded (FFPE) specimens, including cut slide specimens are acceptable.
- 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.

SAMPLE SIZE

- 1** When feasible, please send the block + 1 H&E slide.*

10 unstained slides (positively charged and unbaked at 4-5 microns thick) + 1 H&E slide.*

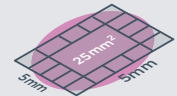


*For smaller samples, providing the original H&E will preserve material for testing.

SURFACE AREA

- 2** **MINIMUM: 25 mm²**

If sending slides, provide 10 unstained slides cut at 4-5 microns thick to achieve a tissue volume of 1 mm³ to enable extraction of ≥200 ng DNA.**



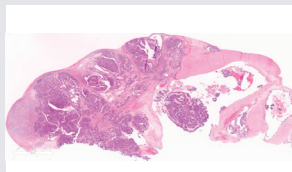
**Specimens with a smaller surface area may meet volume requirements by submitting additional USS or block.

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

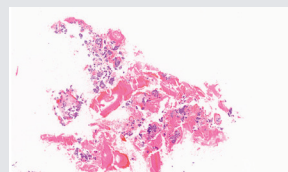
Note for liver specimens: higher tumor content may be required because hepatocyte nuclei have twice the DNA content of other somatic nuclei



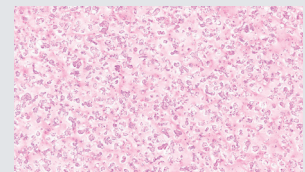
Resection



Small Biopsy



Fine-Needle Aspiration
(Cell Block)



Fluid Exfoliative Cytology
(Cell Block)

Shipping Instructions

1. Place the samples, FoundationFocus™ CDx BRCA requisition form, insurance information, and any other attachments into the FoundationFocus CDx BRCA FFPE 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.
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Cambridge, MA 02141
Phone: 888.988.3639